PhD thesis

The ‘therapeutic privilege exception’. Residual paternalism in an age of informed consent post Montgomery or a valuable tool for healthcare professionals?

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The ‘therapeutic privilege exception’. Residual paternalism in an age of informed consent post *Montgomery* or a valuable tool for healthcare professionals?

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Abstract

Originally formulated by courts in the United States of America, as an exception to informed consent, therapeutic privilege provides a healthcare professional with a complete defence of withholding information from a patient where it is believed that disclosure could result in serious physical or psychological harm. Whilst the exception is rarely referred to, it is even rarer for a defence to be successful and yet the exception survives. In 2015, the Supreme Court in England and Wales, in the *Montgomery* judgment retained therapeutic privilege, albeit in a limited form but still largely undefined. Now renamed therapeutic *exception*, this principle remains shrouded in uncertainty and renders the law unclear.

This thesis revises the recognised nomenclature of the 'therapeutic privilege', introducing the 'therapeutic privilege exception' as a reminder of the residual paternalism in healthcare. The development of the therapeutic privilege exception in a range of other domestic jurisdictions alongside the UK will be examined, and its inconsistency and lack of clarity will be highlighted. Close consideration will be given to whether the exception to the doctrine of informed consent may result, unintentionally, in a return to paternalism which will hinder patient autonomy. This phenomenon will be examined in light of qualitative research directed towards both GPs and clinical pharmacists' clinical experiences of people with intellectual disability and those without.

This thesis will explore whether therapeutic privilege constitutes unacceptable paternalism, or whether there is a clear, defined role for therapeutic privilege in law. It will be argued that should the therapeutic privilege exception have a role, recommendations will clearly set out the elements of the therapeutic privilege exception so that healthcare professionals are not only aware of the existence of the exception but also of its limitations.

283 words

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[1] *Heart of England NHS Trust Foundation v JB* [2014] EWHC 342 (COP) at para 6
[2] Ibid

Chapter 1

1.1 Introduction

In 2015, the Supreme Court judgment of *Montgomery v Lanarkshire Health Board (Montgomery*)[3] brought the UK in line with many other domestic jurisdictions by introducing informed consent. The approach of 'doctor knows best' was rejected, replacing paternalism with a patient-centred approach, where the patient was the centre of the decision-making process.

The central issue explored in *Montgomery* was whether or not Mrs *Montgomery* should have been advised of the risks of shoulder dystocia during pregnancy. When these risks transpired and her baby suffered injury during birth, she alleged that the injuries could have been avoided if she had been advised of the risks and the alternative of a caesarean section. The judgment, which will be considered in far more detail in Chapter 2 established a new test for information disclosure, rejecting the standard set in *Bolam* and substituting it for the test of the reasonable patient. Importantly, the judgment retained the therapeutic privilege in stating that a doctor may withhold information from a patient where he reasonably believes that disclosure would be detrimental to the patient's health.[4] Furthermore, the judgment emphasised the importance of dialogue and communication underpinning the doctor-patient relationship, which may be additionally challenging with patients with intellectual disability, to name one of the cohort of patients considered in this thesis.

Strikingly similar to the facts of *Montgomery*, the 1957 case of *Bolam*[5] also concerned a failure to advise a patient of the risk of treatment, although the real importance of the judgment lies in the standard of care to be applied in clinical negligence cases. In *Bolam* Mr Justice McNair held that the doctor would not be liable in negligence, if a body of similarly qualified medical opinion, would have acted in the same way. *Bolam* was evaluated on many subsequent occasions for example in the case of *Sidaway,*[6] which in the context of risk

[3] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11
[4] Ibid
[5] *Bolam* v *Friern Hospital Management Committee* [1957] 1 WLR 582
[6] *Sidaway v Board of Governors of the Bethlem and Royal Hospital and the Maudsley Hospital* [1985] AC 871

disclosure, carefully considered whether or not a patient should be advised of the risks of treatment.

Lord Scarman's dissenting judgment would prove to be highly influential in the Supreme Court 30 years later in *Montgomery*. By the mid-1980's the courts, together with professional guidance, began to recognise the importance of patient autonomy.[7] In the meanwhile, clinical practice was developing a more patient-focused approach, recognising the right of the patient to exercise their own decisions regarding their treatment.

1.2 The research background to this thesis

A chance conversation with a colleague specialising in clinical pharmacy research on mental health galvanised the theme of this thesis to recognise the potential deficit of the *Montgomery* judgment for those patients with intellectual disability. Early analysis suggested that patients with mild to moderate intellectual disability may be overwhelmed by risk disclosure, which may result in compromising their capacity to consent. Together, we presented '*The impact of Montgomery v Lanarkshire (Scotland) 2015 on patients with learning disability'* at a small, intimate, value-based practice conference at Oxford University, exploring the potential impact of the judgement on people with intellectual disability. Thereafter several papers were published by this researcher exploring the nexus between the judgment in *Montgomery* and patients with intellectual disability with the focus on the extent to which they understood their medication.[8]

It was during this period that the role of the therapeutic privilege exception came into sharper focus, with a concern about its unintended use for capacitous patients with intellectual disability. The issue in particular was whether these patients are more likely to have information withheld. With these issues in mind, the focus had turned to explore how

[7] See, for example, *Pearce v United Bristol Healthcare NHS Trust* [1988] 48 BMLR 118

[8] See the following publications: Claudia Carr and Danielle Adams 'The Implications of the *Montgomery* Judgment on Pharmacy Practice and Patients with Learning Disability' (2017) The Pharmaceutical Journal, online:DOI:10.1211/PJ.2017.20203788; Nina Barnett and Claudia Carr (2018), 'The *Montgomery* Judgment and Pharmacist Consultations,' Prescriber, 29: 16-22, https://doi.org/10.1002/psb.1639; Danielle Adams, Claudia Carr, Daniel Marsden et al., 'An updated on informed consent and the effect on the clinical practice of those working with people with a learning disability' (2018) Learning Disability Practice doi:10.7748/ldp.2018.e.1855; Claudia Carr and Silvan Megoni, 'People with Intellectual Disabilities are often not told about their Medicines and their Potential Side Effects' (2019, Aug 1) The Conversation; Megan Smith, Danielle Adams, Claudia Carr and Silvana Megoni, 'Do people with intellectual disabilities understand their prescription medication? A scoping review' (2019) Journal of Applied Research in Intellectual Disabilities: JARID, 32(6), 1375–1388.

this specific cohort of patients interacted within the healthcare profession. Early research of the practice of pharmacists within a clinical setting, i.e. in hospitals, led to a conclusion that the quality of written material for people with learning disabilities was variable and would be unlikely to comply with the Accessible Information Standard (AIS) 2016.[9] Furthermore, research cautioned that pharmacists working with people with intellectual disabilities, together with those without, needed to ensure they practiced in a way that was *Montgomery* compliant.[10]

Further research with colleagues led to a more detailed scoping review as to what people with intellectual disability understand about their prescription medication which was published in July 2019.[11] Given that people with intellectual disabilities are more likely to experience poorer health outcomes, the research set out to establish what patients understood about their medication and potential side effects. The research involved a scoping review of 10 journals which revealed that patients with intellectual disabilities '*were often confused or unaware of adverse effects associated with their medication'*, while it was concluded that there was a need for '*accessible and tailored information about medication.'* Subsequently, an article in The Conversation was published to highlight the issue to a global academic audience.[12]

The work briefly discussed above highlights the reasoning behind research into clinical pharmacists. It concerns these pharmacists as a specific body of healthcare professionals who, when prescribing medicines in a hospital setting, must obtain informed consent from their patients, some of whom may have intellectual disabilities. The research appeared to suggest that clinical pharmacists may practice paternalistically. If that suggestion was

[9] The Accessible Information Standard https://www.england.nhs.uk/wp-content/uploads/2017/08/accessilbe-info-specification-v1-1.pdf accessed August 30, 2021
[10] Claudia Carr and Danielle Adams, 'The implications of the *Montgomery* judgment on pharmacy practice and patients with learning disability' The Pharmaceutical Journal. Online:DOI:10.1211/PJ.2017.20203788
[11] Megan Smith, Danielle Adams, Claudia Carr and Silvana Mengoni, 'Do people with intellectual disabilities understand their prescription medication? A scoping review' (2019) J Appl Res Intellect Disabil. 32: 1375–1388
[12] Claudia Carr and Silvana Megoni, 'People with Intellectual Disabilities are often not told about their Medicines and their Potential Side Effect' The Conversation http://theconversation.com/people-with-intellectual-disabilities-are-often-not-told-about-their-medicines-and-their-potential-side-effects-119415 accessed 2 March 2023

correct, this practice raised the possibility that information was being withheld from the patient within the paternalistic practice.

1.3 Why the therapeutic privilege exception is the central theme of the thesis

'Therapeutic privilege' is one of the three exceptions to informed consent. Where the defence is successfully relied upon, it acts as a complete defence, negating any claim in negligence for failure to disclose material risks. Whilst it is rarely relied upon, either within the jurisdictions of the UK or globally,[13] the exception survived the Supreme Court judgment in *Montgomery*, providing the doctor with a formal defence to withhold information for the first time. Since the Supreme Court accepted the *therapeutic privilege* - now referred to as '*therapeutic exception'* - the Supreme Court recognised there was some intrinsic value in retaining an exception, although there is no specific commentary to this end.

Given the facts of *Montgomery*, the Supreme Court largely focused on the development of the test of material risk for information disclosure, only making the most limited reference to the standard of care to be applied to withholding information.[14] Moreover, there is no explanation of why the 'therapeutic exception' is retained save that a doctor may consider that disclosure would be detrimental to the patient's health, without being able to 'provide *the basis of the general rule'*.[15] For the purposes of the *Montgomery* judgment, the Supreme Court considered it unnecessary to consider in detail the scope of any of the exceptions,[16] resulting in a lack of clarity and transparency within this element of the law. This has led some academics to conclude that the defence is '*obfuscatory, unnecessary and unjustified'*, and it should not exist.[17] This thesis rejects the positioning that the therapeutic exception should no longer exist, arguing that there is a limited role for the '*therapeutic privilege*

[13] See *Pearce* (n7) where the defence was successfully relied upon, albeit not by name. See also *Batterbsy v Totman* [1985] 37 SASR 524 where the defence was successfully relied on in Australia and discussed in more detail at 4.5.
[14] *Montgomery* (n3) [71] which refers to the *'danger that the provision of all relevant information will harm an unusually nervous, disturbed or volatile patient'*
[15] *Montgomery* (n3) [85]
[16] *Montgomery* (n3) [88] The other exceptions referred to are Waiver see 2.10 and *'where a patient is unconscious or otherwise unable to make a decision'*. The latter presumably referring to where a patient lacks capacity and is treated under the Mental Capacity Act see 1.8
[17] Emma Cave, 'The ill-informed: Consent to medical treatment and the therapeutic exception' (2017) Common Law World Review 46(2) 14-168,140

exception', particularly in cohorts of patients where excessive disclosure could undermine their capacity for example, patients with mild to moderate intellectual disability.

This thesis introduces the '*therapeutic privilege exception*,' as a term that will be referred to throughout and set in the framework of a definition to provide clarity and accessibility. The reasoning for the change of nomenclature is that, whilst withholding risk disclosure from a patient remains an '*exception*' to the requirement to disclose, any healthcare professional should be aware that failure to disclose, even for the reasons which this research will develop, remains benevolent paternalism.

The mere existence of the therapeutic privilege exception is intriguing and occupies an unusual place in the law of medical negligence. It is a recognised legal exception to informed consent, yet has never been successfully relied on in this jurisdiction by name and, only rarely globally. Despite academic opinion about its distinct lack of value,[18] it appears that the defence of therapeutic privilege is firmly embedded in law, with an acquiescence that there may be *'exceptional*' circumstances where risk disclosure may be withheld.

The jurisprudential development of informed consent both in England and Wales and other domestic jurisdictions has seen the principle of information disclosure subjected to three exceptions. Firstly, in the case of an emergency where treatment is a necessity, the patient need not be advised of the material risks as the primary consideration would be the patient's medical welfare and best interests. Secondly, patients have a 'right not to know' (or waiver) in order to decline any information that the healthcare professional may wish to impart. Accordingly, even those clinicians who may wish their patient to be part of the decision-making process regarding their treatment, are obliged to adopt a more paternalistic approach. Finally, the *therapeutic privilege exception* is an exception to the duty to provide informed consent, whereby a health care professional can withhold from a patient information regarding the risks and possible alternatives where he objectively believes that disclosure would be detrimental to the patient's health.

Although the therapeutic privilege exception has been referred to in several domestic jurisdictions, this thesis will focus specifically on decisions in USA, Canada, Australia and Singapore. Save for Singapore, these jurisdictions directly fed into the reasoning for the

[18] Ibid

Montgomery judgment. Singapore is relevant to this thesis as it provides a novel interpretation of the therapeutic privilege exception and therefore worthy of analysis. Importantly, as early as 1972, the case of *Canterbury v Spence* was highly influential in the general evolution of informed consent, where the court observed that '*patients occasionally become so ill or emotionally distraught on disclosure as to foreclose a rational decision.'*[19] Whilst therapeutic privilege in different domestic jurisdictions will be explored in greater depth within this thesis, there have been few judicial decisions where therapeutic privilege has been successfully upheld as a defence to informed consent. More importantly, therapeutic privilege appears to be shrouded in mystery, lacking any consistent definition, and remains undefined with little or no guidance as to its component elements. This thesis intends to challenge the decisions of some domestic jurisdictions and argue that 'anxiety' is a sufficient trigger to invoke the therapeutic privilege exception.

Whilst *Montgomery* is lauded as the gold standard of patient-centred care and represents a final rejection of paternalism in healthcare, it retains a defence which is fundamentally paternalistic in nature. Disclosure of material risks is imperative to support patient autonomy, but supported by the qualitative research undertaken for this thesis, it will be argued that where disclosure risks compromising patient autonomy, it can be withheld.[20] Hence, there appears to be competing values; that of autonomy and non-beneficence ('do no harm') together with an academic and judicial perspective, suggesting that anything less than full information disclosure is unacceptable paternalism.[21] Moreover, whilst the duty of information disclosure is clearly expressed in *Montgomery*, rejecting *Bolam* in its entirety, any legal challenge to therapeutic privilege could well be defended on *Bolam* principles. Consideration would then be given to whether or not this is an appropriate standard in a period that has wholeheartedly rejected the application of *Bolam* in information disclosure.

As some academic opinion has astutely observed, the duty to advise patients of risks and reasonable alternatives is not novel.[22] Indeed, several years earlier, the GMC (General

[19] *Canterbury v. Spence* (1972) 464 F 2d 772, 789 (DC Cir)
[20] See Alan Meisel, 'The "exceptions" to the informed consent doctrine: striking a balance between competing values in medical decision-making' (1979) Wisconsin Law Review 413-88
[21] Kate Hodkinson, 'The need to know- Therapeutic privilege: A way forward' (2013) Health Care Analysis 21:105-129
[22] See for example Michael A Jones, 'Informed consent and other fairy stories' (1999) Medical Law Review (7) 103-134

Medical Council) guidelines had set down the importance of the doctor-patient relationship within which the defence of therapeutic privilege was retained. Even more recently, the GMC guidelines for consultation '*Decision Making and Consent, Supporting Patient Choices about Health and Care: Working with Doctors Working with Patients'*[23] provides further development of the doctor-patient relationship, and despite academic opinion to the contrary,[24] it retains therapeutic privilege by stating, with direct reference to *Montgomery* that '*In very exceptional circumstances you may feel that sharing information with a patient would cause them serious harm and… it may be appropriate to withhold this information.'*[25]

1.4 The research questions

The thesis addresses the following research questions:

1. Prior to the introduction of the therapeutic exception through the introduction of informed consent in UK law, to what extent had the courts in England and Wales previously managed the notion of withholding risk disclosure from patients? What standard of care was applied and have the courts shown incremental steps towards the introduction of informed consent, whilst embracing therapeutic privilege?

2. To what extent and in what circumstances have judgments in other domestic jurisdictions demonstrated that risk disclosure has been withheld from patients and, has there been any consistency in the approach or have the decisions been arbitrarily?

3. Given the rejection of paternalistic practice in healthcare provision, to what extent does the clinical practice of GPs and clinical pharmacists demonstrate that they may withhold information from patients, where they believe that disclosure would cause the patient harm?

4. If it is shown that GPs and clinical pharmacists withhold information from patients, are either cohort of healthcare professionals more likely to do so than the other and, if so, can it be established what these circumstances are?

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[23] About Decision making and consent - GMC (gmc-uk.org) accessed January 1, 2024

[24] Louise V. Austin. *'Hii Chii Kok v (1) Ooi Peng Jin London Lucien; (2) National Cancer Centre: Modifying Montgomery'* (2019) Medical Law Review 27(2) Spring 339–351

[25] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent/the-dialogue-leading-to-a-decision, para 13 accessed May 22, 2022

5. Are GPs or clinical pharmacists more likely to withhold information from patients with an intellectual disability than from patients without and, if they are, is there any clear reasoning why this might be?

1.5 Methodology

In order to address the research questions, it is imperative that the methodology can stand up to scrutiny. The first part of the thesis will adopt a 'doctrinal' or 'black letter law' methodology, which means that some of the research in this thesis will be based upon an analysis of legal rules. Doctrinal research has been defined as *'a detailed and highly technical commentary upon, and systematic exposition of, the context of legal doctrine.'*[26] The thesis also adopts a comparative method, where relevant, to examine the mechanisms of common law decisions in USA, Canada, Australia and Singapore. This method enables the researcher to understand the principles which underpin the legal rules in a range of domestic jurisdictions. One criticism of using a comparative approach is that accessing decisions from other jurisdictions can be challenging but, given that the jurisdictions are English speaking, it is unlikely this challenge will arise. Furthermore, resources such as Lexis+ enable access to many of the selected domestic jurisdictions.

The second part of the thesis transitions from a doctrinal approach to embark upon qualitative thematic analysis, so providing the *'theoretical freedom'* to take a flexible approach to obtaining rich data. The contrast between the doctrinal approach and qualitative thematic analysis intends to provide a novel approach and to reach a sustainable and credible conclusion regarding the existence of the *therapeutic privilege exception.*

Qualitative thematic analysis is the most relevant theory to adopt for this thesis as it can be regarded as organic, being sufficiently creative to meet the reality of interviewing healthcare professionals, particularly over the period of Covid-19. Other methodologies were explored and then dismissed. For example, grounded theory was considered but rejected, as this approach derives the theory from the data rather than exploring the lived experiences of healthcare professionals.

[26] Michael Salter and Julie Mason, Writing Law Dissertations: An Introduction and Guide to the Conduct of Legal Research (2007) Pearson 49

For the purposes of this thesis, the data will be derived from two specific cohorts of healthcare professionals: General Practitioners (GPs) and Clinical Pharmacists The reasoning for selecting clinical pharmacists as research participants is to further develop early research, to gain a greater insight into their clinical practice. GPs were selected as a cohort of healthcare professionals for contrasting reasons. Firstly, it was desirable to contrast data between the cohorts, to ascertain whether there were any specific differences between pharmacists working in a hospital setting and GPs working within the local community, who may have a differing clinical practice style. Secondly, for practical reasons, it was considered that GPs may be more willing research participants than another body of clinical healthcare professionals.

At that time, the Covid-19 pandemic was entirely unforeseeable, but the immediate effect of the pandemic resulted in interviews being delayed and more importantly, the researcher being unable to interview the participants in person. Although 11 research participants had already been interviewed in person, the pandemic had a profound effect on the research as an alternative method had to be found to interview research participants. As the global community moved online, a further 9 interviews were carried on via Zoom. However, the move to an online platform added to rather than changed the narrative, being that aspects such as reading a patient's body language and the potential of digital inequality became apparent.

1.6 Inclusion of General Practitioners and Clinical Pharmacists

As explained briefly in the above section, this thesis focuses only on those clinical pharmacists within a hospital setting. Clinical pharmacists are a growing body of healthcare professionals, who prescribe medication and 'treat' patients without the need for a GP's approval. For example, Pharmacist Independent Prescribers[27] were introduced over a decade ago and PIP's can now prescribe without the approval of a doctor. Although only 11% of all pharmacists are independent prescribers, this figure is likely to grow as education, training and opportunities become more widespread.[28] The widening role of the

[27] Deriving their powers from Regulation 214 of the Human Medicines Regulations 2012.
[28] Carr and Adams (n10)

pharmacists now plays an integral part in medicine management, whether that be in a clinical setting (hospitals) or within GP surgeries.

Furthermore, the Carter Report[29] published in February 2016 emphasises the importance of medicines optimisation and sets out a vision of expanding the role of pharmacists. Even the role of community pharmacists in the traditional high-street chemist setting has expanded, as they often treat patients, for example in travel clinics. Whilst this thesis only considers pharmacists in a hospital setting, the research will have implications for the widening role of pharmacists as set out under the NHS Long Term Plan, with the aim of reducing pressure on GPs.[30]

For at least the past 30 years, pharmacists have been involved with all aspect of medicines-related care whilst, more recently, the role of pharmacists has developed considerably to include far more patient-facing roles.[31] Interestingly, Lords Reid and Kerr have referred specifically to the medicine information leaflets, contained in both prescription and non-prescription medicines, upholding them as an example of how patients are no longer uniformed.[32] Yet, these leaflets are often incomprehensible and are likely to conflict with both the judgment itself[33] and the AIS.

The research will also focus on GPs as a comparative healthcare profession. Currently, GPs provide primary care at the forefront of the community and have patients who have intellectual disabilities and those that have none and can therefore provide useful data contrasting with clinical pharmacy practice. As the judgment simply reflects the pre-existing General Medical Council guidelines which promote patient-centred care, rather than introducing fundamentally novel concepts, the research will examine the extent to which GPs practice in accordance with the *Montgomery* judgment.[34]

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[29] The Carter Report, February 2016 Operational productivity and performance in English NHS acute hospitals: Unwarranted variations – An independent report for the Department of Health by Lord Carter of Coles – February 2016 (publishing.service.gov.uk) accessed June 19, 2021

[30] Interim NHS People Plan Interim-NHS-People-Plan_June2019.pdf (longtermplan.nhs.uk) accessed June 19, 2021

[31] Nina Barnett and Claudia Carr. 'The *Montgomery* judgment and pharmacist consultations' The Prescriber January 2018 The Montgomery judgment and pharmacist consultations (wiley.com) accessed March 2, 2023

[32] *Montgomery* (n3) [76]

[33] ibid [90]

[34] http://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent accessed January 1, 2024

However, the practical implications of the judgment are of particular interest as clinic times might be longer to comply with *Montgomery.* GPs need to advise patients of any material risks and reasonable alternatives, without the patient feeling bombarded by information and the information must be given in a comprehensible manner, which may be more challenging where capacitous people with intellectual disability are concerned. With the current pressures on NHS primary care provision,[35] additional clinic time may be challenging for GPs, particularly in the light of reports of GPs feeling overwhelmed by their current pressure.[36] Despite these observations, the data analysed in chapters 5 and 6 appear to suggest that shorter clinic times are not a barrier to *Montgomery* compliance, and it may be that longer consultation times may heighten patient anxiety and risk clinicians withholding information.

This thesis builds on earlier research which evaluated the degree of information disclosure clinical pharmacists exercised and involved quantitative research, which was piloted in the pharmacy department in the London Northwest Healthcare NHS Trust.[37] Initial responses led to slight changes in the wording of the questions to ensure clarity of understanding. The updated survey was then circulated through the Medicines Use and Safety Network, which provided access to pharmacists based in both primary and secondary care organisations.

In May 2017, 100 responses were obtained from the survey, which were subsequently analysed. It was found that 73% of respondents reported asking patients what they wanted to know about their medicines. However, patients can only know what questions to ask if they are fully informed about the existing medication and alternatives and the consultation is patient-centred.[38] Even post-*Montgomery,* it was apparent that clinical pharmacy practice tended to adopt a more paternalistic '*Bolam-based approach'* which failed to accord with the more patient centred approach established by *Montgomery*.

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[35] The King's Fund, 'Understanding GP pressures' http://www.kingsfund.org.uk/sites/default/files/field/field_publication_file/Understanding-GP-pressures-Kings-Fund-May-2016.pdf

[36] Ibid

[37] See also, 'The right of people with disabilities to live independently and be included in the community' Issue Paper published by the Council of Europe Commissioner for Human Rights, Council of Europe Publishing, June 2012 https://rm.coe.int/the-right-of-people-with-disabilities-to-live-independently-and-be-inc/16807bef65 accessed July 9, 2021

[38] Barnett and Carr (n31)

Thus, it seemed evident that clinical pharmacists were not sufficiently informed of the standard imposed by *Montgomery*. The researcher recommended more comprehensive education of pharmacists and that the General Pharmaceutical Council guidance of 2017 should be updated to include the implications of the judgment, which led directly to training pharmacists to be *Montgomery*-compliant.[39]

1.7 Inclusion of patients with intellectual disability

The importance of including capacitous patients with intellectual disability in this research is that, as explained below, *Montgomery* imposes a duty on doctors to take reasonable care to ensure the patient, including the patient with intellectual disability, is aware of any material risks in any recommended treatment, together with any reasonable alternatives. However, the *Montgomery* judgment also needs to be read together with the AIS which came into force in August 2016 in England. The requirement here is that for all those engaged in adult social care to provide information to patients in a way they can understand.

The aim of the AIS is hence to ensure that those with a disability - a protected characteristic under the Equality Act 2010 - are not treated differently owing to their disability. Given that the raison d'être of the new test on informed consent in *Montgomery* is empowering the patient to make decisions about their own treatment, based on full information disclosure, the challenge is to ensure that the 1.5 million capacitous patients with an intellectual disability in the UK make their own decisions while also remaining equal partners in the decision-making process.[40]

It is unlikely, that in *Montgomery,* Lords Kerr and Reid had people with intellectual disability specifically in mind when they explained that the doctor must provide information to the patient in a way that is '*comprehensible'* and, that the duty would not be discharged by *'bombarding the patient with information which she cannot reasonably be expected to grasp'*.[41] However, these judgements are pertinent to this research as people with

[39] http://www.sps.nhs.uk/meetings/informed-consent-and-the-law-implications-for-medicines-related-consultations/ accessed March 2, 2023
[40] Mental Health Foundation, 'People with Learning Disabilities: Statistics' People with learning disabilities: Statistics | Mental Health Foundation accessed June 28, 2021 https://www.mentalhealth.org.uk/explore-mental-health/statistics/people-learning-disabilities-statistics
[41] *Montgomery* n3 [90]

intellectual disabilities are more likely to suffer greater physical and mental health problems than the general population.[42] Thus, it is imperative for people with learning disabilities to be able to provide informed consent under the legal duty imposed in *Montgomery*, while the inclusion of people with intellectual disability gives this research not only a novel perspective but also one of practical importance.

The following sections set out the cohort of patients to be considered alongside capacitous patients, which includes patients with mild to moderate intellectual disability, the older patient, the older patient with cognitive decline, and the vulnerable patient. However, care has been taken throughout this thesis to ensure that assumptions are not made that every patient falling within these categories lacks capacity, a point that is supported by the qualitative research in Chapter 6.

1.7.a Introduction to people with intellectual disability

Through qualitative research with clinical pharmacists and GPs, this thesis seeks to explore the challenges faced by capacitous people with an intellectual disability when providing informed consent. The term 'intellectual disability' needs some clarification at the early point of the thesis, although it is right to acknowledge that many terms are used interchangeably. The term '*learning disability'* replaced the phrase '*mentally handicap'* and was introduced by Stephen Dorrell, the Conservative Secretary of State for Health from 1995-1997. People First[43] explained a preference for the term '*learning difficulty,'* as they felt oppressed by the term 'learning disability'.[44] The more modern and preferred term is '*learning difference'* which focuses on what the person can accomplish, as opposed to what they are unable to achieve, by account of their disability. However, the term *'intellectual disability'* is used both domestically and internationally and, for this reason it has been observed that intellectual disability represents a more generic term,[45] which is used

[42] Complex Needs (online training), 'Why is Collaboration Significant?' Training materials for teachers of learners with severe, profound and complex learning difficulties: level All (complexneeds.org.uk) accessed June 28, 2021

[43] https://www.peoplefirst.org/ a user-led advocacy group for people with intellectual disability, accessed June 28, 2021

[44] See for example, Jeannie Sutcliffe and Ken Simons, *Self-advocacy and Adults with "Learning Difficulties": Contexts and Debates* (1993), Leicester: The National Institute of Adult Continuing Education in Association with Open University Press

[45] Dreenagh Lyle, *Understanding Profound Intellectual and Multiple Disabilities in Adults*. Routledge, London, 1st Edition, 2

throughout the thesis. The criticality is to remove the deficit model of those patients with a learning difference, to create parity of experience between those patients with a learning difference and those without.

Approximately 1.5 million people in the UK are diagnosed with an intellectual disability and there are doubtless many who remain undiagnosed. The World Health Organisation defines an intellectual disability as '*a significantly reduced ability to understand new or complex information and to learn and apply new skills (impaired intelligence). This results in a reduced ability to cope independently (impaired social functioning), and begins before adulthood, with a lasting effect on development.'*[46] Similarly, the American Association of Intellectual and Developmental Disabilities define intellectual disability as being *'characterized by significant limitations both in intellectual functioning and in adaptive behaviour as expressed in conceptual, social and practical adaptive skills,'*[47] which originate before the age of 18. Adaptive behaviour includes three specific skills: social, conceptual and practical. Those patients who find these skills challenging may also experience difficulties communicating, interacting with others and making decisions regarding their medical care.[48]

It is also worth noting there are people with mild intellectual disability who are not service users but regarding whom very little is known about their health. This research only includes those people with mild or moderate intellectual disability who are known to their service users, so representing only a tiny fraction of the research that needs to be conducted. Without extensive research into the causes of and the treatment of people with intellectual disability, they will continue to experience barriers to social inclusion and health equality.[49,50] People with intellectual disability experience greater health inequality, when

[46] https://www.euro.who.int/en/health-topics/noncommunicable-diseases/mental-health/news/news/2010/15/childrens-right-to-family-life/definition-intellectual-disability accessed June 29, 2021

[47] R.L Schalock, 'The evolving understanding of the construct of intellectual disability' *Journal of Intellectual and Developmental Disability* (2010), 36(4), 223-233

[48] Nandini Devi, 'Supported decision-making and personal autonomy for persons with intellectual disability: Article 12 of the UN Convention on the Rights of Persons with Disabilities' (2013) Journal of Law, Medicine and Ethics Winter 41(4):792-806

[49] See Tony Holland, Editorial 'Determining priorities in intellectual disability research' (2008) January 1, Journal of Intellectual Disability Research, volume 52, part 1 1–2

[50] See also, The Rio Political Declaration on Social Determinants of Health to which the UK is a signatory and recognises that health inequalities are unfair and unavoidable https://www.who.int/publications/m/item/rio-political-declaration-on-social-determinants-of-health accessed July 4, 2021

compared to the wider population, a lower life expectancy rate and higher than average health needs.[51] They may suffer deterioration in their health, which can go unnoticed, find accessing healthcare more challenging, depend more on family, carers and staff to support their needs and are also less likely to complain about suboptimal care.[52]

Patients in this cohort have higher than average health needs resulting from conditions more commonly experienced by this particular group.[53] The interaction of healthcare professionals with people with intellectual disability should be considered a social construct rather than solely a medical construct, and the reasoning is multi-faceted. With more people living longer, there is a greater prevalence of dementia within the community and with societal changes, there are more people with disability (including intellectual) living and being supported within the community. This community living provides greater opportunity but requires effort and skill to encourage people to exercise their capacity as far as possible. The underlying principle of people with disability living within the community is reinforced by the right of all people to be treated equally and not to be discriminated against.[54,55]

An assessment of capacity is important where any person is concerned since it is necessary to ascertain whether they have the capacity to consent to treatment. Where a person has a moderate or severe intellectual disability and lacks capacity, there can be an ethical dilemma between respecting a person's autonomy and the necessity of protecting that person from harm.[56] Where the concept of harm is concerned, John Stuart Mill was highly influential in the field of bioethics. Rather than referring directly to the term autonomy, he

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[51] Editorial, 'People with intellectual disability, their health needs differ and need to be recognised and met' BMJ Volume 329, 2004, 414-415

[52] Disability Right Commission. Equal treatment: closing the gap. A formal investigation into health inequalities. London. Disability Right Commission, 2005 https://disability-studies.leeds.ac.uk/wp-content/uploads/sites/40/library/DRC-Health-FI-main.pdf accessed July 5, 2021

[53] Ibid, 414 which illustrates that where the general population is concerned, cancer is the most common cause of death, followed by heart disease and cerebrovascular disease. Where people with intellectual disability are concerned, the leading cause of death is respiratory disease, followed by cardiovascular disease. They also more commonly experience conditions such as epilepsy, sensory impairments and dementia.

[54] Article 19 of the Convention of the Rights of Persons with Disabilities (CRPD) states that parties to the Convention (of which the UK is a signatory) recognises the right of all persons with disabilities to live in the community, with their choices equal to others and, to be fully included and participating in the community.

[55] Barnett and Carr (n31)

[56] JG Wong et al., 'Capacity to make health care decisions: its importance in clinical practice' (1999) Psychological Medicine 27, 437-446, 437

referred to liberty, stating that *'(o)Over himself, over his own mind and body, the individual is sovereign.'*[57] Where a person's acts did not otherwise cause harm, they were free to act as they wished. Once harm could be caused to others, then the State was free to intervene and regulate a person's behaviour.

Hence, Mill advocated personal freedom, personal liberty and freedom for society, free from inference from the State. Mill opposed paternalism as it interfered with freedom of choice, but appeared to accept that soft paternalism would be appropriate when preventing someone from obvious harm. However, there appears to be a caveat which limits a person's freedom, as Mill appears to specifically disqualify the young and *'those backward states of society, in which the race itself may be considered as in its nonage.'*[58]

It is possible that he discounted those with intellectual disability being that, for Mill, liberty was a process towards fulfilment of both the individual and society. If this is correct, then it would logically follow that neither the young nor those with limited capacity could contribute effectively. The use of the word *'nonage'* may suggest that those with intellectual disability lack capacity and escape Mill's definition of being afforded liberty. Whether Mill would have approved of hard paternalism for people with intellectual disability is unknown, but the suggestion appears to be that liberty did not apply to these cohort of patients in quite the same way as to those who have capacity.

1.7.b The older patient

The older patient is a further cohort of patients who *may* suffer from some degree of intellectual disability. According to the Census of 2021, the population of England and Wales has continued to age, while 18.6% of the total population were aged 65 years or older. This represents a rise of 2.2% compared with the previous census in 2011. Moreover, over half a million (527,900) people were at least 90 years old. Given the significant growth of the older population, one of the many challenges concerns preserving patient autonomy in a culture which tends to infantilise the older patient[59] and question their decision-making ability.

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[57] Stefan Collini, eds. *J.S Mill on Liberty and other writings* (2012) Cambridge Texts in the History of Political Thought, Cambridge University Press, 13

[58] Ibid 61

[59] https://www.psychologytoday.com/gb/blog/speaking-in-tongues/202208/the-infantilization-elders-and-people-disabilities accessed June 30, 2021

Where this issue arises, there is a risk that the older patient or person living in adult social care may not be able to provide informed consent. In these circumstances, there is a greater risk of relevant information being withheld from the person.

A study into the older patient-nurse relationship in a supported-living setting, shows an imbalance of the partnership where the nurse provides information as part of their day-to-day engagement with the person. Although this study may be considered outdated, the relationship between the older patient and the nurse has changed little over the past decade and remains of immense value. The challenge here is that the relationship between the patient and the nurse can be viewed as a form of control and reinforces the concept that the decision-making process has been taken unilaterally rather than enabling decision making through communication, discussion or exchange. In such instances, personal autonomy means more than uncoerced choice.[60]

It may be argued that objective assessments about what is best for the patient are more important than the patient's views themselves.[61] This results in the patient naturally conforming with the nurses' decisions rather than the patient being supported in the decision-making process. Given the natural imbalance of the knowledge and understanding of medical treatment and care options, the reality is that nurses make decisions on behalf of their patients. These decisions may be taken by way of suggestive or linguistic manipulation to give the appearance of patient autonomy, but the underlying reality remains very different. Whilst the nurse's role is to protect the older person's wellbeing, by limiting the choices available to the person they are constraining patient autonomy and the range of choices offered.[62]

This balance of power may affect the older person's individual autonomy adversely and deny that person the opportunity to be an equal partner in the relationship. Moreover, older patients may live in an organisation that is structured institutionally which can put the autonomy of the older person at a disadvantage by preventing risk-taking, which can be perceived as an additional barrier to patient autonomy. It is apparent that more work needs

[60] Martha B. Holstein, Jennifer A. Parks, Mark H Waymack, 'Ethics, Ageing, and Society' The Critical Turn eBOOK Springer Publishing Company 2010, 21
[61] Ibid16
[62] Brendan McCormack, 'Autonomy and the relationship between nurses and older people' Ageing and Society 21, 2001, 417-446, 437

to be done by nurses in how they engage with the older patient, developing an environment that values the views of the older patient whilst recognising that they do not always need to be the final arbiter of decisions.[63]

Reframing communication skills to make dialogue the centre of enhancing patient autonomy in the older person will reverse the culture of paternalism. Ensuring autonomy in the older person has identifiable health benefits, including reducing depression and allowing the older person to retain dignity and a sense of identity. This current approach may save time and be the less challenging option for nurses, but appears short-sighted insofar as clear communication with the older person enhances autonomy and benefits health.

The practice outlined above violates the provisions of the Mental Capacity Act 2005, which specifically state that assumption of a lack of capacity cannot be made merely by reference to a person's age.[64] Yet, there is clear evidence to the contrary simply because the person is older. The Mental Capacity Act Code of Practice assists in adding detail of steps to be taken to help another make decisions for themselves.[65] These include taking the time to explain the information to help the older person make an informed decision and provide information in a way that does not confuse the person. In accordance with the judgment of *Montgomery*, the Code of Practice explains that the risks and benefits must be conveyed to the person and that the person must understand the consequences of their decisions.

Hence, in contrast to benevolent paternalism, to achieve the desirable objective of patient autonomy it appears that communication is key. Simply because a person needs assistance in understanding does not mean that person lacks capacity to consent. According to the statutory provisions, a person is not to be treated as unable to take a decision unless all the practicable steps to help him to do so have been taken without success,[66] but where necessary communication should be supported by the AIS.

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[63] Ibid, 438. A similar finding was made in Terri R. Fried, Michel D. Stein, Patricia S. O Sullivan, Dan W. Brock and Dennis H. Novack, 'Limits of patient autonomy: physicians' attitudes and practices regarding life sustaining treatments and euthanasia' (1993) Mar 22, Archives of Internal Medicine, 153(6), 722-8

[64] Mental Capacity Act 2005 section Section 2 (3) (a)

[65] Mental Capacity Act: Code of Practice 2007, paragraph 3.9 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/921428/Mental-capacity-act-code-of-practice.pdf accessed July 14, 2021

[66] MCA (n64) section 1(3)

According to The Standard, providers of NHS care or adult social care must provide information that meets the person's needs and healthcare professionals need to be aware of this provision when working with older patients. By virtue of s250 (7)(a), the provision of adult social care for the older person is specifically included. Thus, there is a legal duty to provide the older patient with information, such as EasyRead, to aid their understanding with the objective of enhancing patient autonomy. Once patient autonomy is enhanced and the goal of informed consent is achieved, the chance of the therapeutic privilege exception being relied on is significantly reduced.

Whilst there is no discernible data on the role of therapeutic privilege and the older patient, it seems apparent that where information may be intentionally withheld, autonomy is inhibited. In a culture which tends to infantilise the older patient, it is necessary to re-evaluate communication strategies to enable older patients to exercise autonomy and provide informed consent. Care needs to be taken as infantilism can be considered a form of ableism. Where nurses can have meaningful conversations with patients, where information is conveyed and alternatives offered, then less information is likely to be withheld. Although data is limited, it is likely that nurses in a supported care home setting may exercise the therapeutic privilege exception through the prism of benevolent paternalism.

1.7.c The older patient with cognitive decline

The older patient *may* have some degree of cognitive decline, although one must ensure that assumptions are not made about either the older patient or the older patient with dementia, as both may be capable of providing informed consent and thus, information should not be withheld from them.

Dementia is a progressive disease which results in a gradual decline in decision making ability. The term encompasses several disorders which can adversely affect *'memory, thinking, orientation, comprehension, calculation, learning capacity, language and judgment.'*[67] In contrast to an earlier period when patients with dementia were assumed to lack capacity, patients with mild to moderate dementia can still understand and weigh up information to take a decision about their medical treatment.[68] Patients living with mild to

[67] World Health Organisation (WHO), Dementia: A Public Health Priority (2010), 7
[68] Malcolm Goldsmith, 'Hearing the voice of patients with dementia' (1996), London: Jessica Kingsley Publishers

moderate dementia or Alzheimer's disease cannot be assumed to lack decision-making capacity on the basis of their diagnosis alone and have an equal right to know about their medical treatment and to provide informed consent. Gone are the times when the person with dementia or Alzheimer's values were viewed as baseless and communication was in vain. Indeed, it has been argued that society's perception of the individual contributes significantly to the suffering associated with dementia, aside from the actual disease itself.[69]

Where a person is in the early stages of dementia, there may be considerable health benefits for the patient to contribute to the treatment plan whilst they still have capacity to do so and before further cognitive decline.[70] Here research shows that patients are keen to engage with decision-making.[71] Where the condition has progressed significantly, it is still possible that patients with advanced dementia can communicate their decision regarding healthcare provision, where there are supportive communication strategies.[72] Where the person's cognitive function deteriorates further, it may be increasingly likely that capacity and competency are affected, and the person will then be treated according to their best interests under section 4 of the 2005 Mental Capacity Act.

With dementia or conditions such as Alzheimer's diseases, the person's cognitive function can fluctuate and decision-making capacity can be severely affected. Fluctuating capacity is not limited to these conditions and can include a wide range of psychiatric diseases, such as depression and anxiety. According to statistics, there are 944,000 people in the UK with dementia. By 2050, this figure is estimated to be in the region of 1.6 million.[73] Regardless of how advanced the stages of the disease, 54% of patients with Alzheimer's disease and 42% of patients with Parkinson's disease lacked capacity.[74] Conversely, 46% and 58% of patients

[69] Hugh Series, 'Best Interests Determination: A Medical Perspective' in Charles Foster, Jonathan Herring and Israel Doron, eds. The Law and Ethics of Dementia (Oxford: Hart Publishing, 2014) at 102 referred to in Megan S. Wright, 'Dementia, Healthcare Decision Making and Disability Law' The Journal of Law, Medicine and Ethics, 47(S4) (2019) 25-33,27

[70] See Soumya Hedge and Ratnavalli Ellajosyula, 'Capacity issues and decision-making in dementia' Ann Indian Acad Neuro*l* 2016; 19: S34-9

[71] Karl L. Smebye, Marit Kirkevold and Knut Engedal, 'How do persons with dementia participate in decision making related to heath and daily care? A multi case study' (2012) BMC Health Services Research 12, 241

[72] Joann Perry et al., 'Nurse-Patient communication in dementia: Improving the odds' (2005) Journal of Gerontological Nursing 31, bo:4 43-52

[73] https://www.dementiastatistics.org/statistics/numbers-of-people-in-the-uk-2/ accessed July 9, 2021

[74] Manuel Trachsel, Helena Hermann and Nikola Biller-Andorno, 'Cognitive fluctuations as a challenge for the assessment of decision-making capacity in patients with dementia' (2015) American Journal of Alzheimer's Disease and other Dementias, 30(4), 360-363

with Parkinson's disease retained decision-making capacity which supports the premise that focused support on dialogue and communication can support autonomy.

The challenge for healthcare professionals is that capacity is fluid and can fluctuate and the law requires the healthcare professional to take every step practicable to engage with the patient. Section 1 of the Mental Capacity Act sets out the fundamental principle that any person is not to be treated as unable to take a decision unless all the practical steps to help him to do so have been taken without success. The Act, whilst supporting people who lack capacity, also aims to maximise their ability to make decisions or to participate in decision-making, as far as they are able to do so.[75] This entails taking all practicable steps to facilitate the decision-making process.

Where patients have cognitive fluctuation, they can experience periods where they are agitated, tired, depressed or noncommunicative which would be a natural barrier to achieving informed consent. Although it has been recommended that the doctor discusses treatment options, risks and informed consent at a point of the day where the patient is in a positive mindset, this approach appears impractical in terms of access to healthcare provision.[76]

Research shows an assumption that where patients' cognition declines, the patient lacks decision-making capacity.[77] In these circumstances, a healthcare professional may consider they are acting beneficently and withhold information from the patient, if it is believed that disclosure would be detrimental to the patient's health. In contrast, data from a study of patients with mild dementia showed that 92% wanted to be informed of their diagnosis and an even higher percentage would want to be advised of a hypothetical cancer diagnosis.[78] The study therefore suggests that benevolent paternalism is not desirable for patients with mild dementia. On the contrary, evidence suggests that patients do not suffer serious harm

[75] See Mental Capacity Act 2005, Code of Practice, issued by the Lord Chancellor on 23rd April 2007 in accordance with sections 42 and 43 of the Act, 19 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/921428/Mental-capacity-act-code-of-practice.pdf accessed July 14, 2021

[76] Trachsel (n74)

[77] See R Beard *Living with Alzheimer's; Managing Memory Loss, Identity and Illness* (New York, NYU Press, 2016), referred to in Megan S. Wright. 'Dementia, Healthcare Decision Making and Disability Law' (2019) The Journal of Law, Medicine and Ethics, 47, S4 25-33, 28

[78] Gill Pinner and Walter Pierre Bouman, 'Attitudes of Patients With Mild Dementia and Their Carers Towards Disclosure of the Diagnosis' International Psychogeriatrics' (2003) 15(3), 279288

when presented with a diagnosis of Alzheimer's which suggests that the therapeutic privilege exception has no role where patients are not harmed by disclosure of a serious medical condition.[79]

Importantly, the level of cognitive impairment does not necessarily determine a person's ability to provide informed consent.[80] This confirms that particular care must be taken to ensure that all steps are taken to accommodate informed consent. Failure to do so could result in healthcare professionals withholding information from patients. Rather than supporting autonomy, there is a clear risk of benevolent paternalism here.

Further research from Canada confirms that appropriate training is sub optimal for family doctors (physician) and more needs to be done to ensure that decision-making capacity assessments are effective.[81] Supported decision-making has a relevant and empowering role with people with dementia, where the person is supported in their decision-making capacity by someone who they trust and who can assist them in understanding, weighing, and communicating the information.

The advantage of supported decision-making is a fundamental principle of Article 12 of the Convention on the Rights of Persons with Disabilities, wherein it states that *'persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life'*. Thus, the person with dementia or other condition with cognitive decline retains the legal authority to make their own decision, rather than a person with substituted decision-making authority. Rather than seeing persons with mild or moderate dementia as a deficit model, where decisions are made on their behalf, supporting their autonomy with supported decision making and enhanced communication skills is a preferred model to avoid paternalism.

[79] Marcel Bahro et al., 'How do patients with Alzheimer's disease cope with their illness? A clinical experience report' (1995) 43 J Am Geriatr Soc 41-6

[80] Elizabeth Beattie, Maria O'Reilly, Deirdre Fetherstonhaugh, Mitchell McMaster, Wendy Moyle and Elaine Fielding, 'Supporting autonomy of nursing home residents with dementia in the informed consent process' (2019) Dementia 18(7–8), 2821–2835

[81] Lesley Charles, Jasneet Parmar et al., 'Physician education on decision-making capacity assessment' (2017) Can Fam Physician, 63: e21-30

1.7.d The vulnerable patient

The Oxford English Dictionary defines vulnerable as where a person is '*weak and easily hurt physically or emotionally'*.[82] Within healthcare law, there are different definitions of what amounts to being vulnerable. For example, according to Oxford Reference *'vulnerability'* refers to '*a position of relative disadvantage, which requires a person to trust and depend upon others. In a medical context, all patients are vulnerable to an extent, and some may be particularly so owing to impaired decision-making abilities or social position. Any exploitation of a vulnerable person is considered contrary to medical ethics'*.[83] A vulnerable patient has also been defined as a person who '*even if not incapacitated, is under constraint, or subject to coercion or undue influence, or for some other reason deprived of the capacity to make a choice or incapacitated or disabled from giving or expressing a real and genuine consent*.'[84]

Hence, an elderly person, a person with dementia or a person with an intellectual disability may be considered vulnerable as they may have impaired decision-making capabilities. Equally, a person who may be suffering with anxiety may also be considered vulnerable. Moreover, the definition of a vulnerable person as being *'weak and easily hurt physically or emotionally'* is notably similar to the therapeutic privilege exception in *Montgomery,* where a doctor is permitted to withhold information where disclosure would be detrimental to the patient's health. Altogether for the purpose of this research, the cohort of patients who may have impaired or borderline capacity are considered vulnerable. But the disadvantage of adopting this narrative is that a vulnerable person can be stigmatised, while a paternalistic approach is adopted which can enforce the notion of therapeutic privilege exception as an essential and desirable course of action. Here, the model of the vulnerable patient is focused on disempowerment, where vulnerability is viewed as a deficit, rather than challenges where the patient can be supported to achieve autonomous decision-making.[85]

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[82] https://www.oxfordlearnersdictionaries.com/definition/english/vulnerable accessed December 15, 2022

[83] https://www.oxfordreference.com/display/10.1093/oi/authority.20110803120303277;jsessionid=144D7449C7520183F85F51A06DA2C5BB accessed December 15, 2022

[84] *A Local Authority v Man NA and SA* [2005] EWHC 2942, 77

[85] See, for example, Barbara Fawcett, 'Vulnerability: Questioning the certainties in social work' (2009) Int Soc Work, 52:473-84

Where patients are simply perceived as vulnerable, there is an increased risk that benevolent paternalism will triumph over supported decision-making.

As outlined below in section 1.8, the Mental Capacity Act 2005 is written in terms which illustrate two distinct patients: those that do have capacity and those that fail to meet the legal threshold for establishing capacity. Capacity to consent is not binary, existing on a spectrum of being able to consent or lacking capacity to consent.[86] Where vulnerable people who have capacity are concerned, the Court of Protection may exercise their inherent jurisdiction to protect those who may be subject to abuse, coercion or other external factors.[87] The treatment of vulnerable patients has led Lord Justice MacFarlane to acknowledge that whilst a person may have capacity within the perimeters of the Mental Capacity Act, other factors such as undue influence or coercion, *'may combine with his borderline capacity to remove his autonomy to make an important decision'.*[88]

Post-*Montgomery*, it has been observed that 'situational vulnerability' in healthcare may arise as a result of pressure on clinical time, the nature and complexity of the relevant information and other difficulties with comprehension.[89] The qualitative data of this thesis embraces and acknowledged the pressure of clinical time which, unexpectedly, did not correlate with a greater frequency of withholding risk disclosure. It has also been observed that although *Montgomery* counselled against '*bombarding'* the patient with technical information that they are not able to understand, there was little guidance as to how that effective communication should be achieved.[90] It is agreed that there is no specific formulae or detailed guidance, but how understanding would be achieved was beyond the scope of the judgment. Whilst a framework could have been explored, the difficulty with a formulaic

[86] It is also considered to be unhelpful to regard patients as either having capacity or not. See for example Jonathan Herring and Jesse Wall, 'Autonomy, capacity and vulnerable adults: Filling the gaps in the Mental Capacity Act' (2015) Legal Studies 35(4), 698-719

[87] A good example of influence is *Re T (Adult: Refusal of Treatment)* [1992] EWCA Civ 18, where a critically ill pregnant young woman initially consented to a blood transfusion but later withdrew her consent after a private conversation with her mother, a Jehovah's Witness

[88] *DL v A Local Authority* [2012] EWCA Civ 253, 65

[89] Sandip Talukdar, 'Ensuring Risk Awareness of Vulnerable Patients in the post *Montgomery* era: Treading a Fine Line' (2020) Health Care Analysis 28:283-298,289

[90] Jose Miola and Rob Heywood, 'The changing face of pre-operative medical disclosure: Placing the patient at the heart of the matter' (2017) *The Law Quarterly Review* 133 (Apr), 296-321

approach is that it creates narrow boundaries through which the healthcare professional is compelled to act, with potential penalties for failing to do so.

Talukdar argues that complying with the need to advise a vulnerable patient of a material risk could involve weak paternalism at the same time as supporting 'authentic' decision-making about their own treatment.[91] He maintains that where vulnerable people consent to medical treatment, they may do so without fully appreciating the risks they expose themselves to. Moreover, those that subsequently treat the vulnerable patient do so in acknowledging that the patient has provided informed consent, but without further exploring the patient's vulnerability. Thus, the consequences of greater harm cannot be overlooked because they risk abandoning the vulnerable person to a choice that he may have made with no subsequent support.[92] Arguably, the patient-centred test in *Montgomery,* which requires the doctor to develop a dialogue to understand the reasonable person in the patient's position,[93] will go some way to recognising their patient's unique vulnerabilities and being able to understand them. The GMC guidelines also mirror the focus of the patient-centric nature of best medical practice, whilst best practice should be supportive of the vulnerable patient and provide the time to explore what is important to them.[94] Finally, the AIS, if implemented correctly and with sufficient funding, should provide adequate support for communication to all patients, including those with intellectual disability.

[91] See for example, Loretta Kopelman, 'On Distinguishing Justifiable from Unjustifiable Paternalism' (2004) Virtual Mentor, February Volume 6, Number 2

[92] See Jonathan Herring and Jesse Wall, 'Autonomy, capacity and vulnerable adults: Filling the gaps in the Mental Capacity Act' (2015) 35 Legal Stud 698, 713 opine that 'others harm you, and to be told no protection is offered because you have chosen this harm, even though it is against your deepest values is horrific'

[93] *Montgomery* (n3) [88] Lords Kerr and Reid stated that, 'The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.'

[94] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/professionalism-in-action para 2 states, '...treat each patient as an individual'. Para 49 adds that the doctor 'must work in partnership with patients, sharing with them the information they will need to make decisions about their care' accessed Sept 18, 2021

1.8 a The Mental Capacity Act 'Allow(ing) the tail of welfare to wag the dog of capacity'[95]

Having considered the inclusion of GPs and clinical pharmacists in the qualitative research, together with the relevance of the inclusion of patients with intellectual disability, this section briefly refers to the importance of patient autonomy through case law which will be considered in greater depth in Chapters 2 and 3. Thereafter, this section examines the Mental Capacity Act 2005 (MCA), the relevance of which lies in the statutory provisions which establish whether a patient has capacity to consent to treatment. Where it is established that a patient has capacity, they must be able to provide informed consent.

In *Sidaway*, Lord Bridge and Lord Keith acknowledged the principle that a person of sound mind may choose for themselves whether or not to accept treatment recommended by the doctor.[96,97] Similarly, in *Chester v Afshar*, Lord Bingham referred to the rationale of a person '*to make for themselves decisions intimately affecting their own lives and bodies*'.[98] Interestingly, the judgment in *Montgomery* refers to the phrase '*sound mind*' on four separate occasions, emphasising the importance of capacitous decision-making.

Whilst the importance of patient autonomy is undisputed, the focus of this specific issue lies in the binary issue of capacity. Put simply and in contrast to the latter case of *Hii Chii Kok v Ooi Peng Jin Lucien and another*[99] (discussed in chapter 4.6), from *Montgomery's* perspective, a person either has the capacity or does not. Thus, *Montgomery* fails to recognise a potential deviation from normative cognitive boundaries. It is argued that the binary nature of the judgment is a distinct weakness in a seminal judgment, as it fails to recognise that people with intellectual disability may have capacity but it may then have their decision-making ability compromised by excessive disclosure as supported, not only by literature, but also the qualitative research. In turn, this could marginalise people with intellectual disability by adopting an assumption of inequality in the decision-making process.

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[95] *Heart of England (*n1) [6]
[96] *Sidaway* (n6) [50]
[97] Ibid [54]
[98] *Chester v Afshar* [2005] UKHL 41 [84]
[99] *Hii Chii Kok v Ooi Peng Jin Lucien and another* [2017] SGCA 38

The MCA has been described as '*a visionary piece of legislation for its time'*[100] in defining the legal principles to be applied where a person over the age of 16 lacks mental capacity. One of the key principles of the MCA is a rebuttable presumption of capacity.[101] At the root of determining capacity is the relationship between the diagnostic element and the functional test. Section 2 provides the diagnostic element which states that '*a person lacks capacity in relation to a matter if at the material time is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.'* The functional test considers whether the person can understand, retain, use or weigh the information and then communicate the decision.[102] The Mental Capacity Act Code of Practice provides some assistance with regard to what conditions may amount to an '*impairment or disturbance in the functioning of the mind or brain'.*[103] This includes, but is not limited to, some types of mental illness and significant learning disabilities. It seems apparent that whilst mild or moderate learning disabilities may well fall outside the category of *'significant learning disabilities'* to denote a mental illness from which a person with an intellectual disability may suffer, it may also fall within the definition. However, it should be established that the inability to satisfy the legal test for capacity is due to intellectual disability or mental disorder and not, for instance, as a result of being influenced by substance abuse, such as alcohol or drugs.

Although the binary nature of the test in the MCA appears at first glance as a blunt instrument, where the person lacks capacity then his past wishes, feelings, beliefs and values will be considered as far as possible to ensure that his treatment would mirror decisions he would have made if he had capacity.[104] Moreover, where decision-making is concerned, the views of those with an interest in the person's welfare should also be carefully considered.[105]

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[100] Mental Capacity Act 2005: post-legislative scrutiny. https://publications.parliament.uk/pa/ld201314/ldselect/ldmentalcap/139/139.pdf accessed July 07, 2022

[101] *Hii Chii Kok* (n99) section 1

[102] Ibid section 3

[103] Mental Capacity Act: Code of Practice 2007, paragraph 4.12 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/921428/Mental-capacity-act-code-of-practice.pdf accessed July 14, 2021

[104] MCA (n64) section 4(6) (a)-(c)

[105] Ibid section 4(7)

The second stage is a 'functional concept'. It requires the person to understand information relevant to the decision, retain the information, weigh up or use the information as part of the decision-making process and communicate the decision to the person concerned.[106] Where a person can satisfy the test, they are deemed to have the capacity to make their own decisions regarding their medical treatment, even where their decision may appear to be bizarre or irrational.[107]

Nevertheless, it can sometimes be challenging for the courts to determine whether or not a decision is simply bizarre or a 'misconception of reality'.[108] Simply because a person has a mental disorder or an intellectual disability, does not mean that the person lacks capacity to consent to treatment and it must be assumed that a person has capacity, unless it is proved otherwise.[109] Thus, it is the case that a person without a mental disorder or impairment can refuse treatment where, for example, they believe that G-d will cure them, even though they lack any appreciation of their precarious condition.[110]

It is worth noting that the test for capacity is decision-specific, entailing that it is possible for a person to have the capacity in relation to some decisions but not to others. Moreover, where section 3(1)(b) relates to retaining that information, it is sufficient when the information is only retained temporarily. This principle may be particularly significant for patients who suffer from a level of intellectual disability, such as mild dementia, but where time and effort must be invested in this regard. The Codes of Practice assist patients with intellectual disability or those that are vulnerable, as they suggest that every effort must be made to help patients retain information. *'If they have difficulty understanding, it might be useful to present information in a different way (for example, different forms of words, pictures, or diagrams) written information, audiotapes, video and posters can help people*

[106] Ibid section 3
[107] *Wye Valley v NHS Trust v B* [2015] EWCOP 60
[108] *NHS v T* [2004] EWHC 1279 (Fam) [41]
[109] *Hii Chii Kok* (n99) section 3
[110] See for example *Re C (Adult Refusal of Medical Treatment)* [1994] 1All ER 819 where a paranoid schizophrenic was held to have capacity to refuse medical treatment, despite believing that G-d would cure him. His belief, mistaken or otherwise, was not relevant

remember important facts.' [111] Supported by the AIS, this statutory provision should support patients with intellectual disability.

Section 3(1)(a) relates to understanding '*the information relevant to the decision*', and the extent of understanding can be relevant in patients with intellectual disability. Mr Justice Jackson found that it was sufficient that JB had a *'broad, general understanding'*[112] of the recommended treatment rather than a more detailed and specific understanding of the risks of amputation and observed that providing that detailed understanding would in effect '*diminish the scope of JB's capacity'.*[113] Although this statement was made in the context of obviating the need to advise the patient of a range of different procedures, the suggestion appears to be that full disclosure may compromise the patient with a level of capacity determined by intellectual disability. This specific point is particularly relevant for this thesis where the data suggested that disclosure may compromise capacity. Under these circumstances, it is possible that a healthcare professional could beneficently exercise the therapeutic privilege exception to preserve the patient's capacity. Of course, no reference is being made here to the therapeutic privilege exception in the judgment, which was heard pre-*Montgomery* where only a broad understanding of the nature of the medical procedures were required but where it is highly suggestive that information could be justifiably withheld in circumstances where a person's capacity could be compromised.

Mr Justice Jackson also took the opportunity to reflect on how a person's capacity may be assessed by the patient's response to whether they accept or reject advice. Where this occurs, Mr Justice Jackson observed that there was a risk of '*allow(ing) the tail of welfare to wag the dog of capacity'*, suggesting that some capacitous but vulnerable patients may be deprived of the opportunity of making their own autonomous decisions regarding their treatment. Here the judgment demonstrates a unique challenge whereby the determination of a patient's capacity is dependent on the doctor making the assessment and that a patient can be denied their autonomy to take decisions relating to medical treatment.

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[111] Mental Capacity Act, Code of Practice 2007 https://assets.publishing.service.gov.uk/media/5f6cc6138fa8f541f6763295/Mental-capacity-act-code-of-practice.pdf para 4.18 46 (Date accessed??)
[112] *Heart of England* (n1)
[113] Ibid

Where the MCA is concerned, a person is faced with two positions. Firstly, where there is no cognitive impairment, section 2 of the MCA is likely to be satisfied and the patient is deemed to have capacity. Where there is a cognitive impairment but the person satisfies section 3, then they will be deemed to have capacity. In both these situations the person's autonomous decision will not be called into question. In circumstances where a person does not satisfy the diagnostic threshold, it may still be possible for the courts to invoke their inherent jurisdiction to protect patients who have borderline capacity, thereby circumventing the binary nature of the MCA. Where decisions are made as a result of '*constraint, coercion and undue influence or other vitiating factors'*, Mr Lord Justice McFarlane observed that is '*a sound and strong public policy justification for the courts'* for the court to exercise their inherent jurisdiction.[114] Whilst this has been welcomed as a means of supposing autonomy and a person's rights, it has also been criticised for failing to take account of the vulnerable person's perspective.[115]

Where a person fails to satisfy section 3 of the MCA, then substitute decisions will be made for them under section 4 of the MCA and the person will be treated in their 'best interests'. The abject failure of a binary approach to capacity is that it ignores the '*murkier middle ground'*[116] where a person may have borderline capacity. The unpalatable result is that people with dementia or a learning disability could be stigmatised and portrayed within the deficit model, which automatically equates a person's disability with a lack of capacity.[117] This approach was widely criticised in the MCA post-legislative scrutiny which observed a culture of paternalism in contrast to the empowering ethos intended for people with intellectual disability. Moreover, the post-legislative scrutiny found that there was an understanding of the presumption of capacity where patients were deemed to lack capacity based simply on their mental illness or for making an unwise decision.[118] Historically,

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[114] *DL v A Local Authority* [2010] EHWC 1549 (Fam)

[115] See Emily Jackson, *Medical Law: Texts, Cases and Materials*, Oxford University Press. For a similar view, see also, Jonathan Herring, *Vulnerable Adults and the Law* (Oxford University Press, 2016) and Michael C Dunn, Isabel CH Clare, and Anthony J Holland, 'To empower or to protect? Constructing the 'vulnerable adult' in English Law and Public Policy (21008) 28 Legal Studies, 234-53

[116] Sumytra Menon et al., 'How should the 'privilege' in therapeutic privilege be conceived when considering the decision-making process for patients with borderline capacity?' (2021) J Med Ethics, 47:47–50

[117] See also Beverley Clough, 'Disability and Vulnerability: Challenging the Capacity/Incapacity Binary' (2017) Social Policy and Society 16:3, 469-481

[118] https://publications.parliament.uk/pa/ld201314/ldselect/ldmentalcap/139/139.pdf paragraph 57 accessed September 12, 2021

although there is clearly a nexus between an impairment and capacity to consent, it was *presumed* that a person with a *'serious mental illness, mental retardation, or cognitive impairment, lacked capacity*'.[119] The MCA identifies two cohorts of patients: those who have capacity by meeting the legal threshold; and those that fail the test, who are deemed to lack capacity. Where a person has capacity, they can exercise personal autonomy and self-determination to take their own decisions regarding their treatment. Therefore, once a person has reached the legal threshold for capacity, then they are treated as an autonomous agent.[120]

Where the patient has failed to meet the threshold, section 4 of the MCA provides that the court may make declarations as to the lawfulness of any act done or yet to be done. Where a patient is unable to consent, it is lawful to treat a patient according to their best interests. In these circumstances, when treating a patient who lacks capacity the fundamental question is whether it is in the patient's best interests to be treated, not whether it is lawful to withhold the treatment.[121] In these circumstances, the patient's welfare in the widest sense should be considered. As medical best interests cannot be considered in isolation, the social and psychological interests are equally addressed.

The court should also consider the nature of the medical treatment, its chances of success, the potential outcome, and a subjective analysis of how this particular patient would consider this specific treatment. They must also consult those people who are looking after him or interested in his welfare[122] which echoes *Wye Valley v NHS Trust v B*, where Mr Justice Jackson opined that proper weight needed to be given to the patient's wishes, feelings, values and beliefs. In doing so, the application of the MCA appears to determine the patient's interests by reference to the patient's endorsed values, and not solely the patient's best medical interests.[123,124]

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[119] Thomas Grisso and Paul S Applebaum *Assessing Competence to Consent to Treatment: A Guide for physicians and other health professionals*, Oxford University Press, 1998, 18-19
[120] Herring and Wall (n92) [703]
[121] *Aintree University Hospitals NHS Foundation Trust (Respondent) v James (Appellant)* [2013] UKSC 67 on appeal from [2013] EWCA Civ 65 [21]
[122] Ibid 39
[123] See John Coggon, 'Mental capacity law, autonomy, and best interests: An argument for conceptual and practical clarity in the Court of Protection,' Medical Law Review 24(3) August 2016 396–414
[124] This approach is not necessarily a direct consequence of the provisions of the MCA, as *Re Y (Mental Patient: Bone Marrow Donation)* [1996] 2FLR 787 recognised that when deciding whether or not it was in

The patient-centric nature of the materiality test in *Montgomery* mirrors the nature of supported decision-making in the MCA. Both the MCA and *Montgomery* refer to the importance of the patient's values; the former in the context of best interests under section 4(6) of the MCA, and the latter in the patient centred nature of the subjective limb of the materiality test.[125] In effect, it appears that the notion of supported decision-making within the MCA has been extended by *Montgomery* where supported decision-making now applies to capacitous patients, with the patient's wishes and values central to the decision-making process.[126] In contrast, the nature of the MCA (and similar approaches in other domestic jurisdictions, such as Singapore, discussed in more detail in Chapter 4) has been criticised by the Convention on the Rights of Persons with Disabilities, who argue that the binary approach discriminates against people with intellectual disability. Moreover, the Committee on Rights of Persons with Disabilities stated that: *'Mental capacity is not, as is commonly presented an objective, scientific and naturally occurring phenomenon. Mental capacity is contingent on social and political contexts, as are the disciplines, professions and practices which play a dominant role in assessing mental capacity.'*[127]

The CRPD explain that the MCA presumes to '*be able to accurately assess the inner workings of the human mind'*[128] and therefore denies the person equal recognition before the law and recommends supported decision-making, with the benefit of the person's family and/or carers where necessary.[129] Article 12 of the United Nations Conventions on the Rights of Persons with Disabilities[130] acknowledges the right to legal capacity for decision-making for

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the best interests for non-capacitous patient to donate bone marrow, her social and psychological needs had to be considered. However, these 'interests' were the family's interests and not necessarily Ms Y's herself, as she did not demonstrate any values, current or past that would support this decision.

[125] *Montgomery* (n3) [89]

[126] A similar point is also made by Jonathan Herring et al., 'Elbow room for best practise? *Montgomery*, patients' values and balanced decision making in patient-centred care' (2017) Med Law Rev 25(4) 582-603

[127] Paragraph 14 of the General Comment (No1 2014) – Committee on the Rights of Persons with Disabilities – 'Article 12: Equal Recognition before the law https://www.ohchr.org/en/documents/general-comments-and-recommendations/general-comment-no-1-article-12-equal-recognition-1 accessed November 16, 2022

[128] Convention on the Rights of Persons with Disabilities Committee on the Rights of Persons with Disabilities Eleventh session 31 March–11 April 2014 Article 12 para 2 https://documents-dds-ny.un.org/doc/UNDOC/GEN/G14/031/20/PDF/G1403120.pdf?OpenElement accessed November 16, 2022

[129] Ibid 47

[130] https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/article-12-equal-recognition-before-the-law.html accessed November 16, 2022

those people with intellectual disability while establishing supported rather than substituted decision-making. In cases where the person has a severe learning disability and their IQ is under 20, the MCA provides substituted decision-making to authorise decisions being made in the patient's best interest where they lack capacity to act autonomously.[131] Even in those circumstances, the statutory provisions state that consideration should be given as to whether that person is likely to have capacity at some point, and when that will be.[132]As far as possible, the person is encouraged to participate in the decision-making process. However for some people beyond the scope of this research with moderate to severe intellectual disability, this will be challenging.[133]

1.8.b The importance of understanding material risks

Where the patient cannot understand the material risks of the treatment, they are unable to provide informed consent. The *Montgomery* judgment emphasises the need for dialogue between healthcare professional and patient, so that patients understand the seriousness of their condition and the potential benefits and risks associated with the treatment, together with reasonable alternatives. Being able to '*understand the information relevant to the decision*' is a relative notion, and all that was historically required is a '*broad understanding of the kind that is expected from the population at large'.*[134] Facilitating understanding will assist greatly in promoting informed consent amongst people with intellectual disability. The statutory provisions support assisted decision-making and provide that a person should not be treated as lacking capacity, *'unless all practicable steps…have been taken without success'.*[135]

[131] See also Michael C. Dunn et al., 'Constructing and reconstructing 'best interests': An interpretative examination of substitute decision-making under the Mental Capacity Act 2005' (2007) Journal of Social Welfare and Family Law 29(2) 117-133

[132] MCA (n64) section 3

[133] Ibid section 4(4) states that *'He must, so far as reasonably practicable, permit and encourage the person to participate, or to improve his ability to participate, as fully as possible in any act done for him and any decision affecting him'*

[134] Per Mr Justice Jackson in *Heart of England NHS Foundation Trust v JB [2014] EWHC 342 (COP)*. Here, JB had paranoid schizophrenia but also the capacity to understand the nature of the treatment. It is worth noting that the prevalence of conditions such as schizophrenia do not necessarily occur with any greater frequency in those with intellectual disability than those without. See for example, Morgan VA et al., 'Intellectual Disability Co-Occurring with Schizophrenia and Other Psychiatric Illness: Population-Based Study' (2008) 193 British Journal of Psychiatry 364

[135] MCA (n64) section 1(3)

Furthermore, the MCA 2005 Code of Practice also suggests that where people experience difficulty understanding, then alternative methods of communication can help, particularly where people may have difficulty retaining information[136] and the same principle is also put on a statutory footing.[137] This inclusivity is mirrored by the AIS, which aims to ensure that people who have a disability, impairment or sensory loss can get information in a way which they can access and understand.[138] Even before these developments, Mr Justice Bodey had indicated that understanding the '*proximate medical issues'*, rather than the complexities of the medical issues, would be enough for the claimant, a woman with an intellectual disability, to understand the meaning of a contraceptive injection.[139] However, it is also argued that some mental disorders complicate the process of capacity; for example, depression which may not affect the understanding *per se,* but *'due to stifling negativity or impassive indifference towards future possibilities.'* Hence, there are several conditions - including anxiety disorders - where a person may have legal capacity but is unable to act as an autonomous agent.[140]

1.9 Conclusion

There are two points worth noting at this early stage of the thesis. Firstly, there is little of depth written on the therapeutic privilege exception - nor with balanced commentary - which provides different perspectives to evaluate. Regardless of which other domestic jurisdiction is being considered, the therapeutic privilege exception is widely regarded as an affront to autonomy and rejected. Perhaps the two most carefully considered and crafted articles are those of Cave[141] and Mulheron.[142] Written in 2017, after the judgment in

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[136] Mental Capacity Act 2005 Code of Practice, para 4.18 states that 'If they have difficulty understanding, it might be useful to present information in a different form of words, pictures or diagrams. Written information, audiotapes, videos and posters can help people remember important facts.'

[137] MCA n64

[138] https://www.england.nhs.uk/publication/accessible-information-standard-overview-20172018/ accessed October 22, 2019

[139] *A Local Authority v A* [2010] EWHC 1549 (Fam) at para 64, per J. Bodey, *'the test for capacity should be so applied as to ascertain the woman's ability to understand and weigh up the immediate medical issues surrounding contraceptive treatment.'*

[140] Fabian Freyenhagen and Tom O'Shea, 'Hidden substance: Mental disorder as a challenge to normatively neutral accounts of autonomy' (2013) Int'l J L Context 9 53, 56

[141] Cave (n17)

[142] Rachel Mulheron, 'Has *Montgomery* Administered the Last Rites to Therapeutic Privilege? A diagnosis and a Prognosis' Current Legal Problems (2017) 1-40

Montgomery, both papers focus specifically on the therapeutic privilege exception and are thus valuable to consider for this research.

Cave refers to *'therapeutic exception'* as redefined in *Montgomery* as an anomaly, since the paternalistic nature of withholding information from a patient sits uneasily with the patient's autonomous right to refuse medical treatment, even where harm could be caused as a result. Cave contrasts the therapeutic exception with other jurisdictions, where she argues that therapeutic privilege does have a role as it can protect the patient in exceptional circumstances. She argues that therapeutic exception is '*obfuscatory, unnecessary and unjustified*' in this jurisdiction, as the MCA protects those patients who are unable to make decisions for themselves. Whilst the MCA does indeed protect those who lack capacity, she fails to consider in any detail the possibility that disclosure of information in itself might render a patient to lose capacity and in these circumstances the therapeutic privilege exception might be a useful tool.

Mulheron approaches therapeutic privilege from a more international perspective which is relevant to this thesis. She outlines that the therapeutic privilege exception is an *'obscure'* defence which excuses a medical practitioner from risk disclosure where it is reasonably expected that disclosure would harm the patient's health. Recognising that *Montgomery* does little to clarify either the scope of the defence or the elements, she attempts to set out the elements which the defence should adopt, which will be discussed further in Chapter 7.

1.9.a The structure of the thesis

This Chapter has set out the framework of the thesis, the background and outlined why the 'therapeutic privilege exception' is integral to the thesis. It has justified why the cohorts of healthcare professionals have been selected to be research participants and why patients with intellectual disabilities are included in this research. By clearly setting out the research questions and the methodology, Chapter 1 has set out the reasoning for the research and provides a credible framework in which to address the research question.

Chapter 2 takes a doctrinal approach, focusing largely on the judgment in *Montgomery*. It starts with identifying the issues before the Supreme Court before setting out the test established in the case and before drawing out some of the more relevant issues flowing directly from the test. Thereafter, the focus turns to the introduction of the 'therapeutic

exception' and draws out factors relevant to the therapeutic privilege exception, such as dialogue and communication.

In directly addressing the first research question, Chapter 3 examines the development of the *therapeutic privilege exception* through the development of informed consent in England and Wales. The chapter will begin by examining the law from a historical perspective, including the reasoning and the extent to which doctors have withheld information from patients. Whilst this section is for background purposes only, it will serve to illustrate that withholding information is not a new phenomenon. Moving onto the 1980's, case law will be examined to explore the circumstances in which a doctor could avoid liability for negligence where risk disclosure was withheld and the circumstances where such practice was accepted by the courts. Furthermore, the development of the standard of care that would be applied in these circumstances is examined, in order to begin to establish what the preferred standard of care should be.

This chapter also briefly considers clinical practice in ante natal care to illustrate how healthcare practitioners routinely withhold information from patients, where non-disclosure is considered to be in the patient's best interests. Chapter 3 also considers withholding information from cancer patients and whilst this short section bears little relevance to the *Montgomery* judgment, it is of great interest. It demonstrates the disconnect between the information that patients want and what healthcare professionals disclose, highlighting the need for improved levels of communication and dialogue.

The second research question is addressed in chapter 4, which considers decisions from the US, Canada, Australia, and Singapore where information from a patient has been withheld. It will draw out the circumstances in which the courts believed it was justified to withhold information. Although it is likely that many of the cases do not refer to the *therapeutic privilege exception* by name, they will add to the understanding of the nature of harm that has been required to justify withholding information from a patient and, in turn contribute to the proposed framework of the '*therapeutic privilege exception'*.

The fourth and fifth research questions are considered in chapter 6 where data analysis from qualitative research with both clinical pharmacists and GPs are considered. The purpose of these interviews was to explore their understanding of informed consent and

whether either cohort of healthcare professionals withheld information from patients and if so, their reasons for doing so. This thesis also builds on previous research and examines whether the research participants were more likely to withhold information from capacitous patients with intellectual disability, perpetuating the notion of health inequality in patients with intellectual disability.

Chapter 7 sets out a framework of when the '*therapeutic privilege exception'* would apply. In order to provide a clear, structured and transparent definition, this chapter clearly defines each element of the framework. The definition has benefited from analysis of literature and guidance from dicta in England and Wales together with other domestic jurisdictions, including USA, Canada, Australia, and Singapore, which has enabled considerable reflection on the preferred terminology within the definition. In addition, the definition has been supported by the rich data gathered from GPs and pharmacists in qualitative interviews, which have explored their experiences of informed consent and withholding information from capacitous patients with learning disability and those without. Finally, in order to achieve both longevity and credibility of each element, additional case law or statutory provisions, from other areas of medical and tort law have been used to support and justify the precise wording. To avoid doubt, the role of the afore-mentioned case law and statutory provisions is to explain the rationale for each element and has no other role in the thesis.

Supported by a draft Codes of Practice, guidance is provided as to how to avoid the *'therapeutic privilege exception'* as a means of suppressing patient autonomy*,* with guidance for additional skills in communicating and the use of accessible information. The intention is not to encourage healthcare professionals to withhold information, but to develop a professional awareness that there are situations in which it can be appropriate to withhold information from patients within a clear, structured and transparent framework. Thus, where healthcare professionals may be unsure or unclear whether information can be withheld from a patient, the Codes of Practice can be consulted as a means of enhancing the relationship between doctor and patient and ensuring compliance with the law.[143]

[143] Perhaps an interesting parallel could be drawn between the development of a definition of the therapeutic privilege exception, supported by a Codes of Practice and the introduction of the DPP guidelines on Assisted Suicide in 2012. Here, *in R (Purdy) v DPP* [2009] UKHL 45, it was argued that the

Chapter 2: *Montgomery v Lanarkshire Health Board* [2015] UKSC 11

2.1 Introduction

This Chapter examines the judgment which introduced the doctrine of informed consent into UK law. To help achieve a thorough understanding of the judgment, each section will draw out one of the themes within the judgment.

Despite having taken nearly 30 years in the making, the decision in *Montgomery* has been widely heralded as welcoming the doctrine of informed consent into UK law. Whether the judgment was novel or entirely revolutionary was a subject of intense academic speculation, but this thesis maintains the position that *Montgomery* simply consolidated the deliberate and incremental development, a view shared by others.[144] The Supreme Court finally imposed a duty on healthcare professionals to provide information so that the patient can decide for themselves whether to accept or reject advice regarding medical treatment. Although the judgment has been widely welcomed and described as being *'highly significant'*[145] and the final nail in *Sidaway's* coffin,[146] the judgment also has its critics.

2.2 The issues

Here, the facts of the case are discussed, as the subject cannot be appreciated in its entirely without an understanding of the issues which were before the courts. The section starts in the lower courts before culminating in the issues that came before the Supreme Court. Mrs Montgomery was expecting her first baby. She was an insulin-dependent diabetic and described as being of *'small stature'.*[147] Where these conditions co-exist, women are likely to have larger than average babies with an increased risk of shoulder dystocia.[148]

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law on assisted suicide was neither transparent nor accessible. Hence, Debbie Purdy was unaware of whether or not her husband would be prosecuted under s2 of the Suicide Act 1961, if he assisted her to end of life. The House of Lords promulgated the DPP to publish a policy to address the lacuna in the law, to enable people to consult the guidelines and be informed.

[144] See for example Jonathan Montgomery and Elsa Montgomery, '*Montgomery* on informed consent: An inexpert decision?' J Med Ethics 2016 42 89-94

[145] Clark Hobson, 'No(,) More Bolam Please: *Montgomery* v Lanarkshire Health Board' Modern Law Review (2016) 79(3) MLR 468–503

[146] Rob Heywood, 'RIP *Sidaway:* Patient Oriented Disclosure – A Standard Worth Waiting for. *Montgomery v Lanarkshire Health Board*' [2015] UKSC 11 Medical Law Review 23(3) 455–466

[147] *Montgomery* n3 [7] She was just over 5 feet in height

[148] Ibid [8] and [9]. An expert witness whose evidence was consistent with guidance issued by the Royal College of Obstetricians and Gynaecologists stated that shoulder dystocia is considered 'a major

The facts, which were not disputed, were that she was told she was having a larger-than-average baby. However, she was neither warned of a 0.2% risk of shoulder dystocia nor was she advised of the smaller 0.1% risk of catastrophic consequences in some of the cases where shoulder dystocia occurs. In this second category, the baby can suffer from prolonged hypoxia, resulting in cerebral palsy or death.[149] The obstetrician, Dr McLellan accepted in evidence that she did not advise Mrs Montgomery of the specific risks as, if she did, the woman would ask for a caesarean section, which she did not believe was in the pregnant woman's best interest and was a procedure she would not have recommended.[150]

Mrs Montgomery went into labour, the risk materialised and, her baby was diagnosed with cerebral palsy as a result of deprivation of oxygen during birth.[151] In evidence Mrs Montgomery argued that had she been advised of the risk, which she would have considered significant, she would have requested a caesarean section.[152] Had her baby been delivered by caesarean section, it was accepted the injury would not have occurred.

In the lower courts, the Lord Ordinary accepted, following Lord Bridge's dictum in *Sidaway* that there were situations where the patient's right to decide whether or not to accept treatment was so obvious that no prudent practitioner would fail to advise the patient of the risks. This was the case, except in cases of an emergency or *'other cogent clinical reason for non-disclosure'*,[153]seamlessly embedding therapeutic privilege into the early stages of the judgment. In this specific case, the lower court did not consider there was a sufficiently substantial risk of grave adverse consequences, such that disclosure would be required.[154] Although the court recognised that a doctor must answer truthfully and fully when a patient specifically asks a question, the court held that the duty of care had not been breached. On the evidence, although Mrs Montgomery was not advised of the risks of shoulder dystocia,

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obstetric emergency associated with a short and long term neonatal and maternal morbidity [and] an associated neonatal mortality'

[149] *Montgomery* (n)3 [12]

[150] Ibid [14]

[151] Ibid [21]

[152] Ibid [18]

[153] Ibid [27]

[154] The court therefore declined to follow the approach taken in *Jones v North West Strategic Health Authority* [2010] EWHC 178 (QB)

Dr McLellan adhered to the professional guidelines in place at the time by not recommending a caesarean section for a patient in Mrs Montgomery's position.[155]

Whilst the facts are largely undisputed, some accuse the Supreme Court of demonising the doctor and infantilising the patient.[156] They refer to the lower courts, where Mrs Montgomery is demonstrably a highly intelligent woman and Dr McLellan was supportive and attentive throughout. By the time the case progressed to the Supreme Court, the nomenclature had altered. Mrs Montgomery is referred to as '*anxious'*[157] and Dr McLellan is portrayed as an obstetrician, driven by her own agenda. Reference to Mrs Montgomery's *'anxiety'* or to being '*anxious*' is only referred to on four occasions in the judgment and all within the same context of her concerns about delivering vaginally. However, the judgment makes clear that any anxiety she displayed would not have been sufficient to withhold information on the grounds that disclosure may have been harmful, thereby excluding the therapeutic privilege exception.[158] If this interpretation is correct, then one needs to examine why this may be.

One approach may be to acknowledge that, having made its way through the Scottish courts, *Montgomery* was the ideal case on the facts to reject paternalism formally and ensure that protecting patient interests was the foremost principle in medical treatment. The move to patient autonomy from paternalism was already widely recognised in medical law and a failure to formally endorse patient autonomy may lead to greater inconsistency in the law.[159] Nevertheless, the court took the opportunity to emphasise the notion of patient rights rather than autonomy and Lords Reed and Kerr explained that the duty to disclose is '*the counterpart of the patient's entitlement to decide whether or not to incur that risk'.*[160] The word *'autonomy'* only appears three times in the Supreme Court judgment, yet '*respect*' appears on no less than 12 occasions, confirming the judgment's focus on patient's rights

[155] *Sidaway* (n6) [89]
[156] Hobson (n144) [90]
[157] Mrs Montgomery is referred to only 4 times as being anxious throughout the Supreme Court judgment, at paras 14, 73, 94 and 104, although largely in the same context.
[158] *Montgomery* n3 [95]
[159] See for example *Airedale NHS Trust v Bland* [1993] AC 789 per Lord Mustill 'If the patient is capable of making a decision on whether to permit treatment…his choice must be obeyed' and Re *B (Adult: Refusal of Treatment)* [2002] EWHC 429 (Fam) per Dame Elizabeth Butler-Sloss P, 'benevolent paternalism…does not embrace recognition of the personal autonomy of a severely disabled patient'
[160]*Montgomery* n3 [82]

and personal integrity. Lady Hale observes that '*the interests which the law of negligence protects is a person's interest in their own physical and psychiatric integrity, an important feature of which is their autonomy, their freedom to decide…'*[161]

It is somewhat surprising that given the importance of the overall nature of patient autonomy to the development of law of informed consent the term is hardly referred to; instead, the central theme has been placed on a patient's interests. Lady Hale appears to suggest that whilst autonomy is an important aspect of a person's interest, it is not the sole interest, explaining that negligence protects a person's bodily integrity. Here, Lady Hale confirms that a violation of a person's physical and psychological integrity could amount to negligence. If this is correct, then Lady Hale echoes the thinking of early American writers such as Hubert Smith, who demonstrate defensive practice and expressed concern that where disclosure harmed a patient that could amount to negligence in itself.

The Supreme Court examined the judgment in *Sidaway*, re-evaluating the dicta, although it has been argued *Montgomery* represents more of a departure from the principles in *Sidaway*, rather than an interpretation of the principles.[162] The court considered Lord Scarman's dictum where the differing values between doctor and patient were considered, in particular the doctor's medical objectives. It was noted that the patient may have *'circumstances, objectives and values'* in mind which may lead him to a different conclusion regarding treatment than that of the doctor.[163] The Supreme Court dwelt on this issue, exploring the importance of self-determination and how consideration of a patient's personal values are fundamental to the rights of the patient to make their own decisions regarding their medical treatment. The court then reviewed the need to advise the patient of the material risks which are inherent in the treatment. Here, a risk was material '*if a reasonably prudent patient in the situation of the patient would think it significant.'*[164]

2.3 The test in *Montgomery v Lanarkshire Health Board (Scotland)* [2015] UKSC 11

The test that introduced the doctrine of informed consent into UK law stated that:

[161] Ibid [108]
[162] Ibid [37]
[163] Ibid [45]
[164] Ibid [47]

'*the doctor was under a duty to take reasonable care to ensure that the patient is aware of any material risk in the recommended treatment, and of any reasonable alternative or variant treatment'.*[165]

The court then approved the test of materiality in *Rogers v Whitaker* which the High Court of Australia had redrafted to reflect both a subjective and objective test. The subjective test was whether the reasonable person in the patient's position would be likely to attach significance to the risk, if advised. Secondly, the objective test asks whether the medical practitioner is, or should be aware that, if the patient were advised of the risk, they would consider it material.[166] Lord Kerr and Reid adopted the test, stating that:

'*The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should be reasonably aware that the particular patient would be likely to attach significance to it*.'[167]

2.4 The reasonable patient

The materiality test above refers to the reasonable person in the patient's position, yet the identity of the reasonable person is unclear and Lord Bridge had also previously struggled with the notion of the reasonable patient test referring to it as *'unpredictable'*.[168] It seems logical to argue that '*the reasonable person standard encounters conceptual, moral, and practical difficulties',*[169] which may be partly because the concept of the reasonable person has never been clearly defined, given the centrality of individuality. Given that the reasonable patient has no universal determinable characteristics, it would not be possible to define the reasonable patient and the term should be regarded merely as a legal construct. If this is correct, then the reasonable patient should simply be endowed with any characteristic, thereby reducing the notion of the reasonable patient to that *particular* patient.

[165] *Montgomery* (n3) [87]
[166] *Rogers v Whitaker* [1992] 175 CLR 479 [490] referred to in n3 [72]
[167] *Montgomery* (n3) [87]
[168] *Sidaway* (n6) [878]
[169] Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* 5th edition (2001) Oxford University Press 8

2.5 Materiality of risk

The materiality test set by the court above explains that whether a risk was material was not a matter of percentages alone and there were a range of other factors to take into account. These included *'the nature of the risk, the effect which its occurrence would have upon the life of the patient, [and] the importance to the patient of the benefits sought to be achieved by the treatment.'*[170] The patient centred nature is clearly demonstrated where the court stated that *'t(T)he assessment is therefore fact-sensitive and sensitive also to the characteristics of the patient.'*[171] Hence, the materiality test extends not only to risk disclosure but other information which is also relevant to that specific patient.

2.6 The standard of care

Although the Supreme Court endorsed patient autonomy, the decision openly acknowledged that there are circumstances when withholding information from a patient is justified, which allows *'a more orthodox interpretation of Sidaway.'*[172] This statement is made despite the court emphasising that *'there was no reason to perpetuate the application of the Bolam test in this context any longer'*.[173] In *Sidaway*, Lord Bridge approved *Bolam* but stated the courts could find that disclosing risks were so relevant to the patient's decision that no reasonable doctor would fail to disclose the risk. On this specific reading, the gap between Lord Bridge's dictum and Lord Scarman's, which has always been regarded as entirely disparate, begins to narrow.

There seems to be a selective interpretation of *Sidaway* as some flexibility is introduced where the professional standard is rejected, in contrast to a more defensive and conservative interpretation which enables the professional standard to be applied in some circumstances. The balance is indeed delicate. On the one hand, the law affords the patient autonomy in decision making regarding their own treatment through the avenue of risk disclosure, whilst at the same time, adopting a more restrictive approach, where patient autonomy can be denied based on an objective clinical assessment of the patient's personal

[170] *Sidaway* (n3) [89]
[171] Ibid
[172] Hobson (n145) [490]
[173] *Montgomery* (n3) [86]

attributes. Hence, it appears that autonomy only exists subject to a clinician's judgment, suggesting this is not, in fact, autonomy.

A similar approach has been seen elsewhere in medical law, promoting Kennedy to say that *Re R* was driving a *'coach and horses'* through *Gillick* which, on the one hand, afforded the minor child autonomy to consent to treatment, on the other hand denied the same where a child refused treatment.[174] A similar sentiment could be expressed about the notion of therapeutic privilege where a patient's autonomy is respected unless the clinicians objectively believes that the patient's characteristics are such that a protectionist position is taken.

The Supreme Court in *Montgomery* referred to case law from other domestic jurisdictions, paying particular attention to the judgment in *Rogers v Whitaker.*[175] The court acknowledged a differing standard of care between treatment and the issue of information disclosure.[176] With regard to the former, the relationship revolves around the patient informing the doctor of their symptoms and history, followed by the doctor diagnosing and treating the patient according to their level of skill of care. Here, the *Bolam* test would be applicable as these are matters within the ordinary care and skill of the practice of medical practitioners. Although medical opinion would be '*of very considerable significance'*, the court noted that even in these circumstances both the nature of the risks and their foreseeability are not necessarily matters of medical knowledge and expertise are often matters of commonsense.[177]

In contrast, where a failure to disclose information in concerned, this would be a matter for the courts, not the legal profession. In referring to *Rogers v Whitaker,* the court stated that in cases where there is a risk that the information '*will harm an unusually nervous, disturbed or volatile patient*', special medical skill would be required.[178] Where patients did not display these characteristics, communication skills needed to be '*reasonably adequate for that*

[174] Ian Kennedy, 'Consent to Treatment: The Capable Person' in Dyer, C (ed) *Doctors, Patients and the Law* Oxford, Blackwell, 1992, chapter 3
[175] *Rogers* (n166) and discussed at 4.7
[176] *Montgomery* (n3) [71]
[177] Ibid
[178] Ibid

purpose having regard to the patient's apprehended capacity to understand that information'.[179]

Where a patient is either particularly *nervous, disturbed or volatile*, it seems that disclosure would be a matter of medical judgment, where the *Bolam* test would then be applied. However, the judgment is ambiguous as it refers to specific characteristics where different standards appear to apply. Thus, for example, where information disclosure to an *anxious* patient is concerned, no special skill appears to be required. In this situation, if information were not disclosed, then an anxious patient could allege a breach in failing to disclose information which, in principle, could be judged on a different standard to the '*nervous'* patient. In these circumstances, it would lack logic for a court to draw a legal definition between a patient who is *anxious* and a patient who is *nervous.* Whilst it is not expected that a judgment should provide an exhaustive list of a patient's characteristics where information disclosure lies in the hands of the healthcare professional, in the context of the therapeutic privilege exception there is potential for inconsistency.

Where a patient does not wish to be informed of the risks of treatment, they are entitled to waive their right to know, and the doctor no longer has a duty to discuss the risks with the patient. Lords Kerr and Reid observed that deciding whether a patient has waived their rights to disclosure is not a matter that depends on clinical judgment. Thus, the *Bolam* test would not apply. In contrast, where a doctor in their reasonable clinical judgment considers that disclosure would be detrimental to the health of their patient, then they may withhold risk disclosure relying on the therapeutic privilege exception.

The question that needs to be addressed, is what standard of care will be applied to assess the reliance on the therapeutic privilege exception? The answer may lie in the wording of '*the reasonable exercise of medical judgment',*[180] as it suggests that a professional standard of care *would* be applied, particularly where the judgment would involve medical expertise. If medical expertise is not required, then it is possible for *Bolam* not to be applied, but it is challenging to envisage an example where the doctor reasonably exercises their medical

[179] *Montgomery* (n3) [14]
[180] *Montgomery* (n3) [85]

judgment to withhold risk disclosure for concern over harm being caused to their health *and* the judgment is grounded in their medical expertise.

The above position can be supported by Lord Scarman in *Sidaway* who opined that where risk disclosure is withheld, the *'doctor himself will normally be an essential witness: and the reasonableness of his assessment may well need the support of independent medical testimony.'* If the doctor relies on the therapeutic privilege exception, then the doctor must prove it and his medical evidence along with that of medical experts will be relevant in determining the appropriateness of his actions.[181] Similarly, Lord Scarman had stated that the therapeutic privilege exception allowed risk disclosure to be withheld from a patient if it can be shown '*that a reasonable medical assessment of the patient*' would have enabled the doctor to recognise that disclosure would be psychologically detrimental to the patient. Whilst medical evidence would be relevant, it would not necessarily be determinative.

Montgomery supposedly reflects a shift away from paternalism, where the patient is entirely dependent on the information provided by the doctor to one where they are treated *'so far as possible'* as adults who can understand that treatment is often uncertain of success and can involve risks. Patients therefore make decisions about their own treatment having discussed the options with the doctor. In doing so, patients then take responsibility for the risks which affects their own lives.[182] There is no explanation of what '*so far as possible'* means, but these four words seem to pave the way for the therapeutic privilege exception as it suggests that some patients may not be capable of understanding the information given to them.

By rejecting the application of *Bolam* to information disclosure, the court adopted the position taken by Lord Scarman in *Sidaway* and by Lord Woolf in *Pearce,* which in turn was subject to the refinement in *Rogers v Whitaker.* The Supreme Court went further than the prudent patient test in *Sidaway*, where the doctor was obliged to provide information which the reasonable person in the patient's position would want to know. This test, whilst a move towards a patient centred test, would not necessarily take into account the issues unique to the particular patient. The importance lies in the individuality and uniqueness of each

[181] *Pearce* (n6) [889]
[182] *Montgomery* (n3) [81]

patient, who have different values, beliefs and wishes, all of which feed into the importance they attach to each risk and potential alternative. The subjective element of the materiality test enables any healthcare professional to tailor the material risks to '*the reasonable person in the patient's position*'. Individuals, including those with intellectual disability differ and, may have needs distinct from another reasonable patient. Whilst the subjective standard has been referred to as a *'preferable moral standard of disclosure'*, *Montgomery* is correct as subjectivity cannot stand alone as the only standard of disclosure. A solely subjective test would not consider what medical information would be relevant for that patient's specific needs. Furthermore, it would reduce the role of the healthcare professional to one where extensive questioning would elicit the information, on which to provide medical advice. Such a test would be too reliant on a patient's personal recall in a situation where there is unbalance in the relationship between doctor and patient[183] and, would be challenging for patients with intellectual disability.

2.7 Does the judgment in *Montgomery* risk an increase in litigation?

Greater patient autonomy has been enshrined in professional practice for several years. In this respect, it is incorrect to say that the judgment in *Montgomery* heralded patient autonomy; it merely reflected a developing pre-existing culture[184] confirming the patient-centred test which had existed for several years through the GMC guidelines. Some academics suggest that given the best practice guidelines doctors should be reassured that the '*litigation floodgates'* will not follow,[185] although the mere existence of the guidelines does not in themselves preclude the potential of litigation. Nevertheless, the potential 'floodgates' of cases alleging a failure to warn of a risk was not evidenced in Australia, following the decision in *Rogers.* In fact, the reverse was true with a significant decrease in the number of new claims which related to failure to warn of a risk.[186] Despite these observations, there appears to be evidence of an increase in litigation since the judgment in *Montgomery* which tends to reflect a different outcome than that evident in Australia.

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[183] *Montgomery* (n3) [83]
[184] Anne Maree Farrell and Margaret Brazier, '"Not so new directions in the law of consent": Examining *Montgomery* v Lanarkshire Health Board' (2016) Journal of Medical Ethics 42 85-8
[185] Ibid
[186] Malcolm K Smith and Tracey Carver, '*Montgomery*, informed consent and causation of harm: lessons from Australia or a uniquely English approach to patient autonomy?' J Med Ethics 2108 44 384-388,384

A study conducted by Queen Mary University of London demonstrated that the trend of claims per year immediately post-*Montgomery* increased 4-fold for failure to inform and nearly 3-fold where failure to inform was the principal cause. No other material difference in claims were due to other causes and no cases in the study referred to the therapeutic privilege exception.[187] This study seems to suggest that unlike other jurisdictions, the effect of the introduction of *Montgomery* may behave differently in this jurisdiction. Perhaps the more compelling reason for the increase of litigation is a 'knee-jerk' response to the test set down in *Montgomery* as, contrary to the study's data, far fewer cases rely on the judgment post-2020.

Although healthcare professionals have been assured that *Montgomery* will not create excessive litigation,[188] the contrary view suggests that uncertainty in litigation might follow.[189] Lords Reid and Kerr had observed this potential tension but noted that where the choice of whether to proceed with treatment rested with the patient, it '*may be less likely to encourage recriminations and litigation'*.[190] However, they acknowledged the need to balance the new test with the predictability of litigation which would be lost by the departure from the *Bolam* test.[191] If an increase in litigation were to transpire, it is possible that there may be an increased use of the therapeutic privilege exception as the courts wrestle with the standard of care and where clinicians are aware of the exception, they may find it more difficult to determine how the courts will respond.[192] It is therefore imperative that the therapeutic privilege exception is clearly defined, be readily brought to the attention of healthcare professionals and is transparent, which will be discussed in more detail in chapter 7.

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[187] DS Wald, JP Bestwick and P Kelly. 'The effect of the *Montgomery* judgment on settled claims against the National Health Service due to failure to inform before giving consent to treatment' (2020) QJM: An International Journal of Medicine 113(10) October 721–725

[188] See Rob Heywood, 'R.I.P. *Sidaway:* Patient Oriented Disclosure – A Standard Worth Waiting for? Montgomery v Lanarkshire Health Board' [2015] UKSC 11, Medical Law Review, 23(3), 455–466, 461, where a similar view is held

[189] Farrell and Brazier (n184) [89]. However, their observations rely on a re-reading of the patient-doctor relationship and the Supreme Court's interpretation of that relationship. When the authors refer to uncertainty, they do so regarding the court's decision that a caesarean section should have been offered, contrary to professional guidelines. For these authors, these are the aspects that could create uncertainty in litigation

[190] *Montgomery* (n3) [93] and see also Roderick Bagshaw, 'Modernising the doctor's duty to disclose risks of treatment' Law Quarterly Review (2016) 132 182-186

[191] *Montgomery* (n3) [93]

[192] See, for example, n17

2.8 The GMC guidelines

The GMC guidelines in 2008 clearly set out the relationship between the patient and the doctor which reflect a partnership of shared decision-making. Here, the doctor explains the options to the patient, including the risks and benefits of the proposed treatment and the patient weighs up the options, together with any advice, and decides which option to accept and proceed with, if any.[193] From this perspective, the *Montgomery* judgment is not novel as it simply reflects that which has already been embedded into clinical practice. Hence, healthcare professionals should not need to significantly change their clinical practices.

The updated GMC guidelines emphasised the need to listen and to engage with patients so patients can make decisions together regarding their treatment.[194] Where risks are concerned, doctors were required to advise patients of a *'serious adverse outcome'*[195] even where the risk was very small and patients should also be advised of less serious complications if they commonly occur,[196] a theme consistent with this research's data. These guidelines were welcome and where they go beyond the legal duty within *Montgomery,* is a positive step. The reasoning is that whilst a healthcare professional may act unethically, it does not follow that they also act unlawfully. In clinical practice, the full weight of the law is not always welcome and benefits from taking a back step in favour of professional regulations.[197]

The more recent GMC guidelines, effective from November 2020, suggests a more sophisticated model of a doctor-patient relationship.[198] The GMC guidelines attempt to

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[193] A more focused consideration of the GMC guidelines is beyond the scope of this research. However, it is worth noting the subtle change of the Guidelines wording. The 2008 wording refers to what the doctor *should* do, hence suggesting best practice, rather than an obligation. Fovargue and Miola observes that the communication requirement in the 2008 guidelines differed from the earlier 1998 guidelines. They comment that the 1998 guidelines, which are not referred to in the judgment, offered the patient greater autonomy than the 2008 guidelines, which appear to involve the doctor outlining the risks and then leaving the patient to take a decision, but lack an element of shared decision making. See Sara Fovargue and Jose Miola, 'One step forward, two steps back? The GMC, the common law and 'informed' consent' (2010) J Med Ethics 36 494-497, 496

[194] Ethical Guidance for Doctors https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/duties-of-a-doctor para 77 accessed September 18, 2021

[195] This appears to reflect the approach taken by Lord Templeman in *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1AC 871, wherein he stated that disclosure of a particular risk would be obvious where there was 'a substantial risk of grave adverse consequences

[196] Ethical Guidance for Doctors (n194)

[197] Miola and Heywood (n9)0

[198] GMC Guidance for Doctors: decision-making and consent https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-

enforce best practice and here the seven overriding principles clearly reflect the legal duty referred to in *Montgomery.* The principles refer to patients having the right to be involved in decisions,[199] referencing the ongoing process of a meaningful exchange between doctor and patient,[200] the right to be given the information and the time they need in order to understand it.[201] The doctor '*must try'* to understand what matters to the patient, thereby imposing a positive obligation on the doctor to enter, at the very least, into dialogue with the patient and attempt to ascertain what is important to the patient.[202] Although there appears to be little academic analysis on the guidelines, in the context of the judgment the guidelines go a long way to ensure that healthcare practice is *Montgomery*-compliant. The guidelines confer obligations on the doctor to listen to patients, encourage them to ask questions, find out what is important to them[203] and to share information in a way in which the patient can understand.[204] It is also possible that through addressing the communication between the parties and embedding best practice, the guidelines will help redress the imbalance between the historical perception of the doctor-patient relationship.[205]

The guidelines continue by explaining that doctors should consider using materials to enhance understanding, such as visual or other explanatory aids.[206] The new guidelines, which emphasise the importance of accessible information,[207] are relevant to those capacitous people with intellectual disability whom, with support, can provide informed consent. These guidelines complement the AIS which was introduced in 2016. The Health and Social Care Act 2012, makes it mandatory for the NHS, adult social care bodies and all NHS and adult social care providers to comply with information standards. With appropriate support, and with more available accessible material, capacitous people with learning

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84191055.pdf?la=en&hash=BE327A1C584627D12BC51F66E790443F0E0651DA effective from November 2020 accessed September 18, 2021

[199] Ibid principle 1

[200] Ibid principle 2

[201] Ibid principle 3

[202] Ibid principle 4

[203] IIbid 14

[204] Ibid 15

[205] For a discussion on the imbalance of the doctor-patient relationship which stems from a representation of social norms, see n22

[206] GMC Guidance for Doctors (n198) 25

[207] Accessible information is defined as 'information which is able to be read or received and understood by the individual or group for which it is intended' nhse-access-info-comms-policy.pdf (england.nhs.uk) page 38 accessed November 19, 2020

disabilities should have a greater opportunity to exercise autonomy in decision-making regarding their treatment, in the same way as those without intellectual disability. If this can be achieved then patients with intellectual disability could begin to achieve health equality.

2.9 The therapeutic privilege exception

Even before the seminal case of *Montgomery,* it was evident there was a lack of research into both the reliance on the therapeutic privilege exception and its use.[208] Now that therapeutic privilege (now therapeutic exception) has survived the introduction of the doctrine of informed consent into the UK, the jurisdiction has to grapple with an exception which is not only undefined but lacks any clarity or a consistent approach in other domestic jurisdictions.

At the heart of the test of informed consent itself, the court in *Montgomery* has clearly identified an exception to disclosure without specifically referring to therapeutic privilege. In doing so, the court confirmed that the duty of disclosure is not an absolute duty. Lords Kerr and Reid stated that a doctor can withhold information relating to the risk from the patient if he reasonably considers that disclosure would be *'seriously detrimental to the patient's health',*[209] warning that the principle cannot be considered to be the basis for a general rule.[210]

The judgment neglects to develop what might amount to being *'seriously detrimental'* to the patient's health and in this respect, the judgment is disappointing. Although one might assume given previous domestic references to the therapeutic privilege exception that *'health'* refers to both physical and psychological, there is no confirmation of this point. This leaves the law with further uncertainty as it seems that *'anxiety'* would be insufficient to activate the therapeutic privilege exception. As previously discussed, there was reference in the lower courts and in the Supreme Court to Mrs Montgomery being 'anxious'; in itself, this is not unsurprising given that this was her first birth and she was aware that she was having a larger than average baby. Lords Kerr and Reid dismissed the notion that the therapeutic

[208] Margaret Brazier and Emma Cave, 'Medicine, Patients and the Law' (2016) Manchester University Press, 6th edition at 5.16
[209] *Montgomery* (n3) [88]. The court also referred to waiver and cases of necessity but specifically chose not to consider the exceptions any further
[210] *Montgomery* (n3) [91]

privilege exception would apply in these circumstances and observed that the exception is not intended to enable doctors to prevent their patients from making informed decisions. Although the court did not comment further, it appears clear in the eyes of the law that being anxious does not amount to serious harm, sufficient to justify the use of therapeutic exception. If this is correct, then the judgment contradicts other domestic jurisdictions.

Whilst the judgment celebrates autonomy by introducing a patient-centred approach which rejects clinicians deciding what is the best for their patients, it has been criticised for retaining the therapeutic privilege exception that supports paternalism, evidence of which can be seen in the lower Scottish courts. Here, in the Inner Court of Session, Dr McLellan declined to offer Mrs Montgomery another ultrasound scan in case it increased her anxiety, but in the judgment there appears to be a subtle suggestion of the therapeutic privilege exception. The court opined that it was

incongruous…to have been under a legal duty to cause greater alarm by discussing the ways a vaginal delivery could go wrong….as a matter of law, neither reassurance, nor even deferment of a final decision, can qualify as available options for the treating doctor once a patient evidences any generalised anxiety or concern.

Cave comments that paternalism was '*revived'* by the formal introduction of therapeutic exception,[211] although it will be argued that by examining the treatment of healthcare professionals in other aspects of a pregnant woman's care, then paternalism in medical treatment never truly left.

Interestingly, although no further reference was made to the principle of withholding risk disclosure from a patient, it is worth noting that the nomenclature became the 'therapeutic exception.'[212] There is no clear explanation within the judgment as to why this might be, but a reasonable analysis could suggest that the term 'therapeutic privilege' suggested a more paternalistic term which the court would have been keen to avoid. Referring to the term 'therapeutic exception' may appear to balance the doctor-patient relationship and align therapeutic exception more closely with the other exceptions of patient waiver and necessity. Nevertheless, as previously mentioned, this research has introduced the term

[211] Cave (n17) [141]
[212] *Montgomery* (n3) [91]

'therapeutic privilege exception' to remind the healthcare professional that the exception remains paternalistic in nature.

Some argue the therapeutic privilege exception could be abandoned and where, in a doctor's clinical judgment, it is believed that harm could be caused to the patient by risk of disclosure, the defence of necessity could be relied upon. It is argued that relying upon the defence of necessity is permitted where priority treatment protects the life and health of one patient over another.[213] By analogy it is argued that there are also emergency situations where a doctor should be able to protect a patient's legal right at the expense of another of their legal rights and, for this reason, it is argued that the therapeutic privilege exception should therefore fall within the defence of necessity.

It is unclear why this would be a preferred course of action. If the argument is that it removes the doctor's discretion whether to disclose information, then all it appears to do is to move the discretion to the defence of necessity. However, the patient's autonomy could be more severely impacted here. Where therapeutic privilege remains as an exception, there is scope for the doctor to explore communication and dialogue with the patient. If he then believes in his clinical judgment that disclosure would risk serious harm being caused to the patient, then that decision comes at the end of a considered process, as opposed to simply considering withholding information as a necessity without further investigation. This suggests a risk of greater paternalism than the therapeutic privilege exception in itself.

Brazier and Cave explore the following hypothetical situation: '*Would a surgeon be able to justify withholding from a very elderly patient the frightening information about the risk of impotence in an operation the surgeon judged to be essential to maintain the patient's independent living?'* This scenario raises interesting issues. In this situation, a doctor could rely on therapeutic privilege or exception to withhold information which may be seriously detrimental to her health,[214] as the information is referred to as '*frightening*'. *Montgomery* reflects case law in other domestic jurisdictions and states that the therapeutic exception should neither be abused nor used to enable a doctor to act in the patient's best

[213] Margaux Beard and JR Midgley, 'Therapeutic privilege and Informed Consent: A justified erosion of patient autonomy' (2005) 68 THRHR 51, 51-68,68. Here, the authors give the example of vaccinating healthy people to protect others

[214] *Montgomery* (n3) [88]

interests.[215] In the afore-mentioned example, the hypothetical patient has capacity and can act as an autonomous agent; she can decide for herself what treatment, if any, to pursue. Her clinical best interests are that she retains her independent living, and the doctor cannot act beneficently and act in her best interest.

Since *Montgomery,* the subjective element of the test of disclosure would consider whether a material risk is sensitive to the characteristics of the patient; in this case, an elderly lady. *Montgomery* identifies those other factors apart from the percentage risk of harm which would be relevant to the patient. This includes but is not limited to the '*effect of the occurrence would have on the life of the patient*.'[216] In this hypothetical scenario the significance of the risk of impotence is low compared to the benefit she would gain. Her age cannot be a factor to be considered so the risk of impotence must be disconnected from her status as an elderly lady.[217]

Cave argues that following dialogue with the patient, information would be tailored to this patient, and in regard to which the clinician can adapt the information accordingly.[218] She explains that the doctor might discover during communication with the patient, or during a conversation with a carer or relative that the information about impotence would frighten her. Where it is suggested that the information would *'alarm'* the patient and *'disclosure would risk serious harm'*, the information can be adapted to suit the patient's needs. Cave continues *'(t)There is no need in these circumstances to invoke the therapeutic exception'* as the test of materiality enables clinicians to adapt the information. Hence, Cave uses this approach to argue that the therapeutic privilege exception is both unnecessary and unjustified.

Cave's proposal is troubling. Firstly, she acknowledges that the scope to tailor information to a patient's needs is narrow in scope, but it appears that what she recommends is actually, in practice, the therapeutic privilege exception. The only additional factor appears to be that failing to advise a patient of specific information would be recorded in the patient's notes. Whilst this may be good practice, it is already a requirement of the GMC guidelines on

[215] *Montgomery* (n3) [91]
[216] *Montgomery* (n3) [89]
[217] MCA (n64) Section 2(3)
[218] *Hii Chii Kok* (n99) [153] where a similar analysis of the example is referred to in the qualitative research

consent.[219] Secondly, there is no indication within the materiality test that clinicians can adapt information, when considering whether a *'reasonable person in the patient's position would be likely to attach significance to the risk'*. In so doing, this interpretation could be read as enabling a negative obligation on a doctor rather than a positive obligation to engage in dialogue with the patient and establish what is important to her. The risk of impotence may simply not be important to her. Moreover, this approach would risk encouraging an unclear and undefined set of standards for clinicians to work from. Thirdly, the GMC guidelines do not make provision for withholding information outside of the therapeutic privilege exception; only delaying it, which is evidenced in this research's data. Where the information is to be withheld, the GMC guidelines only permit a therapeutic privilege exception in exceptional circumstances.[220] Finally, the GMC guidelines state that the '*serious harm'* requires something more than the patient becoming *'upset'*.

Montgomery states that a doctor may withhold information from the patient, where he believes that disclosure would be *'seriously detrimental'* to the patient's health. Both the professional guidelines and *Montgomery* use language indicating that following a subjective assessment of that particular patient, serious harm would be caused by disclosure. Although the type of harm is not defined, the wording of both professional guidelines and the judiciary confirm narrow parameters. Yet, Cave refers to being '*frightened*' by disclosure of impotence to an elderly patient, as being sufficient to withhold information to her. Unless this hypothetical patient's '*fright'* is detrimental to her mental or physical health, this would not be sufficient grounds to withhold information. If this were permitted, then the boundaries of therapeutic privilege would be wide and exposed and may risk '*devouring the disclosure rule itself*.'[221]

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[219] General Medical Council Guidelines, 'Decision Making and Consent' paragraph 14, states 'There may be circumstances in which you decide not to share all relevant information with a patient straight away. If you delay sharing information necessary for taking a decision, you should let the patient know there's more to discuss and make sure arrangements are made to share the information as soon as it's appropriate to do so. You must make a record of the information you still need to share, your reasons for not sharing it now, and when it can be shared'

[220] Ibid paragraph 15, 'You should not withhold information a patient needs to make a decision for any other reason, including if someone close to the patient asks you to. In very exceptional circumstances you may feel that sharing information with a patient would cause them serious harm and, if so, it may be appropriate to withhold it. In this context 'serious harm' means more than that the patient might become upset, decide to refuse treatment, or choose an alternative. This is a limited exception, and you should seek legal advice if you are considering withholding information from a patient'

[221] *Canterbury* (n19) [789]

Moreover, *Canterbury v Spence* expressly states that the doctor should not remain silent about disclosing information simply because it may lead the patient to refuse treatment, which may be in their best interest. Thus, whilst Cave appears to condemn the existence of the therapeutic exception, she advocates a system which not only appears to be the therapeutic privilege exception, but also is widely constructed in an alternative guise.

2.10 Waiver

Waiver is a further exception to informed consent, retained by the *Montgomery* judgment[222] where the patient can waive their right not to be advised of the risks. In this context, the patient confirms that the doctor can treat them without providing pre- or post-operative information. The judgment explains that the patient can remain ignorant of facts relating to risks in the same way as people may ignore the patient information leaflets when taking over-the-counter medication. For some patients, they would simply prefer not to be made aware of extensive details of the procedure and trust the doctor's judgment and others may disregard the necessity to inform themselves of the potential risks. Where waiver is concerned, it may be argued that a patient exercises their autonomy, although where the patient is not aware of the information, it is questionable whether informed consent can be exercised with regards to information they are not aware of. Hence, there is an undesirable overlap between the right to waiver exercised by the patient and the therapeutic privilege exception exercised by the doctors. Both have the same outcome, although there is little specific research on a patient's waiver of right to disclosure.

If we were to take a hypothetical example, if Patient A were of a particularly anxious disposition which they had masked or had not specifically referred to, and the doctor was not aware, the patient could waive their rights to be informed about the risks of the treatment, together with any associated potential harm. Here, the choice remains with the patient who exercises their autonomy and the patient's right is respected. The doctor may need to assess whether the patient had declined to be advised of the risk but as *Montgomery* confirms, this is not a judgment which requires medical expertise. Whilst the doctor's judgment may require a degree of skill, it is not as the court confirmed the

[222] *Montgomery* (n3) [85]

judgment which *Bolam* requires. Thus, where waiver may be challenged, the test of the reasonable man would apply and the court would be the final arbiter.

However, in circumstances where the doctor *became* aware that Patient A was anxious, the doctor can exercise their professional discretion and withhold risk disclosure from the patient. Here, it could be argued that the doctor does not acknowledge the patient's right to decide for themselves whether or not to accept the potential harmful information, instead choosing to act beneficently to avoid the risk of causing harm. Indeed, the doctor may not withhold information specifically knowing it is done by way of a 'therapeutic privilege' but may do so as a professional discretion having assessed disclosure based on the needs of that particular patient. The outcome is the same insofar as the patient is not advised of the risks of any potential treatment which the patient has decided for themselves (waiver) or the doctor has decided for the patient. An anxious patient with sufficient self-awareness could, in fact, make the decision for themselves which the doctor would have otherwise made.

Where the patient challenges disclosure but waived their right to know - which is unlikely - the doctor would need to demonstrate they were willing to disclose information but the patient declined. This may be difficult to prove but a clear entry on the medical records of the patient's wish to waive their right to information should alleviate this problem. Nonetheless, care should be taken to ensure that the patient is aware of the nature and the purpose of the treatment.

One of the reasons why it may be argued that the therapeutic privilege should be disbanded is due to the supposed overlap between the therapeutic privilege and waiver. It is suggested that a patient may be warned that some of the information may risk upsetting the patient and they may choose to waive the right to the information, which moves the onus from the doctor's disclosure to the patient's decision whether to receive the information.[223] However, it may be difficult to sustain this argument as the therapeutic privilege cannot be invoked where a patient is merely upset, as this defeats the intention of the therapeutic privilege exception where disclosure risks being detrimental to the patient's health. Distress

[223] See for example, Jessica W. Berg, Paul S. Applebaum, Charles W. Lidz and Lisa S. Parker, *Informed Consent, Legal Theory and Clinical Practice* (2001) 2nd edition 83

and anxiety must be disaggregated, and waiver cannot replace the therapeutic privilege exception which can only be applied in specific, limited situations.

Waiver is a less defined concept, where the patient may be content to just be treated, without being fully advised of all the risks. Where a doctor suggests to a patient that information may risk upsetting them, then this may alarm the patient, which in turn affects their informed consent. Waiver and the therapeutic privilege exception have distinctly different roles and attempting to conflate the two, given the lack of clarity surrounding the therapeutic privilege exception, does not support either clarity or transparency.

2.11 The importance of effective communication

This section draws out the importance of dialogue and effective communication from the judgment and then considers these elements in the context of patients with intellectual disability.

Montgomery states that the doctor's role involves dialogue so that the patient can understand the seriousness of their condition, the anticipated benefits and risks of the proposed treatment and any reasonable alternatives. It is only when these elements are completed that the patient can make an informed decision. This duty can only be fulfilled if the patient is not bombarded with '*technical information*' which they can '*reasonably be expected to understand*.'[224] That said, the judgment also recognises that it would be a '*mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent upon a flow of information from doctors.*'[225] The duty imposed on doctors therefore requires a balance. Whilst the Supreme Court states that one should not bombard patients with information, one also needs to recognise that they are, to a certain degree, informed and can understand medical issues. Whilst the two ideas do not sit entirely comfortably, effective communication to achieve this goal is imperative. This also needs to be balanced with the reality of constraints on clinical time, which the courts suggested may result in defensive practice,[226] although this was not borne out by the thesis's rich data (see Chapter 6). Furthermore, the court found it *'necessary to impose legal obligations, so that*

[224] *Montgomery* (n3) [90]
[225] *Montgomery* (n3) [76]
[226] *Montgomery* (n3) [92]

even those doctors who have less skills or inclination for communication, are obliged to pause and engage with the discussion which the law requires.'[227]

There are a variety of reasons why additional support for people with intellectual disability is relevant. For the avoidance of doubt, this section (and indeed the thesis) is not intended to convey that every person with an intellectual disability will need support in understanding, although some undoubtedly will. Although there is awareness of health inequalities for people with intellectual disability, many also suffer more inequalities in health outcomes,[228] together with higher mortality and premature death, than people without intellectual disability.[229] Moreover, *'communication difficulties and reduced health literacy'*[230] together with *'deficiencies in access to and the quality of healthcare provision'* have been identified as two of the five classes of health inequalities faced by people with intellectual disability which would benefit from intervention.[231] The NHS Accessible and Communication Policy notes that a person's intellectual disability will have a significant impact on their ability to communicate and level of support needed. Therefore, where a person has a mild or moderate learning disability, they may need information in 'easy read' format and verbal information explained more slowly and simply,[232] irrespective of the nature of the intellectual disability, which will help facilitate informed consent.

Ineffectual communication between a healthcare professional and a patient with intellectual disability is a significant barrier to providing adequate primary healthcare.[233] Overcoming these barriers is not insurmountable but requires improved communication skills, a greater appreciation and understanding of people with intellectual disability and

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[227] *Montgomery* (n3) [93]

[228] See for example Helene Ouellette-Kuntz, 'Understanding health disparities and inequities faced by individuals with intellectual disabilities,' (2005) Journal of Applied Research in Intellectual Disabilities, 18, 113-121

[229] Jane Tracy and Rachel McDonald, 'Health and disability: Partnerships in health care' (2014) Journal of Applied Research in Intellectual Disabilities 28(1) 22-32, 22

[230] Health literacy is tangentially referred to in n37 [149] wherein it refers to patients *'whose state of mind, intellectual abilities or education may make it impossible or extremely difficult to explain the true reality to them'*

[231] Eric Emerson and Susannah Baines, 'Health inequalities and people with learning disabilities in the UK: Health inequalities and people with learning disabilities in the UK' (2011) Tizard Learning Disability Review 16 42 p. 10. It is worth noting that the authors observe that where less severe learning disabilities are concerned, there is a coincidence of poverty, poor housing, unemployment and discrimination.

[232] *Montgomery* (n3) [85].

[233] See for example, Nigel Lennox and M P Kerr, 'Primary health care and people with intellectual disability: Barriers and solutions' Journal of Intellectual Disability Research 41 365-372

their challenges, together with working in partnership with patients, families and carers.[234,235] Significantly, there has been an accepted dearth of research concerning people with intellectual disability and how specific guidelines or recommendations might directly affect them[236,237] and wider research would be needed to identify ways in which communication in the healthcare setting can be improved.

Montgomery may be significant in the sense that it helps redress the inequality for the patient with intellectual disability. Whilst Lords Kerr and Reid reflect on the importance of effective communication, so that the patient does not feel overwhelmed by information which may be challenging to understand, the emphasis on patient autonomy may not actually benefit those who have mild/moderate intellectual disability. These patients may still be overwhelmed by the information provided and the shift of focus where they are now required to take responsibility for taking decisions about risks which effect their own lives may be divisive and hinder patient autonomy. However, the layering of the GMC guidelines in addition to the legal requirement within *Montgomery* is helpful. The emphasis on meaningful dialogue,[238] combined with the test of materiality, places the healthcare professional under a duty to ascertain whether their particular patient would be likely to attach significance to a specific risk.[239] This approach, together with the duty to provide 'easy read' material under the AIS, should assist patients with intellectual disability but further research would be required to ascertain the impact of these combined factors. Nevertheless, these steps should not be underestimated, as research has shown that

[234] A similar point was made where concerns were raised about complying with the law around consent, together with the lack of understanding of people who work in the health service about appropriate communication with people with intellectual disability. Department of Health, 'Valuing People Now: Summary Report' March 2009-September 2010 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/215891/dh_122387.pdf para3.6 accessed January 2, 2024

[235] It should be noted that many of the health inequalities that people with intellectual disability face can be easily changed.

[236] Sally-Ann Cooper, Craig Melville and Jillian Morrison 'People with intellectual disabilities, their health needs differ and need to be recognised and met' 2004 BMJ 329 414-5

[237] See also Rebecca Fish et al. '"Tell me what they do to my body": A survey to find out what information people with learning disabilities want with their medications' Br J Learn Disabil 2017 45 217-225

[238] Principle 2 states that, *'Decision making is an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual patient.'*

[239] *Montgomery* (n3) [87]

regardless of how skilled a GP is, it is challenging for many people with an intellectual disability to communicate their health needs effectively.[240]

2.12 Where a patient asks questions

The Supreme Court commented on *Sidaway*, where the onus was on the patient to ask the doctor questions regarding their treatment. It seems entirely illogical to place the onus on the patient to ask a question when they do not know the question to ask.[241] *Montgomery* advances the traditional position where the onus was placed on the patient to ask questions relevant to their treatment. As observed by Sedley LJ in *Wyatt v Curtis*[242] where the patient did not ask questions concerning their treatment, or more likely did not know the questions to ask that the doctor was not under a duty to disclose that information. *Montgomery* describes this as a reversal of logic, since the more one is advised about the risks a person faces, the more likely it will be that subsequent questions will flow from the transfer of knowledge. Interestingly, the court observed that the more a person lacks knowledge, the more anxious they are likely to become and it is those patients who are in greatest need of information.[243] However, patients are acutely aware of the limited time they are likely to have with their GP and a doctor in a clinical setting and they may be hesitant in being perceived as a person who questions the doctor extensively in a relationship where there is an imbalance of power. Whilst the subjective and objective test set down in *Montgomery* seeks to remedy this previous defect by introducing a duty to disclose what is materially relevant to this particular patient, the reality may be quite different.

This qualitative research suggests an approach reminiscent in *Poynter*[244] where Sir Maurice Drake held there was a balance to achieve in disclosing risk to a patient when asked, which would deter a patient from consenting to treatment which was believed to be in the best clinical interest of the patient. These circumstances would justify information being withheld. Where information was to be withheld, the *Bolam* test would apply whether a

[240] Jenny Ziviani, Nicholas Lennox and Heather Allison, 'Meeting in the middle: improving communication in primary health care consultations with people with an intellectual disability' (2004) Journal of Intellectual & Developmental Disability September 29(3) 211–225,213
[241] *Montgomery* (n3) [58]
[242] *Wyatt v Curtis* [2003] EWCA Civ 1779
[243] *Montgomery* (n3) [58]
[244] *Poynter v Hillingdon Health Authority* [1993] 7 BMLR 192 and see Hubert Winston Smith, 'Therapeutic Privilege to Withhold A Specific Diagnosis from Patient Sick with Serious of Fatal Illness' (1946) 19 Tenn. L. Rev. 349

responsible body of medical opinion would have done the same. Unfortunately, this sits uncomfortably with the dicta of Lord Bridge in *Sidaway* where he states:

'when questioned specifically by a patient…about a patient…about risks involved in a particular treatment proposed, the doctor's duty must…be to answer truthfully and as fully as the questioner requires.'[245]

Montgomery refers to potential time constraints in the clinical setting,[246] yet the qualitative research in this thesis demonstrates something quite different, as withholding information from patients was more prevalent in clinical pharmacists than GPs, where clinical pharmacists spend on average twice the amount of time with their patients than GPs. This suggests that the objectives set by the judgment are not aligned with clinical practice. The court observed that the less the patient is informed, the greater the potential anxiety. Believing information is being hidden could indeed create anxiety and the unknown could produce more anxiety for fear of the unknown yet, this need to be carefully balanced against fuelling anxiety due to excessive disclosure which could be detrimental to the patient's health.[247] Contrary to the court's view, it does not necessarily follow that patients with anxiety are those who require most information.

Having considered the law in other domestic jurisdictions, the court noted that the doctor-patient relationship had altered over the years. No longer did the law reflect the outmoded views where only '*highly educated man of experience'*[248] would be able to fully grasp and understand the doctor's advice. Patients were not simply *'the passive recipients of …care'* but consumers who were *'widely regarded as holding rights.'*[249,250] This innovative thinking was brought about by a changing society; for example, in the introduction of the internet

[245] *Sidaway* n6 [898]
[246] *Montgomery* (n3) [58]
[247] See Chapter 6
[248] *Sidaway* (n6) [895] See also James Badenoch QC, 'A doctor's duty of disclosure and the decline of The *Bolam* Test: A dramatic change in the law on patient consent' (2016) Medico-Legal Journal 84(1) 5-17,8
[249] *Montgomery* (n3) [76]
[250] It is worth noting that in the US consideration had already been given to the potential role of patients as consumers, although this is largely as a result of the spiralling costs of medical health care. However, the move towards patients as consumers was also initiated by the Patient Rights movements which challenged paternalism within the profession. See Mark A Hall, 'The legal and historical foundations of patients as medical consumers' (2008) 96 Geo LJ 583,585, 586; and George J. Annas, 'The Rights of Patients' 77-78 (Eve Carey Ed, 3rd Edition, 2004)

where health care information can be readily found.[251] This includes *'patient support groups*' and the availability of general information, although the quality of health information on the internet can vary greatly in quality.[252]

The court referred to the information product sheets supplied with pharmaceutical products with approval, as an example of where the law requires the *'citizen to comprehend the information provided'*. In principle, the patient information leaflets are an example of good practice, although it is possible that given the details of the potential harm that can be caused by the ingestion of drugs, the contents of these leaflets could in themselves create anxiety. Although the duty of care requires disclosure of the risks, research has shown patient information leaflets are often complex and can create confusion as they are often written in such a way as create a barrier for those with reduced literacy.[253] Such barriers may raise an interesting dilemma for more common 'over the counter' medication, as the information provided may fail to meet the desired outcome that patients should play a role in their healthcare which cannot be achieved if they are unable to consent to what they cannot understand.

How information is communicated is pivotal and the healthcare professional's ethical obligation must be focused on effective and valuable conversations with their patient rather than just providing a list of risks associated with the treatment.[254] It has been suggested that *'effective communication – the actual understanding on the part of the patient – is less*

[251] It is worth adding that patient autonomy had been a slowly developing process over several years. For example, the introduction of the contraceptive pill in the 1960's began to give women reproductive autonomy and the Abortion Act 1967 enabled women (who satisfied the provisions of the Abortion Act s1) to terminate a pregnancy. With the development of assisted reproductive technologies, IVF was introduced with the birth of Louise Brown in 1978 and the introduction of the European Convention of Human Rights, patient autonomy was slowly eating into the fabric of traditional medicine

[252] Studies on patient's use of the internet to access medical information is limited. However, one study in the US demonstrated that over 50% of patients used the internet to access medical information, while most considered the information they read was reliable – see Joseph A Diaz, MD, Rebecca A Griffith, MD, et al., 'Patients' Use of the Internet for Medical Information J Gen Intern Med. 2002 Mar; 17(3): 180–185. However, with the expansion of internet use over the last 20 years, together with the rise in social media, there is a gap in the literature about reliability of medical information on the internet. However, one example is conspiracy theories concerning Covid on the internet, where misleading information about the vaccine has led to low take up and a lack of trust in the vaccine programme see I. Ullah, K.S. Khan, M.J. Tahir et al. 'Myths and conspiracy theories on vaccines and COVID-19: Potential effect on global vaccine refusals,' Vacunas 2021, 22(92) 93-97, 96

[253] Amber Young, June Tordoff and Alesha Smith, 'What do patients want? Tailoring medicine information to meet patient's needs' (2017) Research in Social and Administrative Pharmacy 13 1186-1190

[254] Jose Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2009) 17 Med L Rev 76

critical'[255] is contrary to the objective of patient-centred care. If the health care professional is simply under a duty to *convey* the information, it does not follow that the patient will understand the information conveyed and it appears there is no legal requirement to understand information in any significant way. All that appears to be required is that a person should be able to '*understand an explanation of that information in broad terms and simple language.'*[256] Nevertheless, prior to *Montgomery* the courts had found in favour of the claimant where the doctor failed to advise her patient accurately and, in a way, which was not misleading so demonstrating that something more than advising in *'broad terms'* is required.[257] However, desirable it may be to set a standard for establishing a patient's understanding so they can provide true informed consent, it may be unduly onerous to require a healthcare professional to ensure understanding which would also require some kind of objective assessment.[258]

However, if the doctor's role is simply to impart information, there is a risk of patients making uninformed decisions in an issue well-illustrated in the case of *Smith v Tunbridge Wells Health Authority.*[259] Here, Mr Justice Moorland explained that the doctor's duty was to:

'take reasonable care to ensure that his explanations of the risks is intelligible to his particular patient.'[260]

He continued that

't*(T)he doctor should use language, simple but not misleading, which the doctor perceives from what knowledge and acquaintanceship that he may have of the patient (which may be slight).'*[261]

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[255] Jose Miola, 'Autonomy Rued OK?' (2006) 14 Medical Law Review 108,111
[256] *Bell and another v Tavistock and Portman NHS Foundation Trust (University College London Hospitals NHS Foundation Trust and other Intervening)* [2020] EWHC 3271 (Admin), 131 citing *Re S (A Child) (Adoption: Consent of Child Parent)* [2017] EWHC 2727 (Fam) at para 36 and citing Chadwick LJ in the Court of Appeal in *Masterman-Lister v Brutton & Co (No1)* [2002] EWCA Civ 1889 at 79
[257] *Cooper v Royal United Hospital NHS Trust* [2005] EWHC 3381
[258] See, Margaret A. Sommerville, 'Structuring the issues in informed consent' (1981) 26 McGill Law Journal 740, 778
[259] *Smith v Tunbridge Wells Health Authority* [1994] 5 Med LR 334
[260] Ibid [339]
[261] Ibid

The reference to the use of accessible language is positive, although it appears to be in the form of guidance rather than mandatory but is echoed in the judgment of *Montgomery.* However, 20 years passed until the language of the *Montgomery* judgment ensured that the doctor's duty of disclosure would only be fulfilled if the information provided is comprehensible.[262] Perhaps a more troubling aspect about the judgment in *Smith* is the suggestion that the doctor may not be well acquainted with the patient, an aspect which would likely hamper his own understanding of how the information should be conveyed. It is only through dialogue with the patient that the doctor can moderate how he conveys the information, where necessary, thus the dictum in *Smith* appears confused and counterintuitive.

In the slightly later case of *Al Hamwi,*[263] Mr Justice Simon observed that whilst clinicians should take

'*reasonable and appropriate steps to satisfy themselves that the patient has understood the information…. the obligation does not extend to ensuring that the patient has understood.'*[264]

Mr Justice Simon continued by questioning *'what steps could be devised to ensure that a patient has understood, short of a vigorous and inappropriate examination,'* a step regarded as '*too onerous'.*[265]*Al Hamwi* confirmed a violation of the patient's autonomy but also suggests a failure to recognise the importance of communication as it was enough for the doctor to simply provide the information to the patient. Mr Justice Simon's dictum is informative in this respect as he stated that

'*A patient may say she understands although she has not in fact done so, or has understood part of what has been said, or has a clear understanding of something other than what has*

[262] *Montgomery* (n3) [290]
[263] *Al Hamwi v Johnston and the Northwest London Hospitals Trust* [2005] EWHC 206 - Mrs Hamwi spoke little English and, alleged that the obstetrician failed to provide adequate counselling and guidance as regards the risk of an amniocentesis. Had she done so and ensured that Mrs Hamwi understood the risks, she would have had the diagnostic test. Subsequently, she gave birth to a child with disabilities, which would have been detected by the test.
[264] Ibid [69]
[265] Ibid

been imparted. It is common experience that misunderstandings can arise despite reasonable steps to avoid them.'

The two concepts are difficult to reconcile. If the objective is to use language to facilitate a patient's informed decision, it seems illogical that the duty does not extend to ensuring the patient understands. There are three issues that potentially arise. Firstly, there is the possibility that the doctor does not have skills to convey the risks in appropriate language, in which case this can be achieved through education and training. Secondly, the reference in both cases is to '*language*' and '*communication*' which does not include written material which may assist a patient, although both cases preceded the AIS 2016. Thirdly, this strongly suggests that although intelligible explanation is part of a doctor's duty, the onus is not on the doctor to ensure understanding. Although challenging to prove, the law did not go as far as to establish a route for negligence where a doctor failed in his duty. In contrast, Mr Justice Buckley had previously suggested, albeit at first instance, that the doctor should have ensured that the patient *'fully understood the nature of the risks,'*[266] perhaps by spending time with the patient to ensure that she fully understood what she was advised. *Montgomery* attempts to remedy these fundamental defects. Although the judgment refers to the doctor's role as being '*advisory*',[267] the role is to *ensure* that the patient understands the seriousness of her condition and has considered the risks, benefits and reasonable alternatives in order to provide informed consent.[268,269]

The requirement of disclosure and the wording of the *Montgomery* judgment has a corollary for people with intellectual disability. Understanding is not a fixed concept and will vary from patient to patient, particularly where the patient has intellectual disability. In contrast to previous judgments, *Montgomery* requires the doctor – or healthcare professional - to ensure understanding.[270] The judgment explicitly states that the duty will not be satisfied by

[266] *Deriche v Ealing Hospitals NHS Trust* [2003] EWHC 3104
[267] *Montgomery* (n3) [90]
[268] Ibid
[269] Although beyond the scope of this research, there is a view that disclosure to a patient, without some level of clinical direction, for example in genetic counselling or, where the responsibility for the decision whether to undergo treatment is left entirely to the patient as stated in paragraph 81, *'effectively abandons the patient to his or her fate and reflects a view that sees autonomy as isolational independence*', which lacks meaning where there is no 'social context'. Alasdair Maclean, 'Autonomy, Consent and Persuasion' European Journal of Health Law (2006) 13 321-338
[270] *Montgomery* (n3) [90]

'bombarding' the patient with *'technical information which she cannot reasonably be expected to grasp'*.[271] The use of linguistics here is important. The emphasis on not overburdening the patient with technical language supports an autonomy which is more inclusive and includes those who are less well-educated and those who suffer from health illiteracy or inequality.[272] However, there are challenges. It can be difficult to a doctor to accurately assess whether a patient understands the information and where it cannot simply be assumed that a patient has understood the information simply because it has been conveyed.[273]

This section has explored the pressing issue of dialogue and communication, the core elements of the doctor-patient relationship, both of which are essential to gaining informed consent from the patient. Whilst *Montgomery* is a significant development in explaining how *not* to communicate, the judgment falls short as it neither provides further guidance on how understanding should be achieved, nor provides any examples of best practice as guidance. Furthermore, it is not entirely clear whether the duty requires the doctor to truly enquire into the patient's definitive understanding of the risk or whether the patient can simply recite the risks back to the doctor.[274] These challenges will be considered further in the recommendations made in Chapter 7.

Finally, it could be argued that a failure of the judgment is to set any standard to assess what reasonable steps have been taken to ensure patient understanding.[275] Arguably, the duty established in *Montgomery* does far less than the GMC guidelines to help establish a meaningful relationship between doctor and patient.

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[271] Ibid

[272] In contrast, where the emphasis of information is simply focused on disclosure rather than the process to ensure a patient can provide informed consent, those who are less well-educated or more vulnerable are not sufficiently protected, see for example n328

[273] See Matthew E. Falagas, M.D., M.S., D.Sc., Ioanna P. Korbila, M.D. et al., 'Informed consent: how much and what do patients understand?' (2009) The American Journal of Surgery 198, 420–435, 435. In an extensive study concerning informed consent by patients when undergoing surgical procedures or participation in clinical trials, it was established that the amount of information proved may be insufficient. They concluded that physicians needed to communicate information more comprehensively. More use of easy read or audio-visual material may increase patient understanding.

[274] See also Alasdair Maclean 'Autonomy, Informed Consent and Medical Law, A Relational Challenge' (2013) Cambridge University Press, 178

[275] For a similar view see Miola and Heywood (n90)

2.13 Examination of cases post-*Montgomery*

In this section the reported cases post-*Montgomery* will be briefly examined to attempt to ascertain the extent to which the new test has been applied. There is well-established evidence that the *Bolam's* influence has been significantly reduced, illustrated by what has become known as the 'pure diagnosis' case in *Muller.*[276] Here, the issue was whether a histologist was negligent in failing to correctly diagnose malignant melanoma on slides. In such a situation, the histopathologist's observation is either clearly correct or incorrect. Mr Justice Kerr observed that it was unlikely that pure diagnosis cases were those which Mr Justice McNair had in mind when expressing the *Bolam* test and considered the approach taken in *Penny,*[277] which was closest to *Muller* on the facts. Here, Mr Justice Peppit noted that the diagnosis of data was objectively wrong, and he consequently found that the defence experts' evidence should be rejected, so applying Lord Browne-Wilkinson's *Bolitho* exception because it did not stand up to logical analysis.[278] Mr Justice Kerr recognised that in *Muller* he was unfortunately bound by precedent and had no alternative but to apply *Bolam* with the additional *Bolitho* gloss. However, in doing so he found in favour of the claimant. *Muller* is particularly relevant in the context of this research as Mr Justice Kerr expressed an unwillingness to apply *Bolam* and dissatisfaction that *Bolam* should be applied in circumstances where it was clearly inappropriate.

However, *Bolam* cannot be entirely dismissed and there are areas of clinical engagement where the *Bolam* test still appears appropriate. Once such example are the 'pure treatment' cases, illustrated by *C v North Cumbria*,*[279]* which concerned the induction of a woman's labour. In these circumstances, where there is a choice of treatment it remains appropriate to assess negligence by reference to whether that given approach would be accepted as

[276] *Muller v King's College Hospital NHS Trust* [2017] QB 987
[277] *Penney v East Kent Health Authority* [2000] Lloyd's Rep Med 41
[278] Ibid 69. In 1997 the House of Lords adopted a more robust approach introduced by the judgement in *Bolitho*. Here, in a case involving treatment of a minor child, the expert witnesses gave opposing views. The importance of the case lies in the judgement of Lord Browne-Wilkinson who reflected on how a court could adjudicate on negligence where expert views were diametrically opposed. The court observed that it would be necessary to ask whether the doctor or healthcare professional acted in accordance with responsible medical opinion. Whilst it would be rare for a court to conclude that views genuinely held by a competent medical expert were unreasonable, there could be circumstances where a judge would be satisfied that a body of expert opinion could not be supported at all. If these rare occasions transpired, then the expert opinion could be disregarded as notwithstanding logical analysis and then the court will be the final arbiter.
[279] *C v North Cumbria* [2014] EWHC 61

proper by a reasonable and responsible body of obstetricians. The discussion of the applicability of *Bolam* in the judgment is particularly instructive as the court were reminded that it was insufficient for a claimant to produce experts, which disagree with the opposing party. All this does is recognise that in an area of expertise, there may be a range of different views, all of which may legitimately be held. As Lord Scarman stated on *Maynard v West Midlands Regional Health Authority*,

'differences of opinion and practice exist and will always exist in the medical and other professions. There is seldom only one answer exclusive of all others to problems of professional judgment. A court may prefer one body of opinion to the other, but that is no basis for a conclusion of negligence.'[280]

If *Bolam* is not fit for purpose to be applied to 'pure diagnosis' cases, can *Bolam* justifiably remain applied to cases where a clinician withholds risk disclosure from a patient, if they objectively believe that there is a risk of harm to the patient? It would appear that removing the *Bolam* test in its entirety from an assessment of a clinician's decision to rely on the therapeutic privilege exception, either knowingly or unknowingly is entirely unrealistic.

Doubtless, some cases would have been settled, but in 2015 there were a number of cases which examined the test set out by the Supreme Court. For example, the test of materiality led the court in A *v East Kent Hospitals University NHS Foundation Trust*[281] to opine that

'*the decision in Montgomery affirms the importance of patient autonomy, and the proper practise set out in the GMC guidance and the proper approach set out in Pierce and Wyatt. It is not authority for the proposition that medical practitioners need to warn about risks that are theoretical and not material*'.

Here, the materiality test was being challenged in circumstances where the risk of chromosome or abnormality was one in 1000 or theoretical/negligible, but the judgment is helpful in confirming the role of autonomy in the decision-making process.

Perhaps of greater concern for this research was the possibility of the *Bolam* test re-emerging, which appeared evident in the case of *Spencer v Hillingdon Hospital NHS Trust.*[282]

[280] *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634, 638E
[281] *A v East Kent Hospitals University NHS Foundation Trust* [2015] EWHC 1038
[282] *David Spencer v Hillingdon Hospitals NHS Trust* [2015] EWHC 1058

Here, although the patient was advised of some of the risks, he was not specifically advised of the risk of thrombosis or embolism which he subsequently developed. In these circumstances, although the court found in favour of the claimant there was a suggestion that the *Bolam* test should be applied with the added gloss of what the ordinary sensible patient would expect to have been told. The court phrased this as follows,

'Whether the ordinary sensible patient would be justifiably aggrieved not to have been given information at the heart of this case when fully appraised of the significance of it.'[283]

Whilst this threatened to re-introduce the professional standard test, it left undefined what might amount to *'an ordinary sensible patient'* and whether that may include patients with intellectual disabilities.

However, in the slightly later case of *Thefaut*[284] the court was cautious about the judgment in *Spencer*, rejecting the notion that the *Montgomery* test was simply a form of the *Bolam* test, as this would reduce the subjective nature of the test in *Montgomery* to a mere irrelevance. The court stated that, firstly, it was not accepted that the *Montgomery* test was a variant of the *Bolam* test or, secondly, that the test could be limited to the reaction of the ordinary sensible patient. The reasoning is that this is reminiscent of the person on the Clapham omnibus and underplays or ignores the subjective element which the Supreme Court has explained is a component part of the test. Finally, the court added that the test for what has to be disclosed is that which would not leave the patient feeling '*justifiably aggrieved.'*[285] Hence, the court appeared anxious to distance itself from the historical remnants of *Bolam.* Although these judgments did not specifically refer to the therapeutic privilege exception, the judgment is both informative and concerning. Where the risk of the *Bolam* test remains, the less opportunity there will be to revisit the standard to be applied if the therapeutic privilege exception were to be relied upon.

[283] *Montgomery* (n3) [68]
[284] *Thefaut v Johnston* [2017] EWHC 496 (QB)
[285] *Montgomery* (n3) [62]

In the slightly later case of *Duce*, the Court of Appeal took the opportunity to set out the extent of the duty that was involved in *Montgomery.* The first limb of the test was set out as follows.

Firstly,

'what risks associated with an operation were or should have been known to the medical professional in question. This is a matter falling within the expertise of the medical professionals'.

and secondly,

'*whether the patient should have been told about such risks by reference to whether they were material. This is a matter for the court to determine. The issue is not therefore the subject of the Bolam test and not something that can be determined by reference to expert evidence alone'* [286]

In this specific case the issue was whether the gynaecologists were or should have been aware of the risks '*is a matter for expert evidence'* and thereafter whether the patient should have been advised of those risks appears to remain a question for the court to determine.[287] If this first limb of the test, as expressed in *Duce* were to be applied to the therapeutic privilege exception, it seems plausible to suggest that the *Bolam* test would *not* be applied. For example, if a doctor in their clinical judgment believed that a risk existed, then their judgment would be subject to expertise of medical professionals. It would then appear that whether disclosure would be detrimental to the patient's health would be a matter for the courts to determine. If *Bolam* does not apply, this suggests that the application of *Montgomery* to the therapeutic privilege exception is less paternalistic than initially envisaged.

Rather alarmingly for patient autonomy, the courts have witnessed a return to the application of *Bolam* which may ring alarm bells for the future of *Montgomery.* In *Bilal*, the Court of Appeal recognised that there were two distinct aspects of a clinician's role; that of

[286] *Duce v Worcestershire Acute Hospitals NHS Trust* [2018] EWCA Civ 1307
[287] Approved of by Yip J in the latter case of *Hazel Kennedy v Dr Jonathan Frankel* [2019] EWHC 106 (QB)

an assessment of treatment options, which was judged on the *Bolam* standard, and material information disclosure which is judged and assessed by *Montgomery,* wherein it states that

'the doctor is therefore under a duty to take reasonable care that the patient is aware of any material risks involved in the recommended treatment, and of any reasonable alternative or variant treatment[288]

However, the court held that when assessing what is *'reasonable'* the *Bolam* test should be applied as what is clinically reasonable is a matter for medical judgment. This contrasts with material risks, as the element of whether something is material is judged from the patient's perspective and is a matter for the courts.[289]

More recently, the Supreme Court had to consider what was described as *'one of the most important medical negligence cases in a long time*'.[290] The key issue was whether the *Bolam* test applied to the question of disclosure of reasonable alternative treatment or whether the court was the final arbiter. Dismissing the claimant's appeal, the Supreme Court held that when obtaining informed consent it is for the doctor to decide what amounts to reasonable alternative treatment, which would be judged on the professional standard test (*Bolam),* subject to whether not disclosing a particular alternative treatment could be logically supported (*Bolitho).* The clinician did not need to advise a patient of each and every alternative treatment option as they would '*bombard*' the patient with technical information, which the court in *Montgomery* was keen to avoid.

However, where a doctor is permitted not to advise the patient of all the possible treatment options, paternalism remains, and it denies the patient their right to determine their own treatment.[291] This decision risks two separate outcomes for the patient where the therapeutic privilege is concerned. On the one hand, not bombarding the patient with all alternative treatment may be beneficial for some patients as it lessens the risk of compromising a patient's capacity. However, the Supreme Court decision risks perpetuating the professional standard, making it more challenging to determine what test would be

[288] *Montgomery* (n3) [87]
[289] *Bilal and others v St George's University Hospital NHS Foundation Trust* [2023] EWCA Civ 605
[290] *McCullough and others v Forth Valley Health Board* [2023] UKSC 26
[291] This would include treatment which may not have been available at the unit provider. The doctor is not under a duty to advise of alternative treatment which is available elsewhere.

applied if the therapeutic privilege exception were relied on and then challenged in the courts. Bearing in mind the judgments of *Bilal* and *McCullough,* there is a distinct risk of the *Bolam* test being applied rather than the courts being the final arbiter.

This chapter has explored the case of *Montgomery,* a seminal judgment which brought the UK in line with many other domestic jurisdictions by introducing informed consent into the UK. This chapter does not purport to consider every element of such an important judgment as there is not simply scope to do so in this thesis. That said, the section on standard of care is relevant as whilst the standard may have been set with regards to informed consent, it does not follow that the same standard would be applied to the therapeutic privilege exception. Indeed, it appears more likely that the standard of care would be assessed on a professional practice standard.

The discussion on communication is particularly relevant to the potential use of the therapeutic privilege exception, as failure to exercise effective communication may lead to excessive disclosure, which could compromise patient capacity. Conversely, a lack of adequate communication skills could lead to withholding risk disclosure in circumstances where, with the appropriate skills, information could be effectively disclosed. Effective communication is imperative with any patient with an intellectual disability to ensure that the patient understands the nature and seriousness of their condition, together with the potential treatment, in order to enable them to provide informed consent. Whilst *Montgomery* did not consider patients with intellectual disability – nor should the supreme court have done so – it remains a crucial part of the thesis.

The chapter finishes with a short review of cases post *Montgomery* to try and assess the extent to which judgment has been applied. Whilst it is undoubtedly here to stay, there is evidence of a potential swing back to *Bolam* and the application of the professional practice standard test. If this is correct then, and if the therapeutic privilege exception were to be considered by the courts, then it would be likely that *Bolam* would be invoked.

Chapter 3: The development of the therapeutic privilege exception in England and Wales

3.1 Introduction

This chapter begins with a historical examination of cases which illustrates how information was routinely withheld from patients, before moving on to the 1980's where the development of informed consent begins from the case of *Sidaway.*

The section that follows traces the extent to which patients were appraised of the facts of their treatment and/or diagnosis from a historical perspective. In doing so, this section does not purport to provide a comprehensive analysis, but it is of great interest to note that withholding information from patients is not a modern construct.

3.2 Truth-telling in medicine

As far back as the Middle Ages, physicians recognised there could be circumstances where it would be inappropriate to advise the patient of the proposed treatment. Early opinion has reflected a largely paternalistic direction, possibly based on a more rigid class and social divide than the present day.

A linear consideration of the historical development of withholding information from a patient can be traced back to Hippocrates. Here, Corpus Hippocraticum advised the physician to *'conceal(ing) most things from the patient…turning his attention to away from what is being done to him…revealing nothing of the patient future or present condition*'.[292] One can only surmise the reasoning behind this, but in Ancient Greece education was limited, and the social structure was such that physicians are unlikely to have perceived the need for being accountable to the patient for decisions taken by the physician who acted beneficently but paternalistically.

Even in Roman times, withholding the truth from another was seen beneficently. An example of such beneficence can be observed in the case of Arria, who regular visited her husband Caecina Paetus in prison but failed to disclose to him that their son had died in

[292] Hippocrates, 'Decorum XVI' in Jones W., ed. *Hippocrates With an English Translation*. Vol 2. (1923) London, England: Heineman 297

order to save him from further pain.[293] Here, it appears that Arria withheld information to protect his psychological wellbeing and from this perspective, it appears that the therapeutic privilege exception is at its grassroots similar in nature to this ancient anecdote. During a similar period, Plato observed that '*…we must surely prize truth most highly. For if it were right in what we were just saying and falsehood is in very deed useless to gods, but to men useful as a remedy or form of medicine, it is obvious that such a thing must be assigned to physicians, and laymen should have nothing to do with it.'*[294] Hence, it was not within the physicians remit to share information with their patient and deception was required to cure the patient.

This approach was followed for many years and the writings of Henri de Mondeville (ca 1260-1325) are particularly noteworthy here. His perspective was that physicians should act with beneficent paternalism to *'(P)romise a cure to every patient but…tell the parents or the friends if there is any danger.'*[295] Here, we can see a suggestion of telling the truth to those closest to the patient but applying a more covert approach by the surgeon who, '*..must not be afraid to lie if this benefits the patient.'*[296]

It is possible that the writings of de Mondeville could be identified as the first specific reference to modern-day therapeutic privilege exception as defined by *Montgomery*.[297] De Mondeville opined it would be acting beneficently to withhold the truth from a patient if their emotional condition justified not revealing the truth. Although faith remained rooted in the prospect of recovery, there was a relationship between adhering to the physician's wishes and the prospect of recovery as illustrated by Isaac Israeli who wrote, '*Reassure the patient and declare his safety even though you may not be certain of it, for by this you will*

[293] https://thepathsofsurvival.wordpress.com/2012/05/01/arrias-wound/ accessed April 7, 2019
[294] Plato, *The Republic*, Book 111, line 389b
[295] Henri de Mondeville, 'On the Morals and Etiquette of Surgeons' as entitled and reprinted from a 1910 source, in Stanley J. Reiser, Arthur J Dyck, and William J. Curran eds., *Ethics in Medicine; Historical Perspectives and Contemporary Concerns* (Cambridge, MA:MIT Press, 1977), 15 and referred to in Ruth Faden and Tom Beauchamp, *A History and Theory of Informed Consent*, Oxford University Press, New York 1986
[296] Henry E. Sigerist, *On the History of Medicine* (1960) New York: MD Publication, Inc. 145
[297] See for example, Simone C. MacDougall, 'The surgeon and the saints: Henri de Mondeville on divine healing' (2000) Journal of Medieval History 26(3) September, 253-267; Clement C. Clarke, 'Henri De Mondeville' (1931) Yale J Biol Med Jul 3(6) 458-81

strengthen his Nature.' Thus, withholding information conveyed therapeutic positivism which was essential for the patient's recovery and ultimate good health.[298]

At a similar period, the views of Dr John Gregory were proving persuasive. Whilst he too regarded the doctor's role as one of beneficence, he also considered the value of truth telling. There could be situations, for example where the patient is extremely ill where '*A deviation from truth is sometimes...both justifiable and necessary'*.[299] Gregory considered that if one were to tell a seriously sick man of the truth, it may cause further harm. Yet, he also recognised that in these situations there was also value in advising the patient of the truth, since he may wish to put his affairs in order. He argued that *'….it behoves a physician never to conceal the real situation from the relations.'*[300] Whilst keeping the truth from the patient was permitted, it was essential for the patient's family to be aware of the patient's condition.

Unfortunately, Gregory did not develop the notion of an informed patient-doctor relationship further, but focused on considering how the physicians' professional role could develop so that patients and physicians would share the same honourable objective of healing and curing the patient. We hence learn from Gregory the clear message that '*deviating from the truth*' or withholding the truth is on occasions both valuable and necessary.

An approach with '*less authoritarian flavour, with more attention to actual practice'*[301] can be witnessed in the writings of Benjamin Rush.[302] He advocated sharing information with patients so they understood their treatment. Rather than empowering a patient's self-determination, the purpose of sharing information was only to ensure compliance as he rejected any challenge to a physician's advice and entirely accepted the notion of deception

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[298] See Jay Katz, *The Silent World of Doctor and Patient* (1984) John Hopkins University Press citing Bar-Sela, A. and Hoff, H., 'Isaac Israeli's Fifty Admonitions to the Physicians' (1962) Journal of the History of Medicine and Allied Sciences 17 245 Reprinted in *Legacies in Ethics and Medicine*, supra note 18 (Admonition # 38)

[299] John Gregory, *Lectures on the Duties and Qualification of a Physician*, Philadelphia: printed and published by M. Carey & Son 1817, based upon the 2nd edition, London, 1772, revised and enlarged by the author p. 36 https://archive.org/details/2555043R.nlm.nih.gov accessed April 9, 2019

[300] Ibid

[301] Ruth Faden and Tom Beauchamp, *A History and Theory of Informed Consent* (1986) Oxford University Press, New York 64

[302] 1745-1813

where necessary, to ensure positive outcomes for the patient. If the patient was unable to understand the information perhaps because of lack of education, then deception was permitted, reminiscent of the Singapore Court of Appeal in *Hii Chii Kok v Ooi Peng Jin Lucien*[303] discussed in chapter 4.

An interesting observation made by Rush suggests the fundamental importance of patient understanding, a theme referred to in *Montgomery.* Rush stated that physicians should '*strip [their] profession of everything that looks like mystery and imposture and clothe medical knowledge in a dress so simple and intelligible, that it may become…obvious to the meanest capacities.'*[304] Rush's views should be celebrated as he suggests that clear and simple language can facilitate patient understanding which would avoid the need for deception. One aspect that will be explored in this research is whether more enhanced professional skills in dialogue and communication might obviate the need for some cases where the therapeutic privilege exception is either knowingly or inadvertently relied upon, so that this exception to informed consent can be reduced to extremely limited circumstances.

In a comparable way, the Supreme Court in *Montgomery* over 200 years later emphasised the need to avoid '*bombarding the patient with technical information which she cannot reasonably be expected to grasp.'*[305] Whilst in the latter example the reference to communication was to facilitate a person's informed consent, the reference of its historic predecessor to communication was such that the patient could follow the doctor's chosen path of treatment. Regardless of the reasoning, there is an unobstructed vision of inclusivity if only to accept the authoritative nature of the physicians.

The common theme between both Rush and Gregory is that whilst there was a move towards the engagement of patients for limited reasons, deception was specifically approved of where it was necessary to retain authority in the relationship between physician and patient. If patients were told the truth of their medical condition or treatment, there was concern that greater distress could be caused to the patient, who may

[303] *Hill Chii Kok* (n99)
[304] Benjamin Rush, *The Progress of Medicine* and *The Vices and Virtues of Physicians (1801)* in *The Selected Writings of Benjamin Rush* (1947) ed. D. Runes New York: Philosophical Library
[305] *Montgomery* (n3) [90]

then refuse treatment which would be contrary to the patient's best clinical interests. Although this perception of medical treatment may be one consigned to an out-of-mode medical practice, the qualitative research in this thesis showed a similar trend whereby clinical pharmacists withheld information relevant to a patient's decision-making. Nevertheless, given that medical treatment during this early period was often unsuccessful, keeping the patients in ignorance had some beneficial effect and may have instilled hope where medicine may have had limited value.

It was in Manchester in 1803 that Thomas Percival published *Medical Ethics* a year before his death in 1804. He considered the worthiness of truth-telling. In a similar approach to Rush and Gregory, Percival believed that withholding information was acting beneficently. He argued that '*To a patient…. who makes inquiries which, if faithfully answered, might prove fatal, it would be a gross and unfeeling wrong to reveal the truth.'*[306] It seems that Percival and those before him appeared to naturally voice the notion of the therapeutic privilege exception. Where harm could be caused to a patient, whether that harm is physical or psychological, or even to ensure obedience to the physician's treatment, truth-telling can be limited in the interests of beneficence.

Percival's views were so influential they were included almost in their original form in the American Medical Association's first Code of Ethics in 1847,[307] from which there are observations relevant to this thesis. The Code states that *'unnecessary visits to the patient, as they give unnecessary anxiety to the patient,'*[308] a view also reflected in the qualitative research, where clinical pharmacists opined that frequent visits to the patient, whilst in-patient, directly lead to additional anxiety. The Code of Ethics adds that *'t(T)he life of a sick patient can be shortened, not only by the acts but also by the words or the manner of a physician'*.[309] Thus, an important theme emerges from early medical practice that are relevant to modern-day practice and indeed this research; namely, that anxiety can be caused by what a physician may say to the patient. Although the reasoning may be different to contemporary practice, it seems to be that deception or withholding information about a

[306] Thomas Percival, *Medical Ethics; or a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons* (1803) Manchester: S. Russell
[307] American Medical Association Code of Ethics 1847 Digital Collections - National Library of Medicine (nih.gov) accessed November 23, 2022
[308] Ibid, p. 4, para 4
[309] Ibid

patient's condition was commonplace practice. Despite the Code of Ethics acknowledging that anxiety can cause a patient harm, a contrast then arises with common-law decisions in domestic jurisdictions which have sometimes struggled with recognising straightforward anxiety as potential harm.

It was during this period that one of the earliest cases to consider the limits of a patient's consent was decided. Although patient's perceptions of early medicine and practice were largely opaque, the judgment in *Slater v Baker and Stapleton* held that the surgeon who employed experimental surgery on a patient failed in his duty to first obtain his patient's consent.[310] Interestingly, the judgment has similar tones to the subsequent test for the standard of care set down in *Bolam*:

'[I]t appears from the evidence of the surgeons that it was improper to disunite the [partially healed fracture] without consent; that is the usage of and law of surgeons; then it was ignorance and unskillfulness in that very particular, to do contrary to the rule of the profession, what no surgeon would have done'. [311]

There was no specific direction in the judgment addressing the need for the consent to be informed, there was simply the mere presence of consent. Nonetheless, the consideration that the patient was aware of what may happen to him was an important development. Rather than respecting a patient's choice to decide for himself regarding the specific treatment, this appears to be more a more '*pragmatic or consequentialist justification for informed consent'.*[312]

The following short section does not aim to provide a comprehensive analysis of one preferred ethical theory over another. Whilst reference is made to deontology, the section does not purport to adopt deontology as a ground to justify lying to a patient. Its value sits within the historical perspective of the section and serves only to illustrate that failure to tell the truth was, in some quarters, fiercely rejected.

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[310] *Slater vs. Baker and Stapleton 95 Eng Rep. 860* (K.B. 1767)
[311] *Bolam* (n5)
[312] Jessica W Berg, Paul S Applebaum, Charles W Lidz, Lisa S Parker, *Informed Consent, Legal Theory and Clinical Practice* OUP 2nd Edition 2001 p. 42

The philosopher Immanuel Kant rejected lying to another by withholding information. To him, veracity was virtuous. From Kant's absolutist perspective, no amount of altruistic motive can ever justify failure to tell the truth. Kant explains this as follows:

'*Truthfulness in statements which cannot be avoided is the formal duty of an individual to everyone, however great may be the disadvantage accruing to himself or to another.'*[313]

Brown argues that Kant's reference to an autonomous agent referred directly to the agent's ability to live their life.[314] The traditional view of Kant's '*Supposed Right to Lie'* is viewed through Kant's account of the moral law in '*Groundwork of the Metaphysic of Morals'*. If lying cannot be applied as a universal law, it follows that lying is not ethically permissible because lying is contrary to a person's enforceable rights and duties owed to another. Moreover, Kant explained in his *Categorical Imperative* that one should only act in a way that may also be applied as a universal law and these maxims (or acts) guide the way that we live in terms of moral duties. Since the maxim of making intentional untrue statements cannot be applied as a universal law, then it follows that making statements that are untrue is not ethically permissible.

Brown argues there are some relationships, such as the doctor-patient relationship, where silence equates to being untruthful. When doctors do not specifically state that they will tell their patients the truth about their medical condition and treatment, *'it rarely enters the patient's mind that material diagnostic or prognostic information may have been withheld.'*[315] Brown concludes that Kant would state that the therapeutic privilege exception is never morally acceptable. Whilst the accepted and common position, this interpretation may do Kant an injustice and provide a further, more acceptable interpretation.[316]

In *'Doctrine of Rights'*, Kant explains that everyone is born with free will to determine their own actions for themselves and to act independently of another. If one were never to lie, it would follow that the person transgressed would have a physical right to that person's information (the property) which would violate that person's personal freedom regardless

[313] Sissela Bok, *Lying: Moral Choice in Public and in Private Life* (1978) Harvester: Sussex 38 referring to Kant, 'On a Supposed Right to Lie'
[314] Chris Brown, 'Kant and Therapeutic Privilege' (2008) Journal of Medicine and Philosophy, 33: 321-336
[315] Ibid, 326
[316] Helga Varden, 'Kant and lying to the murderer at the door...One more time: Kants' legal philosophy and lies to murderers and Nazis' (2010) Journal of Social Philosophy 41(4) Winter 403-410

of the harm caused. Indeed, Bok refers to a right to the information as a narrow definition of Kant's absolutist approach to lying. That is to say, when determining what information to withhold, we impose our own subjective (but acceptable) standards, like that of the healthcare professional withholding information from a patient.[317] Carson argues that this represents a well-known definition of lying where speaking falsely to the person who does not have a right to know cannot be a lie as the person has no right to the truth.[318]

In summary, although a review of ancient as well as 18th and 19th perceptions of truth-telling would be anticipated to reveal an approach that bears no relevance to modern-day practice, this appears not to be the case. Throughout the historical consideration of medical practice there has been a practice of keeping information from patients, which may have been to maintain the authoritarian nature of the physician, to act beneficently or to protect the patient. In many ways, it is most instructive, informative and fascinating to observe that these approaches often reflect both modern day clinical practice together with the qualitative research of this thesis.

3.3 Consideration of therapeutic privilege from 1980's

Beginning with the judgment in *Sidaway* in 1985, this chapter continues by charting the development of the therapeutic privilege exception through an examination of case law within the jurisdiction of England and Wales. Here, the move towards a doctrine of informed consent had been slow, with a notable reluctance to adopt the North American approach witnessed in *Canterbury v Spence,*[319]discussed in more detail in Chapter 4. Here, the courts had established that cases involving allegations of failures of information disclosure should be dealt with by way of negligence rather than of trespass.[320] It will be demonstrated that the courts struggled with the role of *Bolam* and the continuing application of the professional standard of care for information disclosure.

Regardless of the challenges faced by the courts when exploring informed consent, it is apparent from cases such as *Sidaway* that withholding information from a patient was *within* the doctor's duty of care where it was deemed to be in their best interests. Such an

[317] *Bok* (n313) 15
[318] Thomas L Carson, 'The definition of lying' (2006) Nous *40*(2) June 289
[319] *Canterbury* (n19)
[320] *Chatterton v Gerson* [1981] 1 All ER 257

unambiguous approach has led others to comment that the therapeutic privilege exception '*is incorporated within the duty of disclosure itself applying Sidaway*',[321] rather than a specific exception to informed consent. Thus, it is argued that the therapeutic privilege exception did not derive *from* informed consent itself, but from the more straightforward existence of the duty of care.

Although the therapeutic privilege exception is often referred to as a defence, this is largely a misnomer as defences apply *after* negligence has been established. Moreover, defences in medical law are less widely relied upon than in more general tort law. By way of a solitary example, it is unlikely that the patient could have contributed to the negligence despite an attempt to establish lifestyle choices as a contributory factor,[322] although in the case of *Venner* the patient was held to be solely responsible for her injuries. Rather than a specific defence, it appears to be the doctor's justification for withholding information where the doctor believes that disclosure could risk serious physical or psychological harm could be caused as a result.

Although this chapter refers to terms such as doctor or physician, it is important to remember that *Montgomery* modernises informed consent by widening its applicability to those who 'treat'. Accordingly, informed consent and therefore the therapeutic privilege exception will apply to any healthcare professional who treats patients and, for the purposes of this thesis, includes both GPs and clinical pharmacists.

This research focuses on jurisdictions which have introduced informed consent for medical treatment or are beginning to move towards a more patient-centric approach. Jurisdictions (not referred to within this research) which take a more paternalistic approach to medical treatment do not recognise the therapeutic privilege exception as an exception to disclosure simply by virtue of their pre-existing paternalistic practice. The therapeutic privilege exception can only be applied where a traditional professional standard or *Bolam-esque* standard is applied, as the therapeutic privilege exception is the doctor's discretionary exercise of withholding information. Where withholding risk disclosure is challenged by a

[321] Ibid
[322] *St George v The Home Office* [2008] EWCA 1068

patient, the healthcare professional will be asked whether they acted reasonably in withholding the information.

Since the 'formal' introduction of informed consent in the UK in 2015, it seems there are barely visible tectonic standards. Firstly, the reasonable patient test introduced by *Montgomery* emphasises the importance of communication and dialogue between doctor and patient. And secondly, the rarely used exception to informed consent is where the healthcare professional may justifiably withhold information pertinent to risk. The untested question, which will be explored later in this research thesis, is the standard to be applied if the therapeutic privilege exception were relied upon but then challenged in the courts.

Disclosing information to a patient which concerns them affords the patient respect. As Kennedy observed, withholding information should not be widely used as it could amount to *'diminishing respect for the patient as a person.'*[323] Whilst Kennedy does not explore the notion of respect further, it suggests that where the therapeutic privilege exception is relied upon, it could lessen the value of the patient's individuality as the doctor acts paternalistically deciding for himself/herself what the best course of action is for the patient. Kennedy wrote in 1984, shortly before the judgment in *Sidaway*, where Lord Scarman set out the prudent patient test later approved in *Montgomery.*[324] MacLean argued that even where the information could harm the patient, the choice of whether the patient should be told that information should rest with the patient.[325]

The difficulty with this argument is that if the patient is aware of information that might harm them, then that knowledge in itself could cause harm resulting in the doctor being more likely to withhold the information. MacLean continues by stating that where '*the information will significantly impair that patient's autonomous capacity'*, the therapeutic privilege exception may be justified. This statement is challenging. If MacLean's reference is specifically directed to information disclosure, it lacks clarity regarding the nature of the information that may impair a patient's capacity or, how it may be impaired but, confirms

[323] Ian Kennedy, 'The Patient on the Clapham Omnibus' (1984) Mod. L. Rev. 47 478. Whilst this source may on first glance appear dated, Kennedy is an excellent authority worthy of inclusion. Moreover, it is written at a similar time to the judgment in *Sidaway* and therefore it is well within the context of case law of this period

[324] The prudent patient was not directly adopted by *Montgomery* but was relied on to introduce the reasonable patient test.

[325] Maclean (n274) [205]

that the therapeutic privilege exception may be relied upon, where disclosure of risk could cause the patient to lose capacity. This highlights a grey area as it is often alleged that there is no value in the therapeutic privilege exception as, where a patient lacks capacity, the doctor will act in accordance with the provisions of the MCA, yet these provisions apply only where the patient lacks capacity.[326] To avoid compromising a patient's capacity, MacLean suggests that the therapeutic privilege exception could be relied upon to avoid the foreseeable harm that could be caused by compromising the patient's capacity.

3.4 Consideration of the therapeutic privilege exception with reference to *Sidaway*

In the leading case of *Sidaway,*[327] Mrs Sidaway had suffered from pain in the neck and shoulder and her surgeon advised surgery on her spinal column to relieve her symptoms. Although she was advised of some of the risks, the surgeon failed to advise her of 1-2% chance of paralysis even where the operation was correctly performed. When the risk materialised, Mrs Sidaway alleged that had she been advised of the risk she would not have had the operation. But did the surgeon breach his duty of care when he failed to advise her of the risks?

In the Court of Appeal, the Master of the Rolls, Sir John Donaldson opined that whilst it was correct to apply the *Bolam* test to diagnose and treatment, he questioned its application to risk disclosure.[328,329] The rationale was that whilst diagnosis and treatment are matters of clinical judgment, the duty of whether to accept the risk is not one of professional skill but of the patient's autonomous right to decide whether to accept the treatment presented to her. Here, Sir John Donaldson MR drew the important distinction between skills relating to diagnosis and treatment, which could only be a matter of clinical expertise that the reasonable clinician should possess, and the duty of disclosure relating to the risk which would enable the patient to make an effective choice.

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[326] See for example, n17,141 where she states that the therapeutic exception is obfuscatory, unnecessary and unjustified and also n170

[327] *Sidaway* (n6)

[328] *Sidaway v Board of Governors of Bethlem Royal Hospital* [1984] QB 498

[329] The standard of care in advice cases was considered for the first time in *Sidaway* -see Lord Scarman's extra-judicial lecture, 'Consent, communication, and responsibility' [1986] 79 J Roy Soc. Med 697

Sir John Donaldson went further, even stating that the duty to disclose information was to be judged on a different standard to that of diagnosis and treatment, and that the duty was to provide full information for the patient to make an effective choice as this was relevant to other life choices, such as insurance. Yet, he criticised the medical profession uniquely as routinely failing to advise patients of the risks, which is incongruent with other professions who routinely make full disclosure, when far less may be at stake.

Nowhere it would seem more important for patients to have the autonomy to make their own decisions than where their health, or life may be dependent on their decision-making ability. Where this is the case, denying a patient their autonomy is, as Sir John Donaldson MR observes, unethical.[330] He opined that *'[the courts] cannot stand idly by if the profession, by an excess of paternalism, denies their patients a real choice. In a word, the law will not permit the medical profession to play God*.'[331] He continued by criticising disclosure to a patient who asks the relevant questions as, whilst this may seem to be open and frank, it is meaningless to the patient who either does not know the question to ask or does not know how to ask the question. Given the imbalance of the relationship between doctor and patient, it was unrealistic to expect a patient to understand the nuances of medical treatment in the same way a clinician would. This may be particularly relevant for capacitous people with intellectual disability who already suffer health inequality and may need additional support to facilitate understanding, so that they can exercise autonomy regarding their own treatment.[332]

The Court of Appeal continued to struggle with the notion of defining the extent of the duty of disclosure and expressly rejected that the American doctrine of informed consent should become part of English law. Lord Justice Browne-Wilkinson took a less progressive position

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[330] See also Lord Donaldson in *Re T (Adult: Refusal of Medical Treatment)* 1992 4All ER 649, for a similar, later endorsement of patient autonomy wherein he stated that, 'The patient's interest consists of his right to self-determination, his right to live his own life how he wishes, even if it will damage his health, or lead to his premature death'

[331] *Sidaway* (n328) [513]

[332] Improving Health and Lives, Learning Disability Observatory. Health Inequalities and People with Learning Disability in the UK: 2011. Implications and Actions for Commissioners and Providers of Social Care https://www.ndti.org.uk/assets/files/IHaL_2011_healthinequalitiessocialcare_guidance_final.pdf accessed December 12, 2021
For the avoidance of doubt, this does not mean that every patient with an intellectual disability will need support to facilitate their understanding, to exercise informed consent. Furthermore, the term intellectual disability is used in the same way as the report referred to above

than Sir John Donaldson, rejecting that disclosure of information was not a matter of clinical expertise (and in so doing, rejected the prudent patient test in *Canterbury v Spence*). He was unable to distinguish between the different aspects of a legal duty, in the same way as Sir John Donaldson had done. Observing that the patient *'goes to the doctor to be cured*', the patient needed to have confidence in the doctor-patient relationship to fulfil the patient's goal to be cured. This desirable outcome could not be fulfilled if the patient was always informed of all the risks.

Having rejected the North American doctrine of informed consent, he opined that the doctor is under a duty to disclose information or *withhold information* (own emphasis) as he considered reasonable in the circumstances.[333] This would rest on information the doctor knew, or ought to have known, including the patient's wishes. Thus, if the patient waived his rights to be advised of the risk, then the doctor would not be under any duty to disclose the risks. Lord Justice Bridge went further stating that information could be withheld with the objective of putting the patient in a position '*to make a rational decision'*, whether to accept the doctor's recommendations.

Lord Justice Bridge's statement sounds very much like the concept of informed consent, as he stated, '*most people want to know the material risks in taking a particular course of action before they take it.'* He continued by referring to the patient's *'true'* wishes[334] because although the patient may want full disclosure this may not represent the '*reality of the patient's mind.'*[335] This seems to suggest that there would be no duty to disclose if the doctor *'reasonably considered that such disclosure would be medically harmful to the particular patient'*. Here, he appears to introduce the exception of therapeutic privilege that the doctor would be permitted to withhold information from the patient, where harm might be caused to the patient out of the framework of informed consent.

Lord Justice Browne-Wilkinson attempted to modify *Bolam* by explaining that where a doctor did not disclose risks to a patient, this could not be justified in terms of professional

[333] *Sidaway* (n328)

[334] *Sidaway* (n328) [512] 'to take such action by way of giving or withholding information as is reasonable in all the circumstances of which the doctor knows or ought to know, including the patient's true wishes, with a view to placing the patient in a position to make a rational choice whether or not to accept the doctor's recommendation'

opinion and needed to consider that particular patient.[336] Although he rejected informed consent enunciated by *Canterbury v Spence*, the privilege for doctors to withhold information was selectively retained and he opined that disclosure of too much information might hinder a patient rather than assist a patient to decide whether to proceed with treatment.

In reaching this conclusion, Lord Justice Browne-Wilkinson appears to have adopted the approach in the Ontario Court of Appeal, which applied a professional standard of care not only for what material risks were to be disclosed to the patient, but also in relation to whether there had been a breach of duty of that disclosure. Furthermore, the court confirmed that because of '*emotional factors'*, the patient may be unable to cope with factors relevant to their decision whether or not to have treatment and, in these circumstances, the doctor may be justified in withholding information or generalising it. Kennedy, however, notes that Lord Justice Browne-Wilkinson regarded these situations of non-disclosure as *exceptions,*[337] and although he could have wholly embraced the doctrine of informed consent held that these exceptions were a matter for professional judgment rather than a matter for the court, perpetuating the *Bolam* test.

Hence, the Court of Appeal backed away from any rejection of the professional standard or risk disclosure, reinforcing the notion that it was for the patient and not the doctor to decide whether to accept the risk of treatment. Where Lord Justice Dunn was concerned, his approach was an acceptance of the status quo. However, an application of *Bolam*[338] has led Teff[339] to observe that '*modern case fluctuates between this kind of passive acquiescence and an overtly instrumental approach*'. Moreover, Teff highlights the reluctant undertones of the Court of Appeal to move from the Bolam approach to 'informed consent' suggesting that the court considered this to be *'an inevitable recipe for undermining medical practice, encouraging unduly defensive medicine and fostering, costly litigation'*[340]. This can be evidenced by Lord Donaldson MR who opined that adopting a North American approach

[336] Ibid [318]
[337] Ibid
[338] Ibid [515]
[339] Harvey Teff, *Reasonable Care, Legal Perspectives on the Doctor/Patient Relationship* Clarendon Press Oxford 1994 53
[340] Ibid

'*might do a great deal for lawyers and litigation',*[341] whereas Lord Dunn opined that the approach would result in an '*increase in the number of claims for professional negligence against doctors.'*[342]

The judgment fails to add any clarity to the therapeutic privilege exception. Whilst there appears to be no duty to disclose information relating to risk, there was an exception to a 'non-duty' left solely in the hands of the medical professional without any framework or degree of accountability. The court appeared to be more focused on policy grounds to justify not introducing informed consent in case it opened the floodgates to litigation and encouraged defensive practice amongst healthcare professionals. It may be this is the true reason behind permitting a doctor to withhold information from a patient, as the court may have been heavily influenced by the potential of litigation if the patient suffered harm as a result of disclosure rather than a genuine concern for the patient's welfare.

Writing before the House of Lords decision, Kennedy refers to the policy the court adopted as both *'unjustified and inappropriate*',[343] the reasoning of which appears clear that the future of the relationship between healthcare professional and patient lies in a meaningful and transparent dialogue between doctor and patient. Here the patient's wishes are treated inclusively, thereby helping to redress the balance of the doctor-patient relationship. In the House of Lords, the Law Lords agreed on the outcome of the case but, each reached the same decision by five different, often confused[344] 'hotch-potch'[345] speeches. Lord Diplock stood alone in endorsing the professional standard of care without reservation, referring to any warning being given as part of

*'the exercise of professional skill and judgment as any other part of the doctor's comprehensive duty of care to the individual patient, and expert medical evidence on this matter should be treated in the same way. The Bolam test should be applie*d.[346]

It seems clear that Lord Diplock did not wish to uncouple the duty to warn a patient of the material risks from any other part of medical treatment and sought to retain a paternalistic

[341] *Sidaway* (n328) [512]
[342] Ibid [517]
[343] Ibid [458]
[344] Lord Scarman, 'Consent, communication and responsibility' [1986] 79 J Roy Soc. Med 697
[345] Kennedy and Grubb, 'Medical Law' (2000) 3rd Edition Butterworths 691
[346] *Sidaway* (n6) [895]

approach where *'doctor knows best'*, where the doctor will act in the patient's best interests as he or she perceives them to be. Lord Diplock argued that if a patient were to be advised of the risks, it would deter her from any recommended treatment and caution should be given about '*volunteering unsought information about risks of the proposed treatment failing to achieve the result sought or making the patient's physical or mental condition worse than better.'*[347]

Lord Diplock's judgment seems the least forward-thinking judgment in terms of patient self-determination. His dictum failed to distinguish diagnosis and treatment, which are matters of clinical judgment, and non-clinical matters such as risk disclosure, so retaining *Bolam* for both clinical and non-clinical aspects.[348] His reasoning was that assessing risk disclosure required as much a duty of care as diagnosis and treatment, and it was therefore entirely reasonable that *Bolam* should apply to all three aspects of clinical practice.

Perhaps Lord Diplock's dictum provides some balance with Lord Scarman's who himself recognised that he was '*charting the ship of English law into waters where it had not sailed before.'*[349] Rather than focussing on the antithetical judgments, each in a minority of one,[350] careful consideration should be given to Lord Bridge and Lord Templeman, who perhaps present a clearer prism within which to consider the developing doctrine of informed consent in England and Wales.

At the heart of Lord Scarman's dissenting judgment is a judicial acknowledgement that a patient has a right to be informed of the risks of the treatment[351]and needs to be treated holistically, a term not specifically used by Lord Scarman. He advocated that medical practice needed to assist the patient with the decision-making process and, above all, respect patient's rights as a theme referred to in *Montgomery.*[352] Lord Scarman specifically rejected the *Bolam* standard of care which had been applied without reservation, save for the gloss provided by *Bolitho* and, chose to apply the prudent patient test adopted in

[347] Ibid
[348] For a similar opinion, see Miola (n254) [81]
[349] Lord Scarman (n344)
[350] Ibid
[351] There is some academic dispute as to whether Lord Scarman's judgment was in fact the dissenting judgment. For example, Lord Scarman (n344) [691} seems to suggest that Lord Diplock's judgment may be the dissenting judgment as he was the only Judge to apply *Bolam* unequivocally.
[352]*Sidaway* (n6) [877]

Canterbury v Spence which required disclosure of 'material risk'. Lord Scarman opined that the consequences of the *Bolam* standard were 'disturbing'[353] as he recognised the lack of clarity where the courts would uphold a recognition of the patient's rights, but that those rights were subject to the doctor's judgment regarding the circumstances in which the patient should be advised of the material risk.[354]

Importantly, Lord Scarman explained that a doctor '*may avoid liability'* to warn of a material risk if he could show that he '*reasonably believed that communication to the patient of the existence of a risk would be detrimental to the health (including, of course, the mental health) of his patient'*. The use of the term *'avoid'* is interesting and suggests that Lord Scarman considered the therapeutic privilege exception to be more of a defence to be utilised for the benefit of the doctor than a clear patient-focused exception to informed consent. More specifically, Lord Scarman referred to an element of objectivity such that the doctor would have the *'opportunity of proving that he reasonably believed that disclosure of the risk would be damaging to his patient or contrary to his best interest'*.[355]

Lord Templeman did not specifically refer to the *Bolam* test, but he opined that a patient's attention should be drawn to a danger which is '*special in kind or magnitude or special to the patient'.*[356] However, he rejected the notion that the patient is entitled to know everything or, indeed, that the doctor is entitled to decide everything,[357] so appearing to confirm that the courts should be the final arbiters.[358]

Focusing on the contractual nature of the relationship, Lord Templeman considered there should not be an obligation to inform the patient of risks. The reasoning for this non-obligation was that it may not be in the patient's best interests, indicating that *'some information might confuse, other information might alarm a particular patient'.* Lord Templeman observed that the doctor's duty was to provide information to the patient which would enable him to make *a 'balanced judgment'*. That said, the doctor's duty was subject to his overriding duty, which was to act in the patient's best interests, thereby

[353] Ibid [882]
[354] Ibid [882]
[355] Ibid [889]
[356] Ibid [903]
[357] Ibid [904]
[358] Ibid [903] 'It is for the court to decide, after hearing the doctor's explanation, whether the doctor has in fact been guilty of a breach of duty of with regard to information'

displacing patient autonomy. Lord Templeman continued by arguing that whilst the patient could make an unbalanced judgment if he were deprived of information, equally he could make an unbalanced judgment if he were provided with too much information. He reasoned that given a patient's lack of medical training, together with '*his prejudices or his personalities'*, he would be unable to assess the quality of the information. In conclusion, Lord Templeman argued that '*too much information may prejudice the attainment of the objective or restoring the patient's health.*'[359] Therefore, to decide what risks should be disclosed to the patient was, in Lord Templeman's view, part of the exercise of professional skill and judgment in the same way as the other elements of the duty of care.

Lord Bridge (with whom Lord Keith agreed) drew a subtle distinction between diagnosis and treatment and giving advice, opining that where a patient directly questions a doctor, he must '*answer…truthfully and as fully as the questioner requires.'* Whilst Lord Bridge rejected the *Canterbury* doctrine as impractical, he also acknowledged a patient's right to guard against paternalism but cautioned that where a doctor offers information which has not been specifically asked it '*…may lead to that risk assuming an undue significance in the patient's calculations'*. Lord Bridge's dictum suggests that *Bolam* could not solely define a doctor's duty and that disclosure was to be decided '*primarily on the basis of expert evidence, applying the Bolam test.'*[360]

3.5 Lessons from *Sidaway*

Arguably, *Sidaway* failed to provide a clear unified position on the role of *Bolam* in information disclosure. The accepted position appears to be that where a responsible body of doctors would accept non-disclosure of risks, *Bolam* would apply. Therefore, a doctor would simply need to identify a body of medical opinion who would have withheld information, in the same way he would have done in order to defend any allegation of breach of duty of care to disclose.

However, *Sidaway* did leave some scope for departing from a professional approach. Evidence of this can be seen in the House of Lords' endorsement of Lord Donaldson' dictum that the courts should be the final arbiters of risk disclosure rather than the medical

[359] Ibid [904]
[360] Ibid [900]

profession themselves.[361] Yet, if Lord Templeman is correct, then the challenge lies in establishing what is '*special to the patient*', without putting the patient at the centre of the conversation. Only by putting the patient at the heart of the decision-making process, as advocated by Lord Scarman, can a doctor understand this crucial piece of evidence. It then follows that only when communication between doctor and patient becomes real, genuine and meaningful, can the doctor establish whether disclosure of information may harm a patient, such that the therapeutic privilege exception could apply within strict limitations.

3.6 The development of the therapeutic privilege exception post-*Sidaway*

Post *Sidaway*, *Bolam* remained a dominant force and although not formally accepted in law in England and Wales, Grubb observed that '*The need for a 'Therapeutic Privilege'…is at the heart of the majority view in Sidaway that at least prima facie, Bolam should apply.'* [362] Hence, whilst other domestic jurisdictions regarded the therapeutic privilege exception as a formally recognised defence to the duty of disclosure for informed consent, the exception was already at the heart of medical practice within this jurisdiction. Yet, it cannot be a defence in the same way of other domestic jurisdictions because there is no duty to disclose information dependent on informed consent.

It may be that its initial introduction was largely a protectionist policy supporting defensive practice, but the challenge remains as to what amounts to a sufficient 'green light' for the therapeutic privilege exception to be invoked. Moreover, if it were to be invoked then the suggestion is that the professional standard would apply to any consideration of its applicability, rather than just the case of the reasonable man, which would make the legitimacy of withholding information challenging for the patient to dispute.

This next section will draw out elements of the therapeutic privilege exception in decisions post-*Sidaway.* In doing so, it is not intended to produce a detailed analysis of the generality of the judgment, but to focus on the occasions where the court have made direct reference to withholding risks from a patient.

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[361] Ibid [892]

[362] Andrew Grubb, 'Contraceptive advice and doctors – A law unto themselves?' (1988) The Cambridge Law Journal 12-14,13. Whilst this may appear to be an outdated source, the reference to the therapeutic privilege are as equally applicable today

To illustrate the challenge with regard to a consistent approach to withholding information, the court in *Thake v Maurice* went as far as to state that it would have been acceptable if the defendant had withheld information relating to risk, if disclosure '*might have caused worry or concern'* to the patient.[363] If so, then the court would have balanced the need to withhold information with the need to disclose risks to the patient, so he (together with his wife) could have decided on their preferred course of action. What is interesting about this judgment is that Mr Thake sought a non-therapeutic sterilisation procedure as the patient and his wife did not want any more children; therefore, a degree of worry and concern would be a natural consequence of their decision. Following *Sidaway*, one might consider that the court may have adopted an approach more akin to Lord Templeman in the House of Lords, as the risk of spontaneous reversal would be a risk which would be special to this particular patient. However, the court maintained the professional standard approach in *Bolam* and in doing so, appears to have lost sight of the patient's needs and wishes.

A similar approach can be seen in *McAllister v Lewisham and North Southwark Health Authority*,[364] where Mr Justice Rougier opined that where a doctor reasonably believed that recommended treatment was in the patient's best interests, he could be *'economical with the truth where recital of the dangers is concerned.'* However, no explanation was given, or circumstances outlined where withholding risk disclosure might be justified and no consideration was given as to whether being '*economical with the truth'* could be justified by the patient's physical or psychological health; it was simply the case that it would be in the patient's best interest based on the doctor's clinical judgment. Although no direct reference to the therapeutic privilege exception was explicitly made, it appears that it was widely approved of.

The case of *Poynter v Hillingdon Health Authority* appears to have adopted *'an unacceptable version'* of the therapeutic privilege exception.[365] The case concerned a 15-month-old boy whose father alleged on behalf of his son and his wife that the doctor had failed to warn of the 1-2% risk of permanent brain damage, even though the heart transplant surgery was successful. From the evidence, it is apparent that due to the parents' religious beliefs and

[363] *Thake v Maurice* [1986] QB 644 (CA)
[364] *McAllister v Lewisham and North Southwark Health Authority* [1994] 5 Med LR 343
[365] Ibid (n364) 725

personal views about transplants in general, their concerns about the potential risks were overridden by the courts. Obiter Sir Maurice Drake illustrated the balancing act the doctors were required to perform, as they had to *'exercise their professional skill'* of advising the parents of the risks of the operation with the possibility that they would not have consented to the operation, which they believed to be in the baby's best clinical interest. In these circumstances, the doctors would be entitled to withhold that information.

This judgment appears to be in line with the more general judicial inclination of preserving the sanctity of a minor's life in the face of parental objection. However, it is interesting to note that the parents' objection were overruled, not as a result of exercising a balancing act, but by means of withholding information to prevent parents from objecting to treatment which was perceived to be in the baby's best interests in a form of benevolent paternalism.

The therapeutic privilege exception has been sporadically referred to by the courts; for example, in the Northern Irish case of *Smith v Eastern Health and Social Services Board* the patient alleged she was not advised of the risks and complications of a procedure.[366] Had she been advised, she stated that she would not have consented to the treatment. She was described as 'anxious' on no fewer than six occasions in the judgment, and whilst the therapeutic privilege exception was not specifically pleaded, Mr Justice Carswell referred to Lord Scarman's dictum in *Sidaway* where he states that, '*If it can be shown that a reasonable medical assessment of the patient would have indicated to the doctor that disclosure would have posed a serious threat of psychological detriment to the patient.'* Applying the test of *Bolam*, the court found it was reasonable for the patient not to be advised of the risks of treatment. They continued by observing that even if the *Bolam* test were not to apply, it would be the courts who would decide the reasonableness of the case, although they would have come to the same conclusion. This observation is interesting as there seems to be a suggestion that *Bolam* would not apply to the therapeutic privilege exception, making the courts the final arbiters in circumstances where non-clinical skills are assessed.

[366] *Smith v Eastern Health and Social Services Board* (QB 16 December) 1988 referred to in n170

Nevertheless, this case concerned an anxious patient, although unsurprising in itself, as most patients are anxious when they seek medical help.[367] The patient in *Smith* did not present with any other signs of psychological disorder and the word *'distress'* was only used once. It would therefore seem a judicial leap, if risk disclosure were to be withheld on the grounds cited by Mr Justice Carswell. In these circumstances where the claimant did not demonstrate any sign that disclosure would be psychologically detrimental to her health, any attempt to withhold information from the patient in this case would be explained by the doctor having considered it to be in her best clinical interests.

In *Deriche v Ealing Hospital NHS Trust,*[368] Mrs Deriche argued that she was not advised of the risks of contracting chicken pox during pregnancy, and had she been advised that she would have opted for a termination of her pregnancy. Having considered the dicta in both *Sidaway* and *Pearce*, Mr Justice Buckley opined that as part of his overall duty to the patient, a doctor could exercise his medical judgment and withhold information from the patient if he considered disclosure *'damaging'* to the patient Mr Justice Buckley continued by stating that it is the doctor's duty of care to protect the patient from medical injury as far as he is able, and if a doctor's judgment was that injury would be caused from a '*discussion*', then he would refrain from holding this discussion on *'sensible medical grounds'* which the court would support him in.[369] Whilst Mr Justice Buckley emphasised that '*something more than temporary distress*' would merit withholding risk disclosure, he did not elaborate further as to what characteristics a patient would have to display before disclosure could be considered '*damaging*'.

Thus, as Mr Justice Buckley stated, where a doctor formed the view that where psychological injury could follow from risk disclosure, he would not proceed and the Court

[367] There is also an assumption that anxiety is a negative attribute. Studies have shown that where patients are advised of the risk of surgery, patient anxiety did not increase but helped facilitate informed consent, see for example Darryl D Kerrigan, Ravi S Thevasagayam et al., 'Who's afraid of informed consent' (1993) 306 BMJ 298. Further research also demonstrated that patients prefer to be informed of risks, see Jeffrey J. Goldberger, Jane Kruse, Alan H. Kadish, Rod Passman and Daniel W. Bergner, 'Effect of informed consent format on patient anxiety, knowledge, and satisfaction' American Heart Journal 106(4) 781-785,783. Furthermore, the use of videos to inform patients in a cohort of female sterilisation showed that anxiety levels were not increased, supported active participation in healthcare decisions, without increasing clinician workload. Victoria Mason, Alec McEwan, David Walker, Steve Barrett and David James, 'The use of video information in obtaining consent for female sterilisation: A randomised study' (2003) BJOG: An International Journal of Obstetrics and Gynaecology (110) 1062–1071,1069

[368] *Deriche v Ealing Hospital NHS Trust* [2003] EWHC 3104

[369] Ibid [50]

would support him in his decision. This seems a clear application of the *Bolam* test, confirming that withholding risk disclosure remained a purely objective test. Whilst something more than temporary distress would be needed, this was not explored. Doubtlessly any woman being told their baby may have significant abnormalities (which later transpired) would be distressed, giving the unpalatable impression that where women are pregnant or in labour, then healthcare professionals take a more paternalistic approach.

Furthermore, Mr Justice Buckley referred to *Wyatt v Curtis*, a decision in the court of appeal which also concerned a young woman who alleged that she was not adequately advised of the risks of chicken pox and which had only just been reported. Here, Lord Justice Kay had referred to the 'emotional distress' which could be caused to a patient if a patient's second doctor rehearses the risk of abnormality to a foetus. It was observed that adequate risk disclosure had been made, but the court observed that

'…Any doctor considering what was necessary in such circumstances would be bound to place in the balance the potential emotional distress that might be caused to the patient by reopening a question over which it was likely that she would have agonised in making her difficult decision following the initial advice.[370]

Thus, Mr Justice Buckley stated that where a doctor formed the view that injury could follow from risk disclosure, he would not proceed and the Court would support him in his decision. However, something more than temporary distress would be needed. This should be outweighed against the significant devastation a mother would suffer if the undisclosed risk materialised and she was deprived of her right to decide for herself whether to have a termination of pregnancy to avoid that risk occurring.

Hence, Mr Justice Buckley opined that a doctor's judgment that risk disclosure would be withheld would be supported by the court unless objectively '*manifestly unreasonable'*. This statement is troubling. If the court were relying on a *Bolamesqu*e application, then it is likely that he would have indicated this in simpler terms. The suggestion appears to be that *Bolam* would be subject to Lord Browne Wilkinson's dictum in *Bolitho* that the expert opinion could be rejected if it were unable to withstand logical analysis and therefore be unreasonable. But if this were the case, then further problems would arise, as Lord Browne Wilkinson

[370] *Wyatt v Curtis* [2003] EWCA Civ 1779 at para 21

specifically excluded risk disclosure in *Bolitho*. Thus, it is difficult to ascertain Mr Justice Buckley's precise reasoning here and it appears to be more a case of judicial creativity than any intentionally crafted development of the therapeutic privilege exception.

Somewhat surprisingly, there appears to be no analysis of either *Deriche* or *Wyatt* in the context of withholding risk disclosure. Those who do refer to Deriche, do so in the context of failing to advise of the risk and ensuring that the patient '*fully understands the nature of the risk'.*[371] In her exemplary paper on therapeutic privilege, Mulheron identifies *Deriche* as simply one of several cases[372] that refers to withholding risk disclosure tangentially.[373] If the courts in *Deriche* and *Wyatt* intended to develop a standalone exception based on therapeutic privilege similar to that which was already developed in the US and Canada, then it is likely they would have taken the opportunity to delve into it in further detail.

Whilst *Deriche* refers to something more that causing the patient '*temporary distress'* to justify withholding risk disclosure, Wyatt opined that simple *'distress'* would be adequate. The cases are neither consistent with each other in this sense, nor helpful in setting out what factors need to be considered for withholding risk disclosure. As the jurisdiction moved towards accepting a doctrine of informed consent, the notion of withholding risk disclosure was already entrenched in law as part of the doctor's duty but lacked any clarity.

The judgment in *Pearce v United Bristol Healthcare Trust*[374] took the notion of the doctrine of informed consent one step further, seemingly adopting the prudent patient test into English law.[375] The facts are relevant and worthy of brief consideration. The patient, Mrs Pearce alleged she was not advised of the risk of stillbirth associated with non-intervention when her pregnancy became overdue. Had she been made aware of the risk, she may have opted for a caesarean section to reduce or eliminate the risk of stillbirth. As she was not advised of the risk, she had no alternative but to accept the doctor's advice to wait and see, despite being in a '*distressed condition'*.

[371] *Mulheron* (n147) [42]
[372] See *Smith* n366 and *Poynter* n244
[373] *Sidaway* (n170)
[374] *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BLMR 118
[375] Margaret Brazier and Jose Miola, 'Bye-Bye Bolam: A Medical Revolution?' (2000) 8 Med L Rev 85, 109-110

Lord Woolf MR confirmed that the court's duty to scrutinise expert evidence following *Bolitho,* also applied to risk disclosure and took the opportunity to re-evaluate the duty of disclosure in *Sidaway*. Lord Woolf MR explained that the doctor's duty of disclosure extended to disclosure of a *'significant risk'* which, if disclosed, would affect the judgment of the reasonable patient, thereby introducing a more patient-focused test.[376] He continued by arguing that the degree of risk should be disclosed to the patient, so that the patient can determine for themselves what course of action they should take.

This statement, however, raises several issues. Disclosure of a *'significant risk'* is objectively assessed by the doctor based on his clinical expertise and, pre-*Montgomery*, would include a consideration of the percentage risk of harm.[377] The *degree* of harm caused to the patient, if this risk materialises is highly subjective[378] which had led Maclean to state that *'to ignore the nature of the harm and the impact of harm would have on the victim arguably sacrifices substantive justice on the altar of formal justice.'*[379] The importance of subjectivity is further demonstrated in *Wyatt*, where Mr Lord Justice Sedley referred to Lord Woolf, when re-evaluating *Sidaway*. Here, he recognised that what amounts to '*grave*' and '*substantial*' may differ according to the author. To the patient, an increased risk of *'catastrophic abnormality'* may be far more significant to the patient than it is to the doctor, which begins to reflect the nature and importance of subjective element in *Montgomery.*

The judgment in *Pearce* took one step further where Lord Woolf referred to Lord Templeman in *Sidaway* and held that the doctor's overriding duty was to act in the patient's best interests and to provide the patient with information with which the patient can make a balanced judgment. [380] By doing so, the court began to focus on the importance of patient autonomy. Lord Woolf continued by explaining that a patient can make an unbalanced judgment where he is deprived of adequate information but, also and importantly, he can also make an impaired judgment if he is given '*too much information which he is not capable of assessing because of his lack of medical training, his prejudices or his personality'.* In the context of this thesis, this is a particularly interesting observation as it appears to be

[376] *Pearce* (n374) [24]
[377] Although it is worth noting that Lord Woolf suggested 'it is not possible to talk in precise percentages'
[378] See for example n145
[379] Alasdair Maclean, 'Giving the reasonable patient a voice: information disclosure and the relevance of empirical evidence' Medical Law International 2005 (7) 1-40, 6
[380] *Sidaway* (n6) [904]

suggested that where the patient may be overwhelmed with information, their capacity may be compromised.

Moreover, the word 'personality' may refer to stress, anxiety or distress. It may also refer to the patient's intellectual disability where the suggestion is that a patient's vulnerability could invoke the therapeutic privilege exception. Lord Woolf continued by stating that the doctor has to consider all the relevant circumstances, firstly the patient's ability to comprehend what he has been told and, secondly, the state of the patient from both a physical and emotional point of view. The judgment seems to suggest clearly that in these circumstances risk disclosure could be withheld.

Lord Woolf's judgment is significant as the decision heralded the role of the patient in the decision-making process. The patient-focused test was subsequently adopted with approval by *Wyatt* in the Court of Appeal, followed by *Chester v Afshar*[381] in the House of Lords. As the court inched closer to adopting informed consent, the concept of the therapeutic privilege exception formed part of the ratio in this case and is the only case in English law to do so. However, what amounted to *'emotional'* remained entirely opaque.

3.7 Summary of case law in England and Wales

Case Name	Circumstances in which risk disclosure could be withheld.
Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital [1985]	'volunteering unsought information about risks to the proposed treatment failing to achieve the result or making the patient's physical condition worse than better'. 'his prejudices or his personalities' 'too much information may prejudice the attainment of the objective or restoring the patient's health'. (dissenting) 'reasonably believes that that communication to the patient of the existence of a risk would be detrimental to the health (including, of course, the mental health) of his patient.
Thake v Maurice [1986]	'might have caused worry or concern'

[381] *Chester* (n98)15

McAllister v Lewisham and North Southwark Health Authority [1994]	'economical with the truth'
Poynter v Hillingdon Health Authority [1997]	'exercise their professional skill'
Smith v Eastern Health and Social Services Board [1988]	'if it can be shown that a reasonable medical assessment of the patient would have indicated to the doctor that disclosure would have posed a serious threat of psychological detriment to the patient'
Pearce v United Bristol Healthcare Trust [1998]	'too much information which he is not capable of assessing because of his lack of medical training, his prejudices or his personality'
Deriche v Ealing Hospital NHS Trust [2003]	'damaging' 'sensible medical grounds' 'something more than temporary distress'
Wyatt v Curtis [2003]	'any doctor considering what was necessary in the circumstances would be bound to place in the balance the potential emotional distress that might be caused to the patient, by reopening a question over which it was likely that she would have agonised in making her difficult decision following the initial advice'
Chester v Afshar [2004]	'avoid alarming or confusing the patient'
Montgomery v Lanarkshire Health Board [2015]	'The doctor is, however, entitled to withhold from the patient information as to a risk if he reasonably considers that its disclosure would be seriously detrimental to the patient's health'

3.8 Discussion

Where the professional standard of care was adopted, the therapeutic privilege exception permitted doctors to withhold information from patients where some degree of harm may be caused. However, there is a danger of conflating withholding risk disclosure from a patient *within* the framework of the doctrine of informed consent and withholding risk disclosure in circumstances as outlined in *Sidaway*, which preceded the adoption of informed consent in the UK by exactly 30 years.

What, therefore, is the basis of withholding risk disclosure in England and Wales? It would seem apparent that having considered informed consent in the US, the court in *Sidaway* referred to therapeutic privilege exception in the context of that specific case law, but the casual adoption of an exception to informed consent outside of a formal framework is troubling. The therapeutic privilege exception appears to have been accepted insidiously without a clear framework, which provides a *defence* to doctors who choose to withhold information from patients where undefined harm may be caused by disclosure.

Sidaway upheld the application of *Bolam*, choosing not to decouple risk disclosure from the duty. However, the dictum in *Sidaway* ultimately enabled the law to develop a more patient-centred approach which rejected the professional standard of care. Whilst this took many years to achieve, the legacy from the professional standard was the therapeutic privilege exception. Whilst this was not specifically referred to by name until *Montgomery*, the defence appears to be assessed by the professional standard.

One might expect the notion of therapeutic privilege to be slowly reformed alongside the development of the law, but it remained as opaque and undefined as it was in other domestic jurisdictions. Brazier explores an interesting example and asks whether or not a surgeon could justify withholding information about the risk of impotence from an elderly patient, where the operation's objective is to maintain the patient's independent living.[382] In these circumstances, one might conclude that risk disclosure would not be relevant to this particular patient and not worthy of disclosing, but the danger is that this imposes the doctor's objective vie on that particular patient.

Whilst the judgment in *Chester v Afshar* focused on the introduction of more flexible rules on causation, the case is also widely acknowledged as signalling a rejection of paternalism in medical treatment. Lord Steyn proclaimed that *'(i)In modern law medical paternalism no longer rules and a patient has prima facie right to be informed by a surgeon of a small, but well established, risk of serious injury as a result of surgery.'*[383] Obiter Lord Steyn reflected on *Sidaway* and observed that it was often difficult to advise a patient of minor risk, particularly when that patient is already suffering from *'stress, pain and anxiety'*. With the

[382] Margaret Brazier and Emma Cave, 'Medicine, Patients and the Law' (2016) Manchester University Press 146
[383] *Chester* (n98) [16]

stressed and anxious patient in mind, he observed that a doctor would naturally be keen to '*avoid alarming or confusing the patient*'. In this case, the surgeon failed to advise Miss Chester of the very small risk of significant nerve damage which transpired, and she was left partially disabled.

Lord Steyn reflected further on patients who may be particularly anxious and, whether the surgeon may have glossed over some of the risks. He referred back to Lord Templeman in *Sidaway* and indicated that this would not be a proper response. However, Lord Templeman had placed the onus on the patient to ask questions if the patient wanted more detailed answers to their questions. However, Lord Templeman referred to a possibility that Mrs Sidaway was frightened or confused, or unable to understand the information she was given, and may have been suffering from *'stress, pain and anxiety*'. Furthermore, Lord Templeman explained that in these circumstances the doctor should not overwhelm the patient with too much information and appears to accept that information could be withheld from a patient. This reflects a similar observation in *Chester v Afshar*, as Lord Steyn endorsed Lord Templeman's perspective, confirming that *'there may be circumstances, albeit exceptional ones, where information might be withheld from the patient.'*[384]

Thus, parallels can be drawn between these two judgments as both reflect an acceptability to withhold information regarding risk disclosure, where the patient suffered from stress, pain and anxiety. Yet, in *Chester v Afshar* there is little if any reference to the patient's fragile state, apart from the patient's general aversion to surgery which she was anxious to avoid.[385] There is no suggestion that disclosure of any risks relating to the surgery would cause her serious psychological harm. Equally in *Sidaway*, there is nothing to suggest that Mrs Sidaway was particularly vulnerable.

Both cases seem to confirm that a doctor may be less than generous with risk disclosure where a patient is suffering from pain or stress. Yet, this is far removed from Lord Scarman's adopted of the therapeutic privilege exception as outlined in *Canterbury v Spence*, where withholding information would be justified where 'serious harm' would be caused by disclosure.

[384] Ibid[16]
[385] Ibid [42]

To complete an analysis of the casual adoption of the therapeutic privilege exception in England and Wales, in the same year as *Chester v Afshar*, *Re Organ Retention Litigation* dealt with withholding information in an entirely different context.[386] Here, the issue concerned the degree of information that parents were provided with regarding their deceased child's post-mortem. Mr Justice Cage recognised there may be occasions where information relating to their child's post-mortem, in particularly the retention of organs, could be distressing to the parents. However, this needed to be considered on a case-by-case basis, where a blanket practice of withholding information was not justified. Moreover, Mr Justice Cage also observed that disclosing these details were unlikely to be any more distressing than losing their child. Although the therapeutic privilege exception was not referred to directly, the reasons given for withholding information relating to the post-mortem was to avoid adding to any further distress and thereby acting with paternalistic beneficence.

This chapter has considered the trickling effect of the use of the therapeutic privilege exception in England and Wales through a range of case law. Whilst reliance on withholding information from a patient outside of informed consent was expressly approved of the reasoning lacked both clarity and consistency. Moreover, the right of a doctor to withhold information from a patient became truly embedded in English law. Analysis of case law demonstrates the prevalence of beneficent paternalism in healthcare provision undermining patient autonomy. This notion is further demonstrated in the section below which considers healthcare perspectives to pregnant women generally, before considering patients with cancer and how healthcare professionals manage effective communication.

3.9 Paternalistic practice in healthcare and women in labour

Departing from an analysis of case law, this section seeks to evaluate the implication of paternalistic practice in pregnant woman and women in labour. A paternalistic culture can be due to defensive practice in obstetrics and gynaecology, which suppresses the pregnant patient's right to autonomy.[387] It is widely accepted that childbirth or labour is fraught with

[386] *Re Organ Retention Group Litigation* [2004] EWHC 644 (QB)

[387] House of Commons, Health and Safety Committee, 'The Safety of Maternity Services in England' Fourth Report of Session 2021-2022 (HC.19) published 6th July para 87 'The approach to clinical negligence in the UK has cultivated a culture of defensiveness and blame'

stress, anxiety and pain while treatment of pregnant women in the UK can be steeped in paternalism, where the courts and doctors are prepared to override a women's choice of childbirth procedure if they believe the woman's choice poses a risk to the foetus.[388]

Prior to *Montgomery,* despite a widespread recognition of the importance of patient autonomy, the patient's right to refuse medical treatment has been denied. It appears that pregnancy and women in labour is a specific category where a woman's refusal to treatment can result in being declared incompetent. One must not lose sight of the fact that *Montgomery* concerned a woman in labour and although the therapeutic privilege exception was not relevant on the facts, the judgment itself formalised the introduction of the therapeutic privilege exception into UK law. Hence, there is nothing to suggest that the therapeutic privilege exception could not apply in the future,[389] where there is a clinical opinion that the woman may be made so anxious by risk disclosure that it becomes detrimental to the patient's health. In these circumstances, beneficence would outweigh patient autonomy.

However, a brief examination of case law prior to *Montgomery* shows evidence that the courts acted paternalistically and had no hesitation in ordering an emergency caesarean section, so that the woman's health was preserved, and the baby was safely delivered. This principle is well illustrated in *Re S,*[390] where the woman in labour required an urgent caesarean section for an obstructed labour to preserve both her life and that of the unborn child.[391] Her refusal, together with her husband's was based solely on religious grounds which were described by Sir Stephen Brown as *'quite sincere'*. The question as to whether the court could overrule her wishes had been left open by Lord Donaldson in *Re T (Adult: Refusal of Medical Treatment)*[392] but the court relied on the American case of *Re AC*.[393] Despite having capacity, their wishes were overruled by the court and a declaration for an

[388] For a similar view, see Maria T R Borges, 'A violent birth: Reframing coerced procedures during childbirth as obstetric violence' (2018) 67 Duke LJ 827
[389] For a similar opinion, see Aoife M Finnerty. 'The privilege of information – an examination of the defence of therapeutic privilege and its implication for pregnant women' Medical Law Review 29(4), 639-660, 654
[390] *Re S* [1992] 4 All ER 671
[391] A Caesarean section is the surgical delivery of a foetus through the incision into the abdomen and womb of a pregnant woman. National Institute for Health and Care Ethics 2011
[392] *Re T (Adult: Refusal of Medical Treatment)* [1992] 3 WLR 782
[393] In re AC [1990] 573 A, 2d 1235

emergency caesarean was granted. There was no mention of her lack of capacity to consent, simply the urgency of medical intervention to preserve the life of the mother and the baby.

Only slightly later, the courts also held that *MB* lacked capacity temporarily as a result of her needle phobia. However, Lady Justice Butler-Sloss was emphatic when she stated that *'A competent woman who has the capacity to decide may, for religious reasons, other reasons, for rational or irrational reasons or for no reasons at all, chose not to have medical interventions, even though the consequence may be the death or serious handicap of the child she bears, or her own death',*[394] potentially permitting the exercise of benevolent paternalism. Importantly, for any future decisions, the court also added that '*temporary factors such as shock, pain or drugs might completely erode capacity'.*[395]

Only one year later *in St George's NHS Trust v S,* an emergency caesarean section carried out on S against her wishes, was held to be unlawful. Lord Justice Judge defended her wish to refuse medical treatment, even if it resulted in the foetus's death. Lord Justice Judge observed as follows,

'In our judgment while pregnancy increases the personal responsibilities of a woman it does not diminish her entitlement to decide whether or not to undergo medical treatment. Although human and protected by the law in a number of different ways…. an unborn child is not a separate person from its mother. Its need for medical assistance does not prevail over her rights. She is entitled not to be forced to submit to an invasion of her body against her will, whether her own life or that of her unborn child depends on it. Her right is not reduced or diminished merely because her decision to exercise it may appear morally repugnant'.[396]

It is apparent that the courts struggle with the tectonics of respecting a woman's autonomous choice regarding treatment or medical intervention and the mother's underlying overwhelming desire of the safe delivery of her baby. Invariably, a paternalistic practice prevails as this represents the route to the desired outcome to be delivered of a healthy baby.

[394] *Re MB (An Adult: Medical Treatment)* [1997] 2 FLR 426, 436
[395] Ibid [437]
[396] *St George's NHS Trust v S* [1999] Fam 26

More recently, an expectant mother aged 21 with severe agoraphobia was the subject of intervention when the medical teams wanted to avoid the possibility of refusing to leave her home if her preferred home birth plan failed, and she needed to be delivered in hospital.[397,398] The court accepted that her agoraphobia was so overwhelming that she would not be able to weigh matters effectively if it involved her leaving her home. However, it was also accepted that were she in labour in hospital, she would have the capacity to decide on how she wished to deliver. Mr Justice Holman held she lacked capacity and considered that although it would be '*a severe infringement of the mother's personal autonomy and liberty'* the balance needed to be made with the small risk of an emergency which would need the women to be transferred to hospital.

It is also possible that the Australian decision in *Sheppard v Swan,* discussed in more detail in 4.7 may have some influence where information is withheld from a woman in labour in cases of *'significant maternal vulnerability'.* If so, this would support the approach taken by Lady Justice Butler-Sloss in *Re MB*, where a woman who is labour and, in great distress, pain, or receiving pain relieving drugs, may find that she is treated in her best interests or information relevant to informed consent may be withheld.

Balances need to be achieved in this particularly precarious area of medicine. Although there was a small chance that if the home plan did not proceed as planned and the risk were to transpire, then the consequence for the foetus could be catastrophic. The judgment pre-empts the nature of the risk and may be considered disproportionate given the court's declaration to use force if necessary. The woman's autonomy appears to have been entirely displaced despite her desire for a healthy baby having been fulfilled.

Healthcare professionals in obstetrics and gynaecology appear prepared to use the MCA as a sword for safeguarding purposes, restricting patient empowerment. This approach was observed by the House of Lords Select committee on the MCA who commented that

'(a)A consistent theme in the evidence was the tension between the empowerment which the Act was designed to deliver, and the tendency of professionals to use the Act for

[397] *East Lancashire Hospitals NHS Trust v GH* [2021] EWCOP 18
[398] According to the expert obstetrician witness 1-2% of home births occur result in urgent transfers to hospital

safeguarding purposes. Prevailing professional cultures of risk aversion and paternalism have inhibited the aspiration of empowerment from being realised.'[399]

The more recent and approved approach is illustrated in *Montgomery* where Lady Hale observed '*Gone are the days when it was thought that, on becoming pregnant, a woman lost, not only her capacity, but also her right to act as a genuinely autonomous human being'.*[400] In addition, the NICE Guidelines[401] support a shared decision-making approach where the healthcare professional and patient work in partnership with the patient as it states '(*w)When caring for a pregnant woman, listen to her and be responsive to her needs and preferences'.*[402] The NICE guidelines on patient experience in adult NHS services[403] add further detail on how to communicate by active listening and communicating with the pregnant woman in layman's terms with the support of accessible information where appropriate.[404] The pregnant woman must also be made aware of the risks, benefits and implication of any assessment, intervention or procedure and that she has a right to refuse.[405] Her decision to refuse medical treatment, should be respected even when it is contrary to the healthcare professional's opinion[406] and the NICE guidelines reflect both the judgment in *Montgomery*[407] and the provisions of the Mental Capacity Act.[408]

Although the NICE guidelines portray an approach where the pregnant woman remains an autonomous agent, it remains challenging to see how this may transpire in practice, where a capacitous woman refuses medical treatment which could jeopardise the foetus's or her own health. There remains the more paternalistic approach from *Re MB* where the

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[399] Report of Session 2013-2014: Mental Capacity Act 2005: Post-legislative scrutiny (2014) HL 139, paragraph 15
[400] *Montgomery* (n3) [116]
[401] https://www.nice.org.uk/guidance/ng201/chapter/Recommendations#information-and-support-for-pregnant-women-and-their-partners published 2021, 1.3.2 accessed Aug 16, 2022
[402] Ibid 1.3.1
[403] https://www.nice.org.uk/guidance/cg138/chapter/1-Guidance#enabling-patients-to-actively-participate-in-their-care accessed Aug 16, 2022
[404] Ibid 1.5.4
[405] https://www.nice.org.uk/guidance/ng201/chapter/Recommendations#information-and-support-for-pregnant-women-and-their-partners published 2021, 1.3.2
[406] Ibid 1.3.3
[407] *Montgomery* (n3) [90] 'the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision'
[408] MCA (n64) section 1(4) *'A person is not to be treated as unable to make a decision merely because he makes an unwise decision'*

healthcare professional may determine that the patient lacks capacity where there is some '*impairment or disturbance of mental function'* due to pain relieving drugs, shock or drugs during labour and it appears evident from more recent case law that the courts are willing to declare that a woman lacks capacity in a range of circumstances, including the most tenuous suggestions of mental health disorder. The more challenging aspect may be where a woman refuses medical treatment *prior* to labour during the ante natal process, where her rights as an autonomous agent must be respected.

Pregnancy and childbirth are unique and can raise difficult and complex issues with *'its own set of challenges where informed consent is concerned'.*[409] Rather than regarding informed consent in a deficit model framework, the preferred approach would be to ensure that the healthcare professionals engage in dialogue and communication to facilitate effective communication and build a relationship based on trust and understanding. Removing the perception of informed consent as a 'challenge' and regarding the woman as no less an autonomous agent than other patients will help recalibrate the relationship between healthcare professional and patient. This should be achievable given the NICE guidelines which helpfully set out the information to be conveyed to a woman during ante natal care.[410] Adhering to the professional guidelines will inform the patient and her partner and, where appropriate, accessible information should support the dialogue between the parties.

Whether there is room for the therapeutic privilege exception is a more complex issue to address. If information is disclosed in a timely manner with the prospective mother and she is given the opportunity to explore her concerns and ask questions, then disclosure may not risk being *'detrimental to the health'* of the pregnant woman.[411] Healthcare professionals can protect against failing to disclose information relevant to informed consent by ensuring that communication and dialogue remain open and transparent, where a relationship can be established with the patient, to empower the patient to ask question. The prospective mother must be made aware of what lies ahead, the potential complications and how they are addressed. This enables the woman to reflect on the options and make informed choices should the event occur. It is preferable for the woman to make decisions when she

[409] Post legislative scrutiny (n399) 655
[410] NICE (n405) 1.3.8.
[411] *Montgomery* (n3) [85]

has the time and space to make them, when she can reflect with the input of her partner and others (should she choose to do so) and make informed choices or refuse treatment. This may help avoid the need for the woman to make clear, autonomous and informed decisions during labour, at a time of stress and anxiety. Following *Re MB,* the additional possibility of pain-relieving drugs can blur the clear path to informed consent which, in turn, can result in the woman being treated as if she temporarily lacks capacity. The lessons from *Montgomery* can help avoid paternalistic practice by ensuring that a woman understands the nature of any associated condition and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so she can make an informed decision.[412] Importantly, the information provided must be comprehensible and technical language must be avoided in order that she provides genuine and meaningful informed consent.

This approach may help to avoid paternalistic practice but does not resolve the use of therapeutic privilege exception in *Montgomery.* Finnerty argues that withholding information creates an imbalance of power between healthcare professional and patient which results in a lack of trust between parties, resulting in a negative birth experience.[413] Contrary to academic opinion, there is arguably a positive role for the therapeutic privilege exception. Where a woman is particularly anxious, nervous or fragile, it may be argued there may be circumstances for withholding risk where disclosure may be detrimental to the woman's health. One only needs to be reminded of the judgment of *McAllister v Lewisham & North Southwark Health Authority,* where Mr Justice Rougier held that the therapeutic privilege exception could apply where the doctor *may be genuinely and reasonably so convinced that a particular operation is in the patient's best interests that he is justified in being somewhat economical with the truth where recital of the dangers is concerned.*[414]

Although risk disclosure enhances autonomy, where there is a real possibility that anxiety could cause harm to the patient there may be a role for beneficence to trump autonomy. This is particularly relevant where the capacitous patient has an intellectual disability. All too often academic opinion has a twofold approach to the role of the therapeutic privilege

[412] *Montgomery* (n3) [90]
[413] Finnerty (n389) 658
[414] *McAllister* (n364)

exception. Firstly, where the patient has capacity, autonomy should take precedence over beneficence and secondly, where the patient lacks capacity, the healthcare professional will act in the way which conveys the best outcome for the patient, the delivery of a healthy baby. This perspective neglects the middle ground where risk disclosure in a capacitous patient with intellectual disability could remove the patients' capacity entirely. In these circumstances or where the patient suffers from anxiety such that risk disclosure would cause her physical or psychological harm, there is a definitive role for the therapeutic privilege exception.

3.10 Failure to advise of the risk of stillbirth

Empirical evidence from the US shows that women are largely ignorant of the risk of stillbirth.[415] A stillbirth is where a baby is born dead after 24 completed weeks of pregnancy; in England this happens in around 1 in every 200 births, yet doctors do not advise patients of the risk of a stillbirth occurring.[416] Whilst doctors inform women of the risk of foetal abnormality, they are not advised of the risk of stillbirth yet the numbers of stillbirths are significant. For example, in the US there are approximately 70 stillbirths every day, which amounts to approximately 25,000 per year.[417]

The NHS provide some guidance on stillbirth, relating largely on measures a woman can take to avoid the risk together with an outline of the causes. However, obstetricians and gynaecologists still regard stillbirth as an unexpected outcome, despite a 2% risk of stillbirth, and there is no reference to advice given to women about the risk, apart from measures a pregnant woman can take to lessen the risk of stillbirth.[418]

Evidence shows that clinicians feel poorly equipped to discuss the risk of stillbirth, partly because it is an unexpected outcome but also out of the anxiety or stress it could cause a pregnant woman.[419] However, appropriate training and education would provide the communication skill that clinicians may need to have a challenging conversation as stillbirth remains a taboo subject during pregnancy, possibly due to a lack of research on the reasons

[415] Maureen C. Kelley and Susan B. Trinidad, 'Silent Loss and the Clinical Encounter: Parents' and Physicians' Experiences of Stillbirth-A Qualitative Analysis' BMC Pregnancy Childbirth 12(1) 137
[416] https://www.nhs.uk/conditions/stillbirth/ accessed Aug 19, 2022
[417] https://www.cdc.gov/ncbddd/stillbirth/articles.html accessed Aug 19, 2022
[418] https://www.rcog.org.uk/globalassets/documents/guidelines/gtg_55.pdf accessed Aug 24, 2022
[419] Kelly and Trinidad (n415)

why stillbirth occurs. Moreover, cultural issues such as not wanting to talk about loss, stigma and the medicalisation of pregnancy may contribute to a neglect of psychological harm should stillbirth transpire.[420]

If clinicians were required to advise pregnant women of the risk of stillbirth, it is possible they may choose to withhold disclosure risk if they believed that physical or psychological harm could be caused as a result of disclosure. It is possible that this would introduce the therapeutic privilege exception into care for pregnant women which may remove their autonomy and decision making for their birth plan. Whether this is likely is unclear as women are routinely advised of the risk of foetal abnormalities during their pregnancy and offered testing to eliminate (or otherwise) that specific risk.[421,422] For example, in the UK, pregnant women are offered a blood test and screening between 10-14 weeks to detect the risk of Down's syndrome, Edwards' syndrome and Patau's syndrome.[423] Unless there is a lower chance risk, defined as less than 1 in 150, the woman is offered further diagnostic tests, such as an amniocentesis.

Thus, it is apparent that where there is a similar chance of risk of non-fatal foetal abnormality, the expectant mother is routinely advised of the risk of foetal abnormality but not of stillbirth. This suggests that the reasons why obstetricians and gynaecologists do not advise patients of stillbirths is somewhat unclear but may relate to an incomplete understanding of why stillbirth occurs and the lack of measures to manage the risk effectively. Where a woman discovers she is carrying a foetus with an abnormality, she may choose to terminate the foetus after 24 weeks[424] and the pregnant woman is advised of the risks during pregnancy and offered diagnostic tests to enable her to act autonomously regarding outcomes. Where the risk of a stillbirth is concerned, a woman is not afforded the same respect. Should the risk transpire, the woman must deliver the baby and there is evidence that healthcare professionals are not only uncomfortable with delivering

[420] Finnerty (n389)
[421] See for example, https://www.womenshealth.gov/ accessed August 11, 2022
[422] See for example https://www.nhs.uk/pregnancy/your-pregnancy-care/screening-tests/ which lists the tests available to a pregnant woman accessed August 5, 2022
[423] https://www.nhs.uk/pregnancy/your-pregnancy-care/screening-for-downs-edwards-pataus-syndrome/ accessed August 5, 2022
[424] At this early stage of pregnancy, she is likely to satisfy the grounds under s.1 (1) (a) if the pregnancy is under 24 weeks and s.1 (1)(b)– s.1(1)(d) Abortion Act 1967, if the pregnancy exceeds 24 weeks.

distressing information but also unprepared to meet the patient's emotional needs.[425] This area cannot remain overlooked as research shows that failure to advise a woman of the risks of stillbirth increases the mother's risk for depression, PTSD,[426] psychosis and other psychological outcomes.[427]

Where a woman experiences a stillbirth, she must deliver either by induction of labour or by caesarean section. Here, despite the potential psychological and physical risks of a caesarean section, the materiality test in *Montgomery* must be applied and the patient's wishes regarding mode of delivery must be respected. However, given the psychological trauma which the mother is likely to be experiencing, these may be a situation where the therapeutic privilege exception may be relied upon. Doctors opine that a woman would be likely to become emotionally distraught if they are advised of the risk.[428] To avoid the patient's physical or psychological harm, it is possible that a healthcare professional may withhold the risks of mode of delivery of a stillborn baby but in doing so, would violate the patient's autonomy to decide their own treatment plan.

According to the NHS Long Term Plan, there has been a significant reduction of 18.8% in stillbirths,[429] while the NHS is further committed to a 50% overall reduction in in stillbirths by 2025.[430] Saving Babies Lives Care Bundle[431] supports the aims and objectives set out in Better Births. One of their recommended key interventions is offering an early delivery for those women at risk of stillbirth.[432] Concurrent with recommendations made by NICE, women with uncomplicated singleton pregnancies will be offered an induction of their labour at 41 weeks.[433] Although this development still appears to be heavily influenced by how clinicians perceive their patient's best interests, this should also be recognised as offering women some decision-making authority in the management of their own labour.

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[425] Kelly and Trinidad (n415)141
[426] Post-traumatic stress disorder
[427] Jill Wieber Lens, 'Medical Paternalism, Stillbirth, & Blindsided Mothers' (2021) 106 Iowa L Rev 665,684
[428] n389
[429] https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/ para 3.8 accessed August 9, 2022
[430] Ibid para 3.9
[431] https://www.england.nhs.uk/wp-content/uploads/2019/03/Saving-Babies-Lives-Care-Bundle-Version-Two-Updated-Final-Version.pdf Version 2 March 2019 accessed August 7, 2022
[432] Ibid [19]
[433] https://www.nice.org.uk/news/article/nice-recommends-inducing-women-in-labour-earlier-in-new-draft-guidance accessed August 9, 2022

Moreover, this enhances respect for the woman as a person and enables her to be an active participant in her own healthcare and delivery of her baby.

Pearce v United Bristol Healthcare Trust[434] was instrumental in the development of informed consent given Lord Woolf MR's obiter remarks and is relevant to this section, as she was concerned about exceeding her due date and had *'begged'* for a caesarean section but reluctantly agreed to wait until the onset of natural labour when the baby was subsequently stillborn. The court applied *Bolam* and held that the risk of stillbirth was so slight (0.1-0.2%) that it was not a risk deemed sufficiently significant for Mrs Pearce to have been advised of, particularly given her *'distressed'* condition.[435] Lord Woolf MR opined that where a doctor is considering what to tell the patient, several factors should be considered. These include the ability of the patient to comprehend the information and the state of the patient, both from a physical and emotional perspective.

Mrs Pearce was a mother to five children and knew what to expect from labour. Given her experience, it is highly likely she would have been able to understand the information she was being told. Unsurprisingly, since she was two weeks post her due delivery date, she was *'distressed'*, evidenced by the fact that she '*begged*' the doctor for a caesarean section. It does not follow because she was distressed that she was not capable of understanding information relating to her care. It is possible that the risks were withheld not only because they were deemed so small as to not be sufficiently significant but also due directly to her apparent distress. Moreover, even if the risk of stillbirth were to be disclosed, arguably her distressed mental state would be further harmed by the disclosure. Whilst there is no reference to the therapeutic privilege exception in the judgment, the judgment is regarded as the only English case where therapeutic privilege was directly relied upon.[436] Despite the court adopting a *Bolam* approach to this case, *Pearce* undoubtedly marks a shift towards patient centred care.[437] There is however, an underlying, but subtle suggestion by the court

[434]Brazier and Cave (n374)
[435] Ibid
[436] Mulheron(n147)
[437] See for example Alasdair Maclean, 'From Sidaway to Pearce and beyond: Is the legal regulation of consent and better following a quarter a quarter of a century of judicial scrutiny?' (2012) Medical Law Review 20(1) 108–129

that even if the risk was sufficiently significant that the patient should have been advised of the risk. Thus, in failing the *Bolam-Bolitho* test, the risk may still have been withheld.

Whilst Woolf MR opined that '*ordinarily'* a significant risk should be disclosed, the situations he suggested where an alternative course of action could be taken demonstrate the therapeutic privilege exception, although not directly referred to by name. Both physical and psychological elements are referred to, but not in terms of potential harm which could be caused if disclosure to a patient were made. The physical reference may suggest that the course of action Mrs Pearce asked for was contrary to what the doctor thought were her best interests. One can only speculate what might have occurred if the risk would have been sufficiently significant to disclose, but given that Mrs Peace was '*distressed'*, '*concerned*' and '*upset'*, if seems that these characteristics would have been enough to invoke the therapeutic privilege exception. Here, the exception appears to be too widely applied and potentially exposes the exception to abuse as a means of achieving the clinician's preferred approach to Mrs Pearce's labour.

3.11 Paternalism in antenatal care

This short section illustrates professional practice in ante natal care where policies are introduced to protect the woman's health and that of her unborn baby. Whilst the health benefits of avoiding alcohol and not smoking are widely accepted, the practice remains paternalistic.

The nature and treatment of the pregnant woman differs little in Western healthcare systems. For example, the US Centre for Disease Control issued an alcohol advisory in 2016 which recommended that 'women of a childbearing age' not using birth control should avoid drinking alcohol. In the UK, NICE have recommended recording expectant mothers' alcohol consumption regardless of whether they consent. This includes women who have consumed alcohol before knowing they are pregnant. The rationale of the advisory was to avoid an alcohol exposed pregnancy, with health consequences such as growth deficits, low birth weight, congenital anomalies and cognitive deficits. Whilst this may be regarded as an invasion of the woman's right to privacy, it may be argued that the potential risk of foetal alcohol spectrum disorder outweighs the mother's rights and her personal rights should be

secondary to the foetus. Arguably, this will alleviate the physical consequences of Foetal Alcohol Spectrum Disorder[438] and the unintended consequences of the mother suffering from anxiety before the baby is born.

Moreover, there is no data which suggests that light alcohol intake is related to any of these impairments, although heavy alcohol consumption would contribute to these conditions.[439] However, the overall picture is confused with evidence showing that midwives' knowledge of the 2016 Chief Medical Officers' alcohol guidelines was limited, while midwives advised that 'some' alcohol was not harmful.[440] Whilst this appears to be supported by data referred to above, there is clear evidence that the 'rights' of the foetus are placed ahead of the woman's autonomy, indicating a highly paternalistic healthcare approach. Paternalistic intervention in a woman's pregnancy is further evidenced by a campaign to reduce smoking in pregnancy, which increases the risk of stillbirth.

The NHS strategy will require electronic testing of all pregnant women for CO exposure and, where a woman tests positive, she will be referred to a trained stop smoking advisor. Further testing will be carried out at a pregnant women's 36-week appointment, with the results recorded, while there will also be additional testing to identify smokers who have not previously engaged.

This section has explored healthcare attitudes of healthcare professionals towards pregnant women, which demonstrates beneficent paternalism and a willingness to dismiss patient's wishes and values, often to significant personal detriment. Moreover, there is clear reliance on the therapeutic privilege exception with case law, even though it is not directly referred to by name. Thus, this area of the law has demonstrated a prevailing theme of benevolent paternalism, which looks likely to remain.

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[438] https://nationalfasd.org.uk accessed August 9, 2022. FASD is defined as 'Foetal Alcohol Spectrum Disorder is a neurodevelopmental condition with lifelong cognitive, emotional and behavioural challenges. In addition to effects on the brain, FASD is a full-body diagnosis that can include more than 400 known conditions'

[439] Kari Poikolainen, 'Paternalism and alcohol policy' (2021) Drugs and Alcohol Today 21(1) 6-14,9

[440] Lisa Scholin et al., 'Midwives' views on alcohol guidelines: A qualitative study of barriers and facilitators to implementation in UK antenatal care' Sexual and Reproductive Health Care, September 29, 2021 100628

3.12 Disclosing information to cancer patients

This section examines disclosure of information to cancer patients. Whilst this section is unsatisfactorily short given the limitation of the thesis, it begins to explore a valuable narrative where, patients with cancer value information, in contrast to clinical practice which often tries to protect patients from the hard truth. It may be that with improved communication skills, part of the recommendations of this thesis will be realised, and where clinical practice can become more aligned to the needs of the patient.

Whilst the prevailing principle of autonomy in healthcare is widely accepted as a Western liberal democratic construct, often referred to as a *'cultural artefact',*[441] care should also be taken to ensure that healthcare providers do not assume that all persons of a particular culture adopt a similar perspective.[442] Findings of a research study in Togo have shown that most Togolese patients preferred not to be told the full truth of their medical condition, deferring the information to their relatives.[443] Furthermore, over 80% of participants wanted their families to be advised if the patient were psychologically frail. There was no explanation as to what was meant by psychologically frail, but it could suggest an intellectual disability or dementia. As the study suggests, disclosure may be challenging for Western healthcare professionals working in Africa, or for African healthcare professionals working in Europe where autonomous decision-making is prized. In contrast, in many cultures the desire to protect the patient prevails over autonomy. A further study compared American and Japanese physicians and how they communicate directly with a child about his or her cancer diagnosis. The finding suggest that practice differed and recommended that further research was needed to help facilitate both cultural sensitivities and family-centred dialogue and communication.[444] Where the healthcare professional is engaged

[441] See for example, Anthony Tuckett, 'Truth-telling in clinical practice and the reasons for and against: A review of the literature' (2004) Nursing Ethics 11: 500–513; Leslie Blackhall, Shelia Murphy, Gelya Frank, Vicki Michel and Stanley Azen, 'Ethnicity and attitudes toward patient autonomy' (1995) Journal of the American Medical Association 274 820–825; Antonella Surbone, *Communication with the Cancer Patient: Information and Truth* (1996) New York: New York Academy of Science,

[442] See for example, Anthony G Tuckett, 'On paternalism, autonomy and best interests: Telling the (competent) aged-care resident what they want to know' (2006) International Journal of Practice 12 166-173

[443] Lonzozou Kpanke, Paul Clay Sorum and Etienne Mullet, 'Breaking bad news to Togolese patients' Health Communication (2026) 32(11) 1311-1317

[444] Susan K. Parsons, Shigeko Saiki-Craighill, Deborah K. Mayer, Amy M. Sullivan, Stefanie Jeruss, Norma Terrin, Hocine Tighiouart, Kaoru Nakagawa, Yoko Iwata, Junichi Hara, Holcombe E. Grier and Susan

within this jurisdiction, there is a possibility of a conflict between the duty to disclose material risks set out in *Montgomery* and the risk of offending cultural sensitivities and expectations.

During the 1960's, doctors were unwilling to disclose cancer diagnosis to patients, projecting professional paternalism, not only to avoid an *'unfavourable emotional reaction'*[445] but because there was a close connection between cancer and death. By the 1970's there appeared to be a reversal of the paternalistic practice of withholding a cancer diagnosis from patients directly, as an almost identical study mirroring the 1960's study recorded that 97% of all participant healthcare professionals would advise their patients of a cancer diagnosis.[446] Furthermore, it is argued that providing cancer patients with information about their condition assists with the patient's decision-making, prepares them for treatment, reduces anxiety and depression, and improves communication with family and therefore their quality of life.[447] Where there is effective communication between patient and doctor, the patient becomes fully informed and an active partner in the care process.[448] Not only does this lead to better outcomes for the patient personally, but that it is also a reduced risk of medical negligence litigation.[449] This underlines the principles outlined in *Montgomery* that communication between parties enables the patient to provide informed consent by exercising autonomy and in doing so reduce the risks of litigation where the patient takes ownership of their own decisions.

However, a UK study from 1997 still found a lack of transparency amongst doctors as only 37% of research participants confirmed they always told patients about a cancer

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Block, 'Telling children and adolescents about their cancer diagnosis: Cross-cultural comparisons between paediatric oncologists in the US and Japan' (2007) Psycho-Oncology 16 60–68

[445] William Fitts and I Ravdin, 'What Philadelphia physicians tell patients with cancer' (1953) JAMA 153:901-4

[446] Dennis Novak, Robin Plumer et al., 'Changes in physicians' attitude towards telling the cancer patient' (1979) JAMA 241 897-900

[447] See for example, Joyce Davison and Erin Breckon, 'Impact of health information-seeking behavior and personal factors on preferred role in treatment decision making in men with newly diagnosed prostate cancer' (2012) Cancer Nurs.35 411–418; Olga Husson, Floortje Mols and Lonneke van de Poll-Franse, 'The relation between information provision and health-related quality of life, anxiety and depression among cancer survivors: A systematic review' (2011) Ann Oncol. 22 761–72

[448] Gek Phin Chua, Hiang Khoon Tan and Mihir Gandhi 'What information do cancer patients want and how well are their needs being met?' E cancer 2018, 12:873

[449] See for example Crispin Jenkinson et al., 'Patients' experiences and satisfaction with health care: Results of a questionnaire study of specific aspects of care' (2002) Qual Saf Heal Care. 11:335–339

diagnosis.[450] This appears to demonstrate that doctors working with cancer patients still struggle giving bad news to patients and manage patients' emotional responses.[451] Although it can be argued this study does not mirror the GMC guidelines,[452] the wording of the guidelines is worth noting. Doctors are required to listen to their patients, take account of their views and respond honestly to questions; however, if doctors are not forthcoming with information, then patients will not know the questions to ask.[453]

The GMC guidelines also require the doctor to give patients '*the information they want or need to know'*. It is challenging for patients to know the information they want when they are sick and confused and faced with an imbalance of the doctor-patient relationship. Moreover, since the guidelines are not legally enforceable, a doctor may use their clinical judgment to determine that information about their cancer diagnosis is not information their patient *'need(s) to know'*. This may be objectively justified by a belief that disclosure of information may damage the patient's psychological health. Whether this is a genuinely held belief or a lack of finely tuned communication skills is a matter of more extensive research.

A slightly more recent survey from the US demonstrated that there is still room for improvement where communication skills regarding a cancer diagnosis are concerned. Where disclosure of a cancer diagnosis was made in person, rather than by telephone, patient satisfaction was considerably higher, leading to a conclusion that patients should be advised of their diagnosis in person.[454] The relevance of the study to this research is that communication skills amongst healthcare professionals still need to be refined, as evidenced by this research's rich data, and it is possible that oncologists or those healthcare professionals working within oncology may not be *Montgomery* compliant.

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[450] Mary V. Burton and Ronald W Parker, 'Psychological aspects of cancer surgery: Surgeons' attitudes and opinions' (1997) Psychooncology Mar 6(1) 47-64
[451] Ibid
[452] General Medical Council. 'Duties of a doctor registered with the GMC'. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/domain-3---communication-partnership-and-teamwork#paragraph-31 Accessed November 25, 2022
[453] Ibid Domain 3, para 31
[454] William D. Figg, Erika K. Smith, Douglas K. Price, Bevin C. English, Paul W. Thurman, Seth M. Steinberg, and Ezekiel Emanuel, 'Disclosing a diagnosis of cancer: Where and how does it occur?' J Clin Oncol 2010 28 3630-3635

Moreover, where there are difficult conversations with patients and the healthcare professional does not possess the communication skills or is concerned about the effect disclosure may have on the patient, it is axiomatic that there will be a greater risk or withholding information from the patient. Furthermore, it is likely that withholding information is conducted with beneficent paternalism, rather than a clear application of the therapeutic privilege exception.

This section has touched upon the difficult area of treatment of cancer patients. It is apparent that there is a need for further research and for communication skills of healthcare professionals to be improved. Whilst this section, together with that of women in labour and ante natal care, may not appear to be directly related to the nature of the thesis, they demonstrate the frequency with which healthcare professionals, act in their best interests of the patient.

Thus far, this thesis has explored the judgment in *Montgomery* together with the development of the law in England and Wales within the context of the therapeutic privilege exception. Furthermore, specific areas of healthcare have been used to demonstrate inherent paternalistic practices. The next chapter moves from this jurisdiction to consider the therapeutic privilege exception in other domestic jurisdictions, which will chart the development of the therapeutic privilege exception and tease out the circumstances from the judgment where risk disclosure has been withheld.

Chapter 4: The development of the therapeutic privilege in other domestic jurisdictions through the introduction of informed consent

4.1 Introduction

This chapter seeks to achieve three specific goals. Firstly, a systematic analysis of international common law which has considered, tangentially, the therapeutic privilege exception. Secondly, a consideration of the boundaries of the exception and, finally, an evaluation of the criticisms together with a more pragmatic reflection on the existence of the exception. It will be shown that there has been a systemic failure to deliver a clear definition of the exception, which has directly led to criticism, confusion and disdain for an exception which has marked nearly 60 years since its first appearance.

In this chapter the jurisdiction of the USA, Canada, Australia and Singapore will be carefully considered. However, it is recognised that other jurisdictions, such as South Africa, have also had to negotiate the role of the therapeutic privilege exception.

4.2 The therapeutic privilege exception in the United States of America

Historically, Western medical ethics had practiced non-disclosure of medical information in order to reduce patient's distress,[455] which was confirmed in 1847 when the first edition American Medical Association (AMA) Code of Medical Ethics explained that physicians had a *'sacred duty….to avoid all things which have a tendency to discourage the patient and depress the spirit'.*[456] It was this statement, remaining largely unchanged until 1903, which helped inform the judiciary that a physician could withhold information from a patient where full disclosure would either affect the patient's decision-making ability or cause harm to the patient. This section will analyse case law in the USA, paying particular attention to how courts have developed the privilege to withhold information from a patient, whilst simultaneously recognising the introduction of informed consent in the USA, following a

[455] Percival's Medical Ethics 1803

[456] Nathan A. Bostick, Robert Sade, John W. McMahon and Regina Benjamin, 'Report of the American Medical Association Council on Ethical and Judicial Affairs: Withholding information from patients: Rethinking the propriety of 'therapeutic privilege' (2006) The Journal of Clinical Ethics 17(4) Winter 302-6

widely recognised and deep-rooted acceptance of patient autonomy in the decision-making process.

Shortly after the AMA Code of Medical Ethics, in the case of *Twombly v Leach*[457] the judge was of the view that whether or not information should be withheld relevant to a patient's consent was entirely a matter for the doctor. The court stated that *'the testimony of educated and experienced medical practitioner is material and peculiarly appropriate.'*[458] This appears simply to be a question of paternalistic practice rather than an exercise in concern about any potential physical or psychological harm caused to the patient.

By 1905, *Mohr v Williams* acknowledged a patient's right to decide on medical treatment for themselves as *'the inviolability of his person'*, thereby embracing patient autonomy.[459] The judgment made no reference to the therapeutic privilege exception as this notion was not formally conceived until many years later. However, balancing the embryonic notion of patient autonomy, the court also acknowledged that it would not interfere with a *'reasonable latitude'* afforded to a doctor when caring for his patient. Whilst the judgment makes clear that since implied rather than express consent could apply in an emergency situation, the wording that the court used suggested it was possible the latitude referred to could be expanded to encompass the patient's best interests.[460] Alarmingly, this judgment implies that information about a patient's treatment can be withheld from them at a clinician's discretion without any discernible reason.

In the case of *Schloendorff* in 1914, the judicial recognition of patient autonomy was encapsulated by Mr Justice Cardozo's statement that '*Every human being of adult years and sound mind has a right to determine what shall be done to his body'.*[461] In doing so, the law recognised protection for patients regarding the treatment that may be carried out without a patient's consent, albeit limited to emergency situations. However, the court did consider there may be a situation where a patient should not be advised of *'a contemplated*

[457] *Twombly v Leach* 11 Cush.397, 65 Mass 397 (1853)
[458] Ibid [406]
[459] *Mohr v Williams* 104 N.W. 12 (Minn.1905)
[460] Ibid 'Reasonable latitude must, however, be allowed the physician in a particular case; and we would not lay down any rule which would unreasonably interfere with the exercise of his discretion or prevent him from taking such measures as his judgment dictated for the welfare of the patient in a case of emergency.'
[461] *Schloendorff v Society of New York Hospital* 211 NY 125. 1914, 130

operation' until shortly before it is due to take place. Here, the case concerned criticism of a nurse's advice to the patient given during the night, which *'might cause needless and harmful agitation'*, although this statement should be read strictly in the context of the facts where only the nurse's *'strict obedience was required'.*[462] The patient who was referred to as *'nervous and excited'* confirms a doctor's preference for acting in the patient's best interests, even where this may suggest withholding information relevant to a patient's consent. It seems that being *'excited'* was a sufficient characteristic to be denied information about his treatment.

Writing in 1946, Lund struggled with the precept of *'do no harm'* and considered that a patient could be harmed where a patient is told the truth about a diagnosis of a serious condition, such as cancer.[463] According to Lund's thinking, withholding information of serious conditions would be beneficial to the patient where disclosure of information might lead to a delay in treatment through a lack of consent. Whilst it was recognised that communication with the patient's family was necessary, there was no clear statement as to how the degree of harm was defined, save for reducing the risk of shock in the patient. It is possible that Lund's failure to be more specific regarding the degree and nature of the harm that should be avoided was the starting point of defining the therapeutic privilege exception without any clear criteria. It is unclear what Lund's primary motivation for this approach was, save for enabling the doctor to pursue a paternalistic course of action which he believed to be in the best interests of the patient, without the patient's consent.

It appears likely from the writings of early American academics that one of the primary reasons for the existence of the exception is in response to a concern of potential litigation from patients, who may argue that where emotional harm is caused because of disclosure of information then the doctor could be liable for the damages caused as a result. [464] Smith took the view that in the normal course of events, information should always be disclosed and where a patient asks a direct question, then it should be answered truthfully. This is an aspect that was still being explored by the English courts as late as 1997 in *Poynter v Hillingdon Health Authority*. However, he identified that a therapeutic privilege exception

[462] Ibid [134]
[463] Charles C Lund, 'The Doctor, the Patient and the Truth' (1946) 19 Tenn L Rev 344
[464] Smith (n244)

could exist to withhold either part or all the information from the patient, where there was the risk of causing death or serious impairment of his health. In these circumstances, protecting the patient was outweighed by any perceived benefit of disclosure. He justified this approach by explaining that where complete disclosure is made resulting in '*violent psychological reactions'* without any benefit, where this may in fact worsen the patient's condition or adversely affect the chances of recovery. Smith's sense of the physician's primary duty was to ensure that the patient's *'fabric of his psychic resistance'* was not affected to the point that the patient would be unable to consent to medical treatment. What is interesting to note is that the focus was on the potential injury that may be caused to the patient's health and acting beneficently, as opposed to the doctor acting in the patient's perceived best interests.

Slightly tangentially, as early as 1958 *Ferrara v Galluchio*[465] recognised that damages could be recovered for pure mental anguish.[466] In this case, the patient had suffered burns from X-rays and subsequently suffered from cancerphobia, a condition through which she perceived herself to suffer cancer from the radiation burns. It was the information about the treatment rather than the treatment itself which increased the patient's mental suffering. Although the court acknowledged the dangers of opening the floodgates to spurious claims, the court seemed satisfied that they would be able to distinguish false claims from those that were genuine based on physical symptoms causally linked to psychological trauma. Although *Ferrara* has not been cited in any case which has referred to the therapeutic privilege exception, the case assists in setting the scene where courts recognise that stress and anxiety are recognised as potential avenues for exercising the therapeutic privilege exception.

Traditionally, the earliest case credited with a clear reference to the concept of the therapeutic privilege exception, whilst not labelling it as such, was *Salgo v Leland Stanford etc. Bd. Trustees.*[467] *Salgo* recognised a new era of patient-centred medical and clinical treatment and informed consent, where a physician would breach his duty of care by withholding any information necessary for the patient's '*intelligent consent*' to the proposed

[465] *Ferrara v. Galluchio*, 5 N.Y.2d 16 (N.Y. 1958)
[466] This case was not entirely novel as recovery of damages for fear of cancer had been recognised as early as 1912, *Alley v Charlotte Pipe and Foundry Co* 74 SE 885, 886 NC 1912
[467] *Salgo v Leland Stanford etc Bd. Trustees* 154 Cal. App. 2d 560 (Cal Ct App 1957)

treatment. In the same year, *Lester v Aetna Cas. And Sur. Co*[468] held that there was a limited privilege to withhold disclosure of risk to '*avoid frightening'* the patient, although the court appears to be silent on any further reasoning.

In *Salgo*, the patient had brought a case against his physicians for failure to disclose the risk of paralysis during an aortography. The court set out the physician's duty to disclose information in *'broad'* terms stating that the duty extended to '*all the facts which mutually affect his rights and interests and the surgical risk, hazard and danger, if any…'* This suggests that the physician would incur liability if he withheld information which would contribute to *'intelligent consent'* to the proposed treatment. On first glance, this wide-ranging explanation may appear novel but, as Katz observes, is drawn verbatim from the *American College of Surgeons' Brief as Amicus Curiae in Support of Defendant and Appellant Frank Gerode 1956.*[469]

No explanation is provided as to why the court adopted this position, but the court then immediately narrowed the scope of *'intelligent consent'* by introducing the concept (but not the name) of the therapeutic privilege exception into case law. The court considered that the patient's welfare was the physician's primary consideration and he therefore had two alternative courses of action. The first was to advise the patient of any of the risks of the proposed treatment regardless of the potential harm which could be caused together with the risk the patient could refuse treatment, while the second course of action was to consider each case on its own merits which might result in a discretion being exercised.[470] Whilst informed consent appeared to have been adopted into case law by promoting patient autonomy, the scales might also have been tipped towards paternalism by way of the physician's clinical judgment.

However, in *Hunt v Bradshaw,* a case which involved an alleged lack of disclosure, the court simply indicated that it was '*understandable*' that the surgeon would not wish the patient to be operated on whilst *'apprehensive'*.[471] Whilst the court recognised that where failure to advise of a risk might be an error, the doctor would *not* be in breach of his duty of care. Katz

[468] *Lester v Astna Cas. Ans Sur. Co.* 240 F.2d 676, 679 (5th Cor. 1957)
[469] Jay Katz, *The Silent World of Doctor and Patient* John Hopkins University Press 1984 p. 60
[470] *Salgo v Leland Stanford Jr. University Board of Trustees* 154 Cal.App.2d 579
[471] *Hunt v Bradshaw* 88 SE 2d 762 (NC 1955)

sets this judgment in the background of medical treatment during this period where informing patients of potential risks of treatment was unheard of for fear that patients would become anxious and reject their doctor's recommendations.[472] Failing to disclose was not an error in itself. It appears that disclosure would not have been contemplated, but rather be the case that *'a systematic and intentional omission based upon deeply held professional beliefs that silence is in the patient's best interest.'*[473]

Only 7 years later in *Roberts v Wood,* the court explained that *'...the anxiety, apprehension, and fear generated by a full disclosure may have a very detrimental effect on some patients*.'[474]Although not widely recognised or cited, the case should be attributed with defining the therapeutic privilege exception so widely that a clear definition remained elusive. Had the court taken the opportunity to explore with greater care, the meaning and effect of these terms then the *'privilege'* may not have been as extensively criticised as it now is. Arguably, the mere fact that the defence is ambiguous can be traced back to this particular judgment.

The dictum above clearly suggests that withholding information is acceptable where disclosure has an adverse effect on patients, although the clearest formulation leaving no doubt of the scope of the rule was in the case of *Watson v Clutts.*[475] Here, the court said that the physician's primary duty was to act in the best interests of the patient, even where that might mean withholding information from that patient. Whilst not going as far as using the term *'informed consent'*, the physician was under a duty to advise the patient of facts necessary to the proposed treatment and could not withhold the risks in case the patient refused surgery.

However, this endorsement of autonomy was tempered with a subtle balance and an early development of the therapeutic privilege exception emerged. Similar to *Montgomery,* the court now recognised patients as individuals and where the patient's psychological condition was relevant, a discretion could be exercised with regards to full disclosure of facts necessary to an informed consent. It appears from this early case that there was

[472] Katz (n469) [57]
[473] Ibid [5]
[474] *Roberts v Wood* 206 F Supp 579 (1962)
[475] *Watson v Clutts* 262 N.C. 153, 136 E.E. 2d 617 (1964)

judicial consideration of a method by which information could be withheld from a patient, where a doctor considered it to be appropriate.

The reasoning was based on a subjective assessment of the patient and that a patient's mental and emotional condition may sometimes be '*crucial'*, although the court declined to offer any clarity as to what precisely the term might mean. Whether the patient's psychological condition was '*crucial'* to accepting the physician's advised course of action or whether the importance lies in not creating further harm in disclosure is unclear and, in not setting a clear path, this blurred the perimeters of the defence for years to come.

The concern regarding potential abuse is valid. Consideration of case law confirms that in none of the cases where risks of disclosure were withheld from the patient was the doctor required to support his decision with medical evidence, so enabling the doctor to act with impunity. [476] In failing to do so, the USA courts were taking a deferential approach towards the medical profession where withholding risk disclosure could only be assessed by a professional standard and not that of the reasonable man.

4.3 Development of the therapeutic privilege exception during the 1970's in the United States of America

By 1970, it was suggested that doctors' practices were authoritarian, non-equal partnerships which often failed to recognise that their relationship with the patient itself was enough to induce anxiety.[477] Supported by the data of one study gathered from a teaching hospital in the US, it was observed that communication between doctor and patient was both infrequent and inadequate.[478] Within this background of medical practice and with a recognition of the need for personalised relationships between doctor and patient, Lund refers to the therapeutic privilege exception where a doctor can withhold information which he feels is detrimental to his patient, as a *'loophole'* which must be reformed.[479]

The term *'loophole'* is interesting, as it tends to suggest something undesirable or unwanted which should not be permitted by law. Having argued that the standard of disclosure is to

[476] *Hunt* (n471), ibid and *Aiken v Clary*, 396 S.E.2d 668, 674 (Mo.1965)
[477] Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship, 79 Yale L.J (1970)
[478] Charles Brant and Bernard Kutner, 'Physician–Patient Relations in a Teaching Hospital' (1995) 32 J. Med. Educ. 703, 705-706
[479] Restructuring Informed Consent (n477)

be determined by the ordinary reasonable man rather than by a professional standard, Lund considers that the exercise of therapeutic privilege would be judged, if necessary, not by the reasonable man but by a professional standard.

Historically, the privilege was specifically referred to in context of *a 'serious risk of anaesthesia or the diagnosis of cancer'*[480] as examples where it would be justifiable to withhold information from a patient, or where the doctor believes disclosure would disturb the patient to the extent they may decide not to proceed with treatment, or whether the increased anxiety or stress caused by the disclosure would increase the risk itself. This approach relies on the formulation of the rule in *Salgo* where the court opined that the patient's welfare was paramount and that the doctor can be put in a difficult position with competing interests.

Firstly, there is the situation where the doctor explains all the risks to the patient, regardless of how remote they are. However, the consequences of this course of action may be that a patient who is already anxious or '*apprehensive*' may refuse surgery (specifically referred to in *Salgo*, as opposed to treatment) where the risk may in fact be minimal. Secondly, the doctor could take a more subjective approach, recognising that '*the patient's mental and emotional condition… may be crucial and that… a certain amount of discretion'* can be exercised with regards to risk disclosure. The patients' interest in being fully informed of material risks to enable them to provide informed consent sits uncomfortably with the doctor's wish to withhold information which may have a disagreeable effect on their wellbeing. Here Waltz and Scheuneman[481] identify a need to set the boundaries of professional judgment when withholding information about risks to confirm that the privilege is a matter for professional judgment.

There was little further development until the judgment in *Natanson* which confirmed that informed consent was deeply embedded in US law.[482] In this case Mrs Nathanson alleged that the risk of severe burns from cobalt treatment for her breast cancer had not been properly explained to her. The relevance is not whether she consented *per se* but whether

[480] Restructuring Informed Consent (n477) [1564]
[481] Jon R Waltz and Thomas W Scheuneman, 'Informed Consent to Therapy' (1969-1970) 64 Nm U L Rev 628
[482] *Natanson v Kline* 350 P.2d 1093 (Kan.1960)

she had provided informed consent. In finding in her favour, the court confirmed there was a duty on the doctor to provide *'reasonable disclosure'*. The Supreme Court in *Natanson* referred to the earlier Canadian case of *Kenny v Lockwood,*[483] where on appeal the court held that the surgeon's duty was to deal honestly with the patient, explaining the nature of the treatment, its probable consequences and possible alternatives.[484] However, that duty did not extend to advising the patient of the *'dangers'* related to the treatment '*nor to details calculated to frighten or distress the patient.'*[485]

Natanson observed that where the physician had misrepresented the treatment or failed to indicate the probable consequences, he could be liable for *'unauthorised treatment'*. The court did not acknowledge that it was necessary to disclose all the risks of the treatment together with alternative treatment as doing so, might *'alarm a patient'* which would '*constitute bad medical practice'*.[486] It was in this context that the court then acknowledged, albeit exceptionally, there was '*probably a privilege'* to withhold '*the specific diagnosis where the disclosure of cancer of some other dread disease would seriously jeopardize the recovery of an unstable, temperamental or severely depressed patient,'*[487] an opinion reflected earlier by Smith.[488]

Whilst informed consent in the US was still in its embryonic stage, it is clear that the courts remained cautious about disclosing information where potential harm could be caused. Cave suggests this has enabled physicians to '*sacrifice truth for beneficence'*[489] but it is unclear why in the early period of the therapeutic privilege exception the perimeters were so narrowly defined. On the contrary, one might have expected a wider privilege to withhold information only to be narrowed in subsequent cases. An alternative suggestion may be that rather than acting in a way to prevent harm to the patients by disclosing information relevant to informed consent, the courts were providing physicians some latitude in what information they were obliged to disclose, lest patients refused to consent to treatment that the physician considered was in the patient's best interests. There is also

[483] *Kenny v Lockwood* [1932] 1 DLR 507
[484] Reminiscent of the materiality test set down in *Montgomery* n3 [89]
[485] Waltz and Scheuneman (n481) [525]
[486] Ibid 407
[487] Ibid 407
[488] Smith (n244)
[489] Cave (n17) [146]

some evidence of defensive practice as evidenced by the judgment in *Ferrara v Galluchio* and the academic opinion of Smith. Concerns about the possibility of litigation where a person may have suffered '*mental anguish'* from risk disclosure and the potential fear of floodgates may have galvanised a more conservative approach to risk disclosure.

Early academic opinion from the USA may support this approach. For example, Smith from personal recollection and seemingly anecdotally, recalled the case of a young woman who was advised she had syphilis and was so distressed by the news that she committed suicide. Unfortunately, the doctor had failed to advise her that syphilis could be innocently contracted and treated successfully. Smith uses this case to illustrate the precarious consequences of disclosing information in a situation and considers that telling a patient the truth which *'often causes psychological reactions*' might be negligent by, firstly, worsening the patient's condition and, secondly, hampering the patient's chances of recovery. Rather than the negligent act being caused by failure to advise the patient, the perception of negligence lay in causing psychological reactions.

Indeed, these same academics were referred to in *Natanson* as informing the law on informed consent. It is for these reasons that one might conclude that those early judgments in the USA on informed consent which introduced the therapeutic privilege exception were not necessarily considering the effects of disclosure on the patient's psychological condition as potentially compromising the patient's autonomy to make an informed decision on treatment. The concern instead appeared to be that if disclosure were made, it may compromise the outcome of the physician's perceptions of the patient's best interests. The judgment of *Wilkinson v Vessey*[490] supports this point, where withholding information was justified where a doctor determined that it would be in the best interests of the patient.

Four years after the decision in *Natanson v Kline*, the North Carolina Supreme court examined the extent to which a surgeon should advise of the risks. Recognising it was challenging to formulate any clearly defined rule, in *Watson v Clutts* Mr Justice Higgins considered that *Salgo* represented an *'extreme'* view where disclosure was that which was necessary to '*form the basis of an intelligent consent'*, failing which the physician would

[490] *Wilkinson v Vesey* 295 A.2d 676 (1972)

breach his duty of care. Mr Justice Higgins continued by considering that except in emergency situations, reasonable disclosure of a risk should nonetheless be made *'to send to the operating room nervous from fright is often not desirable'*. Whilst the court recognised that the doctor's primary duty was to do what was best for the patient, where there was a conflict between this duty and what was referred to as a '*frightening disclosure'*, the best course of action would be to act in the patient's best interests.[491] Having explored the extreme view, Mr Justice Higgins then referred to a middle ground rule as the preferred option narrowing the duties of disclosure of risks, with it being a matter of clinical judgment as to whether those risks were sufficiently serious and essential to an intelligent decision.[492]

Little more is said of the therapeutic privilege exception in *Watson v Clutts* but having referred to the Harvard Law Review[493] in the context of information disclosure, it seems that on closer reading beyond the judgment that the article is instructive regarding withholding information for therapeutic reasons. It appears to justify limiting or withholding information in two distinct situations. Firstly, *'where the patient's emotional condition is such that full disclosure would seriously complicate or hinder treatment',* and secondly, '*where the patient might justifiably be considered incapable of coping with knowledge of potential dangers and likely to distort them is such a way that rationale decision would be impossible'*. There is no indication as to how an '*emotional condition'* might be defined, but the suggestion is that this may amount to any condition which would cause the patient to retreat from treatment that the doctor considered to be in the patient's best interest.

This interpretation seems to be supported by the second element, where it is feared that disclosing information would make *'rational decision'* impossible. Although, this is not directly referred to in the judgment, it adds credence to the argument that acting beneficently by withholding information may reflect a wider definition of the doctor acting in the patient's best interests.

Through an analysis of case law, it has been demonstrated that there are two approaches here: a narrow interpretation and a broader interpretation. Moreover, there is little

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[491] *Watson* (n475)

[492] 'Physicians and Surgeons. Physician's duty to warn of possible adverse results of proposed treatment depends upon general practice followed by medical profession in the community. Difilippo v Preston (Del. 1961)' (1962) Harvard Law Review 75(7) May 1445-1449,1448

[493] Ibid

consistency across any jurisdiction. Where therapeutic privilege is broadly defined, physicians may withhold information from a patient where, in their clinical opinion, disclosure may have any undesirable effect on the patient. In contrast, the narrow interpretation is that a physician would be justified in withholding information where disclosure would cause serious harm, such that their decision-making ability would be impaired.[494]

Whilst early USA case law developed by endorsing a tightly formulated doctrine of informed consent, case law seemed to confirm that by a widely defined therapeutic privilege exception, information could be legitimately withheld from a patient without any clearly defined rule. On the face of it, this may appear incongruous, but it is completely logical. Since every case is different in terms of both the proposed treatment or diagnosis and the potential effect on the patient, each of whom have distinct psychological perspective, it was simply not possible to identify a common standard or test to be applied to the privilege to withhold information from a patient, given that the privilege falls entirely within the doctor's discretion.[495]

The question remained whether a physician could disclose anything less than full information in order to provide informed consent where '*the patient's mental and emotional condition was such that it would have been therapeutically unwise to inform him of the risks.'*[496] Consideration was given to the approach the court took in *Patrick v Sedwick,*[497] where the physician failed to advise the patient of the risk of paralysis of the patient's vocal cords, which was estimated to be between 1-5% even where a subtotal thyroidectomy was performed correctly. The doctor had minimal contact with the patient himself but had relied on observations made by another doctor that the patient was both nervous and apprehensive, reactions which may well be entirely normal in these circumstances. Whilst the privilege was not specifically relied upon (unlike in *Nishi v Hartwell*),*[498]* the court held that being anxious and apprehensive was enough to limit the

[494] Ruth Faden and Tom Beauchamp, *A History and Theory of Informed Consent*, Oxford University Press, New York 1986, [37]
[495] Waltz and Scheuneman (n481) [643]
[496] Louisell & Williams, Medical Malpractice (1970), 594.62
[497] *Patrick v Sedwick* 391 P.2d 453 (Alaska) 1966
[498] *Nishi v Hartwell* 473 P.2d 116 (1970)

disclosure of risks. Shartsis[499] observes that although physicians were able to limit disclosure, the court did not distinguish between a failure to disclose any risks and selectively choosing which risks to withhold.

The case of *Nishi v Hartwell*[500] in the Supreme Court of Hawaii is widely recognised as one of the few cases whose judgment turned on therapeutic privilege. In this case, the patient suffered paralysis after undergoing a thoracic aortography and alleged that the doctor had failed to advise him of the risks, which had been withheld. The physician had recognised that he was anxious, and that disclosure would frighten him further, which could cause serious harm since he has also suffered from hypertension. In his view, this justified withholding relevant information.

The court acknowledged that whilst the doctrine of informed consent imposes a duty on the physician to disclosure all relevant information concerning his treatment, so that the patient can provide informed consent, the doctrine also recognised that '*the physician's primary duty is to do what is best for his patient and a doctor could withhold disclosure of information, where it would be detrimental to the patient's total care and best interest.'* Citing *Watson and Clutts* and *Covin v Hunter,*[501] the court also recognised that there was no set 'rule' regarding the circumstances, or the kind of information which could be withheld and that it would be fact specific. Where there was a conflict between doing what is best for the patient and that of *'a frightening disclosure'*, the decision would *'ordinarily'* be resolved in favour of the primary duty. The court accepted this approach stating that in this case, *'(t)The medical standard so established was that a competent and responsible medical practitioner would not disclose information which might induce an adverse psychosomatic reaction in a patient highly apprehensive of his condition*.' Furthermore, the duty of disclosure was owed to the patient and not to any family member including the patient's wife.

With regards to establishing the standard of care to be applied, the court rejected the dictum in *Wilson v Scott*[502] where the court held that '*by his own testimony, he established*

[499] Arthur J. Shartsis, 'Informed Consent: Some Problems Revisited' 51 Neb. L. Rev. 527 (1972), 631
[500] Harvard (n493)
[501] *Covin v Hunter* 374 P.2d 421 (Wyo. 1962)
[502] *Wilson v. Scott*, 412 S.W.2d 299 (Tex. 1967)

the medical standard'.[503] A similar approach was taken in *McPhee v Bay City Samaritan Hospital*[504] where the defendant's own evidence was sufficient to establish the standard of care which should be exercised. The court rejected these decisions, confirming that the defendants could not set their own standard, being reminiscent of the challenges regarding the application of *Bolam* in England and Wales. It was acceptable for experts '*to adduce evidence to establish the reasonable standard of medical practice on these questions'*, but determination was to be a question for the jury and not the defendant doctors. It is noteworthy that the term 'questions' here was referred to in the plural, which implies that it was a matter for the court (a jury in this case) and not the medical profession to determine whether withholding information was justified in enabling the patient to provide informed consent.

If it is correct to say that the physicians could not set their own standard relating to information disclosure, and that it was a question for the jury to determine, then the jury are left to unravel the circumstances in this specific case and whether the physicians were justified in withholding information. They do so without any clear delineation and little adduced evidence to encourage or facilitate the patient's decision-making process. The court rejected the notion of disclosing the information to the patient's wife and to involve her in the decision-making process as a means of attempting to determine what his wishes may have been. By failing to do so, physicians could be provided with excessive authority to simply act with impunity and impose their notion of the patient's best interest. Thus, it was accepted that a physician '*would not disclose information which might induce an adverse psychosomatic reaction in a patient highly apprehensive of his condition'*, thereby accepting the use of the therapeutic privilege exception in law.

The case of *Sard v Hardy*[505] in the Appeal Court of Maryland, heard only a few years later than the cases outlined above, shows a clear development in both informed consent and the therapeutic privilege exception. The issue for the court to determine was whether the physician was negligent when he failed to advise his female patient of the risk of a sterilisation procedure failing and of failing to advise her of possible alternatives. The court

[503] Ibid [303]
[504] *McPhee v Bay City Samaritan Hospital* 10 Mich. App. 567 (1968) 159 N.W.2d 880
[505] *Sard v Hardy* 281 Md. 432 (Md 1977)

stated that a duty is imposed on the physician to explain any treatment to the patient and to warn of any material risks, of the chances of success and any alternatives to enable the patient to make an informed choice about whether or not to proceed with the treatment. Yet, the court also recognised that given her medical history she would also suffer from emotional stress and anxiety if a Caesarean section were required. Consequently, the court held that if complete disclosure of the risks would have a detrimental effect on the physical or psychological well-being of the patient, then it was justifiable to withhold the risks from the patient.

The approach in *Sard v Hardy* can also be seen in the Minnesota Supreme court case of *Cornfeldt v Tongen*[506] (even though this case was heard post *Canterbury v Spence*). Here the court accepted that where disclosure would either *'complicate or hinder treatment, cause such emotional distress as to preclude a rational decision, or cause psychological harm to the patient*'.[507]

The broad nature of the privilege was particularly apparent in *Cobbs*[508] wherein the court held the privilege could apply where *'the disclosure would have so seriously upset the patient that the patient would not have been able to dispassionately weigh the risks to refusing to undergo the recommended treatment.'* The test did not refer to either specific psychological or physical harm being caused as a result of disclosure but does suggest the possibility of compromising the patient's capacity. Advising any patient of bad news would be distressing in some form, but the court approved withholding information in its broadest form with the result that the patient's autonomy would be severely curtailed, allowing the doctor to replace patient autonomy with beneficence.

Thus far, case law reflects a wide application of an undefined exception to the developing doctrine of informed consent in the USA courts. It is not possible to clearly discern a uniform standard of where the therapeutic privilege exception would apply as professional standards are applied rather that of the reasonable man. Although rarely applied, successive courts have explored withholding information from patients. It has been argued that since the physician had to consider both the physical and psychological condition of the patient

[506] *Cornfeldt v Tongen* 262 N.W.2d 684 (1977)
[507] Ibid [700]
[508] *Cobbs v. Grant* [8 Cal. 3d 230] 1972

when assessing whether the disclosure of risks would adversely affect the patient, the patient's best interests was a decision that may only be made by the physician and was not a question to be determined by the reasonable man.

Thus, it is argued that a) a practitioner would consider the state of the patient's health both physical and mental and b) this determination involves medical judgment as to whether disclosure of possible risks may have such an adverse effect on the patient, so as to jeopardise success of the proposed therapy, no matter how expertly performed.

It was the case of *Canterbury v Spence*[509] as the seminal USA case on informed consent that continued to highlight the dilemma faced by the courts in defining the therapeutic privilege exception. The case itself concerned an appeal from the District Court of Columbia where the appellant, a young man of 19 years of age underwent surgery to relieve back pain. He alleged the defendant did not advise him of the 1% risk associated with the surgery which the surgeon had described as *'a slight risk'*. Whilst the facts did not raise any issue relating to withholding information relevant to informed consent, the case has been highly instructive to subsequent cases and often incorrectly referred to as the birthplace of informed consent. The judgment adopted a more rights-based approach stating that *'a risk is material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.'*

Obiter, the court referred to situations where information might cause such harm that the information should be withheld. Whilst the court did not define the specific nature of harm that disclosure might cause, the court considered the statement in *Salgo* where it was held that disclosure could be withheld where patients would be so *'ill or emotionally distraught'*[510] that they would be unable to consider making a decision in relation to their treatment in any rational way or at all. The court explained that the privilege should not be so broadly interpreted to enable the doctor to act in the patient's best clinical interests, as this would be contrary to the principles upon which informed consent was built; namely, the patient's right to determine for themselves whether or not to peruse a course of treatment

[509] *Canterbury* (n19)
[510] *Salgo* n (467) [48]

proposed by the doctor.[511] Explaining that the privilege *'must be carefully circumscribed…for otherwise it might devour the disclosure rule itself'*, the court foresaw that the privilege was to operate only where the patient's reaction to disclosure would be *'menacing'*.

Faden[512] criticises the therapeutic privilege exception for establishing a direct conflict between the principles of autonomy and beneficence, which he refers to as the recipe for paternalism, while recognising that *Canterbury v Spence* narrowly interpreted the therapeutic privilege exception. Here, we see that the exception would apply where disclosure would *'pose (s) such a threat of detriment to the patient as to become unfeasible or counter indicated from a medical point of view'*.[513] The decision continues by elaborating what this means by stating that disclosure can make patients *'so ill or emotionally distraught'* that they a) become unable to make rational decisions, b) complicate or hinder the treatment or c) *'perhaps even pose psychological damage to the patient'*. The reasons may appear widely defined at first glance, but this is a narrow interpretation as it specifies the circumstance where the therapeutic privilege exception can be activated. A wider definition would simply not include the reasoning and state that disclosure could be withheld where it is clinically contra indicated to disclose information to a patient.

Whilst patient autonomy remains a fundamental principle of informed consent, where information disclosure impedes patient autonomy then disclosure becomes meaningless in the context of informed consent. Arguably, autonomy is still possible where the clinicians discuss other aspects of the treatment such as the benefits or the alternatives, allowing the patient some autonomy, yet the risks remain a material element of disclosure and the patient cannot be lured into a false sense of having provided autonomy.

Katz has observed that *'only in dreams and fairy tales'* can discretion to withhold information relevant to disclosure be reconciled with full disclosure.[514] But how to balance this is challenging. *Canterbury* suggested that disclosure could be made to a relative in lieu of the patient, but in contrast *Nishi* specifically stated that there is no value in disclosing information relating to the risk to the patient's wife, as it is the patient himself, who is

[511] Ibid [49]
[512] *Smith* (n366) [37]
[513] *Canterbury* (n19) 233
[514] Jay Katz, 'Informed Consent- a fairy tale?' (1977) University of Pittsburgh Law Review 39: 137-174

required to consent. Moreover, if *Nishi's* application of the therapeutic privilege exception for the patient's best interests were to be accepted then that would, in Mr Justice Robinson's words, '*devour the disclosure rule itself*'.[515]

By 1982, the President's Commission took a robust approach to the contentious exception, rejecting mere upset as a justifiable reason for withholding information while suggesting that therapeutic privilege might be acceptable in a situation where the patient had a history of suicidal thoughts '*or susceptible to serious physiological effects of stress*'.[516] It now seemed that an exception to informed consent may be permitted where serious physical or psychological harm could be caused. The reasoning suggests that where disclosure would have such an adverse effect on the patient which results in '*serious self-destructive behaviour',* disclosure would be contrary to the patient's objectives of the treatment.[517] Nevertheless, the Commission's Report tempered the potential application of the therapeutic privilege exception by observing there was little evidence to suggest that greater harm is caused to patients by telling them bad news than by withholding it.

However, this appears to contradict the evidence provided being that 34% of physicians reported withholding information as they felt their patients would be unable to cope with the information, while two-thirds reported not telling their patients bad news (not related to patient waiver). Although the Report accepted the continued existence of the therapeutic privilege exception, their conclusion reflects a deep-rooted reluctance to retain the therapeutic privilege exception:

'*not only is there no evidence of significant negative psychological consequences of receiving information, but on the contrary some strong evidence indicates that disclosure is beneficial'.*[518]

What remains equally challenging is how to determine what harm would have been caused to the patient had the information been disclosed and, indeed, where the *greater* harm is caused. All patients suffer some degree of stress and anxiety, since they are seeking medical

[515] *Canterbury* (n19) [789]
[516] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behaviour Research 1982
[517] Ibid [96]
[518] Ibid [100]

advice for a troubling condition or ailment. The question is whether the greater harm is caused in not disclosing the risk where it is feared that the patient would suffer serious harm from said disclosure, or by withholding information and compromising patient autonomy?

Somerville, writing in 1981 at a similar time to the President's Commission and referring to above, observed that a narrow interpretation of therapeutic privilege is the preferred approach where therapeutic privilege can be relied upon *'where the reasonable physician in the same circumstances would have believed that the disclosure, in itself, would physically or mentally harm the patient to some significant degree.'*[519] She correctly argued that the therapeutic privilege should not apply if the reason for withholding information is that it may cause the patient to refuse treatment which the physician would believe to be in the patient's best interests.

By 1992, in *Planned Parenthood of Southeastern Pennsylvania v Casey,*[520] a seminal case in the USA on abortion which confirmed the (now rejected) decision in *Roe v Wade*, the court appeared to approve the narrow boundaries of the therapeutic privilege exception and the circumstances in which it could apply. The judgment cited the statutory provisions of the *Pennsylvanian Abortion Control Act of 1982,*[521] wherein it was stated that where it was reasonably believed that providing risk disclosure to a woman for an abortion would result in a '*severely adverse effect on the physical or mental health of the patient*' where the statute allowed the doctor to exercise their medical judgment and withhold information.

The case of *Arato v Avedon* raised a unique application of the therapeutic privilege exception. Here, the patient had died of pancreatic cancer and the wife and children alleged a failure to obtain informed consent. It was specifically alleged that the clinicians had failed to disclose to the patient the statistical life expectancy of patients with pancreatic cancer. Had he been advised of the high risk of mortality associated with this type of cancer, he alleged that he would have refused treatment and spent the time he had left arranging his business affairs.[522] In reality, it appears that his action was based on the failure of his

[519] Margaret A. Somerville, 'Structuring the Issues in Informed Consent' (1981) McGill Law Review 26, 741-808
[520] *Planned Parenthood of Southeastern Pennsylvania v Casey* 505 US (1992) 833, 883-4, 112 S Ct 2791
[521] 18 Pa. Cons. Sat. 3205 (1992)
[522] *Arato v Avedon* Supreme Court of California 5 Cal. 4th 1172 (1993) 858 P.2d 598

business, which he did not get into order before his death because he was not advised of his life expectancy. Evidence was adduced that the patient had never asked about the specific data and believed that they had disclosed all information sufficient to enable the patient to make an informed decision.

With regard to the exercise of the therapeutic privilege exception, the reasons for failing to advise the patient of the risks are both illuminating and varied. The patient's surgeon argued that he had displayed great anxiety over his condition to the extent that the surgeon felt it would be detrimental to his health to disclose specific mortality rates. The patient's oncologist expressed a similar sentiment by saying that cancer patients *'wanted to be told the truth but did not want a cold shower'.*[523] This seems to suggest that patients should only be advised of the truth where the news was positive rather than bad news which patients need to be protected from. Other physicians testified that disclosing extremely high mortality rates was inadvisable as it might 'deprive a patient of any hope of a cure.'[524]

Although this case rests on the extent to which the narrow therapeutic privilege exception applied to non-medical considerations, the case also exposes the inability of clinicians to convey vital information in a sensitive and timely manner. Yet, the failure to advise the patient of mortality rates appears to conflict with evidence that cancer patients have greater trust in their doctors when they are fully informed and contrary to the judgment in *Arato* will not necessarily '*destroy hope'*. Challenges remain, as even where communication of the diagnosis is appropriately conveyed, prognosis lacks certainty but does not support a justification to withhold information. This is well expressed in the following:

'Although the anxiety associated with uncertainty is real, it is not a sufficient argument for failing to disclose uncertainty. The evidence that patients want information is overwhelming, and the mere fact that the receipt of information causes distress does not mean that patients would prefer not to know… The mere fact that a patient exhibits anxiety and even some reticence about discussion is not sufficient evidence that discussion should not proceed.'[525]

[523] Ibid [1178]
[524] Ibid
[525] Mark Parascandola, Jennifer Hawkins and Marion Danis, 'Patient autonomy and the challenge of clinical uncertainty' (2002) Kennedy Institute of Ethics Journal 12 245–64,258

In these circumstances, it would seem clear that the clinicians in *Arato* acted incorrectly in withholding information and, from this perspective, the Supreme Court erred in judgment. Similarly, in *Stuart v Camnitz,* another case on abortion, the court observed that the therapeutic privilege exception permits doctor to withhold information relevant to informed consent where, in their clinical judgment providing that information to the patient '*would result in serious psychological or physical harm.'*[526] The court acknowledged that whilst the privilege was important, as it protected the health of '*particularly vulnerable or fragile patients and permits the physician to uphold his ethical obligations of benevolence,'* it should be used sparingly. There appears a conflict here as whilst the boundaries for being able to rely on the therapeutic privilege exception were narrowed to where serious psychological or physical harm was being caused to vulnerable patients, it also allowed the doctor to act benevolently, perhaps in what he perceived his patient's best interests to be. If the latter is correct, then there is a risk of denying patient autonomy.

More recently, a significant move occurred when *The Informed Consent and Shared Decision Making in Obstetrics and Gynaecology, Committee Opinion,*[527] No 819, February 2021, rejected the therapeutic privilege exception in its entirety, regarding it as

'*ethically unacceptable because it suggests that physicians always know what is best for their patients, requires a physician to predict the future, and opens the door for coercive misuse under the guise of the patient's best interest*.'

Furthermore, the American Medical Association, Code of Ethics on Withholding Information from Patients Opinion 2.1.3, specifically rejects therapeutic privilege by focusing on shared decision-making and placing emphasis on information being conveyed over time.[528] The reasoning for this move is that withholding information creates a conflict between the doctor's duty to '*promote patient welfare'* and respecting patient autonomy. However, this also fails to acknowledge that in some albeit limited circumstances, risk disclosure can compromise a patient's decision-making capacity.

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[526] ACOG, Comm. Op. 439, 7. *Stuart v Camnitz* No. 14-1150 (4th Cir. 2014)
[527] Consent and Shared Decision Making in Obstetrics and Gynaecology, Committee Opinion
[528] https://www.ama-assn.org/delivering-care/ethics/withholding-information-patients accessed September 30, 2021. It is also worth noting that disclosing information over separate appointments, rather than withholding information in its entirety, was reflected in the GPs practice in the qualitative data.

The reference to *coercive misuse* is unfortunate, as it presupposes that paternalism will subvert autonomy. Whilst this is plausible risk, a clear framework could negate this. The risk with the current approach in the US is that clinicians may more readily declare that their patient lacks capacity to act as an autonomous agent, rather than engage in challenging and time-consuming conversations.

The table below charts the development of the therapeutic privilege exception in the US and demonstrates that in the early part of the 20th century, clinicians practiced paternalistically, being reluctant to disclose information for fear of causing upset or anxiety. Whether this resulted from less advanced medicine with less predictable results or a concern about excessive litigation due to harm being caused is unclear. It was followed by a period where clinicians could withhold information if they believed that disclosure would result in physical or psychological harm to patients until more recently, where therapeutic privilege has been rejected in its entirety. In so doing, the approach in the US can be contrasted with the position in England and Wales, where professional guidance has retained the therapeutic privilege exception, as previously discussed.

4.4 Summary of case law in USA

Case Name	Circumstances in which risk disclosure could be withheld.
Mohr v Williams [1905]	Clinicians given reasonable latitude to withhold information.
Schloendorff v Society of New York Hospital [1914]	Where a patient was 'nervous and excited', 'avoid causing needless and harmful agitation.'
Hunt v Bradshaw [1955]	Where a patient would be 'apprehensive'
Lester v Aetna Cas & Sur. Co [1957]	To 'avoid frightening' (the patient)
Nathanson v Kline [1960]	To avoid 'alarm a patient'
Roberts v Woods [1962]	To avoid 'anxiety and apprehension'
Watson v Clutt [1964]	To avoid 'frightening disclosure', Where 'fright is often not desirable' Due to 'distort(ing)' potential dangers 'in such a way that rationale decision would be impossible'
Patrick v Sedwick [1966]	Where the patient is 'anxious and apprehensive'
Nishi v Hartwell [1970]	A clinician 'would not disclose information which may induce an adverse psychosomatic reaction in a patient highly apprehensive of his condition'
Canterbury v Spence [1972]	Where disclosure would make a patient 'ill or emotionally distraught' Where there is a 'threat of detriment to the patient as to become unfeasible or counter indicated from a medical point of view.' Where disclosure would render the person 'unable to make rational decisions, complicate or hinder treatment', 'perhaps even pose psychological damage to the patient.'

Cobbs v Grant [1972]	Where disclosure may 'seriously upset' the patient so as to compromise their capabilities
Sard v Hardy [1977]	To avoid 'emotional stress and anxiety'
Cornfeldt v Tongen [1977]	To avoid 'emotional distress as to preclude as to preclude a rational decision, or cause psychological harm to the patient'
Planned Parenthood of Southeastern Pennsylvania v Casey [1992]	Where disclosure would cause 'severely adverse effect on the physical or mental health of the patient.'
Stuart v Camnitz [2014]	Where disclosure would 'severely result in serious psychological or physical harm', 'particularly vulnerable or fragile patients and permits the physician to uphold his ethical obligations of beneficence.'

4.5 The therapeutic privilege exception in Canada

Early Canadian case law seemed to accept the concept of non-disclosure of information but, took no steps to define the elements that would justify non-disclosure. *Kenny v Lockwood*[529] was willing to accept that the duty to deal '*honestly*' with their patients '*did not extend…to details calculated to frighten or distress the patient*' but failed to develop the reasoning behind this. Moreover, the statement lacks any clear detail as to the extent and nature of the distress that may be caused to the patient and to what effect. It lacks clarity as to whether the distress is simply upset or distress or more akin to psychological harm, whether it is temporary or whether it could be permanent. Furthermore, the courts refer to the concept of *honesty* where disclosure is concerned, and whilst it seems fair to suggest that honest dealings with patients require disclosure, it does not seem reasonable to conclude that failing to disclose information amounts to dishonesty *per se*, where the reasoning amounts to avoiding harm being caused to a patient.

[529] *Kenny* (n483) [525]

In the 1976 case of *Kelly v Hazlett,*[530] the court opined that it was a question of medical judgment whether the risk of any proposed treatment should be disclosed to the patient and contrasted this to the USA, where the test of the duty of disclosure was that which the reasonable patient would want to know.[531] Therefore, the medical professional retained the discretion regarding the degree of information that might be disclosed to the patient but was silent, as to the conditions where this may apply.

Perhaps slightly more instructive was the decision a year later in *McLean v Weir*, where the patient was not advised of the risk of paralysis which was then realised following an angiogram procedure. Here, the courts considered that '*t(T)he less the courts try to tell doctors how to practise medicine, the better*' but then carefully discussed the value of communication. It appears that in confirming the role of the doctor as the arbiter of what the patient may want to know, the court confirmed the doctor had a discretion whether to communicate information *'to a patient which undoubtedly would frighten him to the extent that his treatment would suffer, or he would refuse treatment altogether*.'[532] The reasoning for withholding information was not guided by concern over the degree of harm that may be caused to a patient but rather the potential of a patient's non-compliance with the doctor's recommended treatment. Yet, this is entirely inconsistent with the USA case of *Canterbury v Spence* which rejected the notion that risk disclosure might be withheld in circumstances enabling the doctor to act in the patient's best interests.

Whilst two landmark decisions[533,534] contributed significantly to the body of judicial opinion on informed consent, neither case managed to grapple with such a relevant exception. In *Hopp*, the court made some progress but, as Hadskis observes, it failed to go as far as *Canterbury* in adopting therapeutic privilege into Canadian law.[535] This may be entirely reasonable as the patient did not appear to be anxious about the proposed treatment. However, the court stated that:

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[530] *Kelly v Hazlett* [1976] 15 O.R. (2d) 290, 1 C.C.L.T. 1, 75 D.L.R. (3d) 536
[531] Ibid [40]
[532] *McLean v Weir* [1977] 5 WWR 609
[533] *Hopp v Lepp* [1980] 2 SCR 192, 112 DLR (3d) 67
[534] *Reibl v Hughes* [1980] 2 SCR 880, 11 DLR (3d) 1
[535] Michael Ralph Hadskis, 'A critique of Canadian Jurisprudence on the Therapeutic Privilege Exception to Informed Consent' (2018) 12(1) McGill JL and Health 1

'*a surgeon has some leeway in assessing the emotional condition of the patient and how the prospects of an operation weighs upon him; the apprehension, if any, of the patient, which may require placating, his reluctance, if any, to submit to an operation, which, if the surgeon honestly believes that the surgery is necessary for the preservation of the patient's life or health, may demand detailed explanation as to why this is necessary.'*

Although Hadskis comments on the lack of detail as to how to 'placate' a patient who could be apprehensive about their treatment, he neglects to comment further.[536] *Hopp v Lepp* then refers to the New Zealand case of *Smith v Auckland Hospital Board*[537] where the judge's comments contribute to the discussion, where he stated:

'…that the paramount consideration is the welfare of the patient and given good faith on the part of the doctor, I think the exercise of his discretion in the area of advice must depend upon the patient's overall needs.'

It would seem unlikely that the court had the therapeutic privilege exception in mind but *Smith* continued by stating that when advising the patient of the risks, it was relevant to take into account '*the intellectual and emotional capacity of the patient to accept the information without such distortion as to prevent any rational decision at all*'. It is difficult to determine exactly what is meant here which may suggest that a patient with a learning disability or low IQ may be deprived of an opportunity to decide on treatment options for themselves. If this is correct, then it creates an assumption that those with intellectual disability are unable to make decisions regarding their own medical treatment and renders them unequal partners in healthcare. In any event, the court did not explore the relevance of the statement, nor its consequences, which arguably constitutes a missed opportunity to connect with the therapeutic privilege exception.

In contrast, the case of *Reibl v Hughes*[538] provided far more direction about the potential application of the therapeutic privilege exception. In this well-known case, the surgeon advised the patient to undergo surgery to avoid a potential stroke, but failed to advise the patient that there was a 4% chance that the operation might be fatal and a 10% chance that

[536] Ibid
[537] *Smith v Auckland Hospital Board* [1964] N.Z.L.R. 241
[538] *Reibl v Hughes* [1980] 2 SCR 880, 11 DLR (3d) 1

the operation would cause the actual stroke, which was the surgery's objective. Had the patient been advised of the risks, he would have delayed the operation until he had retired and received his pension some 18 months later. *Reibl v Hughes* specifically endorsed the judgment in *Canterbury v Spence* and, in doing so, adopted the doctrine of informed consent into Canadian jurisprudence.

Perhaps more relevant for England and Wales, the decision in *Reibl v Hughes* was referred to with approval in *Montgomery*.[539] *Reibl v Hughes* is considerably more instructive than *Hopps v Lepps* where non-disclosure is concerned. Mr Chief Justice Laskin stated that:

'[I]t may be the case that a particular patient may, because of emotional factors, be unable to cope with facts relevant to recommended surgery or treatment and the doctor may, in such a case, be justified in withholding or generalising information as to which he would otherwise be required to be more specific' [540]

Mr Chief Justice Laskin then continued by referring to Meisel who considered cases of non-disclosure post-*Canterbury*, confirming that '*if the defendant-physician claims a privilege, expert testimony is needed to show the existence of… the impact upon the patient of risk disclosure where a full disclosure appears medically unwarranted*'.[541] Whilst in this case the therapeutic privilege exception was rejected as there was no evidence that the patient was *'emotionally taut'*, the courts clearly indicated that the onus was on the physicians to prove that withholding information relevant to a patient's informed consent was justified. The challenge thereafter would be the standard to be employed and whether a *Bolam-esque* approach would be taken, or whether the courts would be the final arbiters.

It was the Canadian Supreme Court case of *Videto*[542] which adopted the therapeutic privilege exception, enabling physicians to justify withholding information relevant to a patient's decisions concerning their treatment, although the judgment failed to provide any greater clarity regarding the definition. In this case, the claimant unsuccessfully argued that the surgeon failed to discharge his duty to advise of the risk of perforation of the bowel when performing a laparoscopic sterilisation. The court referred to the importance of

[539] *Reibl* (n538) [51] [52] and [70]
[540] *Hopps v Lepp* [1980] 2 SCR 192
[541] Meisel (n20)
[542] *Videto v Kennedy* [1981], 33 OR (2d) 497, 125 DLR (3d) 127 (CA)

disclosure of the material risks and to *Hopps v Lepp*, where the court pointed out that even where the risk was a small possibility, 4but the consequences were serious, then this would amount to a material risk which should be disclosed.

The court opined that '*t(T)he emotional condition of the patient's apprehension and reluctance to undergo the operation may in certain cases justify the surgeon in withholding or generalizing information as to which he would otherwise be required to be more specific'* but held that this specific case did not fall into this category. Whilst the court accepted the therapeutic privilege exception into Canadian law in the context of a more general body of reference on informed consent, the specific reference to the therapeutic privilege exception is interesting.

Although the court acknowledged that the potential fragility of the patient's condition was enough to justify withholding risk disclosure, the same would not apply to a case of *physical* fragility. The wording is more generally challenging, as the reasoning for withholding risk disclosure is not to prevent harm but directly related to an unwillingness to be operated upon. It appears that in this particular situation, the court concern was more focused on the patient's best medical interests rather than the potential psychological harm that could be caused by disclosure.

In 1991, the Supreme Court case of *Meyers Estate v Rogers*[543] paid close attention to the therapeutic privilege exception referring directly to the exception to informed consent and tracing its development from *Canterbury v Spence* in 1972, carefully reciting its history. In doing so, the court had the opportunity to analyse the nature of the exception and although making no reference to *Videto*, they recognised that the doctor has the discretion to withhold information for therapeutic reasons where disclosure would present a risk to the patient's wellbeing. The use of the word *'wellbeing'* is significant, as the court observed that the dictum in *Canterbury v Spence* was only focused on the potential *psychological* damage which might be caused to the patient rather than *physical* harm. In doing so, the court looked for support to Lord Scarman's dictum in *Sidaway,* which took the same approach when defining the exception of limiting risk disclosure to psychological harm.

[543] *Meyer Estates v Rogers* [1991] 2 Med LR 370, [1991] O.J. No 139, 2 O.R (3d) 356

The court recognised there were USA cases that specifically referred to the risk of *physical* harm as well as psychological harm, where the court referred to *Hook v Rothstein*[544] in which the court has acknowledged that in some situations disclosure was 'unnecessary'. These cases would be where

'*the physician reasonably believes that a complete and candid disclosure of possible consequences might have a detrimental effect on the physical or psychological well-being of the patient.'*

The slightly later case of *Pauscher* took a similar approach. Here, the court acknowledged the situation where '*complete and candid disclosure might have a detrimental effect on the physical or psychological well-being of the patient'*.[545] The use of the term 'wellbeing' in this context is also interesting. Whilst the term '*wellbeing*' specifically refers to both physical and physiological, it does not greatly assist the doctor who has the discretion to withhold risk disclosure. What is a failing is the absence of reference to any potential degree of harm which would act as a measure for the discretion to be exercised, as there is potential for doctors to withhold risk disclosure information in situations that are far from transparent. It is possible that patients who would have been able to provide informed consent were denied that very opportunity due to legal obfuscation.

Nevertheless, Mr Justice Maloney in *Meyers Estates v Rogers* rejected the notion that *Reibl v Hughes* had adopted the therapeutic privilege exception into Canadian jurisprudence by referring to Mr Chief Justice Laskin's use of the term *'may'*. Here, he opined that this did not specifically indicate accepting therapeutic privilege into Canadian law but may amount to the starting point for consideration. It does not seem that this can be the correct interpretation as Mr Chief Justice Laskin simply appeared to be taking care to indicate that it was a *possibility* that information *may* sometimes be withheld from a patient. It seems that this may be a mere convenience for Mr Justice Maloney and, that his real reason for rejecting adopting the therapeutic privilege exception into Canadian law was a concern that the US had already experienced *'an unwarranted extension… beyond its original scope which protected patients from psychological harm'.* It appears that Mr Justice Maloney's foremost concern was the

[544] *Hook v Rothstein* 316 SE 2d 690, 281 SC 541 (SC App 1984)
[545] *Pauscher v Iowa Methodist Medical Center*, 408 NW 2d 355, 56 USLW 2034 (Iowa, 1987)

potential for the exception to '*swallow*' the doctor's obligation to disclose information required for informed consent.

Certainly, it is apparent that on closer reading, Mr Justice Maloney was highly influenced by Meisel who writing in 1979 argued that *'(t)The danger that the therapeutic privilege poses to self-determination in medical decision making is so great that we should seriously consider its abolition.'*[546] According to Hadskis, the therapeutic privilege exception was found inapplicable in seven reported cases in the Canadian Supreme Court, of which two cases provided some insight into the parameters of the exception.[547] The earlier case of *Haughian v Paine*[548] is of specific interest to the discussion, as the judgment referred to Lord Scarman's dissenting judgment in *Sidaway*[549] wherein Lord Scarman referred to the need to establish a *'serious threat of psychological detriment to the patient's health*' were therapeutic privilege to be relied on as a justification for failing to advise the patient of a material risk.

On the facts, the surgeon had failed to advise the patient of the risk associated with repairing a soft disc herniation. He argued that he did not advise patients of risks of less than 1%. The court cited *Reibl v Hughes* wherein the court opined that

'*the emotional condition of the patient and the patient's apprehension and reluctance to undergo the operation may in certain cases justify the surgeon in withholding or generalizing information as to which he would otherwise be required to be more specific.'*[550]

Yet, the court preferred the approach of the dissenting judgment of Lord Scarman in *Sidaway*, which reiterated *Canterbury v Spence* wherein the court stated, with respect to therapeutic privilege, that

'*t(T)his exception enables a doctor to withhold from his patient information as to risk if it can be shown that a reasonable medical assessment of the patient would have indicated to the doctor that disclosure would have posed a serious threat of psychological detriment to the patient*.

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[546] See Alan Meisel, 'The 'exceptions' to the informed consent doctrine: striking a balance between competing values in medical decision-making' Wisconsin Law Review 1979; 413-88
[547] n607 [19]
[548] *Haughian v Paine* 37 DLR (4th) 624, [1987] 4 WWWR 97 (Sask CA)
[549] n6
[550] *Reibl* (n538) [61]

Even though the respondent argued that it was not his practice to advise of a small risk, it was held that a 1% risk was sufficiently material and should have been disclosed, as '*there was no suggestion that disclosure would have unduly frightened [the plaintiff], cause him psychological harm or deterred him from taking treatment essential to his health.'*[551] Thus, the therapeutic privilege exception was not a relevant consideration.

4.6 Summary of case law in Canada

Case Name	Circumstances in which risk disclosure could be withheld.
Kenny v Lockwood [1932]	Disclosure 'did not extend…to details calculated to frighten or distress the patient'
Kelly v Hazlett [1976]	Disclosure was for the medical profession to determine
McLean v Weir [1977]	Where disclosure 'would frighten him to the extent that his treatment would suffer, or he would refuse treatment altogether'
Hopp v Lepp [1980]	Where disclosure would affect the 'emotional condition of the patient…. the apprehension….to submit to an operation'
Reibl v Hughes [1980]	Where 'because of emotional factors be unable to cope with facts relevant to recommended surgery or treatment'
Videto [1981]	Where 'the emotional condition of the patients' apprehension and reluctance to undergo the operation'
Cook v Rothstein [1984]	'…where the physician reasonably believes that a complete and candid disclosure of possible consequences might have a detrimental effect on the physical or psychological wellbeing of that patient'

[551] *Reibl* (n538) [61] [65]

Pauscher v Iowa Methodist Medical Center [1987]	Where disclosure 'might have a detrimental effect on the physical or psychological wellbeing of the patient'
Haughian v Paine [1987]	Where disclosure would 'unduly frighten (the patient) cause him psychological harm or deter him from taking treatment essential to his health'
Meyers Estate v Rogers [1991]	'…where disclosure would present a risk to the patient's wellbeing'

4.7 The therapeutic privilege exception in Australia

It would not be possible to provide an analysis of the therapeutic privilege exception in other domestic jurisdictions without consideration of the Supreme Court of South Australia in *Batterbsy v Tottman,*[552] which was heard pre-*Rogers* and is a rare example of a case where the defence of the therapeutic privilege exception succeeded. In this case, the doctor prescribed a high dose of the drug Melleril for the patient's severe mental illness but had failed to advise about the risk of damage to the patient's eyes. He neither advised the patient or the patient's relatives nor arranged for her to regular check-ups to ascertain whether any damage was being caused to her eyes due to use of the drug.

The trial judge (Mr Justice Cox) accepted firstly that the patient had responded to the high dose of Melleril without which she was a significant suicide risk, and secondly, that the doctor reasonably believed that the patient, due to her mental illness, would be unable to make a rational decision if he were to advise her of the risks. The trial judge observed that in the case of a '*normal patient'* the doctor would fail in his professional responsibility if he did not warn patient of the risk, explaining that the purpose of a warning is to allow the patient to decide for herself whether to accept the treatment. However, in this particular case, the plaintiff was not a '*normal patient*', she was referred to as being '*very severely mentally disturbed*', '*acutely depressed'* and '*suicidal'*. Furthermore, and somewhat relevant to the facts, she had a *'dreadful fear'* of something going wrong with her eyes. The doctor was

[552] *Battersby v Tottman* [1985] 37 SASR 524 (Full Ct) affirming: [1984] 35 SASR 577

concerned that if he advised her about the risk to her eyesight from taking Melleril, she would either have a '*hysterical reaction'* and develop symptoms of a defect, or she would stop taking the drug of her own accord and probably kill herself.

Although the majority of the Supreme Court (Mr Chief Justice King and Mr Justice Jacobs) observed that she was someone who was '*likely to react hysterically and irrationally and to refuse treatment not on rational grounds or as a result of calm deliberation*', the dissenting judge, Mr Justice Zelling placed considerable weight on her autonomy. Mr Chief Justice King referred to the judgment in *F v R* where he earlier stated that:

'*…a doctor is justified in withholding information, and in particular refraining from volunteering information, when he judges on reasonable grounds that the patient's health, physical or mental, might be seriously harmed by the information. Justification may also exist for not imparting information when the doctor reasonably judges that a person's temperament or emotional state is such that he would be unable to make the information a basis for a rational decision'.*[553]

The above divides the justification of withholding information into two separate options. Firstly, where the clinician objectively assesses that disclosure would suffer mental or physical harm from risk disclosure. And secondly, where the patient's personality or condition is such that they would be unable to use the information to make a rational decision.

Thus, Mr Chief Justice King's application of his comments made only one year earlier neatly applies to *Rogers*. Here was a patient who the defendant doctor judged to be so emotionally vulnerable that simply knowing of the risk of injury to her eyes was sufficient to present a real risk of hysterical blindness. Furthermore, due to her mental condition, she would have been unable to process the information in a measured way so as to come to a rational conclusion. Disclosure of risk was a two-fold issue for this particular patient. The fact that, objectively, there was a reasonable risk that risk disclosure would have exacerbated the injury itself as the physical consequence of disclosure. And secondly, that due to her mental condition, she would not be able to calmly make a rational decision in relation to her treatment if the risk were disclosed as the mental consequence of disclosure. Moreover, the

[553] *F v R* [1983] 33 SASR 189,193

doctor's objective view was that if risk disclosure were made where her mental condition would deteriorate to the extent that she would become a suicide risk. If this occurred then it would damage the fabric of her mental existence[554] with questionable chances of recovery. Thus, her physical and mental wellbeing would be adversely affected in order to preserve the notion of patient autonomy and it is difficult to see how such an act would benefit the patient's health.

Mr Justice Zelling's dissenting approach is diametrically opposed to the majority and lauded patient autonomy above all, observing that,

'the patient must be allowed to make her own decisions, whether the doctor thinks she is well enough to do so or not, except in the case of a person who is…by reasons of mental infirmity, unable to consider and weigh the risk inherent in the treatment.'

It is unclear what is meant by *'mental infirmity'* but this could suggest a person lacking in capacity which limits the grounds on which the therapeutic privilege exception would be available. Perhaps Mr Justice Zelling grounds his observation on the specific facts of the case, since the evidence of one of the experts accepted by the court was that the risk of cardiac arrest was more significant than that of serious damage to the eyes which was clearly a risk that the patient should be aware of. Mr Justice Zelling recognised the need for a balancing act to be achieved, thus the nature of the greatest risk would be significant in determining whether the risk should be disclosed.

The decision in *Rogers and Whittaker*[555] was highly influential on the decision of *Montgomery,* where the Supreme Court in England and Wales subsequently adopted the materiality test set out by the High Court of Australia. In this well-known case, the patient underwent surgery on an eye in which she had lost sight as a child. He failed to advise her of the risk of a rare condition (sympathetic opthalmia) where damage could be caused to her good eye. Although the risk was approximately 1:14,000, the chance of the risk occurring was slightly greater where there had been an earlier injury to the eye which the surgeon had operated on. Although the operation was carried out with care and skill and no

[554] *Rogers* (n238)
[555] Ibid

negligence was alleged in this regard, when the rare condition manifested shortly after surgery, she was then left blind.

In the lower courts, there was a divergence of views as to whether reputable medical practitioners would have warned their patients of the risk of sympathetic opthalmia and the appellant argued that the *Bolam* principle should not be applied, if it meant that the court would defer to medical experts. This court referred to *Sidaway* where the House of Lords had considered whether the *Bolam* principle should be applied in cases where it is alleged the defendant is negligent in failing to provide information and advice. A detailed analysis of the judgment appears elsewhere in this research, but *Rogers* noted that *Sidaway* had concluded that a trial judge might in certain circumstances decide that disclosure of a particular risk was such a necessary part of the informed consent process that no prudent medical practitioner would fail to make it.[556]

The court opined that the correct approach was that adopted by Mr Chief Justice King in *F v R*, and to that subsequently taken by Lord Scarman in *Sidaway* and although the risk was rare, the duty to disclose was upheld. Furthermore, and importantly for the purposes of this research, the court indicated that disclosure of risks was generally not one which depended on medical standards or practices. Although the therapeutic privilege exception was neither specifically referred to nor relied upon, the court acknowledged that the duty to disclose was subject to professional privilege.

It is apparent that Mr Justice Gaudron wished to establish a more limited exception as he rejected any basis for withholding information, other than where there was an emergency situation or the patient lacked capacity. However, the court limited withholding risk disclosure to circumstances where there was a particular danger that disclosure will harm *'an usually nervous, disturbed or volatile patient'* which would be judged on the professional standard. In all other cases, the court felt that no special skill was involved in risk disclosure. Instead, the court considered that the skill was in

[556] Ibid [630]

'communicating the relevant information to the patient in terms which are reasonably adequate for that purpose having regard to the person's apprehended capacity to understand the information.'

This statement is highly relevant to this thesis as the qualitative research confirms that where a clinician invests time and effort in exercising appropriate communication skills with a patient. There are a number of situations where risk can be disclosed appropriately. This may not be the case in a patient who is potentially suicidal as in *Battersby v Tottman.*

In this instance, it is not immediately clear how a patient who is *'unusually nervous, disturbed or volatile'* presents. The Oxford English dictionary defines a person who is '*disturbed'* as *'having or resulting from emotional and mental problems',* and *'volatile' as 'liable to display rapid changes of emotion'* which may suggest that their capacity could be eroded if the risk were disclosed. This now begins to look more like where disclosure would be seriously detrimental to the patient's health, as defined in *Montgomery.*

The court reflected on the standard of care to be applied and considered that reliance on expert evidence would only be relevant in two situations. Firstly, expert evidence would be relevant to whether a reasonable patient would be likely to attach significance to the risk. Secondly, expert evidence would be relevant in cases where the therapeutic privilege exception would be relied upon. Although the test of *Bolam* is not applied in Australia, rather than the court being the final arbiter of whether risks should have been disclosed from a patient the decision remains entirely in the hands of the medical professional.

Given the guidance in *Rogers,* one might expect the Western Australia Supreme Court to adopt a similar approach in *Tai v Saxon.*[557] In this case, the patient was extremely nervous with a history of depression, but the defence of the therapeutic privilege exception was rejected and the doctor was found to be negligent in failing to advise that recto-vaginal fistula could occur following the patient's hysterectomy. Whilst it was accepted this risk was quite low, the consequences for the patient could be quite unpleasant. The rejection of the therapeutic privilege exception is a little surprising, bearing in mind the likelihood of her

[557] *Teik Huat Tai v. Saxon* (1996) WASC, No 23/95

characteristics satisfying the High Court in *Rogers* but confirms the inconsistent application of the exception and the court's desire to enhance patient autonomy.

A similar inconsistent approach was taken by the Supreme Court in *Di Carlo v Dubois*, which rejected the lower court's attempt to apply the therapeutic privilege exception. Here, the patient was described as being '*anxious* ', '*highly anxious', 'particularly anxious' or 'extremely anxious'* on no less than 19 occasions within the judgment. The mere fact of being anxious was a clinical reason thought by some to justify withholding risk disclosure of treatment, as it could exacerbate a physical reaction, or even precipitate a reaction. Whilst the court acknowledged that the duty to disclose is subject to the therapeutic privilege exception, which is an opportunity to the doctor to prove that he or she reasonably believed that disclosure of a risk would prove damaging to a patient.[558] The court noted that the respondents were not seeking to rely on the exception, nor would there have been sufficient cause to.[559]

Yet, this appears incongruous with the judgments the court referred to,[560] such as Lord Scarman in *Sidaway,* where withholding risk was permitted when a doctor reasonably assessed that disclosure would be detrimental to the patient's health.[561] Similarly, the court noted the judgment of King CJ in *F v R* who said that

'*a doctor is justified in withholding information, and in particular refraining from volunteering information, when he judges on reasonable grounds that the patient's health, physical or mental, might be seriously harmed by the information.'*[562]

Finally, the court referred to *Canterbury v Spence*, cited with approval in *Rogers,* where '*risk disclosure poses such a threat of detriment to the patient as to becomes unfeasible or contraindicated from a medical point of view'*, risk disclosure can be withheld.[563]

With regard to the facts, it is difficult to see why therapeutic privilege was not relied upon. Here was an extremely anxious patient who was to undergo a CT scan with contrast dye to

[558] *Di Carlo v Dubois* [2004] QCA 150
[559] *Di Carlo v Dubois* [2004] QCA 150, 81
[560] Ibid [81]
[561] *Sidaway* (n6) [889]
[562] *F v R* [193]
[563] *Canterbury* (n19) [486]

eliminate the near certainty that he was not suffering from a brain tumour. The risk that his anxiety could have worsened was sufficient to satisfy the notion that disclosure would have been detrimental to the patient's health. One can only conjecture that the court's considered that the patient's autonomy in deciding treatment for himself, outweighed the potential injury to the patient's health by disclosure.

In *Sheppard v Swan*, the Supreme Court of Western Australia considered an appeal similar on the facts to *Montgomery,* where the appellant alleged that she should have been informed of alternative treatment and offered a caesarean section when she was in labour with a large baby. She contended that had she been advised of the option, then she would have had a caesarean and avoided subsequent injury.[564] Whilst the appeal was dismissed, one point is particularly noteworthy. The court observed obiter that there was an additional point supporting lack of duty to disclosure information related to a caesarean section, which *'fell short of therapeutic privilege'.*

The court referred to the duty arising at a time of *'significant maternal vulnerability'* where the patient was experiencing pain and distress which would likely impact decision making skills.[565] Whilst the court could not be drawn on whether this would be a factor in the clinical decision-making process, as there was no medical indication for a caesarean section, there are two approaches the court may have taken if this were to occur. Firstly, the clinicians could have considered the patient's '*maternal vulnerability'* in a similar way to the earlier case in of *Re MB*[566] in England and Wales where the court observed that where the woman is competent, she can decide for herself whether or not to have treatment but that temporary factors, such as shock or pain, can completely erode her capacity. This approach certainly seems to be one, the court may take if these circumstances were to occur.

Alternatively, given the patient's referenced vulnerability here it is possible that the doctor may choose to withhold risk disclosure for fear that disclosure would be detrimental to the patient's health. Either way, it is apparent that the court would take a paternalistic approach in the same way as the courts in England and Wales.

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[564] *Sheppard v Swan* [2004] WASCA 215
[565] Ibid [46]
[566] *Re MB (An Adult: Medical Treatment)* [1997] 2 FLR 426

4.8 Summary of case law in Australia

Case Name	Circumstances in which risk disclosure could be withheld.
F v R [1983]	Where a 'person's temperament or emotional state is such that he would be unable to make the information a basis for a rational decision'
Battersby v Tottman [1985]	Where the patient was 'likely to reach hysterically or irrationally and refuse treatment not on rational grounds or as a result of calm deliberation'
Rogers v Whitaker [1992]	'an unusually nervous, disturbed or volatile patient'
Tai v Saxon [1996]	(Nervousness with a history of depression was rejected)
Di Carlo v Dubois [2004]	Where it would prove damaging to the patient's health
Sheppard v Swan [2004]	'significant maternal vulnerability'

4.9 Discussion

A comparative analysis of the development of the therapeutic privilege in the USA and in Canada shows some interesting similarities. In the USA between 1905-1966 and in Canada between 1932-1981, the rationale of withholding information from patients appears to relate to where disclosure would make a patient anxious, alarmed, or apprehensive. This was directly related as to whether the patient would submit to the operation or treatment. Here, it is apparent that clinicians were acting with benevolent paternalism, where 'doctor knows best' prevailed over patient autonomy.

In 1970, *Nishi v Hartwell* was the first case to suggest that information could be withheld where a physical illness could be aggravated by mental factors. This case helped develop the concept that information could be withheld where either physical or psychological harm

could be caused as a result, which by 1992 was demonstrated in the USA and 1984 in Canada. Close in time to *Nishi v Hartwell*, the seminal case of *Canterbury v Spence* had combined both approaches; the earlier theme of where the patient was ill or distraught so as to '*complicate or hinder treatment'* and a more modern theme of where psychological damage or harm could be caused to the patient.

Whilst the former was more explicitly concerned about the clinician's need to treat the patient in the way he saw fit, the latter theme begins to acknowledge the potential harm that may be caused to a patient where disclosure was made. Nevertheless, the end effect is the same that a clinician could withhold information from a patient based on his reasonable assessment of the patient's characteristics. By 1984, Canada had made specific reference to the situation where disclosure might have a detrimental effect on the patient's physical and psychological health. Meanwhile, a more general approach to '*a patient's wellbeing'* was introduced in 1991 in the US and in Canada until judgments in 1987 reverted to the physical and psychological damage caused to the patient.

In Australia, withholding information from a patient does not appear to have been considered until 1983 (and in 1985) where, in contrast to the Canadian courts and the courts in USA, they erred on the side of withholding information where disclosure could compromise a patient's capacity, or where the patient may refuse treatment which was in his best clinical interests. However, during this period the US and Canadian courts had progressed to the point where information could be withheld when disclosure may have a detrimental effect on the patient's physical or psychological wellbeing, this being a more modern and recognisable dictum, and more akin to that which is referred to in *Montgomery.* There is, however, some similarity between the Canadian courts and the Australian court, where a dictum from Canada between 1977-1980 represents a similar approach to Australia in 1985 insofar as the courts aligned withholding information where a patient might refuse treatment.

The USA courts also added a more beneficent paternalistic alternative in 2014 which could be relied on where a patient was '*vulnerable*' or *'fragile'*. The inclusion of this statement is concerning as it suggests that the therapeutic privilege exception might be relied upon in circumstances where the patient may simply be elderly have diminished cognitive function, such as dementia, or where a person has intellectual disability. In these circumstances,

rather than supported decision-making the mere nature of their personal characteristics would be enough to invoke the privilege. In contrast, the specific reference to physical and psychological damage may try to limit the extent to which information can be withheld but also contrasts with the use of '*wellbeing'* which may suggest a wider definition of the privilege. Although the term '*wellbeing'* is loosely defined, the term tends to cover all aspects relating to a person's quality of life which suggests a more nuanced and widely interpretation of the exception.

This section (excluding England and Wales) has considered the dicta of 31 cases across 3 jurisdictions, 27 of which referred to elements of the patient's psychological or physical health, and so justifying withholding information from a patient. These 3 cases referred to clinical decision-making as the reasoning within the judgment, although it is worth noting that one of the cases was the earliest in time (1905). From the 27 cases referred to above, only 4 made specific reference to physical harm.

When comparing the above domestic jurisdictions to that of England and Wales, there seems to be greater inconsistency between judgments in England and Wales which does not appear to reflect the same incremental development. Moreover, in England and Wales, the court in 1997 (*Poynter*) appeared to be more focused on the role of the doctor in a comparable way to Canada nearly 20 years earlier (*Kelly v Hazlett*), reflecting the slower development towards informed consent. That said, the 1988 case of *Smith v Eastern Health and Social Services Board* [1988] shows a similar approach to that in *Pauscher v Iowa Methodist Medical Center* [1987] and *Planned Parenthood of Southeastern Pennsylvania v Casey* [1992] where all the cases recognised that information might be withheld where disclosure would be detrimental to the patient's psychological health or wellbeing.

However, whereas the cases in the USA referred to physical pr psychological health, Smith v Eastern Health and Social Services Board only referred to psychological health. It was not until the Supreme Court judgment in *Montgomery* that the courts recognised the need to include health as a more holistic concept, where withholding information could be permitted if disclosure would be '*detrimental to the patient's health'.*

4.10 The therapeutic privilege exception in Singapore

Consideration of the therapeutic privilege exception in Singapore takes an independent perspective from the other domestic jurisdictions considered in this thesis. The reasoning is that withholding information has rarely been considered by the courts in Singapore and the leading case of *Hii Chii Kok v Ooi Peng Jin Lucien and another*[567] took a 'novel' approach to the exception to informed consent. This is worthy of separate consideration and of direct comparison with *Montgomery* rather than with the other jurisdictions. In the Singapore Court of Appeal (SCA), *Hii Chii Kok* took an expansive interpretation of the therapeutic privilege exception and, in doing so, rejected the narrower and more conservative approach which had become established in other domestic jurisdictions, and which had been adopted in *Montgomery*.

4.10.a Background to the judgment

Prior to *Hii Chii Kok*, *Gunapathy* had applied the standard of care in *Bolam* to decisions regarding diagnosis, treatment and information disclosure, subject to a more restrictive interpretation of *Bolitho*. Therefore, whether a doctor had reached the standard of care in relation to his patient was to be assessed with reference to the practices and opinions of a responsible body of medical practitioners skilled in that particular art and whose opinion can be logically defensible.[568] In *Hii Chii Kok*, the claimant claimed damages for an unnecessary procedure from which he suffered significant post-operative complications. The court held that *Gunapathy* remained applicable to diagnosis and treatment but where information disclosure was concerned, a more patient-centric test was to be applied.[569]

Hii Chii Kok referred to the Review of the Law of Negligence Final Report September 2002, Commonwealth of Australia,[570] which considered three main situations in which the pro-active duty to inform would not arise.[571] In line with other domestic jurisdictions, the patient may waive the need to be informed and, in an emergency, the proactive duty to inform is not cancelled but suspended. The third situation, more commonly referred to as

[567] *Hii Chii Kok* (n99)
[568] Applying the judgment in *Bolitho v City and Hackney Health Authority* [1998] 3 LRC 35
[569] *Khoo v Gunapathy d/o Muniandy* [2003] 1 LRC 239
[570] More commonly known as the IPP Report.
[571] https://treasury.gov.au/sites/default/files/2019-03/R2002-001_Law_Neg_Final.pdf accessed January 05, 2023

the therapeutic privilege exception,[572] is where the medical practitioner reasonably believes that giving information to a patient would cause the patient serious physical or mental harm. The phrase serious physical or mental harm does not include the harm suffered where the person may choose not to undergo the treatment in question.

The Report states that the *'active duty to inform raises difficult questions of policy that the panel has not had time to consider,*[573] which disappointingly suggests that the report on professional negligence has shied away from negotiating the challenging parameters of an important exception to informed consent. In doing so, the report took a similar approach to the common law in both Australia and other domestic jurisdictions by failing to define an exception to informed consent which could severely impinge on the patient's autonomy to decide for themselves whether to accept treatment.

4.10.b The three-stage test

The SCA court introduced a similar approach to the *Montgomery* test and where diagnosis and treatment were concerned, the *Gunapathy (Bolam*) test would still apply. However, where advice and information disclosure were concerned, the Court of Appeal introduced a new three-stage test.

Firstly, it was necessary to consider what information he would have wanted to know from the patient's point of view. The onus appears to be on the patient to retrospectively identify the information he alleged was not provided to him, and to establish why the information would have been both relevant and material. The first part of the test appears to be highly focused on the patient's autonomy; that is, to be provided with the information which he would consider relevant to take a decision regarding his own treatment. At the same time, it appears to impose an unnecessary burden on the lay patient to ascertain with precision the failings of the relevant clinicians.[574]

Although the court indicated that the court should use common sense when considering whether the information provided to the patient is reasonably material,[575] the onus of proof unreasonably requires the patient to recognise that he failed to ask relevant questions.

[572] Ibid at para 3.61 (c)
[573] Ibid at para 3.68
[574] *Al Hamwi* (n263)
[575] Herring and Wall (n134) [143]

Despite this criticism, the doctor is still required to disclose information that would be relevant to the patient's perspective.

Assuming the patient can pass the hurdle outlined above, the court would consider whether the doctor was in possession of the material which is both reasonable and material. If this element is satisfied, then stage 3 considers the justification of withholding the information from the patient, the central tenet of this thesis. Where the doctor had possession of relevant and material information, the onus then falls on the doctor to explain why he chose to withhold the information. Although medical consideration would be relevant to any justification as to why information was withheld, the court indicated that it is not to be judged by adopting the *Bolam* test. Chief Justice Sundaresh Menon opined that if the *Bolam* test were to be applied to a determination of withholding risk disclosure, the court would be tasked with whether the reasonable doctor acted in accordance with a responsible body of medical professionals. In contrast, the court indicated that the appropriate test to apply when determining the justification of withholding information was *'whether this was a sound judgment having regard to the standards of a reasonable and competent doctor'.*[576] In doing so, the court would remain the final arbiter of whether the exception to informed consent has been violated or whether it is lawfully justified.

4.10.c The therapeutic privilege exception

The SCA then moved to consider a 'broader' therapeutic privilege exception.[577] The court opined that whilst the burden is on the doctor to justify non-disclosure, the court were unwilling to restrict situations where non-disclosure might be justified.[578]

The judgment permits the application of the therapeutic privilege exception where:

'the doctor reasonably believes that the very act of giving particular information would cause the patient serious physical or mental harm. We agree that doctors should have a measure of latitude in invoking the therapeutic privilege, and this should extend to cases where although patients have mental capacity, their decision-making capabilities are impaired to an appreciable degree. These will include patients with anxiety disorders (to

[576] *Hii Chii Kok* (n99) [134]
[577] Ibid [152]
[578] Ibid [149]

whom the mere knowledge of a risk may, without more, cause harm) or certain geriatric patients who, as described by the NCCS, may be 'easily frightened out of having even relatively safe treatments that can drastically improve their quality of life', and whose state of mind, intellectual abilities or education may make it impossible or extremely difficult to explain the true reality to them'.[579]

The court were keen to point out that it should not find the doctor negligent unless there are exceptional circumstances, yet the wording of the judgment suggests a wide range of situations where the therapeutic privilege exception could be invoked. In contrast, *Montgomery (at 91)* emphasised that the exception should not be abused to prevent a patient *'who is capable of making a choice from doing so merely because the doctor considers that choice to be contrary to the patient's best interests.'*[580]

The court's focus, rather than whether the doctor invoked the privilege, was whether the patient was *'suffering from such an affliction that he in fact was likely to be harmed by being apprised of the relevant information.'* Furthermore,

'*where the patient's decision making was impaired, the doctor would be entitled to withhold the information having regard to (a) the benefit of the treatment to the patient; (b) the relatively low level of risk presented; and (c) the probability that even with suitable assistance, the patient would likely refuse such treatment owing to some misapprehension of the information stemming from the impairment.*[581]

The decision in *Hii Chii Kok* took a more paternalistic approach to patients, including towards those with intellectual disability, which may be distinguished from our own domestic legislation. Although the binary nature of the MCA may fail to specifically recognise some patients with intellectual disability, the Act's strength lies in the respect for the autonomous agent to determine for themselves whether to accept or refuse medical treatment. Whilst *Hii Chii Kok* is not binding on the UK courts, decisions in other domestic jurisdictions are often persuasive in England and Wales. Therefore, it is relevant to critically evaluate *Hii Chii Kok* from the perspective of the therapeutic privilege exception. Since *Montgomery* was influenced by the common law in Australia, Canada and the US, it is

[579] Ibid [152]
[580] Ibid [153]
[581] Ibid [154]

possible that subsequent decisions may have been influenced by *Hii Chii Kok* and widen the boundaries of the exception in *Montgomery*.

If the decision in *Hii Chii Kok* were to be applied in this jurisdiction, it seems that there could be a significant conflict between the statutory provisions of the MCA and common law. There is no statutory requirement to fully understand the information provided and a requirement to do so is neither reflected in either the standard or the burden of proof in the Act. Moreover, s1(4) of the MCA states that '*a person is not to be treated as unable to make a decision merely because he makes an unwise decision,'* a provision reflected in s3(4) of Singapore's MCA. Section 2(3) of the MCA states that unjustified assumptions should not be made about a person's capacity, yet the judgment in *Hii Chii Kok* appears to precisely do that.

In reference to a person's state of mind, intellectual abilities and education have the potential to rebut the assumption that the person lacks capacity. This approach echoes the criticism made by Mr Justice Jackson in an earlier judgment where he observed that presuming a lack of capacity appeared to be a strategy for dealing with *'unpalatable dilemmas, indecision, avoidance or vacillation'*[582] which seems to set a higher standard for those whose capacity may be in doubt than those whose capacity is beyond doubt.

The therapeutic privilege exception found in *Hii Chii Kok* is contrary to the statutory provisions in both Singapore and in England and Wales. As the judgment appears to allow the exception to be invoked, where a person may make an unwise decision and where an assumption about a person's capacity can be made. Moreover, the court seemed to suggest that the exception should extend to cases where although patients have mental capacity, the decision would be contrary to a preferred clinical decision.

In contrast, in the MCA the patient must fail to satisfy both s2 and s3 before the patient is treated in their best interests. Thus, a patient can only be treated in their best interests where they lack capacity according to the statutory provisions. Yet in Singapore, the healthcare professional can invoke the therapeutic privilege exception if the doctor believes in their clinical judgement that the patient may be frightened out of having treatment. The standard set in *Hii Chii Kok* is far broader than the MCA and the broad approach was

[582] *Montgomery* (n3) [25]

expressly disapproved of in *Montgomery,* where the court specifically rejected the defendant obstetrician's opinion that it was not in the maternal interest for women to have caesarean sections.[583] The Supreme Court opined that it was apparent from the evidence that the obstetrician's decision not to advise Mrs *Montgomery* of a caesarean section was not based on clinical grounds and deprived her of the information she needed to make a free and informed choice.

From a healthcare perspective, the approach in *Hii Chii Kok* appears troubling as it reinforces a paternalistic approach for those with intellectual disability but who have capacity, albeit potentially compromised. Chief Justice Sundaresh Menon specifically refers to those people within this description as those with 'compromised capacity'. That is, those who may make decisions contrary to their best interests having insufficient understanding to fully comprehend the specific consequences. Here, where the doctor reasonably believed that '*serious physical or mental harm'* could be caused by disclosure, information could be withheld. Whilst the doctors would be permitted a '*degree of latitude'* the courts also adopted the approach taken in *Montgomery*,[584] so approving the principle that the therapeutic privilege exception should not be used to prevent a capacitous patient from making their own decision about their medical treatment, simply because the doctor believed that the patient's decision would not be in his best clinical interests.[585]

The SCA delved further into the types of patients where non-disclosure could be justified, describing it as a non-exhaustive list.[586] The court referred to patients who may have impaired decision-making capabilities which would include patients with anxiety disorders. These patients were referred to as where '*the mere knowledge of a risk, without more, might cause harm.'* Other patients would include some geriatric patients who may be *'easily frightened out of having even relatively safe treatments that can drastically improve their*

[583] *Montgomery* (n3) [118]
[584] Ibid
[585] *Smith* (n286) [789]
[586] *Hii Chii Kok* (n99) [149]

quality of life'[587,588] and '*whose state of mind, intellectual abilities or education may make it impossible or extremely difficult to explain the true reality to them.*'[589] As the court set out situations where the healthcare professionals might withhold information from a patient, it seems reasonable that the list of circumstances is non-exhaustive but it is of concern. It may be argued that benevolent paternalism is desirable where patients have anxiety which might be compromised by disclosure, but the judgment also places a wide range of patients into a category where it will be too easy to bypass their autonomy on spurious grounds.

The court in *Hii Chii Kok* opined that clinicians should have some latitude when invoking the therapeutic privilege, which should *'extend to cases where although patients have mental capacity, their decision-making capabilities are impaired to an appreciable degree.'* The judgment specifically states that this could include patients with anxiety disorders. Whether this refers to a more generalised anxiety or a specific diagnosed anxiety disorder in unclear from the judgment, but it is unlikely that a clinical diagnosis would be required before the therapeutic privilege exception is exercised due to the widely defined exception.

If this is correct, then patients who simply appear stressed and anxious, a natural phenomenon whilst experiencing ill health, may be included in a category where information is withheld from patients, denying them the right to act as autonomous agents in their own medical treatment. There is logic in this perspective as anxiety can paralyse a patient's decision-making capacity, although the relationship between anxiety and decision-making remains relatively unexplored.[590]

It thus seems problematic that the law assumes a nexus between anxiety and decision-making where research is still limited. The therapeutic exception may also include people with learning disabilities, while doctors may consider they can justify withholding

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[587] See for example Brazier and Cave (n374) [146] who make a similar point when she questioned whether a surgeon would be justified in withholding the risk of impotence from an elderly patient, who may be frightened out of consenting to treatment which would improve their quality of life

[588] Jacklyn Yek et al., 'Defining reasonable patient standard and preference for shared decision making among patients undergoing anaesthesia in Singapore' (2017) BMC Medical Ethics 18:6, where it was suggested that some patients, such as geriatric patients, would cope better with less information

[589] *Hii Chill Kok* (n99) [152]

[590] Catherine A Hartley and Elizabeth A. Phelps, 'Anxiety and decision-making' (2012) Biol Psychiatry 72(2) 113-118

information from these cohort of patients, even where they have capacity.[591] Rather than supporting autonomy, this form of therapeutic privilege supports the argument that people with learning disabilities suffer from health inequality,[592] where they do not appear to be equal partners in the decision-making process.

In a closely related approach to the SCA, clinical pharmacists in this research indicated that they withheld some information relevant to a patient's informed consent where some patients were so anxious that simply knowing the risk would be sufficient to cause harm. Furthermore, clinical pharmacists have expressed views echoing the SCA that patients can be so frightened about the risks that they can refuse to take vital medication. The judgment refers to where beneficence can outweigh autonomy and whilst critics may consider this approach to be paternalistic and thus undesirable, there is clearly evidence of this practice amongst clinical pharmacists although less so amongst GPs.

Furthermore, risk disclosure information had been withheld or had, if necessary upon occasions, been couched in euphemistic terminology. For example, one pharmacist observed that '*you do not want to keep on visiting the patient and giving them information if it is causing distress.*' Another pharmacist added that patients should in principle be told of the risks of prescribed drugs, although some patients would become increasingly anxious and some wrongly believe they have manifested those side effects. Pharmacists fear the consequences may be that patients would be less likely to try other medication that would be beneficial to their health which underpins autonomy's function in promoting health. Whilst pharmacists may appear to be exercising beneficent decision-making, the inevitable consequences are that patient autonomy is denied and it may be argued that health inequality is retained as the status quo.

However, one of strengths of *Hii Chii Kok* is its attempt to recognise that capacity is not binary and that capacity exists on a spectrum where shared decision-making helps facilitate

[591] It is interesting to note the difference in terminology, as *Hii Chill Kok* refers to situations where non-disclosure would be justified, suggesting a leaning towards the therapeutic privilege exception being more of a doctor's privilege, rather than the approach taken in *Montgomery v Lanarkshire Health Board* which specifically refers to 'exceptions'

[592] Health Inequalities and People with Learning Disabilities in the UK 2011: Implications for actions for commissioners and providers of social care. Evidence into practice report No. 4. Sue Turner, November 2011

capacity; a significant and positive recognition from the SCA.[593] *Hii Chii Kok* took a different approach to *Montgomery* where 'understanding' was concerned. As the court said, it was not the doctor's role to ensure understanding but to ensure that reasonable steps were taken to support understanding. In contrast, *Montgomery* requires that the doctor's advisory role is aimed at ensuring that the patient understood the information.

In the same chosen wording as that of *Montgomery,* the SCA opined that '*bombarding*'[594] the patient with information, described as an *'information dump'*, can leave the patient '*more confused and less able to make a proper decision.'*[595] The balance to be achieved is that the information must be sufficient to equip the patient with the information that he will need to make an informed decision.[596] This would appear to introduce a legal tightrope between imparting the 'correct' amount of information to the patient, without compromising the patient's decision-making capacity.

Whilst the doctor must take reasonable care in imparting information, but there is nothing in the judgment that requires the doctor to ensure that the patient fully comprehends the information given. This statement is caveated by a recognition that simply giving the patient information is pointless unless it is done in such a way that accommodates the patient's ability to understand the information.[597] The judgment creates the risk where people with learning disabilities are concerned, or those that are vulnerable through lack of education or advanced years, where a doctor may consider that achieving understanding would be too challenging.

An easier option for the doctor, which in turn would save valuable clinical time, would be to assume the patient might not achieve the required level of understanding and use this reasoning to justify withholding information.[598] This unfortunate conclusion may reflect

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[593] In this respect the judgment appears to distance itself from the Singapore Mental Capacity Act 2010, which in a similar way to the Mental Capacity Act 2005, considers patients who either have capacity or not.

[594] A similar approach was taken in *Montgomery* (n3) [90]

[595] *Hii Chii Kok* n99 [143]

[596] Supported by s.6(4) Singapore MCA 2010 *'as is reasonably practicable, permit and encourage the person to participate, or to improve his ability to participate, as fully as possible in any act done for him and any decision affecting him'*

[597] This latter point is recognised by Singapore's Medical Council's Ethical Code and Ethical Guidance 2016

[598] As similar opinion was set out in n116

reality, as this research suggests that where an anxious patient or a patient with intellectual disability is concerned, continually reverting to the patient with information may compromise the patient's mental health. In some circumstances, understanding may simply not be achievable.

Although the judgment refers to itself as patient-centric, the judgment suggests a far more paternalistic approach. The mere fact that the court would consider the benefit of the treatment to the patient and the patient's best interests as a justification for relying upon the therapeutic privilege exception confirms a less than patient-centred perspective.[599]

4.11 The standard of care

Expert medical evidence, which may include psychological evidence, would be relevant in determining whether the doctor acted within the scope of the exception, or may have breached his duty of care. However, the assessment remained an objective one for the courts to determine and was not to be governed by the *Bolam* test. Thus, the court must be satisfied that non-disclosure was justified from the doctor's perspective and, if so, then the court must consider whether that decision was in line with that of '*a reasonable and competent doctor.'*

Cave and Milo argue that because medical expertise might be used to justify the therapeutic privilege exception, the professional standard would be applied with the narrow exception of *Bolitho.*[600] However, on careful reading, this does not appear to be as straightforward as Cave and Milo suggest. The court stated that whilst the doctor would need to provide medical evidence to support withholding information, it would be a matter for the court to determine whether he was justified in doing so.[601] The court would consider not only medical practice *but judgment* as well (own emphasis added).

[599] A similar approach is also found in the Civil Law Act s37 (2) (b) which states that where a doctor is of the view that the treatment would be in the best interests of the patient and, disclosure may deter the patient. Whilst this *by itself* (emphasis added) would not be a reasonable justification for not informing the patient of the risks, the statutory provision confirm that this would be a justifiable contributory factor
[600] Emma Cave and Caterina Milo, 'Informing Patients: The Bolam Legacy' (2020) Medical Law International, 20(2) 103–130. It is also worth noting that Cave has argued that therapeutic privilege is unlikely to be either relied on or developed further in legal proceedings. See also n169 [140]
[601] *Hii Chii Kok* (n99) [149]

With the emphasis on patient autonomy, the court must carefully consider whether the need for beneficence overrides the patient's wishes. The significance of the relevance of the patient's wishes suggests that the court's consideration extends beyond the professional standard and that the objective element is equally compelling. Whilst the court appears to be the final arbiter, there is a risk that *Bolam* may seep back into the assessment.

4.12 Conclusion

The SCA in *Hii Chii Kok Kok* sought to define a novel approach to the decision in *Montgomery* and with regard to therapeutic privilege introduces a new broader scope for an exception. This is contrary to a climate in which different jurisdictions have consistently emphasised the need to narrow the boundaries of therapeutic privilege. Rather than supporting patient autonomy, the suggestion on close examination is that it may suppress it. This judgment represents another opportunity to argue that the therapeutic privilege has no value and should be abolished.[602] However, if this were the case then it is unlikely that the GMC would have included the exception in their recent updated guidelines.[603]

Historically, therapeutic privilege lacks clarity and this decision seeks to define clearer boundaries where none existed before. The challenge may be to find a balance between the narrow exception set down in *Montgomery* and the expansive approach in *Hii Chii.* Although at first glance it seems reasonable to conclude that the SCA took a novel, bold and wide interpretation of the therapeutic privilege exception, the exception is not as novel as it may appear. The 3-stage test appears to combine many of the earlier decisions in the USA and Canada, even so far back as '*where clinicians would be given reasonable latitude'.*[604] The

[602] See for example Louise Austin, 'Commentary: *Hii Chii Kok v (1) Ooi Peng Jin London Lucien; (2) National Cancer Centre: Modifying Montgomery'* Medical Law Review, Vol. 27 (2) 339–351. Austin refers to therapeutic privilege not being included in the General Medical Council guidelines, 'Decision making and consent: Working with doctors: Working for Patients' 2020, although the GMC guidelines make clear reference to the notion.

[603] General Medical Council guidelines, 'Decision making and consent: Working with doctors: Working for Patients' 2020 https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf?la=en&hash=BE327A1C584627D12BC51F66E790443F0E0651DA p13, accessed October 25, 2020 para 15 'You should not withhold information a patient needs to make a decision for any other reason, including if someone close to the patient asks you to. In very exceptional circumstances you may feel that sharing information with a patient would cause them serious harm and, if so, it may be appropriate to withhold it. In this context 'serious harm' means more than that the patient might become upset, decide to refuse treatment, or choose an alternative. This is a limited exception and you should seek legal advice if you are considering withholding information from a patient.'

[604] Smith (n244)

notion of withholding information from a patient who may show signs of anxiety was apparent in both jurisdictions in early case law.

Conversely, underpinning a beneficently paternalistic approach is a refreshing degree of honesty where the court recognises there are cohorts of patients for whom the therapeutic privilege exception should be available. Perhaps more significantly, the finding of this research reflects the judgment which suggest a prevalence of paternalistic practice within the healthcare profession.

This chapter has explored the therapeutic privilege exception in the USA, Canada, Australia, and Singapore and has shown that although it has been referred to, it has rarely been relied upon. It is argued throughout this research that simply because the exception to informed consent is rarely used that does not mean there is no role for it. It is apparent that in the USA, Canada and Australia the courts have tried to develop the privilege over the years from a clearly authoritarian perspective to one of more benevolent paternalism, which has been influential on the Supreme Court in *Montgomery.* In contrast, the Court of Appeal in Singapore, whilst recognising that capacity is not binary could render a patient within a situation where the healthcare professional is more likely to withhold information from them. In these situations, paternalism remains at the forefront of medical practice.

Thus far, this thesis has explored how the courts in various domestic jurisdictions have managed the failure of healthcare professionals to disclose and in the circumstances in which information can be withheld. This thesis now transitions from the doctrinal approach to the qualitative research and analyses how two distinct cohorts of healthcare professionals achieve informed consent and the extent to which they have withheld risk disclosure from their patients.

Chapter 5: Methodology

This chapter explores the methodology for this research. Before proceeding to consider the nature of the interviews with clinical pharmacists and general practitioners, the research methods adopted in this project will be outlined. As previously outlined in Chapter 1, grounded theory was considered but rejected, as grounded theory discovers the theory from the data rather than exploring the lived experiences of healthcare professionals. The ethnographic model of research was also rejected as this would have required observing healthcare professionals in practice, which would have been impractical in terms of time efficiency, and it is unknown whether ethics approval could have been obtained. Moreover, it would have been invasive for patients and healthcare professionals alike and it is unlikely that better data could have been attained. Finally, phenomenological research was briefly considered and then rejected, as its focus is on explaining the nature of things based on the way that people experience them rather than drawing out themes from clinical experiences.

A qualitative method rather than a quantitative method was adopted for the following reasons. Whilst quantitative methods can produce large data sets, which may be both reliable and useful, this method had been adopted in the researcher's previous research. Although this method may provide details of how healthcare professionals gain informed consent and whether they withhold information from patients, quantitative research does not answer the question 'why' which this thesis sought to establish. Moreover, a qualitative method is the preferred method to obtain data that reflects the experiences of healthcare professionals and their attitudes.

5.1 Qualitative thematic analysis

Qualitative thematic analysis is a methodology which builds on *'identifying, analyzing, and reporting patterns (themes) within the data'* and as such is regarded as flexible and should be regarded as a method in its own right.[605] Moreover, thematic analysis has been described

[605] Virginia Braun and Victoria Clarke, 'Using Thematic Analysis in Psychology' Qualitative Research in Psychology (2006) 3(2) January 77–101,78-79

by psychologists Virginia Braun and Victoria Clarke as having '*theoretical freedom'*[606] which lends itself to a flexible approach and can provide a '*rich and detailed, yet complex, account of the data.'*[607] It is argued that thematic analysis differs from other analytical methods such as grounded theory, where the objective is to examine the data and then extract the theory from the data. In contrast to grounded theory, thematic analysis in this thesis is used to examine the experiences of two individual cohorts of healthcare professionals which operates within the healthcare system.

Consideration was given to grounded theory as a possible methodology for this thesis but was subsequently rejected, as grounded theory has been described as '*the discovery of theory form data systematically obtained from social research'.*[608] Whilst grounded theory is '*a highly systematic research approach for the collection and analysis of qualitative data*', *its objective is to generate the explanatory theory that helps the understanding of the phenomena.'*[609] Grounded theory was therefore inappropriate for this study which seeks to explore the lived experiences of healthcare professionals and whether they withhold risk disclosure from their patients.

For the research to have credibility, the theoretical framework must be clear and robust. Moreover, the methodology should be sufficiently creative to meet the real-life conditions faced by the study whilst ensuring the methodology meets the information needs of the research.[610] These considerations were particularly relevant where the qualitative research was interrupted by the Covid-19 pandemic and subsequent interviews had to be managed online through software which was relatively new to most participants and in a novel, challenging and stressful environment. Braun and Clarke have produced a six-phase approach to thematic analysis which this thesis will employ in order to produce a rigorous and methodical study rendering analysis that is close to the data and data-driven:

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[606] Ibid 78
[607] Ibid
[608] Barney Glaser and Anselm Strauss, *The Discovery of Grounded Theory* [1967] Aldine Publishing Co., Chicago, 2
[609] Carole W Chenitz and Janice M. Swanson (eds), *From Practice to Grounded Theory Qualitative Research in Nursing* (1986) Addison-Wesley, Menlo Park, California
[610] Imelda T Coyne, 'Sampling in qualitative research. Purposeful and theoretical sampling; merging or clear boundaries?' Journal of Advanced Nursing, 26: 623-630,630

1) Familiarisation with the data, by transcribing the interviews of GPs and pharmacists, reading and rereading the transcripts.
2) Generating the codes, where early identified features are coded and the data is gathered.
3) Identifying the themes which arise and collating the codes into themes.
4) Reviewing the themes, where they are checked against extracts which have been identified and then a thematic map of analysis can be created.
5) Theme definition, including naming, defining and refining them.
6) Producing the report, including the extract selection and analysis.[611]

Where reference to data is made, the data corpus refers to all the data collected for this thesis which will include the semi-structured interviews with GPs and pharmacists. In contrast, the term 'data set' refers to the specific set of data which is being used for a specific analysis. The data item refers to each individual piece of data which has been collected; this would therefore be represented by each individual interview. The term 'data extract' refers a section of the data which has been coded and taken from the data item.[612]

5.2 Qualitative research

The qualitative research adopted in this thesis '*attempts to understand the world from the subjects' point of view, to unfold the meaning of peoples' experiences.'*[613] In this research, where the objective is to understand the healthcare professionals' approach to risk disclosure with patients, the nature of the semi-structured interview was effective in enabling an appropriate degree of flexibility to elicit the lived experience of GPs and clinical pharmacists interactions with their patients. The interactions between healthcare professional and patient have provided data about their understanding of the exceptions to informed consent and whether their practice supports autonomy or whether their practice is more paternalistic in nature.

[611] Ibid [87]
[612] Ibid [79]
[613] Steinar Kvale and Svend Brinkmann, *InterViews* (1996) Thousand Oaks: SAGE Publications

In healthcare qualitative research of this nature, semi-structured interviews are considered the most frequent qualitative data source.[614] This method involves dialogue between the researcher and the participant, which is directed by a flexible set of rules and allowed the researcher to add follow-up questions and additional comments. The semi-structured interview approach allowed the researcher to collect data which explored the participants practice about whether they withhold information from a patient for fear of causing the patient psychological or physical harm. The nature of the interview also enabled the researcher to address probing questions on the reasons why this may be and obtain open ended data as to whether the participants exercised a different practice for those patients with intellectual disability.

Sample size is often discussed amongst researchers,[615] and it has been acknowledged that qualitative samples tend to be quite small because of the intensity of the contact with the participant and the rich data gathered. In this research the sample size is relatively small, consisting of semi-structured interviews with 10 pharmacists and 11 GPs. However, in healthcare research a *'highly meaningful'*[616] project can be achieved with few participants as demonstrated by Chang[617] where semi-structured interviews were conducted with only 10 research participants to understand weight gain in pregnant patients.[618] This research will demonstrate that meaningful data has been achieved with a reasonably small sample size, hampered by the Covid-19 pandemic.

[614] Melissa DeJonckheere and Lisa M Vaughan, 'Semi-structured interviewing in primary care research: a balance of relationship and rigour' (2019) Family Medicine and Community Health 7(2) March
[615] Carmel Bradshaw, Sandra Atkinson and Owen Doody, 'Employing a Qualitative Description Approach in Health Care Research'. Global Qualitative Nursing Research Volume 4: 1-8, 4
[616] DeJonckheere and Vaughan (n614)
[617] Tammi Chang, Mikel llanes, Katherine Gold and Michael Fetters. 'Perspectives about and approaches to weight gain in pregnancy a qualitative of physicians and nurse midwives' (2013) BMC Pregnancy Childbirth 13
[618] See also Caroline Croxson, Helen Ashdown, & F.D. Richard Hobbs, 'GPs' perceptions of workload in England: a qualitative interview study' (2017) Br J Gen Pract, where 10 semi-structed interviews were conducted with prenatal healthcare professionals; Frances Griffiths, Pam Lowe, Felicity Boardman et al., 'Becoming pregnant: Exploring the perspectives of women living with diabetes' (2008) Br J Gen Pract 58:184–90 where 15 semi structured interviews were conducted with diabetes

5.3 Research participants

Research participants are those who are available and willing to be interviewed with specific knowledge about the specific issues.[619] The interviews began in 2019 with the assistance of Research and Development in the Mid-Essex Hospital Services NHS Trust and Central and NW London NHS Trust, which helped identify potential research participants who were GPs. However, their assistance was limited, although their input subsequently enabled 'snowballing', where one research participant would recommend another potential research participant whom the researcher would then approach. Social media, including a group named Primary Care UK, was also contacted as a means of approaching prospective research participants.

Individuals were approached for interview based on two inclusion criteria. Firstly, the participant needed to either be a GP in an NHS setting or a clinical pharmacist. These two separate and distinct cohorts of healthcare professionals were chosen for specific reasons. The researcher wished to explore the extent to which healthcare professionals withheld information from patients where they were concerned that disclosure could cause serious harm. It was also felt that GPs would be more accessible than more specific disciplines, such as surgeons. Since the inclusion criteria also involved patients with intellectual disability, a more general, local community doctor was felt to meet the criteria.

Where GPs treat patients, they are required to take informed consent into account and by working within the community they develop a close relationship with their patients which enables shared decision-making. A community setting offered a cross-section of the population and for the purposes of this research, it was relevant for the healthcare professional to include patients with intellectual disability in their day-to-day practice. The inclusion criteria of clinical pharmacists were based on the premise of the researcher's earlier work involving clinical pharmacists.

Research had explored the degree of awareness among clinical pharmacists of the *Montgomery* judgment and its potential implications for medicines-related consultations.

[619] See also Barbara DiCicco-Bloom and Benjamin Crabtree, 'The qualitative research interview' (2006) Med Educ 40 314–21

Where there was an intersection of people with intellectual disability, medical intervention and the introduction of the AIS, together with the doctrine of informed consent, it was evident that research was needed. Here this thesis has aimed to highlight two specific issues a) the extent to which patients with intellectual disability understand their medication and b) the extent to which clinical pharmacists understood informed consent.[620]

Approximately three years after the seminal Supreme Court decision in *Montgomery*, the results of a small study suggested that pharmacists were not *Montgomery* compliant and their patients may subsequently not have provided informed consent. Moreover, the failure to comply with the landmark judgment meant that there was an increasing risk of pharmacists exposing themselves to potential litigation.[621] This research has explored neither therapeutic privilege nor the inclusion of patients with intellectual disability. However, informed consent and capacitous patients with intellectual disability have remained a focus while early research had already established that wider research was required to establish how this cohort of patients are supported with achieving informed consent.[622] A scoping review concluded a period of research which identified that people with intellectual disability needed accessible and information about their medication in order to satisfy best practice, professional guidelines and the legal standard.[623]

Initially, GPs appeared unwilling to participate for which two specific reasons emerged. Firstly, the pressure of time placed upon GPs by the nature of their employment meant that the only convenient time for them to be interviewed was during their lunchtime. Secondly, most GPs wanted a fee for contributing to the research project which the researcher considered was unethical. The reasoning was that paid participants would be less likely to have a genuine interest in the nature of the research. Secondly, when the Covid-19 pandemic took hold, the interviews moved online and GPs ceased to be willing to contribute to research as they began to focus on virtual patient care and the beginning of the vaccine

[620] See for example Barnett and Carr (n31)
[621] Smith (n11)
[622] Barnett and Carr (n31)
[623] Smith (n11)

rollout. Thus, the Covid-19 pandemic had a significant impact on available research participants.

Despite these observations, there also came a point where 'data saturation' was reached. Data saturation has become accepted as a way to determine the size of data collection in research involving qualitative design,[624] which can be described as the point where no new further insights emerged from the research participants during the data collection stage.[625] Although other research methodologies may dispute the concept of data saturation on the basis that each participant's experience is unique in itself,[626] it is argued that each cohort of research participant are skilled in a similar art. It appears that there is no definitive answer as to what an appropriate sample size should be, but the research design must be capable of being defended and the sample size should be sufficiently adequate to meet the objective of the research.[627]

5.4 Research questions

The research questions are located in Appendix E. Briefly, the questions began with a soft introduction where the research participant was asked to describe the nature of their clinical practice and used as a means of enabling the participants to settle down to the interview. The answer also enabled the researcher to understand the nature of their practice as, for example, not all the GPs saw patients with intellectual disability. All the interviews began with asking about what the research participants understood about informed consent. Where some seemed less clear about what informed consent was, this lack of understanding suggested that their practice may be less patient centred although the researcher took care to ensure no assumptions were drawn. Follow-up questions on informed consent included what steps they took to ensure their patient has provided informed consent and whether or not they advised of all the risks and reasonable alternatives of the treatment. The above question was aimed at determining the extent to which they were *Montgomery* compliant.

[624] Ibid
[625] Coyne (n610)
[626] Ibid
[627] Ibid

The following section of questions covered whether and in what circumstances the research participant had withheld information from a patient where they were concerned that disclosure may cause serious harm and whether they were more likely to withhold information from a patient with an intellectual disability. Follow-up questions included what serious harm might mean to them. These questions were critical to the research to help determine whether there might be justification in retaining the therapeutic privilege exception. Finally, the research participants were asked whether or not they were aware of the existence of the 'therapeutic exception' (introduced by *Montgomery)* before they were invited to add or clarify any of their answers.

5.5 Ethics

Ethical approval for the thesis was initially obtained through Middlesex University (Application No 4233) and then through IRAS (Project no 244536). In order to ensure the integrity of the research, several other ethical considerations came into play. The research participants for this research were asked about their own clinical practice surrounding informed consent and were assured of confidentiality and anonymity to enable them to discuss these issues freely. Most of the research participants were established healthcare professionals, having been in practice for several years and therefore having more confidence to contribute meaningfully to the research.

However, the researcher discovered a correlation where the younger the healthcare professional, the more concerned they were about giving a 'wrong' answer. These research participants were reassured there was no right or wrong answer, simply a discussion of their own clinical experience. Interestingly, there appeared to be an imbalance of power, often reflected in the patient-doctor relationship. But in these circumstances, it manifested itself in the relationship between researcher and the research participant where the participants appeared keen not 'to make errors.' Some research participants were also concerned about professional repercussions if they demonstrated poorer practice and needed to be reassured of their role.

5.6 Confidentiality

Ensuring research participants confidentiality whilst still presenting rich, detailed accounts of experiences, presented a challenge as there was a potential of deductive disclosure.[628] Also known as internal confidentiality, deductive disclosure occurs where individuals can be identified from the research. In this research the participants were healthcare professional who were asked about their clinical practice and their adherence to the law. Someone with knowledge of the healthcare district could theoretically identify either the pharmacist or the GP. With clinical pharmacists, this was more likely because of the specialism within which they practice - for example, oncology - and together with their age, gender and level of seniority, they could in theory be identified. This could be a cause of concern where there was a risk that they may either have breached professional guidelines or the law on informed consent and research participants must be protected from harm.[629] In this context, although any harm caused would be limited there was still a possibility that harm could be caused if it were apparent that an identifying participant was not compliant with either professional guidelines or indeed the law.

Given the nature of the specific research, there was no risk of identifying patient data as the research focused on the healthcare professionals' clinical practice. Hence, the risk of harm was limited and deductive disclosure was unlikely. In some circumstances, changing data to ensure it was unidentifiable can change the original meaning. However, in this context the data related to clinicians' experience of practice.

Breaching confidentiality through deductive discourse was a concern and can create a '*conflict between conveying detailed, accurate accounts of the social world and protecting the identities of the individuals who participated in the research.'*[630] In order to address the pressing issue of confidentiality, a dominant approach was taken. This involves collecting the data, analysing the data and then reporting on the data, whilst still aiming to protect the complete anonymity of each research participants.[631] It was necessary to remove any information that involved research participants, which is referred to as a clean data set.[632]

[628] Karen Kaiser, 'Protecting Respondent Confidentiality in Qualitative Research' Qualitative Health Research 19(11) 1632-1641
[629] Ibid1634.
[630] Ibid1632
[631] Benjamin Baez, 'Confidentiality in qualitative research: Reflections on secrets, power and agency' (2002) Qualitative Research, 2, 35-38
[632] Kaiser (n628) [1635]

Several weaknesses are associated with the dominant approach, all of which will be considered in relation to this research. Firstly, the dominant approach ensures '*external confidentiality',*[633] although this can be a weakness as those who have a close relationship with the respondent may still be able to identify them. However, this was not relevant for the nature of this research as the data reflected the healthcare professionals' own clinical experiences and not those of their patients. Secondly, the burden falls upon the researcher to determine which data could potentially identify a research participant. This latter point was carefully considered when conducting the semi-structured interviews as the participants were asked not to identify which NHS Trust they were employed by as this data would not be relevant for the research.

Each research participant was also asked to take special care not to refer to any of their patients with identifiable information. This process removed any risk of identifying any parties and ensured external confidentiality. This latter point addressed the third perceived weakness of the dominant approach and assumed that all the research participants preferred complete confidentiality. Indeed, this was one of the aspects which may have persuaded pharmacists or GPs to participate as they were informed that any potential identifying data would be anonymised when the audio recordings of the interviews were being transcribed. This point feeds neatly into the fourth potential criticism of a dominant approach. Here, it is argued that where participants have been promised confidentiality, this can hamper the use of data rich material where research participants begin to speak more freely and openly. However, the above issue was not a concern in this research as the participants were simply reflecting and discussing their own experiences of clinical practice. The last perceived weakness of the dominant approach to confidentiality is that any changes in the data can be altered without affecting the meaning of the data. When interviewing participants, this aspect was not relevant. Even if changes in the data were required to protect confidentiality of the participants, the meaning of the data would not be compromised.[634]

[633] Martin Tolich, 'Internal confidentiality: When confidentiality assurances fail relational informants' (2004) Qualitative Sociology, 27, 101-106

[634] Kaiser (n628) [1636]

The conclusion of each interview ensured a positive closure for the participant.[635] Although the research did not deal with any sensitive issues per se, each participant was thanked for their time, assured of anonymity and offered a transcript of the interview. In two cases, a transcript of the interview was sent to the participants, although no comments were made as to the transcript's accuracy or otherwise. It was felt that the participants simply wished to have a copy for completeness and possibly to evidence their own Continuing Professional Development. Hence it was felt that providing the participant with a copy of the transcript was a nice gesture.

5.7 Limitations of the research

One limitation of this methodology lay in the ability to access research participants. Research and Development in local Trusts assisted in locating and identifying GPs within a reasonable distance to travel and interview. One of the main challenges was imposing on already pressed GPs time. However, research and development could only assist to a limited degree and was not as constructive as was hoped. At this point, the Covid-19 pandemic struck and it seemed unreasonable to impose upon GPs who now became unprecedently stretched in their private practice. As lockdown took hold and more GPs were not seeing patients in their busy surgeries, it no longer became possible to arrange to interview GPs in their surgery.

Thereafter, a snowballing method was adopted in the hope to achieve more participants. A GP known to the researcher assisted significantly in snowballing, while GPs not known to me were willing to give their time to be interviewed by Zoom. Further contacts were made through the Primary Care UK Facebook Group, although far less than expected.

Identifying pharmacists was challenging. Research and Development identified some willing participants, while a snowballing approach was also adopted to identify a greater range of willing participants. In common with all the participants was a genuine interest in research which motivated their willingness to contribute and give their time willingly and free of charge. Therefore, it is possible that the data is skewed to the extent that a greater

[635] Laura Dempsey, Maura Dowling, Philip Larkin and Kathy Murphy, 'Sensitive Interviewing in qualitative Research' (2016) Res Nurs Health 39: 480-490

knowledge of and understanding of the law is demonstrated by the participants, as some were aware of the therapeutic privilege exception despite it being rarely relied upon which suggests that the participants were familiar with the GMC guidelines, perhaps adhering to them more than those who did not participate.

It is highly likely that the Covid-19 pandemic played a significant role in the difficulty in enlisting more research participants. It is not known whether their work commitments intensified by either moving online, with the associated learning curve and challenges brought by such a change in working practice, or whether potential research participants were parents of young children and providing emergency education. Indeed, some potential participants could have been struggling with their own challenges of stress and anxiety, which were prevalent throughout 2020 and 2021.

5.8 Conducting qualitative research via Zoom

Conducting qualitative research via Zoom was an unexpected development in the research. It was unforeseeable that face-to-face interview would no longer be possible from March 2020. However, the transition to a virtual world provided an unforeseen and unique opportunity to explore how healthcare clinicians managed consultations online. In particular, the research investigated how informed consent was affected by online or phone consultations and whether clinicians were more likely to withhold information from patients due to a concern that harm could be caused by disclosure. In essence, Covid-19 provided the opportunity to explore the prevalence of the therapeutic privilege exception where healthcare consultations were conducted online.

Careful consideration had been given to how this was to be conducted. The Zoom platform was selected as earlier research had already identified the advantages of using Zoom, such as rapport, convenience, cost effectiveness and user-friendliness.[636] Zoom is a collaborative cloud-based video conferencing service, and was felt to be the most stable, had a secure record function and above all, in the immediacy of Covid, served as an online platform which was the most familiar to both researcher and participants and performed better than

[636] Mandy M. Archibald, Rachel C. Ambagtsheer, Mavourneen G. Casey and Michael Lawless, 'Using Zoom videoconferencing for qualitative data collection: Perceptions and experiences of researchers and participants' (2019) International Journal of Qualitative Methods 18: 1–8,2

Skype.[637] Interestingly, few studies have explored the researcher and participants perspective of the use of a videoconferencing platform as a data collection method,[638] although it has been observed that '(*t)The potential for video conferencing as a research tool is almost unlimited.'*[639]

Interviewing via Zoom was found to be effective and constructive with only limited exceptions. One research participant who was known to me appeared to be watching a cricket match on television in the background and therefore seemed slightly distracted. Although this was far from ideal, if this GP were interviewed in his practice then there is a distinct possibility that he would have been distracted by work commitments. Another participant, a senior clinical pharmacist answered the front doorbell on two occasions and stopped to have a brief conversation with her builder. On face value, this may seem to be discourteous to the researcher and could adversely affect the quality of the data gathered from the interview. The key was to employ patience and to appreciate that it is unlikely that this pharmacist would have agreed to be interviewed if she were working from her clinical practice given her significant level of professional commitment.

Interviews via Zoom did not experience any significant technological challenges, contrary to limited earlier research on conducting qualitative research via this medium.[640] The possible reasoning may be that the afore-mentioned limited research was carried out when the general population's experience of Zoom was far more limited. In addition, by the time the qualitative interviews for this research took place, all the parties were familiar with the technology, and they recognised and, more importantly, accepted that on occasions the internet connections can briefly drop out. Perhaps it is due to the global climate that we are now living in, but speaking by Zoom is almost as intimate as face-to-face and the researcher did not believe that the quality of the data gathered was less rich. On the contrary, it was felt that some participants were, in fact, more open and less restrained than they may have been in a face-to-face interview, more commonly referred to as the 'disinhibition effect'.[641]

[637] Ibid [4]
[638] Ibid
[639] Jessica R. Sullivan, 'Skype: An appropriate method of data collection for qualitative interviews?' The Hilltop Review 6: 54-60,60
[640] Archibald et al (n636)
[641] John Suler, 'The Online Disinhibition Effect' (2004) Cyberpsychol Behav. Jun 7(3) 321-6

Two pharmacists and four GPs made direct reference to consultations which were conducted either by Zoom or by telephone. There is little doubt that some clinicians found online consultations challenging. Participant P07 (the code given to the 7th clinical pharmacist research participant) observed that face-to-face consultations enabled healthcare professionals to focus on the softer skills, such as reading facial expressions or tone which was not possible over the telephone.

Furthermore, they observed that consultations were shorter, which might in turn provide a barrier for obtaining informed consent. This latter point was echoed by G08 (the code given to the 8th GP research participant) who commented that when GPs were engaged on many telephone consultations, it made them feel anxious that they were not able to give patients the opportunity to provide informed consent. Moreover, whilst on Zoom, they were unable to read signs of anxiety which '*impacts the quality of the conversation around informed consent'*. Whilst that did not necessarily mean that the clinician would be more likely to withhold information, it does suggest that the '*general process is going to be impaired'*.

It was accepted by both G09 and G10 that effective communication with patients had altered considerably, which included the *'ability to read non-verbal cues and the ability to demonstrate empathy'* (G08). Given the challenge of interacting with patients, there was a view that the difficulty of gaining informed consent may also increase the chances of clinicians withholding information material to informed consent. It was felt that the lack of face-to-face consultation would affect both the *'giving of choice and the withholding of choice'*, whilst G10 believed that withholding information from a patient was more likely where interviews were conducted via Zoom, particularly with patients with intellectual disability. More generally, in relation to consultations G08 observed that when consulting with patients via Zoom, *'…you can't see that person's hastily crossing their legs and re-crossing their legs because as a sign of their anxiety. It's lesser and it's limited, and I think that must impact …the quality of conversations around informed consent.'*

Clinicians considered that the Covid response '*aggravates health equality'*, which was explained further by G08 who observed that *'a lot of elderly people with cognitive impairment and some learning disability, haven't been able to access Zoom…so I think they've been disadvantaged.'* From a pharmacist's perspective, the traditional model of consulting with older patients, some of whom may have cognitive impairment, was that

healthcare professionals regularly attended the patient's home or the outpatient's clinic. This became the accepted method of care, where the benefits outweighed any potential risk.[642]

Moreover, it has been recognised that people with physical, mental or cognitive challenges may have found the practicalities of online consultations too challenging.[643] This can be attributed to digital inequality, fear of technology and a lack of understanding of how to access technology which has adversely affected their access to healthcare. Furthermore, due to social isolation, patients who would ordinarily attend clinical appointments with family or carers were unable to do so. Those who would take written material away from consultations to discuss with family or friends were also unable to do so. For some patients with intellectual disability and/or cognitive decline, informed consent may have posed a real challenge. It is possible that in these circumstances, clinicians may have more routinely exercised therapeutic exception.

Interviewee G12 would not be drawn on whether he would be more likely to withhold information from a patient where the consultation was conducted online but did not believe that he had ever intentionally withheld information from a patient. He did however acknowledge that the relationship between doctor and patient had become more transactional with the move to online or telephone consultations and that less time was spent communicating with the patient, which he believed had adversely affected gaining informed consent. The most crucial element absent from Zoom/telephone consultations was the lack of physical examination and the ability to read a patient's body language, a trend he believed would continue post-pandemic, as it was economically cost-effective. Hence, G12's experience of conducting consultations via Zoom was not shared by G11, who did not believe that the nature of his consultations had changed.

Doubtlessly, there are advantages to researchers conducting qualitative interviews via Zoom (or another online platform). Prior to Covid, qualitative researchers conducting interviews

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[642] Jayne Agnew, Dula Alicehajic-Becic, Nina Barnett, Paula Crawford, Carmel Darcy, Emyr Jones, Hilary McKee, Karen Miller, Lelly Oboh and Heather Smith, 'Optimising remote consultations for older people during COVID-19' Prescriber, 32: 9-14

[643] NHS England, Clinical guide for the management of virtual working in secondary care during the coronavirus pandemic. March 27, 2020. Version 1. Available from: https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/C0044-Specialty-Guide-Virtual-Working-and-Coronavirus-27-March-20.pdf accessed April 29, 2020

by Skype were said to assist with building relationships and gave researchers greater flexibility and saved costs.[644] Certainly, from this researcher's experience, participants talked freely about their clinical experiences and there seemed to be a greater sense of openness, who all seemed comfortable with using Zoom and relaxing at home. Some of the participants seemed sufficiently relaxed to 'drop' their professionalism by answering the doorbell to deliveries and multitasking by watching the TV in the background. However, despite these obvious distractions, interviewing online provided an opportunity to gather rich data and the nature of the experience, a view which is shared by other researchers as participants felt comfortable in their own space.[645]

Zoom interviews were simultaneously recorded via the software and via a recording device, in the same way as all the other interviews were conducted before Zoom. Although it was not essential to record on two separate devices, it was reassuring for the researcher to know that the recording was secure so that it could be transcribed in the same manner as for all pre-Zoom interviews. This created clarity for the progress of the interviewing and consistency in the method of transcribing. The recordings were sent to a transcriber by 'We Transfer' as it was felt that this was the most secure system, but all the recordings were anonymised and given a code before they were sent. Thereafter, once transcribed, all the recordings were retained in a password-protected file on the researcher's laptop.

This chapter has focused on the methodology adopted by this thesis, the nature of the semi-structured interviews and the unique contribution of interviewing research participants online due to Covid-19. The following chapter proceeds to analyse the data of the research participants involved in this research.

[644] Hannah Deakin and Kelly Wakefield, 'Skype interviewing: reflections of two PhD researchers' (2014) Qualitative Research 14(5) 603–616

[645] See for example, John L Oliffe, Mary T. Kelly, Gabriela Gonzalez Montaner and Wellam F. Yu Ko, 'Zoom Interviews: Benefits and Concessions' (2021) International Journal of Qualitative Methods, Volume 20 1-8,5

Chapter 6: Data Analysis

6.1 Introduction

This chapter will focus on data analysis derived from the qualitative research consisting of in-depth qualitative interviews. Here, 5 interviews were face-to-face with pharmacists whilst 5 were carried out over Zoom once the Covid 19 pandemic took effect. Then, 9 face-to-face interviews were carried out with GPs, with 2 on Zoom due to the pandemic lockdown. Each interview varied between 40-60 minutes in length and all interviews were audio recorded then carefully transcribed, removing all data which may identify the research participant. Not all of the research participants have been referred to as some of their contributions to the data were not significant. The findings cannot be generalised for all pharmacists and GPs, but themes emerged and were identified. The interviewer was careful to assure the participants that they were not being judged, as it was hoped that the research participants would be as open as possible.

The following 5 themes were identified,

1. Dialogue and communication
2. Underlying paternalism
3. Barriers to health equality, patients with intellectual disabilities
4. Use of the therapeutic privilege exception
5. Patient anxiety: is anxiety serious harm?

6.2 Are clinical consultations *Montgomery* compliant?

Before it can be ascertained whether GPs and/or pharmacists exercise the therapeutic privilege exception, it was first necessary to establish the extent to which patient consultations were *Montgomery* compliant. This was relevant as the therapeutic exception flows from the introduction of the duty to provide informed consent set down in *Montgomery*.

To be *Montgomery* compliant, the doctor, and by implication any healthcare professional, must fulfil the duty to take *'reasonable care to ensure that the patient is aware of any*

material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments'.[646] The judgment defines test of materiality in the following way:

'whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.'[647]

It was relevant to establish how much patients understood the information given. This was particularly important where patients with intellectual disability or cognitive impairment were concerned. This specific theme drew directly on the judgment of *Montgomery*, which acknowledges that the doctor's (or pharmacists) role involves dialogue *'the aim of which is to ensure that the patient understands the seriousness of her condition.'*[648] It is axiomatic that if the patient does not understand the nature of their condition, they will be unable to appreciate the risks and alternatives and will not be able to provide informed consent.

When analysing the data, the first step was to ascertain the extent to which the research participants were *Montgomery* compliant and produced data which supported patient centred practice. The theme of dialogue and communication appeared central to the data gathered, which was important not only for establishing compliance with the subjective test but also to the prevalence of the therapeutic privilege exception. Under the same reasoning, the theme of underlying paternalism emerged which fed into the use of the therapeutic privilege exception. One theme in relation to patients with intellectual disability was the apparent barrier to health equality, although not all of the research participants had regular contact with patients with intellectual disability. This was particularly true of GPs, where some surgeries had practices where patients with intellectual disability were assigned to a specific GP. Due to the climate in which part of the qualitative research took place, Zoom emerged as an unexpected but novel element which intensified the researcher's interest and is discussed in more detail in the previous chapter. Primarily, the researcher sought to explore the therapeutic privilege exception, which is discussed below.

[646] *Montgomery* (n3) [76]
[647] Ibid [87]
[648] Ibid [76]

6.3 Dialogue and communication

Compliance with the test of materiality in *Montgomery* was demonstrated by P07, who observed that

'part of our consultations is finding out about their social background…occupation, what they do, their activities….so we look at their lifestyle, because then that dictates what treatment is more tailored to them.'

A similar thoughtful approach was taken by P03, who observed that *'it should be…a balanced conversation with the patient*', despite admitting that a pharmacist's '*agenda is different from the patient's agenda'*. She added that '*you realise what's important to them…so you have to approach it from the patient's point of view'*. Here, the data shows that pharmacists were keen to ensure their consultations satisfied the test of materiality by establishing what was important to their patient, which was replicated in the research with GPs.

Nevertheless, P05 observed that although it was important to inform a patient of the risks and benefits of one treatment over another, there was a risk of *'bombard (ing) them with too much information'*, reflecting the recent decision in *McCullough.* A similar sentiment was also expressed by G01 who saw his role as '*trying to use as patient-friendly language as possible and also, because of their intellectual disability, trying to not use too much jargon that would bamboozle them….and confuse them.'*

This wording is particularly interesting as *Montgomery* uses this exact phrasing. The judgment explains that the doctor's duty is not *'fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form'.*[649] P05's rationale was that *'I'd rather they understand and get the basics and come away confident from the consultation that they have understood the basics'*, but his statement suggests that some information is withheld due to its complexity. It appears there was a more genuine concern about compliance and adherence to treatment grounded in the patient's best interests than the legal duty of care or professional guidelines. It was observed that

[649] *Montgomery* (n3) [90]

'*if we provide the education and explanations around the diagnosis and how medications fit in…. we can obviously make the right interventions and the patients are compliant and adhering to treatment'.*

The impression given here is that the objective of the pharmacist consultations is compliant with what the pharmacist perceives to be in the patient's best interest rather than informed consent.

Yet, the judgment in *Montgomery* specifically states that the doctor's advisory role involves dialogue,

'the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision.'[650]

Where the pharmacist is satisfied that the patient is aware of only the basics, the consultation is unlikely to be sufficient for informed consent. Here G01 observed the importance of shared decision-making, which was a common theme amongst many GP research participants. Equally, most research participants commented that they did not disclose *every* risk, just the most common risk, as there would not be sufficient consultation time to outline all of the risks. G07 expressed this as follows:

'I would generally not be explaining every single possible benefit and risk. I would normally discuss the common things. Unless the rare thing was of such magnitude that it might an impact on their decision-making.'

Here G07 demonstrated a keen awareness of the limitations of consultation time, but also the relevance of disclosing risks important to that particular patient, bringing their consultation closely in line with *Montgomery.*

G08 described the process of obtaining informed consent as the contract between the parties, *'which relies on the autonomy of the patient…moving away from a kind of paternalistic model but, bearing in mind that the person is seeking an opinion or an*

[650] Ibid

intervention', so reflecting the modern approach of decision-making, adopted by the Supreme Court. Moreover, G08 continued by explaining that the person had to consent to

'*whatever path the doctor and patient negotiate between them, and they cannot do that without being fully informed of the consequences of their action, the consequences of not taking those actions, and alternatives.'*

P02 took a slightly difference approach by asking patients what they were expecting from a consultation. In contrasP06, a clinical pharmacist specialising in optimising communication, had a clear and focused understanding that the aim of consultations was to enable patients to

'understand(s) what medicine they've been given why they've been given it, and more importantly, if they chose to receive the medicine from me, that they understand the benefits, risks, the alternatives to that medicine, and actually maybe not having it at all. Which is, of course with pharmacists very unusual, because we rarely consider the 'what if' we don't give you a medicine option.' This laser focus on the nature of the consultation, is not only entirely *Montgomery* complaint but also complies with guidance from the General Pharmaceutical Council.[651]

Pharmacists often rely on the patient information leaflets which are included within the packaging of tablets. However, as P01 commented '*just giving a printed information sheet and saying, 'here you go' is not providing informed consent because you haven't understood'.* PO8 observed that he gives the patient the opportunity to look through the patient information leaflet and then addresses any questions the patient may have. The challenge here is that patients may not always know the questions to ask.[652] He also considered that patient information leaflets were not user-friendly, describing them as *'quite scary'* as they listed '*every side effect that is possible'*. The implication here is that the more one is aware of the risks, the more reticent a patient may be to take the recommended medication.[653] Indeed, the labelling of pharmaceutical products was held up

[651] Pharmacy Regulation: standards for pharmacy professionals https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf accessed February 12, 2023

[652] Ibid 6.4

[653] See for example A Pines, 'Patient information leaflets: friend or foe?' (2015) Climacteric 18(5) Oct 663-5. doi: 10.3109/13697137.2015.1007697. Epub 2015 Feb 10. PMID: 25668438 who observed a range of

as an exemplar in *Montgomery* as a means of informing patients about the nature of the medication but adds that it is reliant upon the user's ability to comprehend that information.[654]

Paradoxically, G04 observed that they would be less likely to give a leaflet to a patient with an intellectual disability in case they could not understand it. Perhaps this suggests that the quality of easy read material is not sufficiently accessible and more work in this area needs to be undertaken. G05 explained that he tended only to advise of the risks of medication if those risks were very high. Interestingly, G11 observed that he did not always advise on antibiotic side effects, as they were 'often negligible' although he recognised that *'maybe I should, but I don't.'* Furthermore, he drew a parallel between pharmacists working in chemists where they refer the customer to the patient information leaflet when dispensing their prescription. It did seem that he was neglecting his duty, just observing the belief that it was a shared responsibility.[655] The extent to which information leaflets engage service users while being comprehensible to them is a much wider issue beyond the scope of this research, but it appears to be particularly challenging.

P11 observed that patients often speak to pharmacists more readily than doctors, seemingly too scared to tell doctors if they are not taking their prescribed medication. Whilst there may not be a tangible fear of sharing information with a doctor, the longer consultations between pharmacists and their patients may naturally lead to a more intimate conversation where the patients feel more comfortable sharing information.[656] G08 observed that *'…. paradoxically, the more that written information has increased, the more people value the ability to just talk to a human being.'* The authenticity of this observation is humbling as patients' experience of contact with healthcare professionals was radically altered during the Covid-19 pandemic.

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practice regarding whether patients engaged with the patient information leaflets and whether prescribers drew their patient's attention to them. It was also noted since many users have electronic access, it was important that the leaflets were user-friendly and easy to understand

[654] *Montgomery* (n3) [76]

[655] For the avoidance of doubt, the reference to pharmacists in this context is to dispensing chemists. These were not part of the research participants cohort which solely concerned clinical pharmacists.

[656] Pharmacists consistently commented that their consultation time with their patients was between 20-30 minutes, approximately double that of a GP consultation, although P10 observed that when they exceed the consultation time it is because they are 'trying to get more out of the patient'

This section discussed the importance of dialogue and communication and draws out the extent to which both GPs and pharmacists recognised the importance and value of communication with their patients. It has shown that understanding what is important to the patient was a valuable starting point, but that disclosure of risks varied considerably. There also appeared to be a consensus that the patient information leaflet was not adequately informing the patient, and that measuring each patient's ability to understand information was central to gain understanding. Although all of the research participants valued dialogue with their patients, only the most relevant quotes are referred to.

6.4 Underlying paternalism

The nature of patient consultations varied and there was some evidence of residual paternalism. Where people with intellectual disability or reduced cognitive function are concerned, P05 observed that *'I didn't want to worry him, I just didn't want to change the situation*'. Some were more overtly paternalistic in their practice for example, P11 admitted that *'you just…don't tell them everything'* and *'in the vast majority of cases, you will actually convince the patient to take the medication'*, before concluding that *'informed consent…it's a good idea but it's very difficult*.'

The data collected gave the impression that the objective of pharmacists working in partnership with patients is to ensure compliance (P05) and adherence, being directly in the patient's best interests. As P07 stated:

'…we need to make sure that patients are in agreement... because there are so many studies to show that if patients are prescribed medications which they're able to take alongside their lifestyle, it helps so much with adherence and compliance.'

The rationale for pharmacists advising their patients of the risks of treatment appeared to be inextricably linked to the notion of what the pharmacist perceived to be in the patient's best interests. This is aptly illustrated by P05 who commented that '*The bottom line is that we try and tell patients what they need to keep them safe.'*

The specific environment of the pharmacist's clinical practice seemed relevant to the nature of the patient consultation and therefore the degree to which informed consent was obtained. One pharmacist working in an acute ward in a hospital setting observed that '*even*

on normal wards… we're very guilty of just prescribing cause that's what the patient needs in this instance.' It seems that the more acute the clinical setting, the less adherence to the duty in *Montgomery* and the requirements of informed consent.

Nevertheless, there was some evidence of residual paternalism in less acute clinical pharmacy practice with one young pharmacist taking pride in acting *'maternalistically'* over her patients (P03). It seemed that paternalism was intrinsically linked to concern about causing stress to their patients, particularly those pharmacists working in the more acute setting. G02 openly admitted that she probably would not advise of the risks where she had a patient with intellectual disability *'…because of their lack of understanding, I would make a decision based on their best interests,'* adding that '*I would imagine that they're more likely to go along with what I feel would be appropriate for their treatment.'* However, G02 appeared to contradict herself, commenting that she would be willing to take a decision based on a patient's best interests and that there may be circumstances where she might want to withhold information to protect the patient's best interests, but '*in almost every situation*, *a patient has a right to know*'. The consensus amongst GPs was less paternalistic with GPs keener to engage with shared decision-making with their patients.

A 'best interests' approach remained amongst clinical pharmacists with P07 commenting that

'*…the ball lies maybe in the healthcare professional…to then provide the care that you think is most appropriate... I think there are probably a cohort of patients where you think that your judgment is probably in their best interests….and in my experience what usually happens is older patients are more receptive to your clinical judgment.'*

Yet, patient-centred care remained at the heart of patient consultations. P02 emphasised the need to '*make sure the patient understands what they are signing up to,'* whilst P08 recognised that the consultation needed to be *'tailored to the patient'* and P10 commented that '*…it's very important that you have a shared decision making with your patient.'*

In this section, there appeared to be a slight divergence between GPs and clinical pharmacists, with clinical pharmacists displaying a greater degree of paternalism than GPs. One explanation for this may be that the clinical pharmacists were working in a hospital setting, often in acute wards, and their patients were part of a transient community. In

these circumstances, patients were often prescribed lifesaving drugs (such as chemotherapy), where it was felt that paternalism was a preferred approach. In contrast, it may be that GPs are often the patient's family doctor for many years and it was important to retain trust.

6.5 Barriers to health equality, patients with intellectual disabilities

Intellectual disability was widely defined. G07 observed that it

'*could include people who've got cognitive impairment because of ageing with dementia processes; it could include younger people with cognitive impairment because of birth trauma or people with drug and alcohol issues… or people generally with low IQ for all sorts of reasons.'*

It is erroneous to consider patients with intellectual disability as a separate cohort of patients as they are an integral and varied part of the general population. G08 observed that

'*learning difficulties, communication disorders, autism spectrum disorders and a cognitive decline in the elderly are all the background to a reasonable percentage of consultations. They're not usually the specific reason for consultations. But like the psychological factors and like general vulnerability and frailty, these are overreaching, meta considerations on top of acute presentations*.'

Moreover, G08 added '*that about 10% of consultations are about mental health, of which depression and anxiety and also generalised low mood are the main categories.'* Simply because a person has an intellectual disability did not mean they were unable to understand their medication and care needs to be taken before making unsubstantiated assumptions. This was well demonstrated by P01 who observed that '*you could have someone who is very academic…but know nothing about their medication at all. You could have someone…with a mild learning disability, who actually know more about their medicine.'* P08 added a similar observation that capacity fluctuates and is sometimes '*a grey area… some people may have capacity for certain things but not for others.'*

P04 demonstrated the above with a clinical example:

'We've got a 16-year-old autistic patient...it depends what type of conversation you're having with her, (as to) how much information she can process and understand. Then

another patient, high functioning but probably functioning at the level of that 16-year-old rather than the 28-year-old. And…if you have a very high IQ, it can kind of protect you from the debilitating effect of any of these kinds of dementia, so although his disease is quite progressed... What he understands and comprehends and can do is quite advanced for an (Oxford scholar) patient.'

In contrast, a more simplistic and perhaps less informed approach was taken by G04 who stated, *'Clearly if they have a learning disability, they're…less likely to understand so I will try and keep away from that.'* Whilst he did not suggest an intellectual disability is an automatic barrier to understanding information concerning medication, he acknowledged that '*bombarding*' patients should be avoided.

Despite these clinical observations, research has demonstrated that people with intellectual disabilities often lacked understanding of their medication, which included the drug's name, the reasons for being prescribed the drug and instructions about when and how to take it. It is apparent that more research needs to be conducted in this area so that patients with intellectual disability become clear partners in the patient-healthcare professional relationship.[657] There was also an issue with noncompliance, with P02 observing that people with intellectual disability '*are quite uncompliant anyway, so if you were to give them…side effects or something, they would probably be the sort not to take it.'* P06 believed that the nature of their consultation would adapt to meet the person's needs by suggesting that she would *'simplify the concepts'* as '*people with mild dementia really struggle with options.'*

G05 considered the elderly with fluctuating capacity to be a grey area. Whilst they may be living independently, they may also be under the learning disability team for support. He called them '*frequent flyers'* and one of the most difficult types of patients who *'cause absolute chaos in the health service.'* The cohort of patients who suffer health inequality is non-exhaustive and those patients with poor education may suffer health inequality in a similar way to the elderly or those with intellectual disability. This is illustrated by P04 who asked '*How do you gain consent and give information the patients understand, when they are illiterate? It takes longer to ensure they've understood.*'

[657] See for example Pinner and Bouman (n78)

A further example was given by G06 who observed that within his practice there was a significant community of travellers unable to read or write. Yet that illiteracy was often equated with an intellectual disability, meaning that adjustments were often required for their access to services. Whilst G05 considered there was '*an over-provision'* for people with intellectual disability who had a tendency to *'neglect their own health'* by a missing appointment, G06 opined that GPs *'should probably be more proactive in preventing'* health inequality. Yet, there remains an imbalance, particularly with people with intellectual disability,

'*…because they're not able to voice, it's taken with a pinch of salt, especially if the person who they're voicing it knows that they've got (intellectual disability), then that prejudice already exists. It's almost as though you listen to them and think…it's not really what I think is best for you but you're saying it.'*

In these circumstances, the person viewed as having an intellectual disability may be regarded as less valid than those without an intellectual disability.

Montgomery observes that with the changes in society brought about by the introduction of the internet, it is no longer correct to assume that patients are uninformed, incapable of understanding medical matters or wholly dependent on healthcare professionals for medical information.[658] This is confirmed by G04 who commented that *'people from the start of the early 2000's, were looking on the internet and they had access to more information'*.

G01 added that patients *'…are just more savvy about things so they're coming to see me with their diagnosis or their assessment'*. Whilst this may be true for some *'expert patient(s)…they will have researched drugs which they have a perception of what is better for them.'* Nevertheless, there is still a significant section of the population for whom this dictum has little relevance. G05 stated that patients rarely came in, but when they did they showed doctors information they had downloaded from the internet, believing this made it easier to practice medicine. One consequence of access to the internet was that GO1

[658] *Montgomery* (n3) [76]

observed that *'we live in a society where everything is immediate'* which meant that patients now expected immediate results from their doctor.

Inequality was a distinct issue. PO7 observed that '*some of our elderly population don't have access to resources or digital platforms, so they have the tendency to very much go with what we suggest'*. G10 referred to the potential of digital inequality with patients with intellectual equality while GO6 observed that one of his patients who is partly illiterate and was anxious *'because she cannot access information…she can't Google it like normal people'.* The use of the term '*like normal people'* is unfortunate as it presupposes normative social behaviour which is often challenged.[659]

GPs appeared confident in their patient-centred skills. G12 explained how it was important *'to be open and transparent'* about informed consent so that *'the consent that one has achieved is genuine'* and G07 described himself as a '*patient-centred doctor'*. G08 identified the process of gaining informed consent as a 'healthcare professional' being *'skilled and trained and competent at least in listening and…passing the information and having that dialogue'*. It cannot be assumed that all doctors possess these skills as G08 observed that from his own experience as a patient, it is not a skill that doctors particularly excel at.

A clinical oncology pharmacist, P04, commented that *'we have to advise them, for just about anything, death is a risk'.* The impression given here is that whilst medication is fundamental to a patient's life, the nature of prescribed drugs is such that any risk could have serious consequences for the patient. A similar view was expressed by P05 who felt that *'…Informing patients about the risks, unless they are really distressed about medicalisation or being in this environment…it's going to cause less harm than...the risk of them getting that side effect*. In contrast, P07 stated that '…*you learn to gauge what you need to say, but still cover the essentials*.'

All the research participants who expressed a view believed that there were barriers to health equality. This extended to the elderly whom, for some, were less proficient at using online resources than others, along with those with intellectual disability, those who were anxious and some patients who were illiterate. These were patients who may be less willing

[659] Barbara Barbosa Neves, Jenny Waycott & Sue Malta, 'Old and afraid of new communication technologies? Reconceptualising and contesting the 'age-based digital divide' (2018) Journal of Sociology 54(2) 236–248

to ask for intervention and who were not able to inform themselves of a possible condition, or who may be blinded by anxiety to read relevant information.

6.6 Use of the therapeutic privilege exception

Thus far, this chapter has explored the nature of clinical consultations of GPs and pharmacists. This is relevant as before it can be established whether clinicians withhold information relevant to informed consent, their adherence to the duty in *Montgomery* must be explored and analysed. The themes which have emerged now feed into this section whereby one can assess the extent to which therapeutic exception is exercised, together with the rationale.

There are two specific questions which are fundamental to the research. The first question to address is whether clinicians withheld information disclosure relevant to informed consent. If the answer is in the affirmative, then the reasons why clinicians withheld information had to be ascertained. Where information was withheld for concern about the patient's physical or psychological harm then the investigations continued. Whether anxiety and stress were recognised by the clinicians as serious harm was crucial to determine in relation to the extent to which the therapeutic privilege exception is exercised within this jurisdiction.

There is some evidence that GPs and pharmacists withheld information beneficently. The balance between disclosing risks to the patient and the desire to protect the patient appears a delicate balance to achieve. For example, G11 observed that whilst he could not recall a time when he had withheld information from a patient, he admitted to *'dress(ing) something up euphemistically….to soften the blow'.* There seemed to be an awareness that '*you've got to be very careful that if you are going to say something which may have an impact on their…health…doctors could be in a position where they say something which could harm somebody'.* In turn, G04 acknowledged withholding information commenting that

'*I know that patients get very worried by side effects. I'm pretty sure that the treatment I'm giving is safe and going to benefit them, and if I tell them all the possible side effects, they may not take it or…they may get very anxious and it would adversely affect their psychological health.'*

Where patients had intellectual disabilities or anxiety, GO6 added that he would be willing to withhold information to prevent psychological harm being caused to a patient. But he would not do so without a follow up appointment, where he has had time to reflect and further review the patient.

PO8 commented that they *'could pick up quite quickly... those patients who are happy for us to do whatever we need to... but just don't want to know too much because it will just cause them anxiety.'* This suggests a direct relationship between providing information about medicines and whether that information would cause anxiety. In contrast, G01 was more measured, commenting that *'I may withhold some of that information in the short term until a point whereby I could get them to come in with a carer, a loved one, a friend, to share some bad news with them in an appropriate setting.'* This sentiment was shared by G02 who explained that *'not telling somebody information…may potentially case them harm by not knowing in'* and continued by explaining that if they had capacity, they would give them the information but might also ask them to return to the surgery a short time later. In doing so, they would not be withholding the information, *'just delaying it.'*

In contrast, some GPs felt their relationship with the patient, whom they may see over a number of years, meant that trust was pivotal to their relationship, and they were more reluctant to withhold information entirely. However, due to the nature of their practice, where they may need to refer the patient to a specialist, they could be more general with their language until there was a more definitive diagnosis (G07). Furthermore, G07 observed that

'if somebody is presenting is a very distressed way and they are upset, then it may not be appropriate to in the context of that situation to tell somebody something right then and there, doesn't mean I'm going to withhold it from them forever, but it might be that I'm choosing my time about when to discuss something.'

Any anxiety caused could, in G10's opinion, be managed. He stated that withholding information is *'not acting in a fair way towards them'* and added that '*if they did feel anxious and worried and distressed...we would be able to provide them with support in the aftermath of that conversation'.* The difficulty here is that it presupposes that the patient will clearly express their feelings to the GP in the limited time they have available in the

consultation and, in turn, the GP will be able to support the patient. Indeed, G12 could not appreciate why anyone would withhold information from a patient saying, *'What's the point?'*

Contrary to the direction and tone of the *Montgomery* judgment and professional guidelines, there was evidence of paternalism whereby a clinician might withhold information for fear the patient would not take medication prescribed to them. For example, P11 observed that *'...if you told them the information and a neurotic type won't take it, then you can be a little bit economical with what happens'*. Whether being *neurotic* or having a nervous disposition was of serious harm to justify withholding information was a fundamental question to address in light of the common law decisions on therapeutic privilege.

When asked whether having a nervous disposition was serious harm, P11 observed that '*potentially it could cause harm to the patient'.* Similarly, P10 stated that if *'I know there is a 0.1% chance of the person…being harmed, maybe I would…try and find a way of withholding it to an extent but not completely'*. Here, it seems that the law and professional guidance is being largely overlooked in favour of clinical assessment. P10 clearly expressed that where there was a risk that advising the patient could make them suicidal, she would look for alternatives.

It appeared to G09 that the notion of serious harm could be quite widely defined, extending beyond *Montgomery* and stated that

'where information might result in self-harm, where it might result in deterioration in their mental health, to a point where their actual function is affected… loss of relationship, loss of job, loss of monetary gain…potential for abuse arising from that….self-abuse or other – arising from sharing that information.'

Thus, although this participant did not necessary condone withholding information, it suggests that where disclosure could compromise a patient's capacity, then serious harm could be caused.

Where people with intellectual disability were concerned, P10 was concerned '*that there's only so much you can talk to them about*' and assumed that a person with an intellectual

disability would not understand their medication. Such a limited view contrasts with P04 who had previously observed that a person with intellectual disability may in fact have an excellent understanding of their medication but may lack capacity in other areas. In turn, G09 recognised that there were situations where a doctor would, in fact, withhold choices of treatment from a patient. He explained that the 'power relationship' between doctor and patient enabled doctors to use the imbalance between the parties to drive decision-making, particularly where the treatment (or service) was not available, or the doctor had already excluded that treatment as inappropriate for that patient.

There was a consensus that disclosing risk of medication could cause the patient '*distress*' and P03 commented that, '*You do not want to keep on visiting the patient and giving them information if it's causing undue distress'* adding this was especially true for a person with an intellectual disability. It was important to establish whether disclosing information made a patient more anxious or stressed as this could lay the foundation for therapeutic privilege. P08 believed that risk disclosure would, to a certain extent, make patients more anxious saying that

'*I do think they should be told the key side effects but… those types of patients would just get even more anxious, and I said some people psychologically think that they have the side effects when they do not so it will just make them more anxious and less likely to want to try different things.'*

Slightly tangentially, G10 commented that from his experience there were occasions where families were keen to keep information from patients, even in situations where there the patient had no impaired cognition. For example, where a patient may be suffering from lung cancer, the family would want the patient to be told they were being treated for a 'lung condition'. The reasoning G10 gave was that the family believed that if their family member were aware of a cancer diagnosis, it would 'ruin their life'. Here G07 shared the perception of a culture expectation that doctors would behave more paternalistically and accepted that, in these circumstances, he may be less forthcoming with information about a patient's condition and treatment.

In these circumstances, G07 observed that where there was a concern about a potential cancer diagnosis and the patient were to be referred to a clinic, it would not be possible to

avoid a conversation about a potential cancer diagnosis. Then G05 shared a similar experience where he did not share his concerns about his patient's cancer diagnosis as he wasn't asked directly and preferred to wait until he had a definitive diagnosis. G07 also observed that if the patient was unduly anxious or had an intellectual disability, then he might phrase his concerns about a cancer diagnosis differently until a possible diagnosis was clearer.

G10 also observed that keeping any information from a patient was entirely contrary to his medical practice and even where there was a patient with a learning difference or intellectual disability, he would always disclose information to the patient saying, '*it's only a question about how we inform them in a language or with any other additional means to support and enhance…their understanding.'* This suggests that information in an accessible format would be a useful tool for G10 to facilitate disclosure of information as his patient is a '*human being and… (a) basic right to know about their health'.* A further point of interest arises, as previously explored in section 3.9 evidence demonstrates that cancer patients want to be told of their diagnosis. Where families are able to influence the doctor that information should be withheld from the patient, this may be entirely contrary to the patient's wishes.

In this section, the data between GPs and pharmacists shows an interesting disparity. Clinical pharmacists recognised that they had withheld information from a patient whereas GPs generally erred on the side of disclosing information. Once again, these perceptions are perhaps reflective of the nature of their practice as GPs had the 'luxury' of being able to slowly disseminate information to a patient and to see them on consecutive occasions. In contrast, clinical pharmacists were managing several patients in busy wards.

6.7 Patient anxiety: is anxiety serious harm?

Importantly, G07 believed that anxiety can amount to serious harm saying that

'If I have generated a significant level of anxiety in that patient, they may not be able to function…They may not be able to go to work. They may not be able to speak to- they may not have anyone else they can talk to…They may not be able to sleep, they may start to catastrophise. So the potential outcomes of anxiety can be catastrophic'

which was more likely *'with a patient with intellectual disability.'*

Advising patients of the risks of their medication was found to induce some anxiety in patients. P08 observed that '*I want them to be aware of the risks…I select the key ones…to that particular drug and I will highlight those*.' P08 continued by explaining that '*you don't want to keep on visiting the patient and distressing them and giving them information if it's causing undue distress…especially with a learning disability patient.*'

It was commonly accepted that whilst GPs try and discuss as many risks as before, it was also *'impossible to cover every avenue, purely because of time constraints and…because certain treatments have hundreds of risks and it's not feasible to go through every single one.'* (G01) GPs tended to advise the patient of the main risks and then refer them to the patient information leaflet, illustrated by G04, who did not consider it to be his *'job to go through a very long list of side effects that may happen with every single drug'* and that *'anxiety is not serious harm.'*

Whether anxiety amounts to serious harm is a separate issue as it goes to the heart of the recognised parameters of the therapeutic privilege exception, both in this and other domestic jurisdictions. Whilst P07 stated they had not withheld information from a patient, they did agree that disclosure of information can cause stress and anxiety. This was confirmed by P06 who said that '*the side effects are contained in the information sheet so are not being hidden from the patient, but the pharmacists may choose not to highlight the risk because it will heighten their anxiety',* which supports the notion that disclosure of risks in medication can cause anxiety. Interestingly, although G04 observed that a capacitous person with a mild intellectual disability would not necessarily be more anxious than a person without an intellectual disability, he did observe that withholding information could adversely affect the patients' trust, a sentiment shared by G07.

Conversely, P06 recognised some people '*are anxious about everything*' and that '*risk disclosure is going to make them terrified to not want to touch treatment at all, so I'd have to couch it in a way that would actually make it acceptable and feel safe for the patient to consider it. Some patients feel that they have enough trouble in their life they do not need side effects as well'.* It seemed that pharmacists needed to balance the potential harm in risk disclosure with the harm of patients not taking prescribed medication. This is illustrated by P06 who questioned whether serious harm from the patient's epilepsy was worse than potential serious harm caused from risk disclosure. P06 reflectively added that disclosure

would only be serious harm if the patient had a pre-existing mental health condition rather than was an anxiety driven condition. Moreover, if a patient were simply nervous, then P06 would not regard risk disclosure as a potential harm. In these circumstances, P06 would use language to optimise understanding without anxiety blocking understanding.

It could be the complexity of medication risk disclosure that leads some pharmacists to couch the language of risk in a way that may be opaque. P05 observed that over-complicating information with additional explanations, procedures or clinical tests simply exacerbates a patient's mental situation. Furthermore, she believed that serious psychological harm could affect physical deterioration. This was an important element to recognise as it drew the link between a patient's poor mental state caused by anxiety and physical harm.

G05 remarked that, with patients with anxiety, he '*may not tell them everything, but ask them want they want to know. And often they don't want to know so they don't ask the question, they don't want to elaborate'.* Here, it seems as if G05 were drawing a direct link between the degree of anxiety and the amount of information to be disclosed.

When asked specifically whether anxiety was serious harm, there was a divergence in opinion. G11 recognised that '*sometimes doctors could be in a situation where they say something which could harm somebody'*, whilst P04 more keenly observed that a patient can be almost paralysed by anxiety, resulting in being unable to attend treatment or to buy food. Here P04 confirmed that serious harm could be caused by disclosure, *'Not only because of the psychological effect it has on the person but when that happens physically.'*

Meanwhile, P03 recognised the difficulty in disclosing risk acknowledging that *'it's a difficult one because anxiety can cause panic attacks, which is serious harm*'. P02 agreed that anxiety could have serious adverse consequences, '*because it tends to dictate a person's thinking'*. However, P02 confirmed they would not withhold risk disclosure but would downplay the information because *'anxiety may withhold them from taking something that could be of benefit to them'*. In contrast, G08 recognised that if anxiety or stress was serious harm, then they would not withhold information from that patient. In comparison, despite measuring disclosure with the degree of anxiety, G05 did not consider that anxiety was serious harm.

G02 carefully considered the level of harm that could be caused and remarked that *'it's a Catch-22 because not telling somebody information…may potentially cause them harm by not knowing it'* but felt on balance that if disclosure could make them seriously unwell then that would amount to serious harm.

It is also possible that there is a nexus between the length of consultations. P02 observed that longer consultations tended to increase patient anxiety: *'it tends to become longer and then they can sometimes ask you more questions which would build their anxiety occasionally'*. Whilst the length of consultation is beneficial for a patient in terms of the partnership that is formed between clinician and patient, longer consultations also provide greater scope for anxiety. P02 continued by explaining that an anxious patient focuses on the negative and whilst anxiety is predominately a mental attribute, it could also become a physical one where anxiety manifested itself in physical symptoms.

Throughout the qualitative research, there was evidence of paternalism whereby a clinician might withhold information out of concern that disclosure might lead a patient not to take the medication prescribed to them. For example, P11 observed that *'...if you told them the information and a neurotic type won't take it, then you can be a little bit economical with what happens'* while another openly admitted their practice took a '*maternalistic'* approach (a phrase used by a female clinical pharmacist to show the distinction). Paternalism is in direct contrast with the tone of the judgment in *Montgomery* where the Lords observed that the recommended model of the doctor-patient relationship working in partnership had moved away from the model based upon medical paternalism.[660]

Moreover, the General Pharmaceutical Council's 'Guidance on Consent' which was updated post-*Montgomery* in July 2018 emphasises the need for a patient's consent and for that patient to be part of the decision-making process. Whilst the pharmacist is not permitted to act in the competent patient's best interest without their consent, the guidance is unclear on the duty which is now imposed on all healthcare professionals.[661] Thus, any attempt by a pharmacist to act in the patient's best interest, no matter however beneficent, without

[660] *Montgomery* (n3) [8]
[661] Pharmacy Regulation: practice guidance on consent https://www.pharmacyregulation.org/sites/default/files/document/in_practice_guidance_on_consent_june_2018.pdf, at p. 11 accessed February 12, 2023

advising the patient of *'any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments*' will breach the duty of care set down in *Montgomery* and the pharmacists' professional guidelines.

P10 was concerned '*that there's only so much you can talk to them about'*. However, this presupposes that a person with an intellectual disability would not understand their medication and applies assumptions which suggest a lack of understanding of patients with intellectual disability. This is well illustrated by P01 who commented that '*you could have someone who is very academic…but knows nothing about their medicines at all. You could have someone with a mild learning disability, who actually know more about their medicines'*. Thus, a person with an intellectual disability may have a good understanding about their medicines but lack capacity in other areas.

P08 agreed that risk disclosure made patients more anxious, saying that,

'*I do think they should be told the key side effects but not a whole list because those types of patients would just get even more anxious…. Some people psychologically think that they have the side effects when they do not so it will just make them more anxious and less likely to want to try different things.'*

P08 added that from experience '*the more I would tell them, the more it will be detrimental to their wellbeing'* and that sometimes patients are so anxiety about the medication they are taking that they stop taking it and non-compliance is injurious to their health.

Whilst P07 had not withheld information from a patient, she agreed that risk disclosure can cause stress and anxiety. In turn, this was confirmed by P06 who observed that side effects are contained in the information sheet and the pharmacist may choose not to highlight the risk because it will heighten their anxiety. However, P06 also recognised that some people are generally anxious and if there were risk disclosure, *'it is going to make them terrified and not want to touch treatment at all, so I'd have to couch it in a way that would actually make it acceptable and feel safe for the patient to consider.'*

Some patients feel that they have enough trouble in their life they do not need side effects as well. G04 referred to framing the conversation in a way which *'glossed over…the side effects and maybe not give them all the detail that I would otherwise have given*'. The

rationale P04 used here was that failure to do so may risk anxiety, which '*would adversely affect their psychological harm.'*

In this section, research participants considered whether anxiety was sufficient to amount to serious harm. The question was relevant as it has been central to the courts in England and Wales, together with the other domestic jurisdictions. Whilst most research participants who commented recognised that anxiety could amount to serious psychological harm and possibly physical harm, their reasoning differed. For some, the longer the consultation, the greater the risk of anxiety which could also be increased by the amount of information disclosed.

6.8 Discussion

Whether pharmacists are *Montgomery* compliant was explored in 2017 when a small-scale quantitative research project was undertaken to determine the extent to which pharmacists were aware of and adhered to the judgment.[662] When asked, 75% of respondent pharmacists had not heard of the *Montgomery* judgment, while 36% felt they were sufficiently familiar about the requirement for informed consent, although 73% were not aware what *'material risk'* was. When questioned specifically about the nature of their consultations, 88% of respondents confirmed that they discussed common and serious side effects with their patients, but a mere 62% recognised that discussing with the patient what was important to them was a part of informed consent.

The evidence demonstrated that pharmacists had little understanding or knowledge of the judgment while over half had not heard of the case, despite the survey being conducted at least 2 years after the Supreme Court judgment of *Montgomery*. On the face of it, it seemed that pharmacists were not obtaining informed consent from their patients. In effect, the duty of care owed to their patients was breached.

The significance of 'material risk' cannot be overstated. *Montgomery* explains that material risk can be

[662] Barnett and Carr (n31)

'understood, within the traditional framework of negligence, as a duty of care to avoid exposing a person to a risk of injury which she would otherwise have avoided, but it is also the counterpart of the patient's entitlement to decide whether or not to incur that risk.'[663]

Thus, where a pharmacist does not advise their patient of the risks involved in the medication and fails to facilitate the patient in deciding for themselves whether they wish to incur that risk, then the pharmacist may be in breach of their duty of care. Moreover, failing to consider what is important to their particular patient means that their focus will be on percentage risk associated with the medication. Where this occurs, it does not necessarily follow that a healthcare professional will be in breach of their duty of care.[664] Materiality of risk remains at the forefront of informed consent. In *Thefault*[665] what amounted to a material risk was both subjective and objective, while the issue of communication remains paramount as the court stated *'(t)The issue is not so much in the means of communication but in its adequacy'* and there needed to be *'adequate time and space'* for a '*sensible dialogue to occur and for free choice to be exercise*d.'[666,667]

The results suggests that some pharmacists still exhibit a paternalistic practice although there were also examples of excellent practice. One reason that may explain why this practice exists is that the pharmacist participants were working within a clinical setting, rather than a community-based setting where their relationship with the patient is more transient. In contrast, the doctor's relationship with the patient is based more on a long-term relationship where building and retaining long term trust is key.

With regards to the issue of *'adequate time*', the length of pharmacists' consultations is far longer than that of GPs.[668] Pharmacists referred to their consultations as being 20-30 minutes in length whilst GP appointments are routinely approximately 10 minutes. One

[663] *Montgomery* (n3) [82]
[664] *Mrs A v East Kent Hospitals University NHS Foundation Trust* [2015] EWHC 1038 (QB)
[665] *Thebault v Johnstone* [2017] EWHC 497 (QB) (14 March 2017)
[666] *Montgomery* (n3) [79]
[667] See also Joanne M. Fuller, Emmelie Barenfeld & Inger Ekman, 'Why do patients struggle with their medicines – A phenomenological hermeneutical study of how patients experience medicines in their everyday lives' PLoS ONE 16(8): e0255478
[668] See Asha R. Kallianpur, 'Medical consensus and informed consent: the patient needs more time' (2003) The Lancet London Dec 13 362(9400):2011 for a surgeon's honest reflection where a young transplant patient needed more time to reflect on possible options, despite transplantation being in his best clinical interests

would therefore expect that pharmacists would have sufficient time to explain any of the risks of treatment with their patient, but the data supports the argument that there is evidence of withholding risk disclosure, together with an increased risk of anxiety the longer the consultation. The data appears to confirm that GPs practices are not as paternalistic as pharmacists and despite shorter consultations than pharmacists, they have sufficient time to explain the risks of treatment to their patients.

Whilst some GP practice differed, most appeared to share a consensus view that they were working together with their patients and were reluctant to withhold information from their patients, but they may delay conversations until results were available or the patient attended with a friend or relative. In contrast to the clinical pharmacist, their practice appeared to be community-focused and -centred, where the relationship with their patients was central to their practice while withholding information was considered to be a breach of trust. The data was highly suggestive that the GPs practice was *Montgomery* compliant, and that GPs were largely unwilling to withhold information from their patients, despite shorter clinic times.[669]

With regards to why clinical pharmacists may withhold information, there is little literature on this specific area which primarily focuses on the model of the community pharmacist, rather than clinical pharmacists. It has been observed that where pharmacists migrated from community pharmacists to pharmaceutical care, they lacked the scope for managing patient autonomy and found themselves in 'over their heads'.[670] Whilst it is widely recognised that pharmacists are professionally obliged to work in partnership with patients so that they are informed about their drug treatment,[671] these principles are now enshrined in law. Blenkinsopp observes that too much information can overwhelm a patient but too little information will be insufficient for informed consent.[672] This complements *Montgomery* which states that the duty is not '*fulfilled by bombarding the patient with*

[669] See Chapter 5
[670] Rest and Narvaez ,'Moral development in the professions' Psychology and Applied Ethics (Lawrence Erlbaum Associates, Hillsdale, NJ)
[671] See for example, David Resnik, Paul Ranelli and Susan Resnik, 'The Conflict Between Ethics and Business in Community Pharmacy: What About Patient Counselling' (2000) Journal of Business Ethics 28(2), 179–186; Jeanette Wick and Guido Zanni, 'Informed Consent: What Every Pharmacist Should Know', Journal of the American Pharmaceutical Association' (2001) 41(4) 523–527.
[672] Alison Blenkinsopp, 2000, *Health Promotion for Pharmacists*, 2nd Edition (Oxford University Press, Oxford)

technical information which she cannot reasonably be expected to grasp.'[673] To provide informed consent the patient must be part of the decision-making process and it is insufficient for the pharmacist to assume that they know what is in the patient's best interests.

Postgraduate training has recognised the difficulty of putting the patient at the heart of the system rather than simply a passive recipient of drug therapy and associated information.[674] This reflects the tone of *Montgomery* which guards against patients being *'passive recipients of the care of the medical profession.'*[675] Recommendations are set out which include the healthcare professional a) adapting their consultation style to suit the individual patient, b) taking into account any factors which may affect the patient's involvement in the consultation, establishing the most effective way of communicating with each patient, c) encouraging patients to ask about their treatment and condition, and d) being aware that their consultation skills can be improved to enhance patient autonomy.[676] Pharmacists are advised how to conduct their patient consultations, but what appears to be missing from professional guidance is the direct mention of informed consent and that failure to obtain informed consent, may well amount to a breach of duty of care.[677]

Where pharmacy practice remains paternalistic, and information is withheld, the therapeutic privilege exception is being exercised. There may be two distinct reasons why this occurs. The first relates to pharmacy training and guidance where there is a lack of clarity of the reasons why pharmacists must act together with their patients. It may also be that the reason is subject to the second; the complex social interaction of a patient's drug-taking.

There is a lack of research into how people experience taking medication in their day-to-day life, but it is a surprisingly complex picture. Despite strategies to improve patient's medicine taking, some patients do not receive the information they need or the appropriate level of

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[673] *Montgomery* (n3) [90]
[674] Cate Whittlesea, 'Clinical Pharmacy and Therapeutics' (2018) Elsevier 31-32
[675] *Montgomery* (n3) [76]
[676] Smith (n11)
[677] Informed choice only appears only in professional pharmacy guidelines and is phrased as follows 'give the person all relevant information in a way they can understand, so they can make informed decisions and choices' – see https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf p8 accessed February 12, 2023

support to take their medicines as directed.[678] One of the few qualitative research studies took a phenomenological hermeneutical approach where two of the themes that emerged are of particular interest: firstly, that medicines were confusing and concerning, and secondly, that they were intrusive and unwelcome.[679] Whilst patients recognise medicines become part of their day-to-day life, and are lifesaving or life enhancing, some always acknowledge a lack of clarity as to why they have been prescribed them.[680] Significantly, some patients expressed concern about the side effect of their medications commenting that they were not sufficiently explained or that there was insufficient time in the consultations for an adequate explanation.

The above research appears to show a lack of patient understanding in their medication. The pharmacists interviewed placed great value in the length and nature of patient consultations. This is well illustrated by P07 who observed

'…we need to make sure that patients are in agreement… because there are so many studies to show that if patients are prescribed medications which they're able to take alongside their lifestyle, if helps so much with adherence and compliance.'

It follows that where the pharmacist works in conjunction with the patient and where the medication fits in with the patient's lifestyle, then the patient is more likely to take the medication, which will benefit the patient's health. One of the challenges appear to relate to trust in the medicine or a more generalised mistrust in medicines,[681] an example of which can be seen with the Covid-19 vaccine.[682]

It is possible that pharmacists are aware of the challenges that patients have, which may account for why pharmacists appear more willing to withhold information relating to the risks. Where pharmacists know what is in their patient's best clinical interests, the desire to

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[678] See Robby Nieuwlaat, Nicky Wilczynski, Tamara Navarro, Nicholas Hobson, Rebecca Jeffrey, Arun, Keepanasseril, et al., 'Interventions for enhancing medication adherence Review' (2014) Cochrane Database of Systematic Reviews 11

[679] Joanne M. Fuller, Emmelie Barenfeld and Inger Ekman, 'Why do patients struggle with their medicines – A phenomenological hermeneutical study of how patients experience medicines in their everyday lives' PLoS ONE 16(8): e0255478

[680] Ibid

[681] Ibid

[682] See for example, John D. Raymond Vergara, Philip Joseph D. Sarmiento, James Darwin and N. Lagman, 'Building public trust: A response to COVID-19 vaccine hesitancy predicament' Journal of Public Health, 43(2) 291–292

eliminate the elements through which patients find a barrier may result in more paternalistic practice. Where this occurs, the pharmacist fails to obtain informed consent. Pharmacists need to develop a relationship with their patients which is patient-centred, where the drugs aim to produce the best possible outcome for the patient, considering what is important to the patient.

A partnership should thus be developed with the patient who needs to be acknowledged as a partner who has valuable lived experiences. These experiences must then feed into the agreed plan about which medication is right for the patient.[683] Such an approach may avoid the situation where a patient is overwhelmed by the demands of the medication or actively resist taking the medication, having balanced the advantages or disadvantages[684] of the drug regime.[685]

Moving from generalised to personalised decision-making, engaging the patient in the process and listening to the patient's concerns will result in a less paternalistic practice. Where the consultation is patient-centric, informed consent will be achieved. In turn, where informed consent is achieved and there is a clearer understanding of the patient's needs, a pharmacist may not feel the need to withhold risk disclosure.

People with intellectual disability experience poorer health outcomes and reduced life expectancy compared to the wider population.[686] Moreover, a person with intellectual disabilities rights are enshrined in the United Nations' Article 12 of the Convention on the Rights of Persons with Disabilities of 2006. They have the right to expect equal recognition before the law and must be considered partners in selecting treatment options. To achieve this, people with learning disabilities need to be informed and empowered to be able to discuss and, where relevant, challenge their treatment with healthcare professionals. Improving health literacy in people with learning disability, supporting them using appropriate and bespoke resources wherever possible may go some way in addressing these

[683] See Marie Brown and Jennifer Bussell, 'Medication Adherence: WHO Cares?' (2011) Mayo Clinic Proceedings. 86(4) 304-14
[684] Pandora Pound, Nicky Britten, Myfawny Morga, Lucy Yardley and Catherine Pope et al., 'Resisting medicines: A synthesis of qualitative studies of medicine taking' Social Science & Medicine 61 133-155. doi:10.1016/j.socscimed.2004.11.063
[685] See also Anne Townsend, Kate Hunt and Sally Wyke, 'Managing multiple morbidity in mid-life: A qualitative study of attitudes to drug use' (2003) BMJ Volume 327 October 11
[686] Carr and Adams (n10)

issues.[687] GPs valued their relationships with their patients and the trust patients had with them.

G04 had observed that they were no more likely to withhold information from a person with a mild learning disability and practised a model of supported decision-making commenting that general practice was rewarding because the patient returns once they trust you and *'if you don't tell them something once, they won't come back and see you again.'*

By empowering patients with learning disability to be equal stakeholders in relation to their medicines and by encouraging dialogue regarding medication, all healthcare professionals may improve therapeutic relationships, facilitating better overall access to healthcare and improving adherence to pharmacological interventions. This in turn may lead to reduced levels of morbidity and mortality.[688] The challenge is complex where patients may have reduced cognitive function or may be verbally impaired.[689] Research has shown that people with intellectual disability are prescribed more medicines than the general population, have poor health literacy and find their own views more difficult to communicate. Furthermore, it is also widely recognised that there is a lack of literature describing lived patient experiences of use of medications[690] although it is recognised that people with intellectual disability were often confused about their medication or unaware of the side effects. In particular, clinical pharmacy consultations need to rise to the challenge to make information accessible and tailor the information to each person's needs, to meet both professional and legal standards.[691]

This chapter has focused on the rich data obtained from the research participants. Having explored the law in England and Wales, together with other domestic jurisdictions and analysed data gathered from the research participants, this next chapter sets out a framework for the therapeutic privilege exception.

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[687] Danielle Adams, Claudia Carr, Daniel Marsden et al., 'An updated on informed consent and the effect on the clinical practice of those working with people with a learning disability' (2018) Learning Disability Practice doi:10.7748/ldp.2018.e.1855
[688] Carr and Adams (n10)
[689] Ibid
[690] Joan MacLeod and Katie MacLure, 'People with intellectual disabilities and their experience of medication: A narrative literature review' (2020) J Appl Res Intellectual Disabil. 33:976-991
[691] Barnett and Carr (n31)

Chapter 7: Conclusion

7.1 Introduction

As a concluding chapter, this discussion fulfils two objectives. Firstly, it addresses the research questions outlined in Chapter 1 and having done so, thereafter sets out a proposed framework for a robust definition of the therapeutic privilege exception. As explained in Chapter 1, to ensure credibility, each element has been clearly set out. In designing the definition, careful consideration has been given to literature, dicta from England and Wales, together with USA, Canada, Australia, and Singapore, outlined in chapter 4 which has enabled a clear appreciation of the strengths and the weakness of the therapeutic privilege exception.

The rich data from the GPs and clinical pharmacists have informed the extent to which information has been held from patients and the circumstances where it has been considered appropriate. The role of patients, including those with intellectual disability has been informative as to the importance of retaining the exception, subject to limitations. Were each element not clearly justified, the definition would lack credibility and transparency and would reflect the dicta in Chapters 3 and 4, where information had been withheld, without any clear explanation of the process of how the decision had been reached. In order to achieve credibility, it is important to explain the rationale and this is supported by relevant dicta from medical and tort law, together with other statutory provisions. For the avoidance of doubt, the role of the dicta and statutory provisions is simply to assert the justification of the definition and has played no other role in the thesis.

The objective of the proposed framework is to provide a credible and transparent definition of the therapeutic privilege exception, which could be relied upon by professional bodies. Adherence to the framework would empower all patients, including those who are vulnerable and those with intellectual disability, to provide informed consent. A draft Code of Practice, to support the definition appears in Appendix A, as a source of reference for healthcare professionals to consult and to provide greater understanding of the applicability of the therapeutic privilege exception.

This chapter revisits some of the challenges of the therapeutic privilege exception and reflects on doctor-patient relationship before setting out a new definition of the therapeutic

privilege exception in 7.2. The sections that follow (7.1-7.8) take the opportunity to explore in detail each element of the definition, which is analysed by relevant case law and statutory provisions. 7.9 introduces the Code of Practice prior to a short section on the novel contribution of this research and where further research is needed.

This chapter revisits some of the challenges of the therapeutic privilege exception and reflects on doctor-patient relationship before setting out a new definition of the therapeutic privilege exception in 7.2. The sections that follow (7.1-7.8) take the opportunity to explore in detail each element of the definition, which is analysed by relevant case law and statutory provisions. Finally, 7.9 introduces the Code of Practice prior to a short section on the novel contribution of this research and where further research is needed.

7.2 Setting boundaries

The relentless challenge lies in the lack of clarification of the parameters of the therapeutic privilege exception, which has been perpetuated in *Montgomery*, as there is no definition of what amounts to information *'detrimental to the patients' health'*.[692] The unresolved issue is that since '*few cases referred to the therapeutic privilege, even fewer applied and none have accepted it as a defence',*[693] it is argued that the infrequent use of the therapeutic privilege exception should not exist.[694]

It is difficult to identify a single reason why there has never been a clear definition of the therapeutic privilege exception in English law, but it is clear the courts have been unwilling to engage. Even before *Montgomery*, successive judgments were quick to recognise a healthcare professional's right to withhold information from a patient even where informed consent had not been formally embedded in the law in the UK. Lord Justice Bridge specifically confirmed there would be no duty to disclose information to the patient if the doctor *'reasonably considered that such disclosure would be medically harmful to the particular patient*',[695] suggesting a path to beneficent paternalism where the doctor can treat the patient according to his clinical interests.

[692] *Montgomery* (n3) [85]
[693] See Cave (n17) Mulheron (n142) and Farrell and Brazier (n184) for a similar perspective
[694] Austin (n24)
[695] *Sidaway* (n8) [800] per Lord Bridge

Post-*Sidaway*, the courts had justified withholding information where disclosure might cause *worry or concern,*[696] although other decisions gave no indication of reasons why the information could be withheld, simply that a doctor was permitted to be '*economical with the truth'*.[697] Even more recently, it was held that information could be withheld from a patient but 'something more than temporary distress'[698] would be needed, although an entirely conflicting approach was seen the same year where the appeal courts held that 'distress' would be sufficient to justify withholding information from a patient. Although the recognition of patient autonomy has been widely lauded, later judgments still acknowledged the need to avoid risk disclosure which might alarm or confuse a patient.[699]

The law in England and Wales has failed to clearly identify the elements needing to be established to set out a workable therapeutic privilege exception. There is a widely held opinion that the therapeutic privilege exception should be disbanded for three main reasons: a) that it offends a patient's autonomy to decide for themselves whether to accept the doctor's recommendations for treatment, b) because it is vague and obfuscated, and c) it is rarely relied upon and therefore not required by English law.

However, as we move into an era that recognises and protects the reasonable patient and rejects the model of doctor centric paternalism, it is no longer acceptable for there to be a *lacuna* in the law, which leaves the law vague and unspecific. Equally, it is foolhardy to suggest that the therapeutic privilege exception should not exist in case it is abused, as this is an argument born of the fear of the risk to patient autonomy. The argument presumes that something permitted would inevitably be abused and therefore should not be permitted. It is often based on the perception of a slippery slope where, if the therapeutic privilege exception were to be retained in the English law, it would therefore invariably result in the return of paternalism.

However, slippery slopes can in fact be 'sticky' slopes, which act to restrict precisely what is feared. The opaquer the definition and the greater the vagueness surrounding the exception, the greater the scope for abuse. Thus, two fundamental questions present

[696] *Thake* (n363)
[697] *McAllister* (n364)
[698] *Deriche* (n368)
[699] *Chester* (n98) [16]

themselves a) whether a therapeutic privilege exception can be rationally defined and b) whether there is a role for the exception in English law.

We have already seen the clear evidence in English law that material risk has been withheld from a patient, even though it was not referred to specifically by the term 'therapeutic privilege exception'. In *Poynter v Hillingdon Health Authority,*[700] the judge Sir Maurice Drake had to consider what the position would have been had the parents asked specific questions about the risks of their baby's brain surgery. He balanced the arguments between advising the parents of the risk, which may have deterred the parents from providing consent, and acting in the baby's best interest and observed that *'it is arguable that they were entitled to withhold that information.*'

Only slightly later, in *Pearce,*[701] where the patient was a pregnant woman, her obstetrician did not advise her of the risk of stillbirth, nor offer her any alternative intervention, preferring '*nature to take its course'.*[702] The baby died in utero and was stillborn. The court held that the risk was too low to be significant, but Lord Woolf also endorsed withholding the material risk from Mrs Pearce as she was distressed and *'(t)The obstetrician was entitled to take account of the effect that disclosure might have on the state of the patient at the particular time, both from the physical point of view and an emotional point of view'.*[703] It is therefore erroneous to argue that the therapeutic privilege exception should not exist as it is rarely relied on, as there is clear evidence of withholding risk disclosure, both in obiter and in dictum.

Since the therapeutic privilege exception is specifically referred to in *Montgomery,* it seems clear that the Supreme Court visualised the doctrine of informed consent with recognised exceptions to the duty to disclose material risk. Moreover, the GMC guidelines updated in 2020 specifically permit the therapeutic privilege exception and state as follows:

'*You should not withhold information from(sic) a patient who (sic) needs to make a decision for any other reason, including if someone close to the patient asks you to. In very exceptional circumstances you may feel that sharing information with a patient*

[700] *Poynter* (n244)
[701] *Pearce* (n7)
[702] Ibid
[703] Ibid

would cause them serious harm and, if so, it may be appropriate to withhold it. In this context 'serious harm' means more than that the patient might become upset, decide to refuse treatment, or choose an alternative. This is a limited exception, and you should seek legal advice if you are considering withholding information from a patient.[704]

Since both common law and professional guidelines recognise the exception to informed consent, it seems there is a role for the exception in UK law. However, it is surprising to note the divergence of the common law from that of professional guidance, where the professional guidance postdates the common law by about 6 years. Once again, there is no explanation as to why this may be. The guidance appears to be drafted wider than the therapeutic privilege exception in *Montgomery,* which permits withholding information from a patient where disclosure could be '*detrimental to the patients' health',* whereas the GMC guidelines refers to *'serious harm'*, something more than mere distress.

It is highly unlikely there is a perfect formula for a therapeutic privilege exception, as although this proposal builds on the novel interpretation of *Hii Chii Kok* it intends to balance the overtly paternalistic approach taken by the courts in Singapore. The proposal aims to measure that approach with the need to respect a patient's autonomy, whilst recognising the challenges faced by those with borderline capacity.

So far, we have seen that dialogue and communication rests at the heart of establishing the relationship between doctor and patient. Effective communication is the key to aiding understanding in both patients with intellectual disability and those without. Simply providing patients with information does not mean the patient has understood the information, but in being tailored to specific needs Easy Read or Accessible Information will benefit supported decision-making in those patients with intellectual disability.

A patient may not wish to be advised of material risks.[705] However, this requires them to have sufficient foresight to anticipate the conversation between the healthcare professional and themselves and so be able to articulate the nature of the information they do not want disclosed. It is suggested that the burden is changed so that the healthcare professional

[704] GMC, 'Guidance on professional standards and ethics for doctors: Decision-making and consent' (2019) DH: London p. 13, para 15
[705] *Montgomery* (n3) [85]

advises the patient that whilst there is a duty to disclose, a patient does have the right not to be told of any risk. Patients are invariably vulnerable and cannot be expected to be aware of the option not to be advised of the risks.

It is worth noting that taking this approach compliments the extensive GMC guidelines which states that

'You should not make assumptions about a) the information a patient might want or need B) the clinical or other factors a patient might consider significant or c) a patient's level of knowledge or understanding of what is proposed.[706]

Not only do the Guidelines reflect the path towards patient autonomy by confirming the need for patients to be advised of information pertinent to informed consent, but they can also be read that a doctor cannot assume the patient wishes to be advised of all material risks.

This proposal does not presume to withhold information; it is simply that patients should be provided with options, including the option not to know. Furthermore, this is evident in *Montgomery* where the court referred to Lord Justice Sedley in *Wyatt* who observed '*that there is something unreal about placing the onus of asking upon a patient who may not know that there is anything to ask about'*.[707] The Supreme Court observed that a patient must be given information, including that which they had not specifically enquired about, '*but it is those who lack such knowledge, and who are in consequence unable to pose such questions and instead express their anxiety in more general terms, who are in the greatest need of information.'*

One of the most compelling reasons for reversing the burden is the inevitable nature of the relationship between doctor and patient, where there is an imbalance of power between the parties which may inhibit the patient from asking questions, together with the time constraints of the consultation.[708] However, there is a subtle distinction between a patient asking questions to fulfil their enquiring mind and one where the patient generates questions fuelled by anxiety. The advantage of imposing a duty to provide information is

[706] GMC, Guidance on Professional Standards and Ethics for Doctors: Decision-making and Consent, (DH: London, 2019) p. 12, para 12
[707] *Montgomery* (n3) [58]
[708] Ibid

that it obviates the need for the patient to ask questions. Conversely, it could be disabling to impart information to a patient with an intellectual disability or to one who is anxious.

Throughout this thesis the term '*therapeutic privilege exception'* has been intentionally used in contrast to the term *'therapeutic exception'* introduced in *Montgomery.* The term '*privilege'* was removed in *Montgomery* due to a perception that the term was paternalistic in nature in an age where paternalism has been rejected. On the face of it, it would seem there is no place for the term 'privilege'. However, this thesis reintroduces the term as a salutary reminder that any clinician's interaction with the patient should fundamentally respect patient autonomy and that, on occasions, there may be grounds to withhold risk disclosure, and to do so remains beneficently paternalistic.

The notion that the therapeutic privilege exception should be disbanded because there is no role for the exception is, on the basis of the results of this research, an error of judgment.[709] To say that every capacitous patient is an autonomous agent fails to acknowledge what lies within the very essence of the test set down in *Montgomery.* Namely, that a duty is imposed on every healthcare professional to consider a reasonable person in this particular patient's position.

Prior to 2015, where a patient alleged that a healthcare professional had failed to advise of the risks, the courts (despite a growing move towards patient-centred care) would have had to consider the skill of the ordinary healthcare professional: the *Bolam* test. The Supreme Court judgment clarified that the clinician must consider a range of issues, including the nature of the risk, the risk it would have on the patient's life if it occurred, and the importance of the benefits of the treatment to the patient. The consideration of these factors is sensitive not only to the facts of the case but to the patient themselves[710] and is not limited to solely medical considerations but also *'circumstances, objectives and values which might lead him from a decision different from a wholly medical man.'*[711]

This part of the dictum also lays the groundwork for the role of the therapeutic privilege exception in clinical treatment, as it provides the clearest indication that risk disclosure can be affected by the characteristics of the patient. The reasoning is that the clinician can rely

[709] See Cave (n17) and Mulheron (n147)
[710] *Montgomery* (n3) [89]
[711] *Sidaway* n6 [885-886]

on these specific characteristics of this '*particular patient'* to identify the need to rely upon the therapeutic privilege exception. To ascertain the identity of the reasonable patient requires further consideration as *Montgomery* failed to identify the nature of the reasonable patient, unlike the expansive interpretation in *Hii Chii Kok v Ooi Peng Jin Lucien and another* heard two years after *Montgomery.* The individuality of humanity is such that every patient is endowed with differences, including intellectual disability, precarious mental health or idiosyncrasies.

For the purposes of this thesis, the focus is on the subjective test which refers to the sensitivity of the patient, considering their attributes and qualities. It follows that it is relevant whether the patient is elderly with some degree of cognitive impairment or the patient has a more generalised intellectual disability. The personal attributes of Mrs. Montgomery were undoubtedly relevant in the *Montgomery* judgment as the Supreme Court referred to her as *'a highly intelligent person'* who was not only a graduate but a specialist in the pharmaceutical industry. Her mother and her sister were medical practitioners, who supported her in her choices.[712]

In the context of the Supreme Court judgment, this background is intended to demonstrate that she understood the progress of her labour, that she was being supported by an informed family and understood the context of the advice given. These were characteristics specific to this 'particular patient', Mrs. Montgomery. Her intelligence, together with the nature of her academic background, was considered by the lower court's judgment in relation to the degree with which she was satisfied with Dr McLellan's care. It is highly unlikely that the lower court considered these characteristics in the context of the therapeutic privilege exception, but reference to the patient's intelligence and education is significant for the following reason:

It is apparent that Mrs Montgomery's intelligence was of some relevance to the court in the context of understanding the information she was told. It therefore follows in the same way that in a capacitous patient intellectual disability, cognitive decline and anxiety would also be relevant in any other given judgment and significant for the exercise of the therapeutic

[712] *Montgomery* (n3) [6]

privilege exception. For example, if Mrs Montgomery was demonstrably a highly anxious patient, it is probable that the lower courts would have made reference to this fact.

How might this characteristic affect the version of events? Whilst this may be highly speculative, it is likely that the events would have unfolded in a similar way. Mrs Montgomery was not advised of the risks of shoulder dystocia as, according to the evidence, the risk of grave problem being caused to the baby was very small.[713] So far, it makes little difference to the amount of information disclosed whether the patient was intelligent or nervous. However, it is possible that a doctor may withhold the fact that she was carrying a larger than normal baby from a woman with anxiety, if they believed that disclosure may adversely affected her anxiety.

The above is further demonstrated by the qualitative research where several of the clinical pharmacists confirmed that they would withhold risk disclose of medication from the patient because of the benefits of the treatment to the patient. This echoes the sentiment within the judgment that the benefit of the treatment is one factor to be considered when assessing whether the risk is material. Whilst this does not give the clinician carte blanche to withhold risk disclosure, the inference is clear that if disclosure were to be detrimental to the patient, then it can be withheld. Although clinical pharmacists did not shy away from admitting they acted paternalistically, they were adamant that risk disclosure of the risks of some medication could deter patients from taking prescribed medications that would clearly benefit their health.

In order for the therapeutic privilege exception to be applied, the landscape has to be clarified. The exception is a defence available to a healthcare professional, where it is alleged that there has been a failure to warn. Unless there is a duty to disclose material facts, the duty to warn cannot be engaged and for the duty to be engaged in the first place, then the patient must have capacity. Thus, at the material time, the patient must have capacity to consent; that is, they must be able to understand, retain, weigh up and communicate their decision. The therapeutic privilege exception is now parasitic on the duty to disclose and where no duty exists, the defence to disclosure cannot survive.

[713] *Montgomery* (n3) [13]

The *Montgomery* judgement explained that it was not necessary for the purposes of the case to consider the scope of the exception of therapeutic privilege. Whilst this is entirely in line with other domestic jurisdictions who have shied away from the challenge, it is unclear why, in such a seminal judgment, the Supreme Court would not take the opportunity to clarify the boundaries of the therapeutic privilege exception when entrenching the exception in law. One obvious reason may be because, on the facts presented to the court, the therapeutic privilege exception was not relevant. Nevertheless, the court could have taken the opportunity, albeit obiter, to provide the clarification which is so clearly needed. It is possible the Supreme Court considered closer analysis of the therapeutic privilege exception would be more relevant where it was specifically relied upon, but since this rarely occurs then any clarity is unlikely to be forthcoming in the foreseeable future. Given the importance of the *Montgomery* judgment, it would not have been overly ambitious for the Supreme Court to have clarified its boundaries, and to some extent, it was remiss of them not to have done so.

In the absence of any clear definition from any court, this thesis takes the opportunity to set out a clear proposal of when the therapeutic privilege exception could be applied. To ensure both clarity and transparency of a proposed definition each element of the proposed definition will be explored.

7.3 Proposed definition of the therapeutic privilege exception

It is proposed that the therapeutic privilege exception should apply where it is reasonably foreseeable that disclosure of material risk would risk serious physical or psychological harm to this particular patient.

The following sections will now examine each of the elements of the proposed definition in turn in order to provide both clarity and transparency.

7.4 It is <u>reasonably foreseeable</u> that disclosure of material risks would risk serious physical or psychological harm to this particular patient

This section will examine the meaning of 'reasonably foreseeable'. To do so, it would be prudent to consider briefly what is meant by the term reasonable foreseeability to provide credence to the proposal. Whilst medical law rarely considers reasonable foreseeability as a contentious issue, foreseeability remains an element of negligence to be established, in the same way as duty, breach and causation. In simple terms, the defendant may argue that the consequences of their negligent action were too remote, in which case causation will fail in law.

A conservative illustration of foreseeability can be seen in *Khan*[714] a judgment which echoed the dictum taken in *South Australia Asset Management Corp v York Montague Ltd.*[715] Here, the Court of Appeal held that a doctor who had negligently failed to identify that a woman was a haemophilia carrier was not liable by the losses incurred by the woman, who subsequently gave birth to a baby suffering from both haemophilia and autism. The doctor was not liable for the losses specifically associated with the baby's autism which were not reasonably foreseeable and did not flow from his negligence.

To ensure clarity, it is recommended that the standard conservative approach to the reasonable foreseeability is taken. *Montgomery* sets out the importance of dialogue and communication, together with a test of materiality so that patients are empowered to provide informed consent. Yet, clinical time is precious and limited, as demonstrated by the qualitative research which shows that whilst clinical pharmacists may spend up to 20 minutes with their patients, GPs spend around half the time, a mere 10 minutes. Within this time, the clinician must assess the patient, find out what is important to the patient and ultimately, treat the patient. It seems that requiring the application of the therapeutic privilege exception to be assessed on a balance of probabilities would be inappropriate for two specific reasons as, firstly it would be too challenging to establish the risk of harm materialising on a balance of probability and secondly, if a balance of probability were to be applied, it would be inconsistent with other areas of medical law where risk is assessed.

[714] *Khan v MNX* [2018] EWCA Civ 2609
[715] *South Australia Asset Management Corp v York Montague Ltd* [1996] UKHL 10

7.5 It is reasonably foreseeable that disclosure of material risk would risk serious physical or psychological harm to this particular patient

In this context, it is proposed that a similar approach to that of the Abortion Act 1967 be adopted. In the said Act, section 1(1)(a) refers to where continuing a pregnancy would involve a risk of injury to the mental or physical health of the mother, yet the risk need not be proven nor even materialise. In a comparable way to the Abortion Act, the assessment of the potential harm caused to a patient by risk disclosure should not need to be proved nor even materialise for the therapeutic privilege exception to be legitimately relied upon.

Under the Abortion Act, the assessment will include consideration of any risk to the woman's physical or mental health as one of the lawful grounds. The identification of where the threshold of risk to the physical or mental health of the woman lies is a matter for the clinical opinion for each of the doctors.[716] Given the purpose of the therapeutic privilege exception is to avoid the potential harm from occurring, it will be a matter of professional opinion whether it is reasonably foreseeable that disclosure of risk would cause either physical or psychological harm. In a similar way to the Abortion Act, two healthcare professionals would attest to the risk of serious physical or psychological harm.

The issue here is to consider what *degree* of risk must be intrinsically linked to the potential harm for the therapeutic privilege exception to be legitimately relied upon. Without an established degree of risk, the boundaries of the therapeutic privilege exception cannot be defined and, where this occurs there is a risk that the exception could *'devour the rule itself.'*[717] It follows that where the risk is only minimal, the less likely it is that the therapeutic privilege exception would be relied upon. Thus, the greater the risk to the patient physical or psychological health, the greater the possibility of withholding risk disclosure.

Insights into this research will emulate the approach taken in relation to abortion law to establish the *degree* of risk to be established before the therapeutic privilege exception can be relied on. The Abortion Act states that for an abortion to be lawful under section 1(1)(a),

[716] 'Guidance in Relation to Requirements of the Abortion Act 1967 for all those responsible for commissioning, providing and managing service provision' Sexual Health Policy Team, Public Health Directorate 10250, May 2014,13
[717] *Canterbury* (n19)

'*the continuation of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman…'*. Under section 1(2), the doctor is directed that *'account may be taken of the pregnant woman's actual or reasonably foreseeable environment.'* Thus, it appears that the doctor requires some level of medical skill to assess whether the patient continuing the pregnancy would involve greater risk than if the pregnancy continued. However, it seems axiomatic that there is a greater risk to a woman's physical or mental health in remaining pregnant and progressing through to labour and childbirth in circumstances where she has requested an abortion.[718]

Similarly, but perhaps more pointedly, the Human and Fertilisation Embryology Act 2008 Schedule 2, section 3, 1ZA (b) states that '*A licence under para 1 can authorise the testing of an embryo where there is a particular risk (own emphasis) that the embryo may have any gene, chromosomal or mitochondrion abnormality.'* The explanatory notes explain that a particular risk might be evidenced by a family history of the disease, while suggesting that a higher degree of risk is required than when considering a potential abortion.

Thus, where embryo screening is concerned, a '*particular risk'* is required in contrast with a more straightforward *'risk'* under the Abortion Act. Furthermore, section 3(2) states that

'A licence under paragraph 1 cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied— (a)in relation to the abnormality of which there is a particular risk, and (b)in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b),that there is a significant risk (own emphasis added) that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.'

Thus, there is statutory evidence of differing standards of risk within medical law. However, it is unlikely that the *degree* of risk reflects the acute nature of the risk. If this were the case, then it would be likely that under the grounds for abortion, a *'significant risk'* might be required, given the nature of the potential termination of a foetus. The reasoning may be that if the standard of risk were too high (*particular* or *significant*), then the objective of the

[718] See also Jackson (n115)

legislation would be thwarted. The Abortion Act was introduction in the 1960's during a period of social emancipation to prevent illegal and unsafe abortions which often resulted in maternal morbidity or mortality. Hence, if specific wording of the provisions required a higher standard of risk, then this objective may not have been fulfilled.

Bearing in mind the above observations, what degree of risk should be applied to the therapeutic privilege exception? It is accepted that an assessment of this nature is highly speculative as the risk need not materialise for a healthcare professional to consider withholding risk disclosure. To demand otherwise would be illogical as the objective of the therapeutic privilege exception is to *prevent* harm being caused to the patient and if the harm needs to be evidenced, then harm would have occurred. In these circumstances, the fundamental principle of '*do no harm'* would have been violated. To require a significant or particular risk then seems unnecessary as the harm to be prevented is damage to the patient's psychological or physical harm, which may be regarded by some as less harmful than termination of a pregnancy or unrestricted embryo screening. Certainly, the consequences of embryo screening without having to establish a *significant* risk could lead to eugenics, a most undesirable outcome. In conclusion, it is sufficient that a mere *risk* would be an adequate level of risk.

It is acknowledged that the use of term 'risk', as opposed to 'particular' or 'significant', largely retains the status quo of the therapeutic privilege exception. Dicta from England and Wales and the other domestic jurisdictions considered in Chapters 2, 3 and 4 demonstrate withholding information in circumstances where there is a 'risk' of harm. Indeed, no judgments from any jurisdiction show an attempt to establish a higher degree of 'risk' before withholding information, as there is potential for the patient to be harmed which conflicts with the ethical principle of 'do no harm'. However, this thesis has the benefit of rich data gathered from the research participants which has addressed the 3rd research question and which demonstrated that information is often withheld.

Given the doctor (or other healthcare professional) would make that assessment, it is acknowledged that it remains challenging to move entirely away from benevolent paternalism but, as explained above, it would lack logic to raise the risk of harm occurring before withholding information.

That said, whilst the status quo may be retained, the recommendation for improved communication between doctor (or healthcare professional) and patient referred to in *Montgomery* may reduce the risk of benevolent paternalism. Furthermore, a need for wider access to accessible information was also apparent in the qualitative research, together with a focus on improved communication skills, particularly where clinical pharmacists are concerned.

It is unlikely that the risk of benevolent paternalism can be removed entirely, but a framework supported by a Code of Practice may help reduce the risk of benevolent paternalism.

7.6 It is reasonably foreseeable that disclosure of material risk would risk serious physical or psychological harm to this particular patient

The risk of physical or psychological harm must be a more significant risk than that of withholding material risk. The importance lies in the principle that the therapeutic privilege exception should not be abused. It is a salutary reminder that the exception should not be used to override the principle that the capacitous patient is an autonomous patient whom, once informed, can provide consent or otherwise, even where that decision may not be in their best interests.

Montgomery refers to the risk of disclosure being *seriously detrimental to a patient's health,*[719] and a similar sentiment expressed by Lord Scarman who opined that *'(e)Even if the risk be material, the doctor will not be liable if upon a reasonable assessment of his patient's condition he takes the view that a warning would be detrimental to his patient's health*.'[720] Similarly, it was stated that *'(t)The doctor could however avoid liability for injury resulting from the occurrence of an undisclosed risk if she could show that she reasonably believed that communication to the patient of the existence of the risk would be detrimental to the health (including the mental health) of her patient'.*[721] This suggests that the term '*detrimental to a patient's health*' is the preferred term, although this apparent clarity was

[719] *Montgomery* (n3) [88]
[720] *Montgomery* (n3) [48]
[721] *Montgomery* (n3) [49]

slightly skewed in *Sidaway* by the specific clarification that health includes mental health, as an aspect that should be taken for granted.

Whether the term *'detrimental to the health'* or '*serious physical or psychological harm'* is preferred in the context of withholding risk disclosure is debatable. The World Health Organisation defines 'health' as '*a state of physical and mental wellbeing, not necessarily an absence of disease or infirmity'.* Wellbeing is subjective and multi-faceted with no overarching definition although social, psychological, and emotional are recognised as elements within a 3-factor model.[722] Within this model, autonomy, personal growth, and personal effect all exist amongst other elements in subsets and have been referred to directly by the Canadian courts (see chapter 4.5). Although being beyond the scope of this research, this may seem to suggest a conflict where the therapeutic privilege exception may be invoked where a person's autonomy may be interfered with in order to protect their personal growth or emotional wellbeing. If this occurs, then elements of wellbeing such as autonomy and personal effect are subjected to tectonic forces, defeating the very purpose of the term 'wellbeing'.

7.7 Which terminology is preferred?

Somewhat contentiously this thesis rejects the current wording of *Montgomery*, where risk disclosure can be withheld where it may be *'seriously detrimental to the patient's health'*. When considering the circumstances when the therapeutic privilege exception can apply, the preferred approach recommended by this research is where '*serious physical and psychological harm'* may be caused, to ensure both clarity and transparency. In this regard the dictum in the 2014 USA case *Stuart v Camnitz*[723] is adopted*,* wherein it stated that

'(*t)Therapeutic privilege, however, permits physicians to decline or at least wait to convey relevant information as part of informed consent because in their professional judgment delivering the information to the patient at a particular time would result in serious psychological or physical harm... It is an important privilege, albeit a limited*

[722] Christine Robitschek and Corey L. M. Keyes, 'Keyes's model of mental health with personal growth initiative as a parsimonious predictor' (2009) Journal of Counseling Psychology 56(2) 321–329
[723] ACOG, Comm. Op. 439 (n526) and Stuart v Camnitz, a highly controversial case where interested parties challenged a North Carolina statute that requires physicians to conduct an ultrasound, show the pregnant woman the sonogram, and then describe the fetus to the women who is seeking an abortion.

one to be used sparingly. It protects the health of particularly vulnerable or fragile patients and permits the physician to uphold his ethical obligations of benevolence.'

Decided only a year before *Montgomery*, the USA judgment arguably provided greater insight of how the therapeutic privilege exception could be defined than in the Supreme Court. The following reasons justify why the reasoning in *Stuart v Camnitz* is relied upon:

Firstly, the judgment suggests either withholding risk disclosure or waiting to convey important information to the patient. This point sits comfortably with the results of interviews from some GPs who indicated that rather than withholding information altogether, they might choose to wait until a slightly later appointment to allow the patient to slowly adjust to their medical condition before imparting additional information. Secondly, the court referred to the healthcare professional's judgment where disclosure might cause physical or psychological harm. This is a preferred term as it suggests that additional care is required for healthcare professionals when withholding information in order to ensure that one of both types of harm may be caused.

Thirdly, the court emphasised that the exception was to be used sparingly; an important addition to emphasise that the therapeutic privilege exception should only be used in limited circumstances, failing which the rule could *'devour itself'*. It is also a pertinent reminder that where possible, the healthcare professional must focus on the patient's potential to act autonomously.

Fourthly, the judgment refers to protecting *'the health of particularly vulnerable or fragile patients.'* Whether this specificality of the nature of patients is desirable is questionable. Whilst it serves to highlight the characteristics of patients where the therapeutic privilege may apply, it may conversely disempower patients who are vulnerable or fragile but are still capable of reaching decisions regarding their own treatment by an assumption that their capacity will be compromised by risk disclosure.

Although the judgment in *Rogers v Whitaker* was largely adopted by *Montgomery*, the Supreme Court were selective and did not include the descriptive nature of patients where the therapeutic privilege exception is applied. The framework distinguishes this approach as it rejects specifying particular groups of patients. *Rogers v Whitaker* referred to specific categories of patients and where there was *'a particular danger that the provision of all*

relevant information will harm an unusually disturbed or volatile patient',[724] then the therapeutic privilege exception could be applied. This contrasts with the earlier case of *Chappel v Hart* where the emphasis was on patients who are *'inquisitive, persistent and anxious.'*[725]

Similarly, the wording in *Cook v Rothstein* in the Canadian courts states that the therapeutic privilege exception could be relied on *'where the physician reasonably believes that a complete and candid disclosure of possible consequences might have a detrimental effect on the physical or psychological wellbeing of the patient'.* Whilst this lacks the additional observation of fragile or vulnerable patients, there would be little doubt in the clinicians' mind to who this exception applies.

Stuart v Camnitz bears some resemblance to the position taken in the Singapore Court of Appeal in *Hii Chii Kok v Ooi Peng Jin Lucien,*[726] although the court took a far broader view. The test in *Hii Chii Kok* risks undermining patient autonomy, hence the recommendation of this research departs from the judgment. Where a person satisfies the legal criteria for capacity, they may fail to satisfy the test under one of the many common law options set out in the judgment. This presents two conflicting standards of care, one set by the executive and one set by the judiciary. Where the rationale of statutory provisions is to offer protection for the patient, a doctor's assessment would appear to be on an equal footing. But this must be incorrect as the statutory provisions must not be displaced by a doctor's clinical judgment. In this situation, those with intellectual disabilities are being treated simply *because* of their disability. Their disability is taken as prima facie evidence of a lack of capacity, without an assessment of the disabled person's capacity.

Furthermore, this approach is contrary to the Singapore Mental Capacity Act 2008, as amended in 2020, which is drafted in similar terms to the Mental Capacity Act 2005 and states that incapacity cannot be established merely by reference to a condition of the person, which might lead others to make unjustified assumptions about the person's capacity.[727] Moreover, the dictum by the Singapore Supreme Court may also be contrary to

[724] *Rogers* (n166) [490]
[725] *Chappel v Hart (1998) 295 CLR 232*
[726] *Hii Chii Kok* (n99) [152]
[727] Mental Capacity Act 2008 as amended 2020, section 4(3)(b)

the Convention on the Rights of Persons with Disabilities, (CRPD), Article 25 (3) which requires '*health professionals to provide care of the same quality to persons with disabilities as to others, including on the basis of free and informed consent.*'[728]

The decision in *Hii Chii Wok* may contravene the CRPD as the same quality of care may not be afforded to patients with disability compared to patients without disabilities. The *nature* of the care may be the same for patients with disabilities and those without, but even this small assumption can be cast into doubt. Media reports of a woman with Down's Syndrome being denied a hospital transfer to the ITU during Covid, supports the argument that patients with intellectual disability can experience a lower standard of care, simply because of the disability.[729] Where the person with a disability is not supported to provide informed consent, the same quality of care is not given to the patient, as they have been deprived of the opportunity to weigh up the recommended treatment and consider whether they wish to adopt the healthcare professional's recommendation.

This section has explored the therapeutic privilege exception and how it has developed in other domestic jurisdictions with reference to the nature of the patient's characteristics. If the characteristics of a patient were specifically defined within this jurisdiction, it might give the impression of a broader definition of the therapeutic privilege exception. It may also unintentionally exclude a relevant characteristic, which may transpire to be relevant on the facts of that particular case. However, the reality is such that even if specific characteristics were not overtly stated, then a healthcare professional would have little difficulty in recognising that patients of this nature *may*, but not necessarily be, of a nature where information may be withheld.

7.8 It is reasonably foreseeable that disclosure of material risks would risk serious physical or psychological harm to this particular patient

Here, consideration must be given to the required threshold to satisfy *'serious'* psychological harm to justify the therapeutic privilege exception being relied upon. To do so, it is helpful

[728] https://www.un.org/development/desa/disabilities/convention-on-the-rights-of-persons-with-disabilities/article-25-health.html accessed November 16, 2022
[729] https://www.theguardian.com/society/2022/jul/10/they-gave-her-a-bed-to-die-in-family-of-woman-with-downs-syndrome-denied-intensive-care-seek-answers-from-covid-19-inquiry?CMP=share_btn_tw accessed July 11, 2022

to consider claims of psychiatric injury within negligence and thereafter question the synergy between the tort relating to psychiatric injury and the exception to information disclosure in order to ascertain whether any parallels can be drawn.

As far back as 1861, the courts observed that '*(m)Mental pain or anxiety the law cannot value'*[730] and although the law now recognises that psychiatric harm can exist separately from physical harm to enable a claimant to recover damages for pure psychiatric harm, provided it is a '*recognisable psychiatric illness,'*[731] the law has not significantly developed. As Lord Steyn observed, '*the law cannot compensate for all emotional suffering even if it is acute and truly debilitating'*[732] and subsequent decisions have confirmed that it is not possible to recover damages for mere grief, anxiety or distress.[733] Lord Bridge expressed the test as follows:

'Anxiety and depression are normal human emotions. Yet an anxiety neurosis or reactive depression may be recognisable psychiatric illnesses, with or without psychosomatic symptoms. So the first hurdle which a plaintiff claiming damages of the kind in question must surmount is to establish that he is suffering, not merely grief distress or other normal emotion, but a positive psychiatric illness.'[734]

Whilst this thesis is not concerned with recovery of damages, private (civil) law has made it clear that it does not recognise anxiety or distress as more than *'mere emotions'*. Although injury must be more than *de minimis*, should the same standard be applied to the therapeutic privilege exception, thereby restricting use of the exception to *'serious psychiatric harm'* where serious amounts to a recognisable psychiatric disorder? Even if the answer were to be positive then inconsistency within the law remains, as Mr Justice Comyn has observed that *'no absolutely clear picture emerges and many of the judgement speak with different voices,'*[735] suggesting that even where the distinctions appear clear, the reality may be very different.

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[730] *Lynch v Knight* [1861] 9 HKC 577,590 per Lord Wensleydale
[731] *Hinz v Berry* [1970] 2 QB 40,42 per Lord Denning
[732] *White v Chief Constable of South Yorkshire Police* [1998] at 491
[733] *Hicks v Chief Constable of South Yorkshire Police; Brock v Northampton General Hospital NHS Trust* [2014]
[734] *McLoughlin v O'Brian* [1983] AC410, 431 per Lord Bridge
[735] *Whitmore v Euroways Express Coaches Ltd* The Times 4 May 1984

It appears tenuous at best to draw any significant parallel between the law relating to psychiatric injury and the therapeutic privilege exception, as policy reasons have heavily influenced the development of the law on recovery of damages for psychiatric injury. It seems that the threshold has been set high to avoid the potential of floodgates, if emotions such as mere anxiety or distress were recoverable.

The need for a recognisable psychiatric illness is also mirrored in the criminal law, where after many years of resistance, the law finally acknowledged that a person can suffer psychological harm without accompanying physical harm.[736] Lord Justice Hobhouse sought to restrict any further expansion observing that psychiatric injury '*does not include mere emotions such as fear distress or panic, nor does it include as such, states of mind that are not in themselves evidence of some identifiable clinical condition.'* In contrast, *'minor'* psychological harm was more recently criminalised as 4(1) of the Protection from Harassment Act 1997 prohibits behaviour that causes '*fear'*, reflecting how a *'mere emotion'* can be actionable.

Since *'states of mind'* are not easy to identify, expert medical evidence would be required in criminal law, mirroring the position taken by private law.[737] For the purposes of this thesis, it would seem highly unlikely that any diagnostic criteria would be relied upon by clinicians who may decide to withhold risk disclosure from their patients, as it is likely that a more instinctive clinical assessment is adopted on a case-by-case basis. In addition, given that healthcare professionals are unlikely to be well versed with the exception to informed consent, analysis of the claimant's clinical condition alongside the law is unlikely to occur. Whilst not undermining the importance of patient autonomy or the risks of perceived paternalism, the risk of the floodgates of civil liability or the potential loss of livelihood in the criminal law is arguably more significant than a failure to disclose risk. For this reason, it is not recommended that the level of seriousness required for *'serious physical or psychological harm'* should be extended to the same level as that required in other areas of private and public law.

[736] *R v Ireland and Burstow* [1997] UKHL 34

[737] A similar point is made by Russell Orr, 'Speaking with different voices: the problems with English law and psychiatric injury' (2016) Legal Studies 36(4) 547-565

For those who advocate abolishing the therapeutic privilege exception on the grounds that it either bears no fundamental value or it is used as a vehicle for paternalism,[738] they would doubtlessly approve of the requirement of a recognisable psychiatric illness before the therapeutic privilege exception can be invoked. However, if a recognisable psychiatric illness were required before the therapeutic privilege exception could be relied upon, then the law would be most unsatisfactory. Once a diagnosis was made, then a mental capacity assessment would require the patient to satisfy the diagnostic threshold under section 2(2) of the MCA, followed by the functional threshold under section 3 and if the standard could not be reached, the patient will then be treated under their best interests under section 4. Hence, disclosure could result in compromised capacity which is an undesirable outcome.

Supported by the qualitative research, it is argued that in the context of exercising the therapeutic privilege exception, anxiety is sufficient to establish psychological harm.[739] Anxiety is a commonplace response to a wide range of situations or a response upon learning information, and a simple medical appointment or medical treatment can routinely cause anxiety. However, some patients may find it difficult to control their anxiety and this may affect a person's mental and physical health, resulting in more generalised anxiety.[740] Diagnosed and generalised anxiety disorder can generate a wide range of physical conditions, such as heart palpitations, a shortage of breath, trembling or shaking and insomnia, symptoms that a patient may have experienced, even without a specific diagnosis. This research's rich data supports the proposal that anxiety is sufficiently serious to cause serious psychological or physical harm, which could be *'seriously detrimental to the patient's health.'*

Although there has not been a consensus of opinion, most clinical pharmacists in this research supported the notion that anxiety can be debilitating and the more information that is provided to a patient, the greater the anxiety can be caused. There is evidence that anxiety can dictate a person's thinking and can make a person reclusive, while some patients can be so paralysed by anxiety that it precludes decision making. Thus, even where a person may have legal capacity, they may be unable to act as an autonomous agent. The

[738] Cave (n17) and Mulheron (n147)
[739] See for example Meisel (n20)
[740] https://www.nhs.uk/mental-health/conditions/generalised-anxiety-disorder/overview/ accessed August 30, 2022

potential seriousness of anxiety cannot be underestimated and can have significant and permanent lifestyle consequences. Thus, it can be argued that in some circumstances, disclosure can directly and perhaps irrevocably cause harm. Therefore, risk disclosure needs to be carefully weighed and withholding information from a patient can protect their future autonomy.

The Hippocratic Oath directs doctors to act in a way that benefits the patient[741] together with an obligation not to harm their patient.[742] Whilst these core principles largely co-exist comfortably, where the therapeutic privilege is concerned then there is the potential for these principles to clash. Let us explore a thought experiment. Patient B has been diagnosed with cancer and Doctor A is of the clinical opinion that Patient B should be prescribed a particular drug, which will significantly slow the progression of the cancer. There is a very low risk of an acute side effect associated with the drug, which can also be managed with different medication. Doctor A is aware that Patient B is a particularly anxious person, as he confided in her that it took many months managing his worries and concerns to even seek her medical advice. It is likely that if he sought advice at an earlier stage, then his cancer would not have progressed to its current stage.

Doctor A is concerned that if she advises Patient B of the risks, then Patient B will refuse to take the drugs and his condition will rapidly decline. Doctor A considers herself a committed autonomist rejecting paternalism and respecting her patients' right to decide for themselves whether to accept or refuse treatment. However, she also believes that she has the legal and ethical discretion to withhold risk disclosure if she reasonably believes that disclosing risk would cause her patient physical or psychological harm. In this example, it will be demonstrated there is a conflict between beneficence and not doing harm. Doing good or acting beneficently would be to treat her patient to the best of her ability and enable him to decide whether or not to accept the recommended treatment. But it is questionable where the greater harm is caused.

One may argue that the greater harm would be to disclose the risks to her patient. Doctor A is aware of her patient's anxiety and disclosure could compromise his decision-making

[741] Beneficence
[742] Primun no nocere or non-maleficence

capacity, thereby removing his autonomy to make his own decisions regarding his treatment. In effect, the chilling effect of disclosure would be to compromise the very autonomy that she is seeking to enhance. In these circumstances, Patient B would then be treated according to his best interests under section 4 of the MCA. Here, his 'best interests' are most likely served by being prescribed the drugs to manage his cancer. The challenge for any clinician is the balancing act between disclosure to enhance autonomy and disclosure which compromises autonomy. In this specific example, it is apparent that given the patient's anxiety, the greater harm is caused by disclosing the risks. Whilst this may be supported logically, decisions from domestic jurisdictions vary in their approach as demonstrated in the 1993 case of *Arato v Avedon* in the Supreme Court of California, where it was found the judge in the lower court erred in considering the application of therapeutic privilege. Indeed, some opine that simply because a patient suffers with anxiety does not mean disclosure should not occur.[743]

Case law from this jurisdiction and other domestic jurisdictions lacks a linear approach to whether anxiety is sufficient to support the therapeutic privilege exception. Dating back to the American Code of Ethics in 1847, it was recognised that a patient could be adversely affected by how, or more importantly, what the physician told the patient. Early case law from the USA acknowledged that it could be information about the treatment rather than the treatment itself that could increase patient suffering.[744] More generally in other domestic jurisdictions, case law appeared to be coy at stating definitively that anxiety was sufficient to invoke the therapeutic privilege exception and the last case to specifically refer to *'anxiety'* was in 1966.[745] Instead, language such as *'threat of detriment to the patient', '..perhaps even pose psychological damage to the patient'* or similar was more commonly used in the USA.

Whilst this does not specifically clarify whether anxiety constitutes sufficient serious harm, subsequent cases in the USA phrase the therapeutic privilege exception wider, enabling anxiety to be included where appropriate, to be judged on the facts of the case. Singapore remains the one domestic jurisdiction referred to in this thesis where the courts make

[743] See for example, Mark Parascandola, Jennifer Hawkins, and Marion Danis, 'Patient autonomy and the challenge of clinical uncertainty' (2002) Kennedy Institute of Ethics Journal 12 245–64.
[744] See for example *Ferrara* (n465)
[745] *Patrick* (n497)

specific reference to anxiety disorders as reasoning where the therapeutic privilege exception would apply. Mere distress would be insufficient, provided that the distress is not of the nature that it becomes debilitating.

This section has established that a recognisable psychiatric condition is not required for the therapeutic privilege exception to be invoked. It has established that anxiety in itself is sufficient for the exception to be relied on. However, every patient with anxiety must be considered on their own merits and on a case-by-case basis. No two patients are the same. Each patient's anxiety and the potential debilitating nature of it differs and it is not enough to opine that anxiety *in itself* is a reason for either disclosure or non-disclosure. However, communication and dialogue, the core elements of *Montgomery* may help to guard against an overarching assumption that withholding risk disclosure is the preferred option with patients with anxiety. Where a person's characteristics suggest that disclosure would have a deleterious effect on the patient, withholding information is an *option* and benevolent paternalism should not be regarded as unacceptable.

7.9 Duty to as far as possible ensure understanding

Where patients have intellectual disabilities, healthcare professionals are under an additional duty to ensure as far as possible that the patient has understood the information given to them and the patient has been given sufficient time and space to process the material risks and to come to a decision.

To improve consultations between healthcare professionals and patients with intellectual disabilities, healthcare professionals should be required to undergo compulsory evidence-based training. The objective would be to hone their skills and use appropriate accessible resources to help meet the needs of patients with borderline capacity. This may facilitate a greater understanding of this cohort of patients to take part in the decision-making process, act autonomously with support and thereafter provide informed consent. Importantly, this will enable greater consideration to be given to the healthcare professional who considers the capacity of their patient. Given that mental capacity is in the 'eye of the beholder', this observation in relation to whether a patient has capacity or lacks capacity is equally important to those health professionals who may decide to withhold risk disclosure.

Although there may be a limited role for the therapeutic privilege exception, enhanced skills may be at the root of naturally limiting the therapeutic privilege exception.

Appropriate training would be dependent on several factors. These include public funding to provide a range of easy-read and accessible material to both GPs in a community setting and healthcare providers in a clinical setting. It requires the nature and range of the accessible information to be adequate to meet the needs of a diverse cohort of patients with intellectual disabilities. Whilst doing so, it is also recognised that accessible information cannot meet the needs of every patient.

The judgment in *Montgomery* recognises the importance of dialogue and communication as the '*doctor's role is not fulfilled by bombarding the patient with information with technical information which she cannot reasonably be expected to grasp'* and the challenge with patients with an intellectual disability is so much greater. Thus, it was necessary to impose legal obligations upon healthcare professionals so that those '*who have less skill or inclination for communication, or who are more hurried, or obliged to pause and engage in the discussion which the court requires.'*[746] The rationale is that where the doctor and patient have committed to dialogue and communication and the patient is fully informed so that they can provide informed consent, there is less likelihood of litigation as the treatment which the patient undergoes reflects her informed choice.

GPs and pharmacists in a clinical setting (together with all other healthcare professionals) need to be provided with the skills and competencies to consult with patients with learning disabilities by providing accessible information. In doing so, this is likely to enhance patient autonomy and help facilitate the appropriate level of communication so that patients with an intellectual disability truly become equal partners in the doctor-patient relationship. Evidence-based strategies have been developed to improve clinicians' communication to improve patient satisfaction with positive results.[747] This constructive approach is forward thinking and attempts to strike a balance between staff and patients. Patients in a hospital setting are invariably unwell, anxious, stressed and in an unfamiliar environment where they

[746] *Montgomery* (n3) [94]

[747] Irma D'Antonio, Joy Peters and Brendan Swanson-Bierman, 'Evidence-Based Communication Strategies to Improve Patient Satisfaction: A Quality Improvement Project' (2022) Nurse Leader 20(6) 560-564

have expectations to recover. In contrast, staff are often overworked and may not have the skills required to communicate compassionately. Improved communication skills have shown to directly result in improved patient satisfaction. Accordingly, the power of communication and dialogue cannot be overestimated.

Effective communication may obviate the situation where non-disclosure could be justified in situations where it is alleged that a patient lacks an appropriate level of education to understand the information being conveyed. The onus must be on the healthcare professional to convey the information in such a way that the patient is able to understand. This crucial point is made both in *Hii* and in *Montgomery* and healthcare professionals would be wise to adhere to the notion that conveying information in layman's terms rather than in medical terms can only serve to enhance a person's understanding.

The AIS 2016[748] was implemented within the National Health Service in England. Where information is provided in accessible formats, the desired result is to enable patients '*to make informed decisions about their health and care, and to better manage their own health, due to increased knowledge, skills and confidence'* thereby increasing a patients' ability to act autonomously.[749] Furthermore, the United Nations Convention on the Rights of Persons with Disability states that providing clear information in appropriate formats is a key part of promoting independence.[750]

The notion of accessible information has been widely referred to as facilitating those with intellectual disabilities to become a more active partner in healthcare. The objective of accessible information in medical treatment is to empower those previously excluded from the decision-making process to exercise their voice and provide informed consent. The COVID-19 pandemic highlighted the continuing inequality faced by people with intellectual disabilities.[751] At present, there is little evidence of a clear nexus between the use of accessible information and changes in health behaviour, and further research needs to be

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[748] AIS (n9)
[749] Ibid 49-50
[750] United Nations Convention on the Rights of Persons with Disabilities https://www.un.org/disabilities/documents/convention/convention_accessible_pdf.pdf '(v) Recognizing the importance of accessibility to the physical, social, economic and cultural environment, to health and education and to information and communication, in enabling persons with disabilities to fully enjoy all human rights and fundamental freedoms,' accessed December 14, 2022
[751] Melody M. Terras, Dominic Jarrett and Sharon A. McGregor, 'The important of accessible information in promoting the inclusion of people with an intellectual disability' (2021) Disabilities, 1, 132-150,132

conducted on whether accessible information enhances patient autonomy.[752] Data from the qualitative research failed to demonstrate that accessible information was widely available in either primary care unit providers or clinical settings. Only one of the GP research participants acknowledged a lot of information was now available, but he also observed that *'the more that written information has increased, the more that people value the ability to just talk to a human being.'* Two pharmacists welcomed *Easy Read* information but one still questioned the value of them while another pharmacist simply believed that it was sufficient *'for patients who have limited understanding….you could hold up a smiley face or a sad face or somewhere in between.'* Overall, it seems that the research participants' experience of the use of accessible information was very limited, despite the Accessible Information Standard being in force since 2016.

It is acknowledged that it is not possible to provide accessible information to meet the needs of every person with an intellectual disability, as the need for accessible information is patient-specific. Whilst the terms *Easy Read* and *Accessible Information* (AI) are often referred to interchangeably, Accessible Information is used to describe not only the means of delivery but also the method of delivery. Hence, we are not only concerned with the physical resource that may support a person with an intellectual disability but also the communication support itself.[753,754] Communication can be facilitated by using more simple language with pictures supporting the text and used for people who have intellectual disabilities. There is, however, little research on whether accessible information offers choices to people with intellectual disabilities, including the option not to have any treatment at all.

Providing accessible information has two essential limbs. Firstly, providing the information resource itself which needs to be appropriate for that particular patient and, secondly, the importance of dialogue which accompanies the information to facilitate understanding. As we move forward from the COVID-19 pandemic, it is axiomatic that health provision will

[752] Deborah Chinn and Claire Homeyard, 'Easy read and accessible information for people with intellectual disability: is it worth it? A meta narrative literature review' (2017) Health Expectations 20 1189-1200

[753] Claire Mander, 'An investigation of the delivery of health-related accessible information for adults with learning disabilities' (2016) Tizard Learning Disability Review, 21(1) 15-23, 15

[754] See the Accessible Information Standard overview 2017-2018 https://www.england.nhs.uk/wp-content/uploads/2017/10/accessible-info-standard-overview-2017-18.pdf accessed July 11, 2022

become increasingly digital.[755] The provision of accessible information within a digital environment which serves the purposes of people with intellectual disabilities to provide informed consent must become a healthcare imperative. Failure to do so may result in those with intellectual disability, being beneficently treated under the umbrella of the therapeutic privilege exception.

Where **elderly** patients are concerned, relationships within the family often rely on assumed decision-making and although well meaning, they may often result in a more benevolent paternalism approach and often to protect the person from difficult truths. Again, the stereotypical portrayal of the elderly as frail and in need of protection has led healthcare professionals to 'infantilise and patronise' the older person. In doing so, they may be protecting the person from perceived risk, but they may also be denying them their dignity and autonomy.[756] Evidence confirms that where the older person is involved in their own decision-making, the more positive the health benefits as they retain control over their life.[757] Conversely, loss of autonomy can lead to negative physical and psychological outcomes including poorer health, diminished morale and lower self-esteem.

7.10 The standard of care to be applied to the therapeutic privilege exception

Since the withholding of risk disclosure lies in the hands of the clinician, consideration must be given to the standard of care to be applied. In contrast to opinion, such as Waltz and Scheuneman in 1969, where the healthcare professional has withheld information from a patient, the court will be the final arbiter as to whether withholding material risk was reasonable. Expert professional opinion may assist the court but will not be determinative. Medical evidence may be adduced to help determine whether there was a reasonably foreseeable risk that physical or psychological harm would be caused to the patient if material risk were to be disclosed. Where medical evidence is not available, the court can rely on the medical records, but the court must also take account of the patient's evidence.

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[755] Terras et al (n75) [147]

[756] Ibid and see also Gay Becker, 'The oldest old: Autonomy and the face of frailty' (1994) Journal of Aging Studies 8: 59–76,20; Rachel Herring and Betsy Thom, 'The right to take risks: Alcohol and older people' (1991) Social Policy and Administration; 31: 233– 246; Betty Hasselkus, 'Everyday ethics in dementia care: Narratives of crossing the line' (1997) Gerontologist 31: 640–649

[757] Loretta Pecchioni and Jon Nussbaum, 'The influence of autonomy and paternalism on communicative behaviours in mother– daughter relationships prior to dependency' (2000) Health Communication 12 317–338

The *Bolam* test will not be relied upon where the healthcare professional has relied upon the therapeutic privilege exception.

As a reminder, *Montgomery* held that a doctor may withhold risk disclosure if he *reasonably considers* that disclosure would be seriously detrimental to the patient's health.[758] The objective assessment echoes Lord Steyn in the earlier case of *Chester v Afshar*[759] wherein he stated that

'A surgeon owes a legal duty to a patient to warn him or her in general terms of possible serious risks involved in the procedure. The only qualification is that there may be wholly exceptional cases where objectively in the best interests of the patient the surgeon may be excused from giving a warning.'[760]

Historically, the *Bolam* test would be applied to judge the standard of the clinicians' actions. If the clinician could demonstrate that a body of similarly qualified physicians would have done as he did, he would not be negligent. In *Sidaway*, Lord Diplock suggested that the three component parts of the doctor-patient relationship; diagnosis, information disclosure and treatment would all be judged according to the *Bolam* professional standard and considered that it was '*neither legally meaningful nor medically practicable'*[761] to draw a distinction between the nature of the duty between each of the three stages. Nevertheless, over recent years the influence of the *Bolam* test has waned and whilst it is correct to say that a doctor or healthcare professional has an overarching duty to the patient, it can manifest itself in different forms.

The *Montgomery* judgement disposes of the *Bolam* test for the purposes of informed consent, and it seems unsatisfactory and beholden to the past that *Bolam* should remain as the test for determining the reasonableness of the clinician's actions when withholding information. Indeed, given the gradual demise of the applicability of *Bolam* in areas of medical treatment, it would be preferable to seek an alternative avenue of assessment for the therapeutic privilege exception.

[758] *Montgomery* (n3) [88]
[759] *Chester* (n98)
[760] Ibid
[761] *Sidaway* (n6) [883]

Whilst the *Bolam* test could apply, the *Bolitho* 'gloss' would give the court the scope to reject medical evidence where the court believed that the risks and benefits were not weighed up, so that the opinion could not withstand logical analysis. By adopting a more robust application of *Bolitho*, the court could remain the final arbiter of the clinician's decision to withhold information relating to risk. Although expert evidence would be adduced in support of the *Bolam* test, the evidence may inform the courts but should not be determinative.

However, if the *Bolam* test with the *Bolitho* gloss were to be applied to assessment of the therapeutic privilege exception, the result may lack a logical application. The reasoning is that the extent to which a healthcare professional may be inclined to discuss risks with a patient is not determined by any level of medical learning or experience. It may result in negligence being established against healthcare professionals where there are divergent attitudes amongst healthcare professionals and the extent of respect owed to their patients.[762] Even the mere notion of a professional standard of information disclosure defies definition and has been referred to as a *'nonsense',* as clinicians have not even established the standard between themselves.[763]

Should the responsibility for determining the extent and nature of a person's right rest with the courts or the medical profession? Arguably, the courts should determine the appropriateness of withholding information rather than the medical profession because the skill and judgment required for disclosing or withholding risk are not the kind with which the *Bolam* test is concerned. If the *Bolam* test were to be applied to the therapeutic privilege exception, a doctor or healthcare professional would simply seek to identify other healthcare professionals who would similarly withhold risk information without a precise and exacting professional standard. Put more simply, a healthcare professional could withhold what he wants, provided others would have done the same and if this occurred, *'*s(S)uch an outcome is incompatible with even a modest notion of patient autonomy.*'*[764]

If the test in *Bolam* with the *Bolitho* 'gloss' were to be replaced, careful consideration must be given as to what it will be replaced with. It should not be '*so complex, uncertain or*

[762] *Hii Chii Kok* (n99) [8]
[763] Kennedy (n323)189
[764] *Hii Chii Kok* (n99) [122]

onerous that doctors who do not have the luxury or unlimited time, to ponder and reflect before they make a decision' about disclosing information[765] and therefore it would be prudent not to do anything radical in terms of changes in the law.

It is therefore proposed that where information is withheld, it is initially viewed from the doctor's perspective. Thus, if a patient were particularly anxious and the healthcare professional were concerned that disclosure could cause serious harm to their physical or psychological health, the decision would be viewed from the doctor's perspective and although the decision may be informed by medical evidence, the evidence would be persuasive and not determinative. However, the court would remain the final arbiter and the *Bolam* test would be redundant for determining the appropriateness of relying on the therapeutic privilege exception. This proposal is supported by the fact that withholding information is not a part of clinical judgment and can be assessed by both applying commonsense and assessing the communication skills of that particular healthcare professional. Whether a healthcare professional exercises sound judgment in withholding information should remain a question for the courts and one they are well equipped to decide on.

7.11 The importance of adequate guidance: Codes of Practice

Part of the challenge of the therapeutic privilege exception is that healthcare professionals are not routinely aware that they can withhold information in specific conditions. Although this thesis confirmed that some research participants were indeed aware, they tended to be those who were more engaged in informed consent, with some more detailed knowledge.

It should not be beyond the realms of possibility to develop an awareness of the therapeutic privilege exception without the risk of abusing it.[766] Given that healthcare professionals are familiar with a patient's right to waive their rights to disclosure and the importance of treating a patient who lacks capacity (whether temporary or permanent) without their consent, shrouding the therapeutic privilege exception in mystery is of no intrinsic value.

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[765] Ibid

[766] This is slightly reminiscent of Lady Hale who in the Supreme Court judgment of R (on the application of Nicklinson and another) (Appellants) v Ministry of Justice (Respondent) [2014] UKSC 38 expressed that 'It would not be beyond the wit of a legal system to devise a process for identifying those people, those few people, who should be allowed help to end their own lives'

Furthermore, it risks harming patients where disclosure of risk information results in a patient's capacity being compromised.

Devised through a Code of Practice (see appendix A) which would be supplementary to the GMC guidelines, or developed more fully within the guidance itself, the newly proposed definition of the therapeutic privilege exception will be expressly stated together with the reasoning of each component element. The objective of specifically setting out the elements is to enable healthcare professionals to fully understand and appreciate the consequences of their actions, even if it were to risk additional potential litigation. Currently, the GMC guidance is limited, which is inadequate as the healthcare professional lacks the information he needs to advise his patient and the only guidance is to seek legal advice, which can result in defensive practice possibly resulting in the healthcare professional withholding information *without* seeking legal advice for fear of legal repercussions. Moreover, examples of best practice must be included within the GMC guidance so that the doctor can gain some appreciation of the therapeutic privilege exception.

It may be argued that bringing the exception to informed consent to the knowledge of healthcare professionals may invite overt paternalism in healthcare treatment, but the results of research with participants confirms use of the therapeutic privilege exception, regardless of having no prior knowledge. It must be preferable for healthcare professionals to be aware of the exception so they can act accordingly, creating consistency in knowledge and understanding in this narrow and rarely relied upon area of the law.

Further, where material risk has been withheld the nature and reasons for withholding the information must be recorded in the patient's medical records, together with all the steps taken to facilitate informed consent.[767] The relevance of closely recording the reasons for withholding risk disclosure is that the contemporaneous records could be relied upon where a breach of duty of risk disclosure is alleged by the patient. Moreover, a closely structured Code of Practice with inbuilt accountability will likely deter overt paternalism.

The healthcare professional *should* account to the patient, advising them that information relevant to material risk is being withheld and the reasons why. However, where it is felt, in

[767] The GMC Guidelines 'Decision making and Consent', already make this a requirement.

the clinician's view, that this information by its very nature causes additional harm, these further details can be withheld.

This section has explored the need for the therapeutic privilege exception to be both transparent and accessible so that doctors can understand the legal consequences of this rarely relied upon exception to informed consent. In a similar way, other professional bodies will adopt the same guidance to aim for a wide body of professional understanding of this little understood area of the law.

7.12 Contribution to topic and possible future research

This thesis has explored the nature of withholding risk disclosure from patients from a historical perspective, before embarking upon an examination of the therapeutic privilege exception in a range of other domestic jurisdictions, together with England and Wales. The rich data which has been gathered demonstrates the frequent use of withholding information from patients in a clinical or hospital setting, although this was less evident amongst GPs. Contrary to extensive opinion arguing to the contrary, it has been demonstrated that there is a role, albeit limited, for withholding risk disclosure from a patient. This may be alleviated by more extensive training in dialogue and communication to engage more closely with the patient, particularly those with intellectual disability, in order to enable health equality. This would require a significant investment in funding both in training and accessible information to aid communication, where appropriate.

This thesis defies the critics by setting out a potential definition of the therapeutic privilege exception to aid transparency and remove one of the exceptions to informed consent from the shadows. Furthermore, it seeks to create parity of treatment between those with intellectual disability and those without, so that all patients can have an equal stake in the patient-healthcare profession. Case law post-*Montgomery* continues to challenge its boundaries; it may not be too long before the 'therapeutic exception' retained within the 2015 Supreme Court is challenged by the courts.

This thesis also identifies a number of areas where further research is required which includes qualitative research with research participants conducted online and more generally what other cohorts of healthcare professionals understand by informed consent and the exceptions to it. Perhaps more importantly, for the purposes of this thesis, the

availability of and the impact of accessible information for patients with intellectual disability is an area where research is imperative. It is only by highlighting these current inadequacies that health inequality may eventually be achieved.

Word count: 84,716

Appendix A

Codes of Practice for HealthCare Workers – Use of the therapeutic privilege exception in informed consent

Introduction

This document contains suggested codes of practice for healthcare professionals describing the standard of conduct and practice within which they must work. The document acts as an addendum to all professional bodies' professional guidelines. The brief introduction is intended to help you understand what the codes are used for and the implementation they will have for you as a healthcare worker who treats patient.

What are the codes?

The codes of practice for healthcare professionals who treat patients describe the standards of the therapeutic privilege exception and the circumstances in which it can be applied as an exception to informed consent. This is the first time that such standards have been set down and it is expected that all healthcare professionals who treat patient adhere to them.

What will the codes mean to you?

The codes of practice enable you to reflect on one of the three exceptions to informed consent and to provide clarity and transparency where the potential use of the therapeutic privilege exception is concerned.

The codes are to remind all healthcare professionals, that the relationship between themselves and the patient is key to facilitating effective dialogue and communication concerning the risks relating to a patient's treatment, so that patients can make decisions about their own treatment. There may be situations, albeit rare, where information can be withheld from a patient and where benevolent paternalism replaces patient autonomy.

Status

This code of practice requires all healthcare professionals to meet this code. Those healthcare professionals who fail to do so, may be held legally accountable.

Healthcare professionals must, in addition to their own professional bodies' guidance:

- Engage in effective dialogue and communication in a way which best facilitates awareness of material risks, so that the patient can understand the seriousness of their condition, the options to treatment, including none and all and any alternative treatment.
- Where the patient needs support in awareness and understanding, appropriate aids for that particular patient are employed. This may include visual or auditory aids.
- As far as possible facilitate the means to enable a patient's autonomy to make their own decisions regarding healthcare.

The therapeutic privilege exception

The therapeutic privilege exception applies where it is reasonably foreseeable that disclosure of material risk would risk serious physical or psychological harm to this particular patient.

1.Healthcare professionals must consider whether it is reasonably foreseeable that disclose of risk would risk the type of harm referred to above. In this context, reasonable foreseeability means whether a reasonable healthcare professional would recognise the risk associated with disclosing the risk, by applying commonsense or knowledge. Where reasonable foreseeability is disputed, the court will be the final arbiter and the *Bolam* test will not apply.

2.When considering the degree of risk that disclosure could cause on a patient, a mere more than minimal 'risk' would be sufficient.

3.The risk of physical or psychological harm, must be a more significant risk than that of withholding material risk.

4.When referring to the risk of serious physical or psychological harm being caused to the patient, anxiety in itself is sufficient to amount to serious harm.

5 Healthcare professionals are under a duty to ensure as far as possible, that the patient has understood the information to them. Where appropriate, communication and dialogue must be supported by accessible resources suitable for that particular patient.

This Code of Practice is not intended to be exhaustive but, to act as preliminary guidelines for the understanding of, and implementation of the therapeutic privilege exception.

Appendix B

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Training materials for teachers of learners with severe, profound and complex learning difficulties http://www.complexneeds.org.uk/

United Nations Convention on the Rights of Persons with Disabilities https://www.un.org/disabilities/documents/convention/convention_accessible_pdf.pdf

World Health Organisation (WHO), Dementia: A Public Health Priority (2010) https://www.who.int/publications/i/item/dementia-a-public-health-priority

World Health Organisation ICD-10 Guide for Mental Retardation. Geneva. World Health Organisation; 1996 https://apps.who.int/iris/bitstream/handle/10665/63000/WHO_MNH_96.3.pdf?sequence=1&isAllowed=y

World Health Organization: Mental Health https://www.euro.who.int/en/health-topics/noncommunicable-diseases/mental-health/news/news/2010/15/childrens-right-to-family-life/definition-intellectual-disability

Appendix C – Questions for Qualitative Research

Version 2 24/04/19 IRAS no: 244536

General question and soft introduction:

1. In terms of the type of patients you see, please describe your clinical practice.

Questions on people with intellectual disability:

2. Please describe in your own words how you define PWID (people with intellectual disability).
3. Does your practice include capacitous PWID?
4. Do you welcome carers/relatives into your consultations with PWID?

Questions on informed consent:

5. Thinking about your practice in general, what do you understand by the term 'informed consent'?
6. What steps do you take to ensure that your patient has provided informed consent?
7. When treating patients, do you tend to discuss all the risks associated with the treatment?
8. If not, could you explain why?
9. Would you also discuss reasonable alternatives to the treatment?
10. If not, could you explain why?

Questions on therapeutic privilege:

11. In your practice, have you ever withheld information from a patient because you were concerned that by doing so, you might cause the patient serious physical or psychological harm?
12. In this context, how would you define 'serious' harm?
13. If you have withheld information from a patient, for the previously mentioned reasons, can you recall what harm you were hoping to avoid?
14. Do you think you would be more likely to withhold information from a PWID and if so, can you explain why?
15. Would you provide the information to a carer/relative instead?

Concluding questions:

16. Were you aware that withholding information from a patient, where disclosure could be detrimental to a patient's health, is a legal exception to informed consent?
17. Is there anything you would like to add or clarify?

Appendix D – Ethical Approvals

Law School REC

The Burroughs

Hendon

London NW4 4BT

Main Switchboard: 0208 411 5000 02/07/2018

APPLICATION NUMBER: 4233

Dear Claudia Rebecca Carr

Re your application title: Informed Consent in Medical treatment **Supervisor:** Ciara Eleonore Renu Barton-Hanson Kofman Staunton **Co-investigators/collaborators:**

Thank you for submitting your application. I can confirm that your application has been given approval from the date of this letter by the School of Law Research Ethics Committee (REC).

Please ensure that you contact the REC if any changes are made to the research project which could affect your ethics approval. There is an Amendment sub-form on MORE that can be completed and submitted to your REC for further review.

If you require more time to complete your research, i.e., beyond the date specified in your application, please complete the Extension sub-form on MORE and submit it to your REC for review.

Please note, you must notify your supervisor and the REC if there is a breach in data protection management or any issues that arise that may lead to a health and safety concern or conflict of interests.

I hope your research goes well.

Yours sincerely

S.Bradshaw

Chair Prof Sarah Bradshaw

School of Law REC

Appendix E – NHS Health Research Approval

Miss Claudia Carr
Senior Lecturer
Email: hra.approval@nhs.net
University of Hertfordshire
Hertfordshire Law School
De Havilland Campus
University of Hertfordshire
AL10 9EU
c.r.carr@herts.ac.uk

21 March 2019

Dear Miss Carr

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Informed consent and therapeutic privilege; the implications of the judgement of *Montgomery* v Lanarkshire Health Board [2015] on healthcare professionals**
IRAS project ID:	**244536**
Protocol number:	**4223**

Sponsor **Middlesex University**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales? You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Participating NHS organisations in England and Wales **will not** be required to formally confirm capacity and capability before you may commence research activity at site. As such, you may commence the research at each organisation **immediately** following sponsor provision to the site of the local information pack, so long as:

- You have contacted participating NHS organisations (see below for details)
- The NHS organisation has not provided a reason as to why they cannot participate
- The NHS organisation has not requested additional time to confirm.

You may start the research prior to the above deadline if the site positively confirms that the research may proceed.

If not already done so, you should now provide the local information pack for your study to your participating NHS organisations. A current list of R&D contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose. After entering your IRAS ID you will be able to access a password protected document (password: **Redhouse1**). The password is updated on a monthly basis so please obtain the relevant contact information as soon as possible; please do not hesitate to contact me should you encounter any issues.

Commencing research activities at any NHS organisation before providing them with the full local information pack and allowing them the agreed duration to opt-out, or to request additional time (unless you have received from their R&D department notification that you may commence), is a breach of the terms of HRA and HCRW Approval. Further information is provided in the "*summary of assessment*" section towards the end of this document.

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The attached document *"After HRA Approval – guidance for sponsors and investigators"* gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, including: Registration of Research

- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Claudia Carr
Email: C.R.Carr@herts.ac.uk / CC1643@live.mdx.ac.uk

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **244536**. Please quote this on all correspondence.

Yours sincerely

Gemma Oakes
Assessor

Email: hra.approval@nhs.net

Copy to: *Ciara Staunton, Middlesex University [Sponsor Contact]*
c.staunton@mdx.ac.uk
Ms Amal Qureshi, NIHR Clinical Research Network [Lead NHS R&D Contact]
Amal.qureshi@nihr.ac.uk

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Public liability insurance]	1.0	28 September 2017
HRA Schedule of Events	1	12 February 2019
HRA Statement of Activities	1	12 February 2019
IRAS Application Form [IRAS_Form_07022019]		07 February 2019
IRAS Application Form XML file [IRAS_Form_07022019]		07 February 2019
IRAS Checklist XML [Checklist_07022019]		07 February 2019
Letter from sponsor [Registration confirmation]	1.0	16 October 2018
Letter from statistician [Registration report]	1.0	21 January 2019
Letters of invitation to participant	1	07 October 2018
Non-validated questionnaire	V1	08 October 2018
Other [Professional negligence and indemnity insurance]	1.0	05 January 2018
Participant consent form	1	18 August 2018
Participant information sheet (PIS)	1	18 August 2018
Research protocol or project proposal	1	01 May 2018
Summary CV for Chief Investigator (CI) [CV - Carr]	1.0	21 September 2018
Summary CV for student [CV - Carr]	1.0	21 September 2018
Summary CV for supervisor (student research) [CV - Staunton]	1.0	21 January 2019

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to

participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	The applicant has confirmed (in addition to the sites already listed at Part C of IRAS), the following NHS sites are also participating in the study: • Central and NW London NHS Trust • The Mid Essex Hospital NHS Trust
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A statement of activities has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.
4.2	Insurance/indemnity arrangements assessed	Yes	The sponsor has confirmed there are appropriate insurance arrangements in place to cover the study.
4.3	Financial arrangements assessed	Yes	External funding has not been obtained to run the study, and as such will not be provided to participating NHS sites.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
Section	**Assessment Criteria**	**Compliant with Standards**	**Comments**

5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Not Applicable	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There is one site type participating in the study. All research activities taking place at the participating NHS sites is detailed in the study protocol and supporting documentation.

Please note that the remit of HRA Approval is limited to the NHS involvement in the study. Research activity undertaken at non-NHS sites is therefore not covered and the research team should make appropriate alternative arrangements with relevant management at these organisations to conduct the research there.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS, the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and Wales, and the minimum expectations for education, training and experience that PIs should meet (where applicable).

Principal Investigators and Local Collaborators will not be required at NHS sites participating in the study. Should additional NHS site types be added to the study then a new assessment of the need for Principal Investigators or Local Collaborators will be required.

A local contact may be required to facilitate the booking of meeting room for the interviews to take place, depending on the participant's choice of location.

GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

As the research activities involve NHS staff as participants in non-clinical areas, access arrangements are not expected for the study.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales to aid study set-up.

The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix F

Middlesex University Research Degree

Candidate Declaration form

Student details

Student name:	Claudia Rebecca Carr
Student number:	M0055527
Thesis Title:	The 'therapeutic privilege exception'. Residual paternalism in an age of informed consent post *Montgomery* or a valuable tool for healthcare professionals?
Degree for which thesis is submitted	PhD Law

Candidate Declaration

1 Research Integrity

I declare that the work presented is wholly my own, unless clarified as part of the submission.

Material submitted for another award

either or	*I declare that no material contained in the thesis has been used in any other submission for an academic award *I declare that the following material contained in the thesis formed part of a submission for the award of ……PhD……(state awarding body and list the material below)

*delete as appropriate

Research Ethics

I confirm that the research submitted has been subject to ethical review and has not deviated from the terms of ethical approval given by the Research Ethics Committee. Ethics ID number(s):……4233…… (this can be found in the MORE system or in your ethics approval letter) The approval letter(s) is/are attached.

Statement by the Student

Signature of Student: Claudia R Carr	Date: 22/09/2023

Candidate Declaration Form Nov 2021