Improving Legal Interpretations of Informed Consent in Practice

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Abstract

The four publications included in this thesis embody a programme of research aimed at improving interpretations of informed consent to medical treatment in the United Kingdom (UK). Paper one considers the application of solidarity - often a concept associated with political debate - to bioethical issues. It examines leading conceptualisations of solidarity in healthcare and their relation to the practitioner-patient dynamic and standards of informed consent. In considering the interplay between ethical principles of solidarity and autonomy, the paper explains how current concepts of healthcare solidarity may undermine individual patient autonomy by creating imbalance in the practitioner-patient dynamic. Current constructs of solidarity are also considered to be exclusionary which, it is argued, may potentially lead to the othering of patients. The effects of patient exclusion and othering are examined in paper one and throughout the subsequent papers. In response to these issues, the novel concept of 'conjoint solidarity' is presented in contribution to the existing scholarship. It calls upon healthcare stakeholders (incorporating healthcare practitioners *and* patients) to adopt a duty to assist in the identification and achievement of improved healthcare outcomes. By recognising the epistemic value of both practitioners and patients, conjoint solidarity is said to promote an *inclusive* form of solidarity that promotes balance in the practitioner-patient dynamic and that will support, rather than undermine, autonomy. It is anticipated that by facilitating greater patient involvement in the decision-making process, trust can be rebuilt, and healthcare outcomes improved. From this ethical grounding, informed consent is explored through the subsequent three papers which address deficiencies in current interpretations of the legal standard for informed consent and propose new ways in which shared decision-making can be enhanced to mitigate against the kind of harms which have been witnessed in recent years.

Paper two explores the evolution of the legal standard of informed consent to medical treatment in the UK. It examines the development of the judicial precedence pertaining to informed consent through key cases such as *Bolam* v *Friern Hospital Management Committee* [1957], *Sidaway v Board of Governors* [1985], *Bolitho v City and Hackney HA* [1998], and *Montgomery v Lanarkshire* [2015]. Comparative analyses are drawn between concepts such as 'significant' and 'material' risk, and between the 'reasonable person' and 'particular patient' standards. It is argued that the legal interpretation of material risk is broad, and that patterns of judicial reasoning are suggestive of a move towards recognition of majority views on reasonableness. The paper describes how financial interests can influence healthcare practitioners to the extent that their practice may be harmful to the

patient and, therefore, concludes that potent financial interests – namely those likely to have greatest impact upon patterns of practice – may be interpreted as disclosable material risks under existing common law standards.

Paper three examines standards of informed consent in relation to the issues surrounding the use of pelvic (vaginal) mesh - as detailed in the 2020 Cumberlege Report - and questions whether improved interpretations of the informed consent process could mitigate against future harms. It is recognised that treatment selection - which remains a matter of professional judgement according to *Bolam v Friern Hospital Management Committee* [1956] - could be deemed exclusionary towards patients. Drawing on the concept of conjoint solidarity, it is suggested that patient-based evidence should be afforded greater consideration as part of evidence-based practice to promote a more inclusive healthcare system which affords greater recognition to the epistemic value of the patient to enhance overall shared decision-making. The concept of risk disclosure is also re-examined in relation to medical device implantation, and it is recommended that the long-term risks deriving from implantable devices, or indeed unknown risks associated with innovative treatment proposals, be deemed disclosable. In this way, patient autonomy can be upheld so that patients are afforded the opportunity to decide whether, or not, to incur such risk.

Paper four considers how the process of shared decision-making, which precedes informed consent, can be enhanced by facilitating active discussion [4]. In returning to the concept of relational autonomy, persuasion is presented as a means of promoting greater patient-practitioner dialogue and engagement which can allow patients to question and explore the information that is presented. The example of vaccine hesitancy is used to describe the ways in which the informed consent process can be used to tackle misinformation and promote confidence in medical treatments. The standard set out in *Montgomery* requires that patients be informed of benefits, material risks and reasonable treatment alternatives when consenting to medical treatment. On these grounds, it is suggested that informing patients of the benefits of vaccination could be a means of addressing misinformation. Threads of conjoint solidarity also run through the argument as it is suggested that disclosure of vaccination benefits, should relate to both the *individual* and *collective* benefits in terms of individual and herd immunity. This example is particularly reflective of the bridge which exists between relational autonomy and conjoint solidarity. The thesis then explores risks and expands upon the disclosure of 'individual risk'. It is suggested that risk of *not* vaccinating also be disclosed – both in terms of the risk of disease posed to individual and the most vulnerable in society. Persuasion is employed, not as a means of coercion, rather

as a means of engagement to ensure patients understand the information provided which may also help to address misinformation. Similarly, the patient is afforded the opportunity to 'persuade' the practitioner to understand their perspective, which is a departure from traditional models of the practitioner-patient relationship.

In presenting this work three key themes emerge: deficiencies in shared decision making arising from the practitioner-patient relationship, analysis of informed consent and its deficiencies, and proposals for improving interpretations of informed consent to ensure patients are engaged and informed. It is anticipated that the proposed recommendations will have utility for rebuilding patient trust and to enhance patient involvement to mitigate against recurrences of harms seen in the past.

Key Words: Conjoint Solidarity, Autonomy, Informed Consent, Relational Justice, Shared Decision Making, Healthcare Law, Ethics.

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This body of work is also dedicated to my inspirational mum, Elizabeth, who has provided me with constant support, encouragement and understanding. She has instilled a strong work ethic in me; always leading by example. My mum taught me the importance of moving forward no matter the set-back and to never be constrained by the limitations set by others. Had it not been for her belief in me, this work would not have been started, let alone finished. Thank you, Mum.

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[1] O'Neill J. (2021). Towards Conjoint Solidarity. *Bioethics*. 1-12. https://doi.org/10.1111/bioe.12940

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[2] O'Neill J. (2021). Materiality of Conflict of Interest in Informed Consent to Medical Treatment in the United Kingdom. *Ethics & Behaviour.* DOI: https://doi.org/10.1080/10508422.2021.1963251

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[3] O'Neill J. (2021). Lessons from the Vaginal Mesh Scandal: Enhancing the Patient-Centric Approach to Informed Consent for Medical Device Implantation. *International Journal of Technology Assessment in Health Car, 37(1), E53.* DOI: https://doi.org/10.1017/S0266462321000258

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[4] O'Neill J. (2020) Case for Persuasion in Parental Informed Consent to Promote Rational Vaccine Choices. *Journal of Medical Ethics*. 10.1136/medethics-2020-106068

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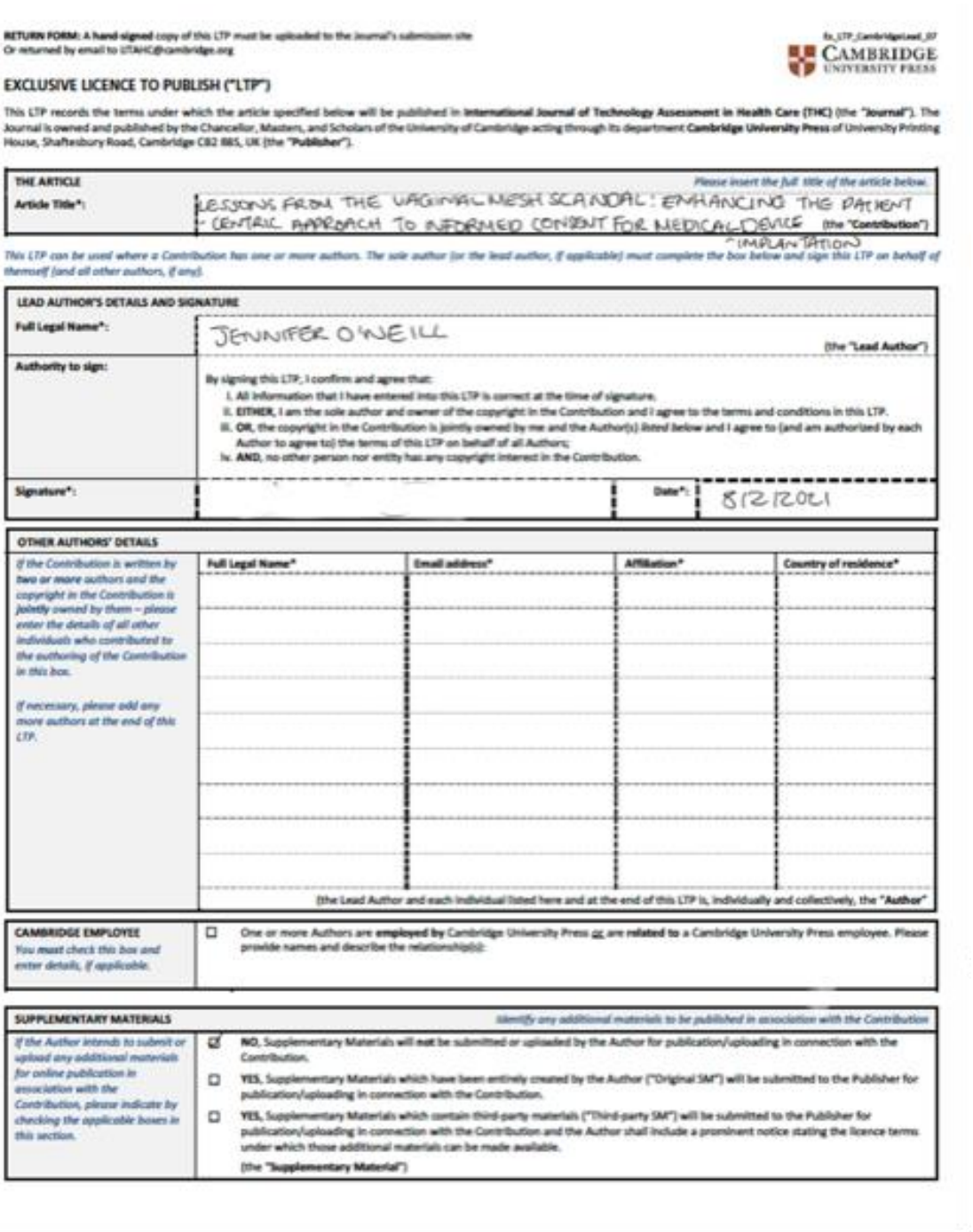

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Section 1

Explanatory Essay

References to the publications submitted are in square brackets [ ]. References to other papers are in round brackets ( ).

1. Theoretical and Conceptual Underpinnings

The four papers presented in this thesis incorporate theoretical and conceptual approaches aimed at improving informed consent by means not extensively addressed in the literature. This thesis will consider informed consent as it applies to adults with capacity – young persons, vulnerable adults or those with incapacity will be excluded from this body of work. Each paper, and approach, has its strengths and limitations. Paper one explores the nature of the practitioner-patient relationship and its influence on determining standards of informed consent whilst addressing the interplay between individual patient autonomy and collective healthcare solidarity [1]. Autonomy has etymological roots in the Greek word αυτόνομός (self-law) and is a concept with modern application to themes of 'self-governance' or 'self-determination'. As applied to the healthcare context, it has come to broadly represent patient rights of decision-making [1]. Whilst *political* solidarity has long underpinned European healthcare systems, there has - until recently - been little consideration of solidarity as applied *within* those healthcare systems (Giaimo & Manow, 1999; Whittall in Prainsack & Buyx, 2017: xi-xiv). Paper one considers how current interpretations of healthcare solidarity may undermine patient autonomy by promoting imbalance in the practitioner-patient relationship that could lead to exclusionary othering of patients - the effects of which are explored throughout the subsequent papers [1: 3-4] [2][3][4]. Instead, paper one proposes a new *inclusive* concept of *conjoint* solidarity be adopted [1]. Conjoint solidarity calls upon healthcare practitioners and patients - otherwise referred to as healthcare stakeholders - to adopt a duty to assist in the identification and

achievement of improved healthcare outcomes [1: 2]. As a concept, it embodies a series of recommendations which *support* autonomy, such as *inclusivity, mutual recognition of epistemic value and mutual persuasion;* threads of which run throughout the series of ensuing papers, connecting them in an overarching single body of work.

The subsequent three papers explore deficiencies in interpretations of the informed consent process and make key recommendations [2][3][4]. A recurrent theme identified is the failure to engage with patients in the decision-making process, from initial selection of treatment to a lack of information disclosure during shared decision-making. Recommendations include greater inclusion of patient epistemic contributions through recognition of patient-based evidence in the medical decision-making process [3]; enhanced stakeholder engagement through mutual persuasion [4]; and enhanced interpretations of material risk so that the long-term risks of device implantation [3]; potent and harmful practitioner conflict of interest [2] *and* relational forms of risk deriving from vaccine choices [4] are considered disclosable. Collectively, these recommendations aim to have utility for rebuilding patient trust and involvement. This explanatory essay will first consider the background of consent and the practitioner-patient relationship before exploring three key themes which, in presenting this work, have emerged for discussion:

Theme I: Deficiencies in Shared Decision-Making Arising from the Practitioner Patient Relationship.

Theme II: Analysis of Informed Consent and its Deficiencies.

Theme III: Proposals for Improving Interpretations of Informed Consent to Ensure Patients are Engaged and Informed.

2. Background

2.1. Consent and the Practitioner-Patient Relationship

There are divergent accounts of the historical origins of informed consent in the literature. Whilst historian Martin Pernick (1982) considers that "…*truth-telling and consent-seeking…"* behaviours have long been components of medical practice (in Faden *et al*., 1986: 56), psychiatrist Jay Katz (1984) contests that *"…the history of the physician-patient relationship from ancient times to present…bears testimony to physicians' inattention to their patients' right and need to make their own decisions…."* (3-4). This view is somewhat shared by colleagues Faden, Beauchamp and King (1986) who have written extensively on the subject. They explain how beneficence – a principle that has long been seen as the driving force of the practitioner-patient relationship – has historically been used to justify non-disclosure or 'benevolent deception' of the patient (60). Whilst cautioning that the *"…history of informed consent can no more be reduced to a linear narration of social events and practices than can the history of major concepts in Western thought such as "democracy," "autonomy," or "scientific law"…",* the colleagues agree with Katz that consent is a relatively novel concept in long history of the practitioner-patient relationship (Faden *et al*., 1986: 60, 68; Katz, 1984: 15-18). Furthermore, there appears to be consensus that standards of consent are inextricably linked to the dynamics of the practitioner-patient relationship (Faden *et al*., 1986).

The ancient principles outlined in the '*Corpus Hippocraticum*' or Hippocratic Oath(s) continue to have a prevailing influence over the practitioner-patient relationship to this day, despite promoting a form of authoritarian beneficence that views the physician as *"…the one who commands and decides, while patients are conceived as persons who must place themselves fully in physicians' hands and obey commands…*" (Faden *et al*., 1986: 62). Medical authoritarianism prevailed throughout the medieval period as Hippocratic and Christian ideals aligned to promote the notion of patient obedience (Faden *et al*., 1986: 63).

During the eighteenth century, the Hippocratic Oath – albeit with a *"…less authoritarian flavour…"* – was instated by newly established medical schools as a pledge to uphold professional values (Faden *et al*., 1986: 64). The Enlightenment period, that was synonymous with political and social reform, saw revolutionaries such as the physician Benjamin Rush, call for the "…*demystification of medicine…"* (Faden *et al*., 1986: 65). Whilst Rush promoted medical honesty - believing there to be a correlation between free choice and patient health - his prevailing concern was not one of patient autonomy, rather, that 'Hippocratic beneficence' and deception could damage the medical profession's reputation (Rush, 1801; Faden *et al*., 1986). Rush's former teacher, physician John Gregory, was similarly concerned with the medical profession's image and considered physicians duty-bound to educate patients about medicine - so long as such openness and honesty aligned with beneficence (Gregory, 1772). Gregory's premise was that medical practice would progress at a greater rate if *"…under the inspection and patronage of men qualified to judge their merit…"* (Gregory, 1772 in Haakonssen, 1997: 70). Therefore, whilst Pernick suggests that both Rush and Gregory sought to promote an "*Enlightenment version of Informed Consen*t", their proposals were not wholly borne of a concern for patient rights of autonomy (Pernick, 1982: 10; Faden *et al*., 1986).

The work of another prominent student of Gregory, Thomas Percival, was also highly influential. His landmark publication '*Medical Ethics'* – described as a "…*reinterpretation of the old Hippocratic guild ethos, seen through the eyes of an 18th century medical officer and Christian gentleman…*" - encouraged professional self-regulation (Percival, 1803; Boyd, 2005: 481). It would later form the basis of the American Medical Association's (AMA) first Code of Medical Ethics in 1847 (AMA, 1847). Yet it is criticised by Boyd as being "…*a prospectus for the style of professional medical ethics, self-regulating, paternalistic, and often benign, which typically prevailed until around the middle of the 20th century…*" and, by Faden and colleagues, for embodying the *"…the living creed of*

[authoritarian] professional conduct in the United States…" (Boyd, 2005: 481; Faden *et al*., 1986: 70). However, physician Worthington Hooker's "…*brilliant and ingenious…*" response to the AMA'S Code of Medical Ethics is considered by Faden and colleagues to be a *"…ringing, uncompromising denunciation of lying and deception in medicine…[that] demonstrates an extraordinary sensitivity to the feelings of patients and their needs for information…"* (Faden *et al*., 1986: 70). Hooker argues that there is no justification for benevolent deception, cautioning that "*…the good which may be done by deception in a few cases, is almost as nothing, compared with the evil which it does in many cases…"* (Hooker, 1850 :252). By the nineteenth century there was greater emphasis on professionalisation as medics sought to distinguish themselves from '*quackery'* and, whilst this meant that pre-surgical consent became routine, benevolent deception remained a common component of such consent. It was not until the early twentieth century that the risk of legal malpractice began to emerge (Faden *et al*., 1986: 76-82).

The impact that the atrocities of the Second World War had upon modern medical ethics is widely recognised (Germany, 1949). Drafted in response to the Doctors' Trials at Nuremberg in 1947, the Nuremberg Code cautions future generations with the now infamous opening words *"…[t]he voluntary consent of the human subject is absolutely essential…"* (Germany, 1949: s.1). The full text of this opening provision is a cautionary tale outlining the importance of "*capacity*", "*non-coercion*", and of patients having "…*sufficient knowledge…*" to make "*enlightened*" decisions (Germany, 1949: s.1). Despite its importance, Faden and colleagues (1986) were unable "…*to locate a single substantial discussion in the medical literature of consent and patient authorisation…"* prior before late 1950s - a time associated with the civil rights movement when individuals actively sought greater rights of equality across various aspects of society (87). They suggest that the *"…Nazi atrocities and the celebrated cases of abuse of research subjects in the United States raised suspicions about the general trustworthiness of the medical profession…"* had

contributed to patients' pursuit of protection (Faden *et al*., 1986: 87). By 1964 the World Medical Association (WMA) had introduced the Helsinki Declaration to provide ethical guidance on involving human subjects in research. However, both the original version, and its subsequent revisions, have been criticised for *'watering down'* the Nuremberg Code's objective (WMA 1964; Maehle, 2009: 606; Botbol-Baum, 2000:238; Germany, 1949). It, arguably, fell to Henry Beecher and his explosive 1966 article '*Ethics and Clinical Research'* to pave the way for stronger adherence to guidelines on informed consent to human experimentation in the United States (US). Therein he warned of "…*troubling practices…*" whereby *"…many…patients …never had the risk [of research participation] explained to them… [even when such risk was of] …grave consequences*…" (Beecher, 1966: 274). Nonetheless, it was not until 1979 that guidelines were published in the Belmont Report, seen as an *"…attempt to summarize the basic ethical principles…*" required of research ethics, such as *"…respect for persons…as autonomous agents…"* and *"…information, comprehension, and voluntariness…"* (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979; s.B.1, s.C.1, s.C.2).

Meanwhile, in the United Kingdom (UK), it was Maurice Pappworth's publication '*Human Guinea Pigs'* that exposed how National Health Service (NHS) patients were, similarly, being used for research without their knowledge or consent (Pappworth, 1967). Pressel (2003) explains that there is a close link between research consent and medical consent – a connection that is evident upon consultation of the case law pertaining to informed consent in the UK, where both forms of consent are founded in the tort of battery (1221-1223) [2]. Whilst this is explored in more detail in Theme II, it is pertinent to note that from 1956 to 2015 the prevailing legal standard on matters of treatment consent - established in case of *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 - facilitated medical paternalism, self-regulation and excluded patients from *meaningful* involvement medical

decision-making. In ruling that a practitioner would not be negligent so long as they had acted in *"…accordance with a practice accepted as proper by* a *responsible body of medical men…"* the judiciary facilitated imbalance within the practitioner-patient relationship (*Bolam v Friern Hospital Management Committee* [1957]: 587).

It was not until the Supreme Court ruling of *Montgomery v Lanarkshire* [2015] UKSC 11 that patients were afforded greater rights of involvement in medical decision-making. By recognising patients' right to be informed of the material risks, benefits, and reasonable treatment alternatives before consenting to treatment, the Supreme Court Justices effectively aimed to rebalance the practitioner-patient relationship (*Montgomery v Lanarkshire* [2015]: 81). To meet this standard, they placed a duty upon practitioners to tailor information to the needs of a '*particular patient'* thus creating a requirement for greater engagement. In doing so, a new era of healthcare was introduced in the UK, punctuated by terminology such as *'patient-centredness'*, *'patient-centricity* and '*shared*' or *'supported'* decision-making (see *Montgomery v Lanarkshire* [2015]: 87, 90; General Medical Council (GMC), 2020; Royal College of Surgeons (RCS), 2018). Patient-*centredness* may be *"…narrowly defined as [reflecting] the patient's active role in determining his or her treatment and care…"* and should be distinguished from the broader concept of patient-*centricity*. (Robbins *et al*., 2013: 350). The term '*centric'* has etymological roots in the Greek word κεντρικός which pertains to a central, regulatory point or focus (Etymonline.com, n.d.). As applied to health care, such centricity views a participant as the central *"regulating fulcrum*" from which the decision-making process is controlled (Curro *et al*., 2015; 3). Therefore, terms such as *'doctor-centric'* or *'patient-centric'* may relate to the seat of decision-making power in the patient-practitioner relationship. Robbins *et al* (2013) liken patient-centricity to a form of "…*patient sovereignty…*", describing it as a *"… dynamic process through which the patient regulates the flow of information to and from him/her via multiple pathways to exercise choices consistent with his/her preferences, values and beliefs…"* (350). A similar distinction can

be made between the terms '*shared'* and '*supported'* decision-making. The narrower term '*shared decision-making'* is defined as a *"…joint process in which a healthcare professional works together with a person to reach a decision about care…"* (National Institute for Clinical Excellence, n.d.) however, this may imply that the practitioner has a *"…major role in making the decision…"* (Hamilton, 2020). Notably, the Royal College of Surgeons of England (RCS Eng.) guidance on consent is aptly entitled *"Consent: Supported Decision Making*" (RCS Eng., 2018). Whilst it offers no formal definition of '*supported'* decision-making *per se*, the guidance explains that the *"…aim of the discussion about consent is to give the patient the [tailored] information they need to make a decision about what treatment or procedure (if any) they want…"* thus clarifying the practitioner's role as an advisory one (RCS Eng., 2018: 3). Whilst these distinctions are not necessarily made in the series of published papers, this explanatory essay considers *'patient-centricity'* and *'supported'* decision-making to reflect the legal standard of *Montgomery v Lanarkshire* [2015] most accurately. Yet, as will be seen, this legal standard has yet to be universally adopted into practice.

2.2. Poor Healthcare Outcomes

In the years following the *Montgomery v Lanarkshire* [2015] ruling, several large-scale inquiries into healthcare failings in the UK have been published which suggest that, in practice, *Bolam's* enduring legacy continues to influence interpretations of informed consent (Cumberlege, 2020; James, 2020; *Bolam v Friern Hospital Management Committee*, [1957]). 'First Do No Harm', the report by Julia Cumberlege, CBE – also referred to as 'The Cumberlege Report' - investigated the effect that sodium valproate, hormonal pregnancy tests and pelvic (vaginal) mesh use had in the UK. The report identified key, overarching themes associated with patient harm including: "…*no-one is listening - the patient voice dismissed…*"; "…*I was never told – the failure of informed consent…*" and "…*conflicts of interest – we deserve to know…*" (Cumberlege, 2020: 22, 33). Whilst parts of the report

precede *Montgomery v Lanarkshire* [2015], others – such as that pertaining to mesh - describe ongoing deficiencies in informed consent which transverse the period of *Montgomery's* induction and extend to as recently as 2019 (Cumberlege, 2020). 'The Inquiry into the Issues Raised by Paterson' ('The Paterson Report') examined the case of Ian Paterson - a surgeon who undertook unnecessary, mutilating surgeries on patients without adequately or truthfully involving patients in the consent process (James, 2020). The consent failings outlined by these inquiries are also supported by the findings of a recent multi-speciality study by Knight and colleagues (2019), said to represent the largest post-Montgomery study of informed consent. The study indicates that more than 75% of survey respondents (medical practitioners) were familiar with the *Montgomery v Lanarkshire* [2015] ruling, yet only 25% of those consulted had subsequently adjusted their practice (Knight *et al*., 2019: 282). Furthermore, up to 55.4% of patients consulted by the study had consented *on the day of surgery* – at which stage, "*significantly*" fewer practitioners were likely to disclose risks (Knight *et al.,* 2019: 279). The authors also identified a more general, widespread failure to inform patients of treatment alternatives - including the 'no treatment' option. They found that in over two thirds of cases, no relevant discussion on alternatives had taken place - whether that be at an earlier time (i.e., in the clinic) or on the day of the procedure itself (Knight *et al*., 2019: 279). These combined findings indicate that, in practice, consent processes remain deficient and require improvement (Knight *et al*., 2019).

3. Discussion

Theme I: Deficiencies in Shared Decision Making Arising from the Practitioner-Patient Relationship

The practitioner-patient dynamic has evolved from an independent relationship to one embedded within larger healthcare systems. Such healthcare systems must consider both the needs of the individual and the patient collective and so principles of healthcare solidarity and patient autonomy are relevant modern-day ethical considerations [1]. Paper one

explores solidarity through a chronological analysis. Whilst there is no single definition of the concept there is, however, consensus that it be characterised by some form of shared bonds [1].

3.1. The Origins of Solidarity

Notions of solidarity can be loosely traced back to antiquity - from the shared commitment of those in the basic social unit that was the Ancient Greek οἶκος, to the Roman concept of a shared legal duty to repay debts *obligatio in solidium* (Roy, 1999; Bayertz, 1999). Also widely employed in theological ethics as a means of promoting unity amongst a congregation, solidarity is, for example, expressly mentioned and enshrined within the Catechisms of the Catholic Church where solidarity is *"...articulated in terms of "friendship" or "social charity", [...and as...] a direct demand of human and Christian brotherhood...*" (Catholic Church, n.d.). Throughout *political* history, the pendulum has swung between apparently opposing ideals such as liberalism and communitarianism. In the 17th century, prevailing authoritarianism was met with the classic liberalism of the Enlightenment period. Prominent political thinkers, such as Hobbes (2010 [1651]), John Locke (1948 [1632]) and Jean-Jacques Rousseau (2018), favoured liberal views of the relationship between individual and society which recognised the social contract and thus acknowledged the role of solidarity in ensuring mutual protection. In his famed publication *'The Social Contract'*, Rousseau asserts that individuals are happiest when living in a '*State of Nature'*, yet he also acknowledges that such individuals may collectively unite to overcome hardships, thus providing '*mutual assistance'* to one another (Rousseau, 2018). Such liberal interpretations of social contract theory would eventually contribute to the French Revolution and its notions of '*liberté, égalité, fraternité'* that sought to encapsulate notions of freedom from oppression, equality, and fraternity (or solidarity) amongst the nation's citizens. Indeed, during the European Enlightenment period, various guises of solidarity were used to further political causes (Bristow, 2017). Whilst conservatives - who

opposed the revolutionaries' calls for radical reform - preferred the political pragmatism that favoured tried and tested tradition alongside incremental change, they also somewhat acknowledged the importance of solidarity (Gamble, 2012; Kekes, 1997). In his famed publication '*Reflections on the Revolution in France'*, moderate conservative Edmund Burke - fearing that liberal revolutionaries threatened the very fabric of society - called upon citizens to rally together to uphold honour (Burke, 1790: 28). In an early nod to communitarian ideals – and thus solidaristic traits – he emphasised that *"…[t]o be attached to the subdivision, to love the little platoon we belong to in society, is the first principle…of public affections…"* (Burke, 1790: 39). In the late 1800s, one of the fathers of modern sociology, Émile Durkheim (1984 [1893]), cautioned against individualism and proposed that his mechanical and organic forms of solidarity, which were aligned with the advancement of society, be extended to all. Nearly a century later, Rawls promoted his liberal "…*abstraction [of] the familiar theory of social contrac*t…" in his famed publication '*A Theory of Justice*' which proposes that individuals are equal due to an imaginary 'veil of ignorance' which hides any advantage they may or may not hold, thus creating an equal platform known as the '*original position*' (Rawls, 1971). It is from this '*original position*' that he proposes collective goals could derive from values such as freedom, equality, and opportunity (Rawls, 1971). Yet his approach was viewed by some as too liberal and may have contributed to a responsive rise in communitarianism ideals in the 1980s, as explored by Western scholars such as Alasdair MacIntyre (1981), Charles Taylor (1979; 1985) and Michael Sandel (1982) as a means of promoting the 'common good'. Sandel and Taylor are critical of liberals such as Rawls for failing to recognise that individuals are embedded within society, however it is pertinent to note that Rawls' recognises that *"…only in a social union is the individual complete…*" (Sandel, 1982; Taylor, 1985; Rawls, 1971: 460). Notably, communitarianism was also adopted as a means of describing the form of prescribed thinking associated with authoritarian regimes in Asia, which uphold the common good over individual rights (Fox, 1997). Therefore, Etzioni proposed a concept of '*responsive*

communitarianism' that is differentiated from such authoritarianism (Etzioni, 2003). '*Responsive communitarianism'* seeks to bridge the gap between the core values of individual rights and collective good; thus, remaining dynamic so as to pull society back towards the centre should it move to favour one over the other. 'Responsive communitarianism' shares similarities with the aim of conjoint solidarity which seeks to bridge the gap between the individual and collective need in a healthcare setting (Etzioni, 2003) [1]. Notably, responsive communitarianism also lends itself well to public health policy which can adapt to allow societies to deal with potential conflicts between individual and collective goods. For example, individual rights of medical autonomy upheld under Article 8 of the European Convention on Human Rights (ECHR) may be curtailed if the collective good requires, according to subsection 2 of the article (Council of Europe, 1952). According to Etzioni, this is not considered to be a form of paternalism, rather it is viewed as an intent to improve cultural norms that influence non-rational decision making and so is justified in relation to public health (Etzioni, 2013).

As a concept exclusively applied to the field of bioethics and healthcare, solidarity has been explored by several scholars. Paper one identifies a commonality in approach that necessitates the fulfilment of pre-requisites - such as bearing of costs, coercion or identifying similarity in others - a concept considered to present distinct difficulties in healthcare, particularly in relation to patient autonomy [1]. As will be explored, it is suggested that such models inadvertently promote exclusion and so threaten to undermine individual autonomy (see Prainsack & Buyx, 2011; Davies & Savulescu, 2019; Dawson & Jennings, 2012) [1]. Instead, an innovative notion of 'conjoint solidarity' will be presented to contribute to the existing scholarship. Conjoint solidarity is defined as deriving from the "*…shared goal of all healthcare stakeholders (encapsulating all healthcare professionals and service users) to accept a duty to assist one another to achieve improved healthcare outcomes…"* [1]. In building the case for this inclusive form of solidarity, paper one first identifies the

deficiencies in existing theories and then recommends that conjoint solidarity - which is founded upon mutual recognition of epistemic value amongst stakeholders and the 'pooling of information' - be adopted [1].

3.2. Solidarity at the Expense of Autonomy

In the comprehensive body of work produced for the Nuffield Council on Bioethics, Prainsack and Buyx (2011) present their three-tiered model of solidarity. Existing at the interpersonal, collective, and societal level, it incorporates *"…manifestations of the willingness to carry costs to assist others with whom a person recognises sameness or similarity…*" (s8.25: 87). Although a *"willingness"* to carry costs could be deemed reflective of autonomous decision-making, the requirement to bear costs could pressurise individuals - who wish to act in solidarity with others - into bearing costs when they otherwise would not have wished to do so (Prainsack & Buyx, 2011: s.8.25: 87) [1]. Their theory is applied to ethical issues in their 2017 publication, such as the governance of large biobank databases that contain biomedical data. The example of biobank governance is considered a pertinent one as it illustrates the way in which Prainsack and Buyx's model of solidarity promotes a broad model of consent that could directly undermine the hard-fought gains of *Montgomery's* informed consent in practice (Prainsack & Buyx, 2011; *Montgomery v Lanarkshire* [2015]; 28). Whilst biobanks may be of great public utility – given their scope to predict patterns of disease or health behaviours – they also present a data protection risk. This is particularly concerning for individuals who may subsequently be re-identified. Re-identified participants may, potentially, be profiled for exhibiting 'high-risk' health behaviours and, as a result, may face discrimination and exclusion from healthcare provisions (Prainsack & Buyx, 2011; 2017: 101). However, Prainsack and Buyx suggest that solidarity can balance *"…the value of public benefit [of biobanks] and the protection of personal goods"* whilst moving away from the "…*dominant…focus on individual autonom*y…" (2017: 99,119). Whilst they also assert that *"…autonomy of the person from*

whom the data [derives]…remains an important guiding principle…", their model of solidarity ultimately fails to reflect this (2017: 118). As will be explored there are several examples of the downplay of autonomy in both *their* proposal and those of their contemporaries.

3.2.1. In Relation to Respect for Bodily Integrity. Whilst Prainsack and Buyx (2017) acknowledge the *importance* of informed consent to protect against *"…intrusions into one's bodily integrity…"*, they also suggest that rights of bodily integrity are not applicable to the matter of biobank research (114). The right to bodily integrity has been described as the right to "*…exclude all others from the body, which enables a person to have his or her body whole and intact and free from physical interference…*" (Herring & Wall, 2017: 581) and is protected by Article 3 of the European Charter of Fundamental Rights (CFR) which states that *"…[e]veryone has the right to respect for his or her physical and mental integrity"* particularly *"…[i]n the fields of medicine and biology... [where] …the free and informed consent of the person concerned [must be obtained] according to the procedures laid down by law...*" (European Union, 2010, art. 3(1)(2)(a): 380). Whilst the enactment of the European Union (Withdrawal) Act 2020 means that the CFR will no longer *directly* apply in the UK, the ECHR *does* still apply. Accordingly, rights of bodily integrity remain protected under ECHR Article 8, the '*Right to Respect for Private and Family Life'* which is interpreted "*broadly*" to encompass *"…multiple aspects of the person's physical and social identity…"* (Council of Europe, 1952: art. 8; *Pretty v The United Kingdom* [2002]: 61; *Denisov v Ukraine* [2018]: 95). Therefore, whilst the potential risks associated with biobanks are unlikely to lead to *physical* interference with bodily integrity, the re-identification of participants could lead to potentially degrading treatment, prejudice, discrimination, and exclusion of those who display 'high risk' behaviours which could undermine values such as 'well-being', 'dignity' and 'psychological integrity' that are protected under Article 8 ECHR (Herring & Wall, 2017; *Beizaras & Levickas v Lithuania*

[2020]: 117; *Söderman v. Sweden* [2013]: 80; Council of Europe, 1952: art.8). Feminist ethics have also been used to argue that digital images of one's body (arguably also a form of biodata) could be considered to as "*…digital prostheses – [or] extensions of ourselves, of our will and agency – [that] do not merely represent us but also embody us…*" (Rey & Boesel, 2014 in Patella-Rey, 2018: 788). If, theoretically, this argument is extended to include digitalised data then one's DNA profile - the genetic blueprint of our physical identity that is commonly held in biobank databases - could be deemed to be a digital extension of the *physical* self so that interference with such data would constitute an inference with bodily integrity in its broadest sense. Indeed, as we look ahead to the mid twenty-first century - with the increasing integration of artificial intelligence (AI) with medicine - it is likely that our interpretation of bodily integrity will also need to adapt. So too will interpretations of autonomy, arguably in a manner that offers greater - not less - protection to individuals. It is to this end that constructs of solidarity which uphold autonomy, such as conjoint solidarity, are considered more desirable. Conjoint solidarity, by contrast, promotes an educationally intensive, rather than coercive, approach to the collective needs of society in a dynamic manner that is reflective of 'responsive communitarianism' (Etzioni, 2003) [1].

3.2.2. In Relation to the Importance of Informed Consent. Prainsack and Buyx (2017) appear to view informed consent as a litigious risk management tool - a *"…quasi-synonym for autonomy itself…"* - that merely acts as a 'stamp of approval' to confirm participant understanding and acceptance of risk (114, 117). Whilst possibly true from an *institutional* perspective, this interpretation of consent fails to acknowledge that, for the *participant*, truly informed consent promotes educated decision-making. Instead, Prainsack and Buyx (2017) conclude that *"…informed consent procedures are effectively aimed at preventing and minimising risk…"* and they subsequently *"…perpetuate[s] the implicit expectation that once participants are duly informed of as many risks as possible*

and of all efforts in place to prevent these risks from materialising, they will be 'safe' - which they never are…" (120). There is ambiguity surrounding this interpretation: when a researcher or practitioner discloses risk it is not to prevent those risks materialising, rather to ensure the individual makes an informed decision of whether to incur such risk. Indeed, their approach to information disclosure could be viewed as further undermining autonomy. Prainsack and Buyx (2017) explain that an *"…important feature…"* of their solidarity-based data governance model is that participants *"…who knowingly and voluntarily contribute data …are willing to accept costs…"* - with those costs equating to the acceptance of risk (110). Accordingly, individuals should be informed of the risks which a *"…reasonable person would normally expect…"* to be made aware of, or of "…*particular other risks…*" (Prainsack & Buyx, 2017: 107). Whilst the concept of '*knowingly*' accepting cost would appear to reflect the informed acceptance of risk '*as per informed consent*' and, similarly, the standard of disclosure would appear to relate to the legal '*reasonable person standard*', the authors simultaneously seek to downplay *how much* information need be known about such participation. Of the nature of participation, the authors propose that *"…[r]ather than being confronted with technical language detailing protocols and risks, potential participants should… [instead come to] …understand the …way a database operates, and for what goals…"* (2017: 119). Here, the focus shifts to disclosing information about the system of participation rather than its associated benefits or risks, which would traditionally be required in terms of informed consent. Of the associated risks, Prainsack and Buyx (2017) distinguish the risks of biobank participation from the "…*considerable…*" health risks associated with other forms of research by describing them as "…*very small, both in terms of the nature and the degree of risk…"* and *"…extremely rare…"* (110, 114, 116). Notably, from a legal perspective - albeit in terms of *treatment* consent - adjectives such as "…*considerable…*" and "*…very small…*" would indicate a quantitative assessment of risk that has been rejected by the courts on account of their failure to encompass the impact that a risk could have upon the life of such a reasonable person (Prainsack & Buyx, 2017: 114,

116; *Montgomery v Lanarkshire* [2015])[2]. In somewhat of a contradiction, the authors are also dismissive of such disclosure as *"…in the case of virtually all research biobanks, it is impossible to predict all the ways in which data and samples will be used in the future […and so…] informed consent models trying to achieve full risk reduction and disclosure at the moment of joining are doomed…"* (Prainsack & Buyx, 2017: 115). Furthermore, in terms of benefit, the authors encourage a 'collective' *commitment* to incur costs yet there is little corresponding explanation of 'collective' benefit to be enjoyed by individuals beyond broad generalisations such as 'future treatments' (2017: 105). Finally, the authors conclude that once a willingness to accept costs has been demonstrated – albeit without those risks necessarily being explicitly disclosed - a participant is deemed to have *"…accept[ed] a certain level of risk…"* which may include the loss of some of the "…*benefits…*" of autonomy, such as control over *"…future use of data…*" (2017: 119). It is to this end that the authors justify broad models of consent for biobank governance: where a participant initially consents to biobank data collection, such consent would be extended to other, similar uses of their data in future without the need to 're-consent' (Prainsack & Buyx, 2017: 115). Such limited information disclosure is in direct opposition to the ethos of conjoint solidarity which promotes 'pooling of information' to support relational autonomy [1].

3.2.3. In Relation to Exclusive Solidarity and Othering. A common theme identified in relation to current models of solidarity in healthcare is the potential for exclusivity and othering. For example, Prainsack and Buyx's requirement to carry costs (2011; s.8.25:87) could be deemed exclusionary and is described by Dawson and Jennings (2012) as an "…*unnecessary condition for solidarity…"* (74)[1]. Instead, they propose that individuals should 'stand up beside' one another in response to injustice or disadvantage, although this too could be viewed as placing unnecessary limitations upon the scope of solidarity by requiring individuals to sense injustice or acknowledge disadvantage in another (Dawson & Jennings, 2012: 74). Prainsack and Buyx (2011) also propose that individuals

need identify some form of "*…sameness or similarity…"* with another to foster solidarity. However, solidarity that is founded upon similarity could exclude dissimilar demographics within our diverse healthcare systems (34) [1]. Furthermore, it may also foster inter-generational, inter-racial or intersocietal tension which may erode empathy and contribute to dehumanisation of the patient [1]. Such dehumanisation may manifest in various ways such as gender or racial treatment bias. One study into gender treatment bias described how women in pain are less likely to be taken seriously than men upon admission to Accident and Emergency (A&E) departments (Chen *et al*., 2008). Hamberg (2008) describes gender treatment bias as a wider problem, encompassing a *"…large variety of conditions such as coronary artery disease, Parkinson's disease, irritable bowel syndrome, neck pain, knee joint arthrosis and tuberculosis [where] men are investigated and treated more extensively than women with the same severity of symptoms…"* (238). Similarly, a study by Hoffman and colleagues (2016) described racial treatment bias in the study into the attitudes of 418 medical students and residents. The authors found that "*…many white…*" medical practitioners falsely believed that there were "*…biological differences between blacks and whites…"* with those practitioners also demonstrating racial bias in their management of black patients experiencing pain (Hoffmann *et al*., 2016: 4299).

Another form of potentially exclusionary solidarity is described by Davies and Savulescu (2019), who closely align solidarity with the fulfilment of obligations. They propose that where individuals do not fulfil their solidaristic healthcare obligations they could forfeit benefits of healthcare access (Davies & Savulescu, 2019). In one example, Davies and Savulescu (2019) suggest that if patients autonomously make "*…unhealthy choices [this could] violate [the] obligations of solidarity…*" and lead to revocation of healthcare access (136). The authors apply this model to obesity and suggest that individuals are obliged to act upon a "*Golden Opportunity"* to address their inactivity (Davies & Savulescu, 2019: 133). This approach would appear to coerce patients to act in a certain way and may also

penalise those most in need of healthcare assistance [1]. Although the authors *acknowledge* that other factors influence obesity, a focus upon inactivity alone fails to acknowledge this (Davies & Savulescu, 2019: 138). In the UK, growing food insecurity and food bank utilisation - factors associated with "…*stress, depression, and weight-gain…*" - present an additional socio-economic barrier to healthy food choices that could contribute to obesity (Thompson *et al*., 2018: 100) [1]. It is therefore argued that penalising patient demographics who are subject to complex health and social care needs should not be considered the basis of solidarity in healthcare [1].

In exploring such exclusionary forms of solidarity further, paper one also considers Goodin and Spiekermann's (2015) political concept of *epistemic* solidarity that relates to 'elites' and 'masses'. They explain how political 'elites' have greater access to information compared to the 'masses', yet those 'masses' can overcome their disadvantage by 'pooling information' in a process they refer to as epistemic solidarity (Goodin & Spiekermann, 2015: 2). If applied to the healthcare setting, healthcare practitioners could represent knowledgeable 'elites' - a theory strengthened by considering the imbalance resulting from *Bolam's* professional judgement standard which excludes patients (see Themes II, III; *Bolam v Friern Hospital Management Committee* [1957] 587) [2][3] - whereas patients represent the epistemically 'disadvantaged masses' [1]. Patient 'masses' can, however, unite to overcome this imbalance, as is evidenced in the Independent Medicines and Medical Devices Safety Review (IMMDSR) in which patient support groups such as '*#MASHEDUPBYMESH'*, '*Sling the Mesh'* and '*Welsh Mesh Survivors'* collectively 'pooled' information to have their voices heard (Cumberlege, 2020; Independent Medicines and Medical Devices Safety Review, 2019: Written Evidence: Patient Groups) [1]. Indeed, the prelude to the Cumberlege Report (2020) praises such groups as being *"…well informed, knowledgeable, and research based…"* (pi). However, this current dynamic - of elites and masses - also promotes exclusion and othering of the patient who may be perceived as being

"…*unschooled, and too simple to know how to take care of [themselves]…"* by paternalistic practitioners (De Zulueta, 2013; Monya, 2004: 55) [1]. Such a model of the practitioner-patient relationship is therefore considered to be deficient and may contribute to adverse outcomes.

3.3. The Effects of Othering the Patient

Exclusionary othering and solidarity fostered in 'subgroups' within our healthcare systems can lead to othering, the erosion of empathy and eventual dehumanisation of the 'other' group [1]. De Zulueta (2013) explains how *"…doctors may [become] immersed in the white coat group of individuals…"* that excludes patients or, they may become overly focused upon treating the disease rather than the individual (65). As is explored in paper two, where practitioner interest takes precedence over professional duty to maintain the patient's interests as the primary concern, a conflict of interest may arise that can be harmful to patients (See Robertson *et al*., 2012) [2]. The effects of such othering, exclusion and conflict of interest are examined throughout this body of work by addressing the select body of healthcare inquiries outlined below which underline the need for an alternative, inclusive, approach to healthcare solidarity [1].

3.3.1. The Francis Inquiry, 2013. The Francis Inquiry into the Mid-Staffordshire NHS Foundational Trust examined evidence of widespread failings at Stafford Hospital in the period between 2005 and 2008. During this time *"…appalling care [standards were] able to flourish…"* including poor standards of infection control, widespread failure to address patients' basic hygiene needs and to provide essential assistance with eating and drinking (Francis, 2013: 1, 26, 30). The report concedes that "…*the system as a whole failed in its most essential duty – to protect patients from unacceptable risks of harm and from unacceptable, and in some cases inhumane, treatment that should never be tolerated in any hospital"* and that there was *"…no culture of listening*

to patients…" (Francis, 2013: s4, s1.9). Instead, HCPs were focused upon *their* collective goal of attaining Foundation Trust status which resulted in a "…*callous indifference…*" towards patients which resulted in such adverse outcomes (Francis, 2013: 13). De Zulueta (2013) blames an institutional "…*emphasis on dissimilarity…*" within Mid-Staffordshire NHS Trust for the patient exclusion and dehumanisation responsible for such disturbing outcomes and increased mortality (122).[1] The Report found that there was no need for a "…*radical reorganisation…*" of the health service, but instead called for a refocus upon a *"…commitment to common values throughout the system by all within it…"* which it considered to be "…*truly important…*" (Francis, 2013: s.1.119). The series of recommendations aimed to *"…put patients where they are entitled to be – the first and foremost consideration of the system and everyone who works in it…*" (Frances, 2013: s1.237). Such an approach, which values inclusion of patients, is reflected in the model of conjoint solidarity that will be outlined later in section 3.4 [1].

3.3.2. The Cumberlege Report, 2020. Whilst the Francis Report, 2013 specifically concerned Mid-Staffordshire NHS Trust, themes of epistemic imbalance and exclusion, have also been identified throughout the NHS in subsequent inquiries. The IMMDSR (2018; 2019) and subsequent Cumberlege Report, 2020 address concerns relating to the use of medicines and medical devices in the NHS from the 1950s until the present-day. They addressed three key areas:

- The ongoing use of anti-epileptic drug sodium valproate – albeit now under stricter conditions - despite being known to be a potent teratogen since first licensed in 1972 (Cumberlege, 2020 s4.1: 98).
- The continued use of hormonal pregnancy tests until the late 1970s, despite concerns of teratogenicity as early as 1958 (Cumberlege, 2020, s3.1: 62).

- The prolonged use of pelvic (vaginal) mesh for more than twenty years, despite patient reports of "*crippling, life-changing, complications*" (Cumberlege, 2020, s1.2).

This body of work focuses upon the report's analysis of pelvic (vaginal) mesh in papers two and three as the issues identified in relation to mesh transverse several themes touched upon in this thesis, such as conflict of interest, exclusion of the patient, inadequate information disclosure and erosion of trust [2][3]. Whilst some patients reported that their mesh implantation surgery was successful, harmful complications of mesh may still develop as they often take years to emerge (Cumberlege 2020, s5.5: 140) [3]. It is evident from the testimony of the patients who *did* suffer harm that there is a disconnect between practitioners and patients that impedes positive healthcare outcomes. Paper three explores the findings of the report and proposes that 'informed' elites – encompassing industry, practitioners, policy makers and even the judiciary – often exclude patients when determining whether a treatment represents a suitable standard of care (Cumberlege Report, 2020; see also *Bolam v Friern Hospital Management Committee* [1957]: 587) [3]. Furthermore, as addressed in Theme II, the law also dictates that patients are not involved in treatment selection, which remains a matter of professional judgement (*Bolam v Friern Hospital Management Committee* [1957]: 587). As the pelvic (vaginal) mesh inquiry illustrates, this creates epistemic imbalance that excludes the patient and may have contributed to the ongoing use of harmful vaginal mesh [3]. Mesh injured patients described how they were not only poorly informed of the risk of mesh implantation but that they were also subsequently ignored when they reported their "*taboo*" mesh-related symptoms (IMMDSR, 2018: s5.12.1). Patients who reported symptoms of dyspareunia were dismissed with comments such as "…*lucky girl, you now have a designer vagina…*" or "…*a lot of women would be very jealous…*" (see IMMDSR, 2018: Box 8, 167). Other patients reported being told that their symptoms were *"…all in [their] head and [that they] needed to see a psychiatrist…"* (IMMDSR, 2018: Box 7, 165). One mesh-affected patient described the culture of gaslighting patients as being

"*rife*" (Cumberlege, 2020: 17).[2] As a result, patient symptoms were flippantly disregarded and instead, the "…*blame and onus* [was put] *back on the patient…*" to such an extent that it constituted an "…*institutional denial of pain caused by mesh erosion…*" (IMMDSR, 2018: s5.12.3, s5.12.6: 167). This not only indicates a lack of empathy towards patients' pain and suffering but is also illustrative of a process of dehumanisation that leads to poor healthcare outcomes. As is argued in paper three, this failure to listen to, and involve, patients allowed the use of pelvic (vaginal) mesh to continue for far longer than it need have [3]. In her report, Cumberlege (2020) reminds healthcare practitioners and policymakers to *"…recognise that patients are its raison d'etre…"* – a profound statement that indicates that the practitioner-patient relationship needs to be rebalanced (pii).

3.3.3. The Inquiry into the Issues Raised by Paterson, 2020. Paper two also explores themes of patient exclusion in relation to conflict of interest and examines both the Cumberlege Report and Inquiry into the Issues Raised by Paterson, the 'Paterson Report' (James, 2020; Cumberlege, 2020) [2]. Paterson, a Consultant Breast Surgeon, driven by his own "*significant*" financial self-interest, embarked upon a decade-long campaign of patient deception (Rowland, 2019, s.5: 5). This involved incentivising general practitioners to recommend patients to his private practice. He also encouraged his existing NHS patients to see him privately, claiming they would otherwise face long NHS waiting lists for treatment - despite British Medical Association (BMA) guidance expressly prohibiting practitioners from initiating discussions about private practice with NHS patients (James, 2020: 19, 120; BMA, 2020). Through his private practice, Paterson sought to promote his own self-interest and financial gain. He often requested unwarranted investigations and then purposefully misinterpreted results so that further surgical interventions were indicated (James, 2020: 48, 88, 106, 120). He went so far as to erroneously inform some patients that they had cancer when they were free of the disease (James, 2020: 47). Furthermore, he often performed excessive, unnecessary, and even unproven treatments including his own

'cleavage sparing mastectomy'– a procedure with *"…no definition …[that] is not recognised practice…"* (Rowland, 2019, s.5: 5; James, 2020: 11, 52-53). Paterson actively misinformed patients and so perpetuated the concept of patients as disadvantaged, uninformed 'masses' [1][2]. He used a distorted version of a paternalistic practitioner-patient relationship which was fuelled, not by hard-line beneficence but instead by self-interest, to facilitate deception and dehumanisation of patients. For Paterson, patients were a 'means-to-an-end' rather than as individuals with their own, unique healthcare needs. Paper two explores how conflict of interest can propagate epistemic imbalance and may be associated with harmful outcomes for patients. It is to this end, that paper two argues that significant (or 'potent') financial conflicts of interest should represent a disclosable, material risk that the patient be informed of [2].

3.4. Towards Conjoint Solidarity

Having identified the potential impact that exclusionary models of solidarity may have upon the practitioner-patient dynamics, conjoint solidarity is proposed to add to the existing scholarship [1]. As a concept, conjoint solidarity is founded upon a model of inclusivity which promotes epistemic balance in the practitioner-patient relationship so that a united approach to healthcare be adopted. It is anticipated that this will uphold, rather than undermine, autonomy and can serves as a means of promoting trust and of collaboratively addressing healthcare issues [1].

3.4.1. Inclusivity and Relational Autonomy. In an adaptation of Goodin and Spiekermann's (2015) epistemic solidarity, it is proposed that 'elites' and 'masses' unite in healthcare to pool information *amongst all* healthcare stakeholders [1]. The term 'healthcare stakeholder' is preferred over 'practitioners' and 'patients' as it serves to signify an *inclusive* form of solidarity that unites those distinct groups which share the same goal - in this case, improved healthcare outcomes [1]. It is on this basis, that conjoint solidarity

calls upon healthcare stakeholders to *collectively* pool information as part of their *'duty to assist one another"* in achieving those outcomes [1: 2]. This is not intended to be a consequentialist ideal based purely on the attainment of the shared interests or goals of the collective. Rather, it is argued that *relational* autonomy enables an understanding of solidarity that takes the individual seriously without failing to show consideration for the needs and others. It is to this extent that conjoint solidarity describes 'the nature of duties' amongst individuals that arises *from* relational autonomy. Paper one develops this argument by exploring a spectrum of interpretations of autonomy through analysis of the well-established concept of 'self-interest' in moral theory. It concludes that a relational approach is the most appropriate to the healthcare setting [1]. Ordinate self-interest is a concept widely explored in Nicomachean ethics as a necessary part of the pursuit of *eudaimonia* (Aristotle, 2000 [n.d]). Whilst individualistic interpretations of autonomy hold the individual to be the ultimate point of reference in determining self-interest, in a way reflective of the 'self-absorption' of egotism, relational interpretations of autonomy reflect the prudent pursuit of self-interest [1]. This, it is argued, aligns with ethical egoism and *its* wider consideration of external influences such as family and community [1]. Paper one concludes that even when autonomy is interpreted as a liberal concept, such a social dimension exists that is suggestive of compatibility between autonomy and solidarity [1: 7].

Strength is given to this argument by consulting the work of Kant (2005 [1785]) who described autonomy in relation to individual self-governance yet simultaneously acknowledges that it should be interpreted in a *relational* manner. According to his maxim of universality, individuals are required to only act in a way which may be applicable to all (see Kant, 2005 [1785]). Further support of this notion of relational autonomy is offered by the idea of 'freedom as independence', as described in the Republican literature. Pettit, for example, describes freedom as the emancipation from the power that one agent has over another, which he calls '*antipower'* (Pettit, 1996: 577). In the *Metaphysics of Morals*, Kant

provides a stronger basis still for relational autonomy in outlining the *Universal Principle of Right* which holds that *"…[a]ny action is right if it can coexist with everyone's freedom in accordance with a universal law, or if on its maxim the freedom of choice of each can coexist with everyone's freedom in accordance with a universal law…"* (Kant, I. (1996 [1797]); 6:230). Therefore, the doctrine holds that moral autonomy reflects freedom of will rather than the independence from the choice of others. Accordingly, independent people are identified within the relational context of owing moral duties to others upon which their mutual independence or freedom are secured. Ripstein proposes that such Kantian ideals remain relevant to modern notions of equal freedom, such as in relation to the law on private rights and, indeed, within the wider penal system (Ripstein, 2009).

In '*A Theory of Justice',* Rawls also acknowledges a social dimension of liberalism when he proposes that free and equal individuals may choose to endorse and engage in social principles of justice (Rawls, 1971). This is further supported by the rich body of literature on social contract theory explored in paper 1 which demonstrates the potential alignment between liberalism – which promotes individual rights - and solidarity [1]. Building upon the theories of eminent scholars such as Hobbes, Locke and Rousseau, paper one identifies a broad consensus that the 'solidaristic' union may be supported by individual, rational choice to support the collective (Hobbes, 2010 [1651]); Locke, 1948 [1632]; Rousseau, 2018) [1]. Indeed, Rousseau's 'contract theory' concedes that social union is permissible so long as there is no net loss of freedom and acknowledges that 'mutual aid' or 'assistance' can be given to support the collective (Rousseau, 2018). This theme of mutual assistance underlies the principle of conjoint solidarity which distinguishes *itself* from other, consequentialist, notions of solidarity [1]. Prainsack and Buyx's proposal, which is rooted in the consequentialist outcome of the duty to assist, promotes an inordinate form of self-interest which holds that individuals should act *against* their own self-interest and, through an act of generosity, relinquish their own justifiable rights of autonomy (Prainsack & Buyx,

2011; Prainsack and Buyx, 2017) [1]. By contrast, conjoint solidarity describes an ordinate, prudent form of self-interest which aligns with ethical egoism. It promotes responsible action to safeguard the individual's legitimate wellbeing whilst considering others in the context of attaining improved healthcare outcomes. The crucial distinction is that conjoint solidarity and relational autonomy are viewed as twin pillars of decision-making which, together, promote rational thought for the individual and collective. It is upon this reasoning that conjoint solidarity distinguishes itself from the existing scholarship, as an *inclusive* form of solidarity that is founded upon free will and rational choice [1].

3.4.2. Benefits of Inclusivity. It is anticipated such a relational approach to conjoint solidarity will enrich standards and interpretations of informed consent in a manner that supports, rather than undermines, autonomy by promoting mutual assistance and collaboration amongst stakeholders. The benefits of inclusivity are outlined in paper 1 and include improved job satisfaction, increased morale, and improved trust. Enhanced trust is said to be linked to improved disclosure by both patients and practitioners that is likely to improve diagnostics, treatment selection and overall treatment adherence. It is further anticipated that it may tackle issues such as treatment bias and discrimination [1]. In considering the earlier example of biobank participation, under a conjoint solidarity model, biobank participants would be fully informed of the risks and benefits of participation - both from an individual and collective perspective. Such consent would likely be dynamic - as explored by Whitley *et al.* (2012) - to afford participants to the opportunity to reconsider their involvement. It is anticipated that such an approach is likely to have utility in building trust, particularly amongst demographics who are wary of involvement in medical science (Steinsbekk *et al.*, (2013) [1]. Paper one also considers how conjoint solidarity would be used to address questions of distributive justice in healthcare [1]. A relational approach to justice is proposed to align with conjoint solidarity and is considered preferable to egalitarian interpretations of justice which, whilst based upon principles of equality, may inadvertently

perpetuate disparity by failing to recognise *pre-existing* inequality [1: 10] (see also Agnol, 2005). Similarly, liberal egalitarian interpretations of justice, such as that described by Rawls, may be deemed exclusionary as they suggest that rights take the form of *opportunity* and the extent to which an individual takes *advantage* of opportunity determines their subsequent allocation of resources (Rawls, 1971). Indeed, Ter Meulen argues that if applied to healthcare justice, this could lead to the humiliation of those who fail to take advantage of their opportunities and the familiar pattern of exclusion, othering, and dehumanisation might arise [1: 10] (Ter Meulen, 2017).

Notably, due to the scope of paper one, only a cursory analysis of Rawls's overall work is provided, and it is prudent to acknowledge here that the Rawlsian form of distributive justice is not purely limited to opportunities alone. Rawls's '*equality of opportunity'* is but one of the subprinciples of the second principle of justice and, it may be argued, that the subsequent 'difference principle' - which governs resource distribution - could address other relevant issues of healthcare resource access. Rawls's difference principle holds that inequalities are just so long as they benefit the worst off in society (Rawls, 1971). However, such an approach may fail to account for disability. A future exploration of this discussion - beyond that which is included in paper one - may look to Sen's proposed *'capability approach'* which instead focuses upon individuals' freedom to achieve well-being and the opportunities for them to attain what they are capable of (see Sen, 1992). Sen's concept of 'basic capabilities' was further developed by Nussbaum who considered basic capabilities to encompass *"…that which individuals need for developing more advanced capabilities…"* (Sen, 1980; Robeyns, 2016; Nussbaum, 2000).

Further critique of Rawls's difference principle may be drawn from Cohen's work which argues that Rawlsian justice fails to look beyond 'coercive' institutions and so does not recognise the role of personal choice in maintaining 'non-coercive' informal institutions

such as families – the concept of free choice being critical to their existence. Indeed, the notion of free choice is also central to conjoint solidarity, yet Cohen simultaneously presents an 'incentives argument'. This holds that it may be just to provide incentives to those with special capabilities, advantage, or talent – even though this may lead to greater inequality – as such a move may lead to more goods being available to the worst off (Cohen, 1997 pp3-30). Paper one, instead, looks to *relational* justice which incorporates aspects of conjoint solidarity such as communication, cooperation, and dialogue amongst stakeholders and relational autonomy by recognising the inextricable links between individuals and society – without the need for such incentivisation which could undermine the validity of autonomy through coercion (Raines, 1989; Ter Meulen 2017; Casanovas & Poblet, 2008) [1]. It is suggested that by aligning interpretations of justice and solidarity in this manner, healthcare stakeholders can better recognise and accept individual responsibilities in relation to healthcare utilisation [1]. Whilst this is not proposed as a one-stop solution, it is intended to serve as a reference point for debate and contemplation. Furthermore, whilst conjoint solidarity, relational autonomy and relational justice necessitate greater dialogue with patients - which may raise concerns over time constrained on an already pressurised system - it is anticipated that this represents an investment so that the 'pooling of information' can facilitate improved interpretations of desirable healthcare outcomes and their attainment. By re-balancing the practitioner-patient relationship in this way, interpretations of informed consent can be enhanced which can help to rebuild trust [1].

4. Theme II: Analysis of Informed Consent and its Deficiencies

4.1. The Law of Informed Consent and its Enduring Paternalism

As outlined, epistemic injustice and paternalism have been facilitated by authoritarian constructs of the practitioner-patient relationship, by judicial deference to the medical profession and, more recently, through inaccurate interpretations of the new legal standard of information disclosure, such as those outlined by the GMC as described in paper two

(Austin, 2018; GMC, 2020) [2]. The second paper on conflict of interest addresses two key aspects of this thesis: the evolution of the common law standard of informed consent in the UK and the interpretation of disclosable material risk through an examination of the relevant case law and guidelines [2]. It is argued that, despite advances in legal standards, such changes have been slow to influence medical practice and so informed consent processes remain skewed towards the paternalistic in many areas [2][3]. This premise is supported by a 2021 study from Kennedy and colleagues which examines consent standards on labour wards. They found that "…*uncertainties and ambiguities in consent practice…sometimes falls short of legal and professional requirements…"* (Kennedy *et al*., 2021: 150). These findings were recently confirmed by the Ockenden Report which exposed maternity failures at The Shrewsbury and Telford NHS Trust and outlined essential action to *"…ensure women have ready access to accurate information to enable their informed choice of intended place of birth and mode of birth, including maternal choice for caesarean delivery…"* (Ockenden, 2022: 211). Whilst it is recognised that obstetrics is a complex and challenging area of practice, similar findings were also described in relation to surgical consent by Ricketts and colleagues (2019). In their 2019 review of the literature, the authors concede that *"…[a]necdotally, the number of 'lack of consent' claims against doctors has gone up in the past two years…"* and surgeons are probably obtaining consent with a *"…sense of unease…*" (Ricketts *et al*., 2019: 44). As will be explored, perhaps such unease could be attributable to the evolution of the current legal standard which may have created ambiguity [2].

4.2 Evolution of a Legal standard

For adult patients with capacity – that is, the ability to understand and process information to make a reasoned decision - the law is clear that consent must be obtained prior to treatment, however the requirements of such content have long been the subject of judicial analysis, particularly in relation to how much information a patient needs to reach such a decision (see *Devi v West Midlands RHA* [1980] C.L.Y 687) [2]. In 1957, the *Bolam* test

was established so that a practitioner would not be deemed negligent in treatment selection or information disclosure if their actions were in "*…accordance with a practice accepted as proper by a responsible body of medical men skilled in the particular art…*" (*Bolam v Friern Hospital Management Committee* [1957]: 587). Arguably, this ruling excluded patients from meaningful decision-making - an issue that Lord Scarman sought to address in the subsequent case of *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871 when he proposed that disclosable information be determined by a *"reasonably prudent patient standard"* (800). He was, however, in the minority. Lord Templeman perceived the practitioner's duty of beneficence to outweigh the patient's right to be given *"…all [of] the information…"* about a proposed treatment, however information should be disclosed if a patient asked the relevant questions. Lord Bridge considered that practitioners should inform patients of *"…substantial risk of grave and adverse consequences…"* (*Sidaway v Board of Governors* [1985]: 904; 900). In adopting a 'reasonably prudent doctor' standard, Lord Diplock distinguished *himself* from the patient masses as he explained that a judge would want the *"…right to decide [what is] done to [their] body…[and] to be fully informed of any risks…"* whilst patients need not have access to such information (*Sidaway v Board of Governors* [1985]: 895; 897) [1][2]. The issue of information disclosure was revisited in *Pearce v United Bristol Healthcare NHS Trust* [1998] 48 BMLR 118 - although an unsuccessful case, it was an early attempt to refine the parameters of disclosable risk by introducing terminology such as '*significant'* risk and '*the [judgement of the] reasonable patient'* (124). A full account of the interceding case law is provided in paper two, however, it was not until the 2015 judgement in *Montgomery v Lanarkshire*, that disclosable risk was defined according to a test of materiality (81) [2].

4.3 Montgomery and Beyond

The Supreme Justices in *Montgomery v Lanarkshire* [2015] revisited the judicial reasoning in *Sidaway v Board of Governors* and rejected the *"profoundly unsatisfactory"* majority

view that placed a burden upon patients to ask the correct questions (*Montgomery v Lanarkshire* [2015]: 58; *Sidaway v Board of Governors* [1985]: 886). They also rejected the notion of a "*substantial*" risk standard recognising that decision-making involves consideration of other, non-quantifiable factors (*Montgomery v Lanarkshire* [2015]: 45, 58). They differentiated between the adjectives "*substantial*" and "*significant*", explaining they have "…*different shades of meaning…*" with the latter being to more appropriate term (*Sidaway v Board of Governors* [1985]: 900; *Montgomery v Lanarkshire* [2015]: 66). They clarified that significant risk is embedded within the wider concept of material risk as they outlined the new legal standard:

> An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it *(Montgomery v Lanarkshire* [2015]: 87).

This new test of materiality considers both a *reasonable* person standard and the needs of a *particular* patient. According to UK law, the 'reasonable person' is "…*the man on the Clapham omnibus…*' - a theoretical representation of the ordinary man with reasonable judgement (*McQuire v Western Morning News* [1903]:109). Whilst the Supreme Court Justices referred to this standard during their judicial reasoning, they appear to have instead adopted a collective version of this rule which may reflect the opine of '*passengers on the*

Clapham omnibus' [2]. Lords Kerr and Reed clarify that *"…no woman would, for example…likely [be willing] to face the possibility of a fourth-degree tear, a Zavanelli manoeuvre or a symphysiotomy with equanimity…"* (*Montgomery v Lanarkshire* [2015]: 94). This '*collective*' view of *women* appears to mark a departure from the individual reasonable man standard. Furthermore, Baroness Hale considers a collective analysis of 'mothers' when she describes the *"…risks that any reasonable mother would wish to take into account …in order to balance said risks against benefits in relation to each eventuality…*" *(Montgomery v Lanarkshire* [2015]: 121) [2]. Paper two argues that this 'collective' reasonable person standard could, potentially, facilitate the use of empirical evidence in court to address questions of materiality and causation [2].

The issue of materiality has been explored in the cases that followed *Montgomery v Lanarkshire* [2015]. In *A v East Kent Hospitals University NHS Foundation Trust* [2015] the Court of Appeal considered negligent non-disclosure of the material risk of restricted intra-uterine growth being linked to chromosomal abnormality. Ultimately, Justice Dingemans considered the risk to be:

> 'theoretical', 'negligible' or 'background', which in percentage terms is less that 1 in 1,000 [and so there was] … no need to discuss this risk with Mrs A and in any event any reasonable patient, and Mrs A, would not have wanted to know about it and would have ignored it in the same way that she had ignored the residual background risk of Down's Syndrome… (*A v East Kent* [2015]: 69).

However, the Justices in *Montgomery* clearly sought to emphasise that material risks cannot be *"reduced to percentages*" as material risk is both "…*fact sensitive, and sensitive to the characteristics of the patient…*" - an acknowledgement that patients are entitled to take *"…[their] own values, [their] own assessment of the comparative merits […of a*

treatment…]…" into account (*Montgomery v Lanarkshire* [2015]: 87, 89:115) [2]. Whilst the *East Kent* ruling potentially marked an early departure from the *Montgomery* standard, the 2017 case of W*ebster v Burton* upheld *Montgomery's* assertion that risk should not be reduced to percentages (*A v East Kent* [2015]; *Montgomery v Lanarkshire* [2015]; *Webster v Burton* [2017]). The court heard that despite ultrasound indications of polyhydramnios (excess amniotic fluid) there was negligent management of Ms Butler's pregnancy and a failure to offer an early induction of labour which could have avoided the subsequent umbilical cord compression and hypoxic brain injury sustained by her baby (*Webster v Burton* [2017]: 11; 2). Lord Justice Simon clarified that the *Montgomery* standard holds that assessment of risk cannot be reduced to percentages and, as such, Ms Butler should have been informed of "*…emerging but recent and incomplete material showing increased risk of delaying labour in cases with this combination of features…"* (*Webster v Burton* [2017]:29; 40).

The influence of the judicial reasoning in *Montgomery* cannot be understated - not only did it redefine the legal duty to give greater respect to patient autonomy but, in doing so, it placed a duty upon practitioners to get to know the 'particular' patient (*Montgomery v Lanarkshire* [2015]: 81) [2]. This can be seen in the way material risk is interpreted to facilitate consideration of the *"…significance of a given risk…"* in terms of the *"…nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives…"* (*Montgomery v Lanarkshire* [2015]: 89). However, in paper two, it is argued that this is not necessarily reflected in current guidance from the GMC which may, inadvertently, promote a paternalistic interpretation of the legal standard in advising practitioner to inform patients of the *"…recognised risks of harm…"* that *they*, the practitioner, believe "*…anyone in the patient's position would want to know…"* (GMC, 2020: 15) [2]. If interpreted as a requirement to disclose only the information that the *practitioner believes* that a patient need

know, then the guidance not only falls short of the legal standard, but may also fail to *"…treat […patients…] so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices…"* (*Montgomery v Lanarkshire* [2015]: 81) [2]. Such insufficient interpretations of the legal standard facilitate imbalance in the practitioner-patient relationship that is propagated by exclusionary forms of solidarity as described in paper one [1]. By instead adopting an *inclusive* approach to the practitioner-patient relationship – incorporating themes of conjoint solidarity and relational autonomy [1] – these interpretations of the legal standard may be improved. Papers two, three and four consider the parameters of 'materiality' in relation to disclosable risk and question whether interpretations should be expanded to potentially improve patient care. These papers also acknowledge that the subsequent case of *Duce v Worcestershire NHS Acute Hospitals Trust* [2018] EWCA 1307 determined that medical consent would now be interpreted as a two-staged process:

> First stage: The duty of care required in treatment selection is determined according to a test of professional judgement (*Bolam v Friern Hospital Management Committee* [1957]).
>
> Second stage: The duty of care required in disclosing information is according to a test of materiality (*Montgomery v Lanarkshire* [2015]).

This ruling restrained *Montgomery's* aim for greater patient-centricity and determined that matters of treatment selection remain subject to the traditionally paternalistic *Bolam* test (*Montgomery v Lanarkshire*, [2015]; *Bolam v Friern Hospital Management Committee*, [1957]: 583; Devaney & Holm, 2018) [2]. This is a pertinent distinction as, in paper three, it is argued that the *Bolam* test standard facilitates exclusive epistemic solidarity amongst healthcare practitioners that may undermine healthcare outcomes, particularly in relation to

treatment (*Bolam v Friern Hospital Management Committee* [1957]) [1][2]. As already emphasised, the pelvic (vaginal) mesh inquiry is a key example of how a disregard for patients' epistemic value during treatment selection may not be conducive to positive healthcare outcomes. As will be touched upon in Section 5.1, had patient concerns over mesh been heeded then implantation may not have been deemed best practice and fewer patients may, ultimately, have been maimed by the devices (*Bolam v Friern Hospital Management Committee* [1957]) [3]. Finally, it is of note that the decision in *Duce v Worcestershire* [2018] has further contributed to the ongoing judicial '*toing and froing'* on informed consent standards which have created uncertainty amongst the medical profession over informed consent requirements in practice [2].

5. Theme III: Proposals for Improving Interpretations of Consent to Ensure Patients are Engaged and Informed

Having outlined the deficiencies in the practitioner-patient relationship and of the deficiencies in legal and policy interpretations of informed consent, this thesis now turns to outline the potential solutions presented within this body of research as follows:

- First, consideration will be given to rebalancing the practitioner-patient dynamic through mutual persuasion, a practical application of conjoint solidarity and relational autonomy [4].
- Secondly, suggestions will be made on how to improve the first stage of consent in line with the prevailing *Bolam* standard (*Bolam v Friern Hospital Management Committee* [1957]: 582) [3].
- Finally, enhanced interpretations of material risk are considered in relation to information disclosure as a means of improving patient awareness of risk [2][3].

5.1 Rebalancing the Practitioner-Patient Dynamic

Paper four considers how to rebalance the practitioner-patient relationship. It examines the lack of trust in relation to vaccine hesitancy - defined as *"…the reluctance or refusal to vaccinate despite the availability of vaccines…"* - and concludes that a model of mutual-persuasion may present a solution (World Health Organisation (WHO), 2019) [4]. It explores parental consent to childhood vaccination - which often falls to those with parental responsibility - and considers how the process of shared decision-making can be enhanced through mutual persuasion to tackle vaccine hesitancy and underlying misinformation (Family Law Reform Act, 1969) [4]. As a form of prophylactic treatment, vaccination presents a unique challenge in developing trust as it aims to *prevent future disease* rather than treat existing illness. This means that the risk of side-effects, rather than disease, are often forefront. Vaccination represents one of the greatest achievements in medical science, having eradicated diseases such as Smallpox, yet has long been associated with suspicion (Williamson, 1984). However, Andrew Wakefield's now disproven and retracted study that linked the combined Measles, Mumps and Rubella (MMR) vaccine to Autism and Crohn's Disease has had lasting effect and has contributed to prevailing vaccine hesitancy amongst parents (Wakefield *et al*., 1998; Williamson 1984; Gayle 2019; Hardt *et al*., 2013). It has been suggested that vaccine hesitancy may also be attributable to a more generalised lack of trust in the medical profession and, according to Lalumera (2018) patients may perceive practitioners as being solely in pursuit of their own *"…hidden agendas [other] than public health, such as achieving benefits from Pharma companies…*" (20). Whilst some have argued that a vaccine mandate could provide a solution, paper four recognises that improving standards – and indeed interpretations - of informed consent could present a more sustainable solution by addressing these underlying causes of vaccine hesitancy such as misinformation and mistrust (Walker, 2019) [4]. To this end, a model of 'mutual persuasion' is proposed to re-balance the practitioner-patient dynamic [4].

According to MacLean (2006) the pre-*Montgomery* legal standard of informed consent simply involved a duty to bestow information on the patient, that *"…effectively abandon[ed] the patient to his or her fate…"* (328). He proposed that respect for autonomy requires an attempt be made to challenge an "…*apparently irrational decision…*" through a process of 'persuasion' that would allow the practitioner to challenge apparently irrational choices (MacLean, 2006: 331). Whilst, at law, there is no requirement for adults with capacity to make *rational* decisions, there is a requirement that patients fully understand the information given to them. According to MacLean (2006), by actively challenging irrational decisions, practitioners can ensure patients have sufficiently understood information. Persuasion is employed, not as a means of coercion, rather as a means of engagement and so, in this way, it can also be used to tackle vaccine misinformation whilst autonomy is upheld [1][4].

This approach is presented as a having several advantages. Ensuring patients *understand* the information presented to them is a necessary consideration for consent to be legally valid. It can simultaneously provide patients with an opportunity to ask questions or even persuade practitioners of their perspective (see *Montgomery v Lanarkshire* [2015]: 90) [4]. It is anticipated that mutual persuasion could promote greater depth of engagement between patients and practitioners which can help to improve the practitioner-patient dynamic and build trust [4]. As will also be addressed in Theme III, mutual persuasion also provides an opportunity to consider societal risks and benefits associated with vaccination as part of the decision-making process [4]. Therefore, the incorporation of mutual persuasion into shared decision-making can also serve to align relational autonomy with the principles of conjoint solidarity outlined in 'Theme I' [1][4]. By doing so, it raises patient awareness of social benefit and so may encourages patients and practitioners to adopt a duty to assist in attaining improved vaccination outcomes [1][4]. It could also have facilitated greater pooling of information between practitioner and patients in relation to the use of pelvic (vaginal) mesh, which could - arguably - have averted the ongoing use of mesh that maimed so many patients

[3]. Paper four outlines supportive measures that may facilitate this approach, such by improving patient access to trained healthcare practitioners (NHS Digital 2018) [4]. Investing time in supported decision-making can not only improve standards of informed consent but may also build trust, set more realistic patient expectations, and so enhance treatment compliance – all of which may improve outcomes and save time in the long-term (Graham *et al*., 2015; Frampton *et al*., 2017).

5.2 Improving the First Stage of Consent: Patient Input into Treatment Selection

As identified in Theme II, the case of *Duce v Worcestershire NHS* [2018] established that matters of treatment selection remains subject to a test of professional judgement. Paper three first explores the impact this might have on treatment selection standards by exploring the pelvic (vaginal) mesh inquiry and recommends a more *inclusive* approach to the first stage of consent be adopted [3]. Polypropylene mesh was first used in the treatment of abdominal herniae and, following a clinical trial that was heavily influenced by mesh manufacturer Ethicon, mesh was indicated for pelvic implantation in the treatment of stress urinary incontinence (SUI) and, subsequently, 'pelvic organ prolapse' (POP) (IMMDSR, 2018: 15-31; Gornall, 2018). Despite ongoing concerns over the efficacy of the treatment, it was rapidly adopted into practice as a quick and cheap alternative to the pre-existing treatment available. Patient concerns were disregarded so that the harmful practice continued for decades which indicates that qualitative evidence that is patient-based could have future utility in determining treatment standards (Cumberlege Report, 2020). Paper three, therefore, argues that *had* patient reports of complications been acknowledged earlier, then mesh implantation would not have been considered best practice [3]. Support is given to this argument by consideration of *Bolitho v City and Hackney Health Authority* [1996] All ER 771 which determined the *Bolam* test to be subject to additional considerations of logic and reasonableness, so that evidence-based practice may now be adopted to support a

test of professional judgement (243; *Bolam v Friern Hospital Management Committee* [1956]*:* 587) [2][3]. Evidence-based practice involves consultation of academic literature and clinical trial data to determine the best standard of care however such evidence may be subject to conflict of interest that may adversely affect such recommendations (Mulheron, 2010) [3]. This was case for the European Re-vascularisation Guidelines which set the standards of best evidence-based practice (Neumann, *et al*., 2019; Stone, *et al*., 2019) [2]. The industry-sponsored study that underpinned the guidance recommending stent use had actively suppressed data that found stents to be associated with 80% higher mortality rates (Cohen & Brown, 2020) [4]. Paper three, therefore, considers the value of patient-based evidence as a means of potentially mitigating against such evidential bias [3]. Whilst such qualitative evidence is often disregarded by practitioners in favour of quantitative data, patient-based evidence is increasingly used by organisations such as the National Institute for Clinical Excellence (NICE) (Sharma *et al*., 2015). It is therefore proposed that the limitations set by the prevailing *Bolam* standard be mitigated against by incorporating patient-based evidence (*Bolam v Friern Hospital Management Committee* [1957]: 587) [3]. This approach, which is reflective of concepts of conjoint solidarity and relational autonomy, pays recognition to the epistemic value of patients and could also help buffer against the financial bias addressed in paper two by consulting patient feedback on the success or failures of treatments [1][3].

5.3 Improving the Second Stage of Consent: Expanding Materiality

As outlined in Theme II, the introduction of a materiality standard in determining disclosable information for the purposes of informed consent marked a substantial shift towards greater patient-centricity, however the parameters of what constitutes material risks have not been fully tested by the courts through test cases (*Montgomery v Lanarkshire*, [2015] at 81). Papers two, three and four explore the boundaries of materiality and make suggestions for improved interpretations of materiality that may be beneficial in improving healthcare

outcomes. Research suggests that where patients are fully informed of risks through a process of shared decision-making, outcomes are more likely to be improved (Frampton *et al*., 2017).

5.3.1. Potent Financial Interests as Material Risks. Paper two recommends that material risk should be expanded to incorporate potent financial conflict of interest. Materiality is explored by way of a critical analysis of the case law to explore concepts such as 'significant' and 'material' risk, and the 'reasonable person' and 'particular patient' standards [2]. On such grounds, the paper then challenges current GMC guidelines, which influence practice, as being deficient interpretations of the legal standard (GMC, 2020). It reasserts that the practitioner, in establishing materiality, should actively engage in dialogue with individual patients in order to determine their respective values in line with the particular patient stipulation of *Montgomery v Lanarkshire* [2015]) [2]. It is argued that the legal interpretations of material risk are broad, and patterns of judicial reasoning suggest of a move towards recognition of majority views on reasonableness which could see empirical evidence playing a greater role in questions of materiality and causation in future (Spece and colleagues (2014). The paper concludes that potent financial interests – those which have a detrimental impact upon practice and are associated with erosion of trust – should be considered disclosable material risks [2].

5.3.2. Long Term Risks from Implants as Material Risks. Paper three recommends that disclosable risk should be expanded to consider the risk inherent to medical device implantation. It argues that risk disclosure has traditionally focused upon the immediate risk inherent to the surgical procedure - such as the risk of infection or rupture which could be addressed during the peri or post-operative periods — and not the long-term risk of device-induced tissue erosion (IMMDSR, 2018; *AH v Greater Glasgow and Clyde NHS* [2018] CSOH 57). Whilst it is accepted that practitioners may not have known of the

long-term risks of mesh implantation – and that in law practitioners cannot be expected to inform patients of unknown or unforeseeable risks - it is argued that unknown risk *was* foreseeable when implanting a device without long-term data to support its permanent use (*Duce v Worcestershire* [2018] at 43; Campbell *et al*., 2018). It is recommended that the risk disclosure be more widely interpreted to include longer term risks deriving from implantable devices, or indeed unknown risks associated with innovative treatment proposals [3]. In this way, patient autonomy can be upheld so that they are afforded the opportunity to decide whether, or not, to incur such risk.

5.3.3. Individual and Societal Material Risks in Public Health. Paper four also makes recommendations in relation to *both* material risks and benefits of vaccination. In adopting a model of mutual persuasion that can "…*appeal to …self-interest… [or a] sense of social obligation …or both…"* it is suggested that disclosure of vaccination *benefits* relate to both the *individual* and *collective* immunity (Bell *et al*., 2010: 853) [4]. This approach also reflects threads of conjoint solidarity and relational autonomy [1]. In relation to material risk, it is suggested that, alongside the risk of side-effects, the risk of *not* vaccinating also be discussed [4]. This would include the risk of disease posed to the individual and the wider risk posed to the most vulnerable in society. It is anticipated that expanding upon the interpretation of materiality to incorporate a collective, societal perspective can challenge vaccine misinformation and promote conjoint solidarity's duty to assist in promoting improved healthcare outcomes by tackling vaccine-preventable disease [1][4]. By interpreting materiality in its broadest sense, it is anticipated that trust in the practitioner-patient relationship be rebuilt - a factor associated with improved healthcare outcomes (Graham *et al*., 2015; Frampton *et al*., 2017)

6. Conclusion

This body of research considers the interplay between the practitioner-patient relationship and standards of informed consent. Themes of exclusion, othering, and dehumanisation are explored in relation to the practitioner-patient dynamic and are linked to poor healthcare outcomes. A new approach involving conjoint solidarity, relational autonomy and relational justice is proposed to rebalance and enhance this dynamic. The evolution of case law pertaining to informed consent is also addressed and deficiencies identified. Three key recommendations are made to improve interpretations of informed consent in the UK. First, that the practitioner-patient dynamic should reflect an inclusive and collaborative partnership that can serve as a vehicle to improve - not only standards of consent - but overall healthcare outcomes. Secondly, that patient-based evidence be afforded greater value when analysing treatment suitability to be more inclusive of patients. Finally, that material risk for the purposes of informed consent be interpreted more broadly. This, it is argued, will improve engagement, build trust, and potentially mitigate against the kind of harms that have been witnessed in the past.

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[1] A draft report in 2009 suggested that between 400 and 1200 deaths occurred in a 50-month period, however in the final report Sir Francis asserted that these mortality statistics could not be relied upon as a measure of avoidable deaths. See Francis, R (2010) Independent Inquiry into Care Provided by Mid-Staffordshire NHS Foundation Trust January 2005 – March 2009. Volume I. HC375-1https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279109/0375_i.pdf Section G p352

[2] The Cumberlege Report 2020 has the following definition of gaslighting (footnote, page 17): *"Gaslight (vb): To manipulate (a person) by psychological means into questioning his or her own sanity. Oxford English Dictionary. Etymology: title of George Cukor's 1944 film 'Gaslight' (based on a play by Patrick Hamilton first performed in 1938) in which a man psychologically manipulates his wife into believing that she is going insane".*