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Materiality of conflict of interest in informed consent to medical treatment in the United Kingdom

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ABSTRACT

The UK Supreme Court ruling of Montgomery v Lanarkshire clarified that in obtaining informed consent to treatment, practitioners are under a duty to inform patients of material risks. Traditionally such risk has pertained to the clinical risks inherent to treatment. In examining empirical and judicial evidence, this paper makes the case for disclosure of potent financial interests; with potency relating to those interests likely to have greatest influence over practice. The paper explores how financial interests may detrimentally influence practice patterns and how non-disclosure of such interests may be linked to the erosion of patient trust and subsequent disinclination to consent to treatment. Judicial notions of material risk are explored, and the conclusion reached that they offer a broader interpretation of disclosable risk compared to current UK GMC guidance. It is anticipated that empirical evidence could be used by the courts in determining questions of both materiality and causation in cases of negligent non-disclosure of potent financial interests. The paper concludes that there is sufficient reason to surmise that a test case could successfully apply the principles identified therein to establish the materiality of conflict of interest in informed consent to medical treatment.

KEYWORDS

Conflict of interest; materiality; informed consent; medical treatment; united kingdom

The United Kingdom (UK) common law standard of informed consent – set out in the case of *Montgomery v Lanarkshire Health Board* – holds that in obtaining consent to medical treatment, medical practitioners must inform patients of *material* risks associated with treatment (Montgomery v Lanarkshire Health Board, 2015). The decision called for collaboration with patients through shared decision-making which marked a departure from the paternalism which had become embedded medical law following the *Bolam* ruling some sixty years earlier (Bolam v Friern Hospital Management Committee, 1957). The Cumberlege Report into the findings of the United Kingdom's (UK) Independent Medicines and Medical Devices Safety Review (IMMDSR) exposed how conflict of interest can lead to poor treatment outcomes for patients, erosion of trust and the invalidation of informed consent (Cumberlege, 2020; Independent Medicines and Medical Devices Safety Review, 2018a). In addition, recent empirical studies have also demonstrated that practitioner's financial interests – and subsequent conflict of interest – can result in harmful changes to practice patterns (Robertson et al., 2012). The purpose of this paper is to explore the case for conflict of interest as a disclosable material risk required for valid informed consent. This manuscript will examine physicians' financial conflicts of interest, their potential influence upon patterns of practice and the subsequent harm that a failure to disclose such interests poses to patients. The case will then be made, through provision of empirical evidence, for including disclosure of certain financial interests as an essential element of informed consent post-Montgomery. These recommendations are subject to

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certain limitations: namely that only financial interest which can be demonstrated to be 'potent' or high-risk for patient harm should be disclosable to prevent a tide of information disclosure overwhelming the patient; that empirical evidence is likely to be required in proving materiality to the reasonable person and that a test case in the UK would likely be required to clarity the scope of materiality at common law. Finally, consideration will be given to future directions of research.

PRACTITIONERS' CONFLICT OF INTEREST

In exercising professional judgment medical practitioners have a duty to "[m]ake the care of … patients [their] first concern" (General Medical Council, 2019, p. 4) and so the patient interests take primacy over any secondary interests of the practitioner. Conflict of interest may arise when "professional judgment concerning a primary interest … [such as] … patient's welfare … .[is] … unduly influenced by a secondary interest [such as financial gain]" (Thompson, 1993, p. 573). These secondary interests may be broadly categorized as being 'non-financial' or 'financial' in nature (Wiersma et al., 2017). Non-financial interests encompass a range of factors, such as "political, academic, ideological or religious" considerations which have the potential to influence professional judgment (PLoS Medicine Editors, 2008, e1299). In healthcare, such interests may derive from practitioner autonomy, such as a preference to undertake a particular type of surgery; practitioner paternalism, such as the influence derived from a perceived belief that an action is in the patient's best interests (Strauss & Merios, 2009) or even practitioner egotism, such as the preference to undertake innovative treatment so as to fulfil a personal "desire for prestige and career progression" (Wiersma et al., 2017, p. 319; Cumberlege, 2020).

Financial conflict of interest

Financial interests linked to patient referrals

Financial interests include monetary factors, such as payments or incentives, given to the practitioner in relation to their professional capacity. Montgomery and Lipworth (2019) describe financial interests as the financial 'conflicts and quandaries' which are endemic across all levels of patient care; from the upper 'macro' level incorporating regulators, policy-makers and healthcare organizations, to the intermediary 'meso' level of care concerning those professional organizations, researchers, or academics with indirect influence over patient care (Montgomery & Lipworth, 2019, chpt. 1). Yet, it is the financial interests of the individual practitioner, affecting the micro level of patient care, which are most pertinent to the issue of informed consent (Montgomery & Lipworth, 2019). In a study which will be explored later, Spece and colleagues propose that practitioners should disclose "potent" financial interests to patients (Spece et al., 2014, p. 271). Potent may be defined as "having great power, influence, or effect" (Lexico, n.d.) therefore, for the purposes of this paper, financial interests are those likely to have great influence over treatment decisions. In a review of the empirical evidence relating to how financial interest can affect practitioner behaviors, Robertson and colleagues identified three main categories of financial interest in the United States (US) healthcare system; insurer-based financial interests, financial interests linked to patient referrals, and financial interests linked to pharmaceutical or medical device companies (Robertson et al., 2012). The latter two categories are most readily applicable to the UK healthcare system. Funded by a government mandated national insurance system, the UK public National Health Service (NHS) affords universal access to all UK citizens. Approximately ten percent of the population opt for supplementary cover by way of "duplicative private insurance" (Papanicolas et al., 2019, p. 369). Private insurance confers added benefits including choice of practitioner and improved access to services and specialist treatments (BMA, 2021). Any practitioner registered with the UK medical regulator the General Medical Council (GMC) – in accordance with the Medical Act (1983) – is eligible to undertake such private work, including those whose primary contract is with the NHS (Medical Act, 1983, s3). It is a practice which has rapidly increased in recent years with data from 2016 showing that approximately half of the

46,000 consultants employed by the NHS were involved in some form of private practice (Smyth, 2016). Full time NHS consultants with a pre-2003 contract can undertake private work so long as the gross private earnings do not exceed 10% of their gross NHS salary, however post-2003, there is no limit on consultant's private work – yet there is an expectation that they prioritize NHS overtime (BMA, 2021). The British Medical Association (BMA) recognize that such private work could create a conflict of interest and therefore advise their members not to initiate conversations about private care with their NHS patients. However, such discussions can take place if it is the patient who initiates the enquiry. Furthermore, where patients seek to be treated privately, there is nothing in the guidance to say that practitioners need disclose the *nature* of any associated financial interest they may have with the provision of such private healthcare (BMA, 2021). A study by Rowland for the Center for Health and the Public Interest (CHPI) found that private hospitals in the UK provide consultants with "substantial" hospitality incentives for referring patients to them (Rowland, 2019, pp. 4, p11). In the year 2017–18, a staggering £1.5 million was spent on corporate hospitality by seven private UK hospitals alone, including "numerous lavish trips to sporting events worth over £1000 a head" (Rowland, 2019, pp. 4, p11). This, despite NHS guidance that employees should receive no more than £75 in hospitality or gifts (National Health Service (NHS) England, 2017; Rowland, 2020). Furthermore, Rowland identified that 546 NHS consultants owned shares, equipment or had pay-per-scan arrangements with private institutions (Rowland, 2019, p. 4). At one NHS hospital – the Royal Surrey County NHS Foundation Trust – 50% of its consultant oncologists were found to hold shares, or own equipment, in private hospitals whilst the same could be said for 45% of orthopedic surgeons at another NHS hospital in the city of York (Rowland, 2019, p. 8). Whilst it is widely acknowledged that the private sector offers valuable support to the NHS, particularly when contracted to help tackle long waiting lists, it is clear that the ties between public and private sector healthcare in the UK create the potential for conflict of interest to arise. In 2020, the UK House of Commons published its Report of the Independent Inquiry into the Issues raised by Paterson, otherwise referred to as 'the Paterson Report' (James, 2020). The inquiry explored one of the largest known examples of patient overtreatment in the UK associated with conflict of interest between the NHS private healthcare sector (Rowland, 2019, s.5p5). "Rogue" NHS breast surgeon, Ian Paterson, was described was having "significant" financial incentives to preferentially treat patients in the private sector rather than the NHS (Dyer, 2017; James, 2020, p119; Rowland, 2019 at s.25, p. 4). In the period between 1997 and 2011, Paterson harmed 750 patients by undertaking investigations or surgical procedures for ailments which patients did not have (Rowland, 2019, s.5, p. 5). This included mastectomies and surgeries for the removal of cancer in individuals not suffering from the disease. In one instance the inquiry heard that soon after a cancer diagnosis, Paterson had starkly told 'patient 162′ that they faced a three year wait for treatment on the NHS, or could pay £10,000 to undergo the surgery in the private sector within one week (James, 2020, p119). The Inquiry heard that patient 162 " . . . [was] convinced she had unnecessary surgery that she didn't agree to" and that her medical records had since "disappeared" – thus removing any pathological evidence of the existence of the cancer (James, 2020, p52-53). Evidence from the CHPI presented to the Paterson Inquiry attested that whilst there was, as of yet, still no evaluation of Paterson's financial interests, the interests were estimated to be "significant" and "in the region of £3 million" (Rowland, 2019 at s.5, p5; Centre for Health and the Public Interest (CHPI), 2019 s.25, s.26, p. 4). Furthermore, the Paterson Inquiry heard how Paterson had, in turn, incentivized general practitioners (GPs) in his local area by providing hospitality so that they would preferentially refer patients to his private practice (James, 2020, p120).

Financial Interests Linked to Industry. Financial conflict of interest in the UK may also derive from the links with the pharmaceutical or medical device industries. Such links are often recognized as a necessity of medical advancement, yet Rowland cautions that it may be difficult to "distinguish payments that inappropriately influence clinical decision-making from those which are made for contributing to scientific innovations" (Rowland, 2020, para 16). The pelvic mesh scandal exposed "the extent to which individual surgeons, researchers and professional bodies are reliant on device

manufacturers for financial support" through its investigation into the use pharmaceuticals and medical devices (Gornall, 2018a, para 18). It revealed how one medical device manufacturer, Ethicon, marketed its pelvic mesh as a solution for stress urinary incontinence (SUI) and, more recently, pelvic organ prolapse (POP) (Gornall, 2018b). The company had "highly [and] aggressively marketed to gynaecologists . . . [through] the Ethicon 'buy a Lamborghini' and 'Surgery is the Chachin thing' campaigns'" which proved "highly lucrative for private surgeons" (Independent Medicines and Medical Device Safety Review, Dr Vincent Argent, p15). Ethicon also influenced medical education through its sponsorship of the Royal Colleges' continuing professional development (CPD) programmes, thus extending its influence to individual practitioners (Cumberlege, 2020). The company also comprehensively marketed its product at conferences where it offered individual surgeons' financial incentives (Gornall, 2018b). As a result, such financial interests are often inextricable from the training which practitioners receive, making it difficult to identify the source of such influence. Therefore, as will be explored, it is likely that only financial interests which can be demonstrated to pose high risks to patients – ideally through the provision of empirical evidence – will be disclosable due to the difficulties in establishing legal causation.

Failure to disclose conflict of interests

Interests linked to patient referrals

Rowland (2020) describes UK patients as being "very poorly protected" from the influence of practitioner's financial interests under current voluntary disclosure arrangements (Rowland, 2020, para 6). In 2019, of approximately 300 NHS consultants who owned shares in private hospitals in the UK, only 19 had declared their interests via their NHS Trust – indicating wide-spread non-disclosure of financial interests (Rowland, 2019, p. 20). The Paterson Inquiry – which heard how the breast surgeon had preyed upon patient fears following cancer diagnoses by exaggerating NHS waiting times – had failed to provide independent information to patients to facilitate informed decision-making, with a lack of valid informed consent obtained for one-third of patients (James, 2020, p115,119). The CPHI considered that it was unlikely that Paterson's patients were informed or had knowledge of his financial interests as the information was either missing or difficult to find on the websites of private hospitals (Centre for Health and the Public Interest (CHPI), 2019 s.20, p. 3). Indeed, Rowlands describes a general "lack of willingness across parts of the profession to be open and transparent [about financial interests]" (Rowland, 2020, para 21). This was reflected in the Private Healthcare Investigation (PHI) by the Competition and Markets Authority (CMA) which uncovered a widespread lack of disclosure and concluded that "clinicians should be required to disclose to their patients any equity interest they have in a facility to which they propose to refer the patient, or in any major item of equipment . . . which they propose to use to conduct tests on or to treat the patient" (Witcomb et al., 2014. para 11.463 p11-99 as cited in Rowland, 2020, p. 76).

Interests Linked to Industry. Rowland also describes the large number of incentive schemes designed to influence practice which remained "largely hidden from patients and the public" (Rowland, 2019, p. 18). A recent report by McCartney in the British Medical Journal (BMJ) explored the difficulties associated with finding conflict of interest disclosures linked to pharmaceutical or medical device companies in the UK (McCartney, 2018). McCartney describes being caught in a time-consuming "game" of trying to find a practitioner's conflict of interest (McCartney, 2018, para 1). The most promising disclosure tool available in the UK is that which the Association of the British Pharmaceutical Industry (ABPI) oversees. The ABPI publishes payments made by the pharmaceutical company to doctors on a voluntary basis (Association of the British Pharmaceutical Industry (ABPI), 2020). However, only half of the £53million of payments made have thus far been declared (McCartney, 2018). Arguably, such disclosures could enable patients to make a truly informed treatment choice of whether to accept such treatment and facilitate greater patient autonomy. However, such disclosure databases place a burden on the patient, as described

by McCartney, to source the relevant information which is likely to create a barrier. Such information does, however, appear to be valuable to patients. In patient testimony to the IMMDSR, one patient reflected upon the retrospective knowledge that conflict of interest had played a role in the promotion of pelvic mesh, stating "[a]s patients, we allow the medical profession access to all manner of information [so they can determine] the best course of treatment. We, the patients, deserve the same [we should] be aware of clinician's allegiances or [financial] involvement" (Independent Medicines and Medical Devices Safety Review, 2018c, s5.7.2). The Cumberlege Report addressed the lack of disclosure in the UK by suggesting that the GMC medical register be extending to include the financial interests of its registrants, however, Rowland cautions that this is unlikely to fulfil the aim of making patients "aware of financial conflicts so that they can reach informed decisions about who is best to treat them" as currently on 11% of those who access the GMC Medical Register are patients (Cumberlege, 2020; Rowland, 2020, para 17).

Changing practice patterns

Interests linked to patient referrals

Practitioners' financial interests may be associated with changing patterns of practice. Robertson and colleagues describe a growing body of evidence which suggests that practitioner practice alters when influenced by conflict of interest (Robertson et al., 2012). The degree to which conflict of interest creates practitioner bias is largely dependent upon the nature of the secondary interest, such as whether it be derived from the private sector or industry (Robertson et al., 2012). This was a key finding of the Paterson Inquiry as, not only did his financial interests lead to self-referrals in the private sector, but there were also significant changes in his practice patterns. Paterson was involved in the provision of unnecessary, and often, disproportionate treatment which even included the non-indicated treatment of minors (Centre for Health and the Public Interest (CHPI), 2019, s.9 p2; James, 2020, pp. 98-100). Paterson was also involved in undertaking unwarranted investigations, performing "unnecessary positron emission tomography (PET) scans, which exposed patients to radiation" the purpose of which was to afford Paterson further opportunity to misdiagnose disease so as to prompt further surgical intervention, such as biopsies (James, 2020, p106). Paterson even went so far as developing his own unproven "cleavage sparing mastectomy (CSM)" which the Paterson Inquiry describes as being driven by the financial gain derived from referring patients for such surgery in the private sector (James, 2020, p100). Upon sentencing Paterson to a 15 year prison term for 17 counts of Wounding with Intent, Mr Justice Jeremy Baker described how Paterson had "carried out surgical procedures on . . . breasts, which [he] knew that no responsible body of duly qualified and experienced breast surgeons would have advised, because none of the procedures [were] necessary to maintain . . . health" (Regina v Paterson, 2017 at s75). As will be explored later, the Inquiry also heard how Paterson's adjusted practice patterns resulted in physical and psychological harm of patients.

Interests Linked to Pharmaceutical or Medical Device Companies. Similar findings were revealed by the IMMDSR in its exploration of changing patterns of practice relating to the use of select medicines and medical devices. Evidence provided to the review showed that the Ethicon's influence upon the medical profession as a whole had led to an exponential rise in rates of transvaginal mesh implantation which corresponded with a sharp decline in the alternative, tried and tested, colposuspension surgery (Gornall, 2018b; Independent Medicines and Medical Devices Safety Review, 2018b, p15; 17–20). Notably, as Robertson et al attest, the links to changing practice patterns can be difficult to precise-lypinpoint. Indeed, Rowlands cautions that in relation to mesh, it may be difficult to illustrate the links between financial conflict of interest and the subsequent *harm* suffered by patients (Rowland, 2020). This is particularly true given the cost saving and perceived benefit mesh had, which was likely to have further fueled its popularity amongst practitioners and healthcare providers (Gornall, 2018a).

However, even when the mesh was found to be associated with increased harm, the fact that its use still continued could be indicative of financial interest continuing to influence practice (Independent Medicines and Medical Device Safety Review, 2018c, Annex 6).[1]

Potential harm to patients

Interests linked to patient referrals

Changes in practice can be beneficial or harmful, depending upon the given circumstances. For example, where there is inherent *under* treatment, an increase in treatment could be representative of raising care standards to more optimal levels. However, any course of investigation or treatment must be appropriate and in the overall best interests of the patient. The concern, as Spece and colleagues attest, is that financial interests can "skew physician's advice and possibly lead to bad decisions" which can propagate these patterns of unnecessary or unsuitable treatment which may ultimately prove harmful to patients (Spece et al., 2014, p. 256). Such harmful practices were evident in the case of Paterson, who, adopted harmful and unnecessary breast augmentation procedures into his practice despite patients being at little to no risk of developing cancer (Spece et al., 2014, p. 256; Regina v Paterson, 2017 at 6). Justice Baker heard that Paterson's victims had all been left with "physical scarring to their bodies, and those who underwent mastectomies … [had] had their breast tissues [permanently] removed" (*Regina v Paterson*, 2017, at 60). For at least one patient this meant the inability to breastfeed her child, which Justice Baker described as having "particularly pernicious" long-term psychological effects (Regina v Paterson, 2017 at 44). This example, thus illustrating the individual impact that harm deriving from financial interests can have upon particular patients.

Interests Linked to Industry. Such psychological effects were also described in the patient testimony presented to the IMMDR in relation to pelvic mesh. Evidence from a patient support group demonstrated that the majority of mesh-injured patients consulted had physical symptoms – including dysuria, dyspareunia, organ dysfunction and tissue erosion leading to chronic pain and morbidity – in addition to increased rates of depression, suicide and self-harm (Independent Medicines and Medical Devices Safety Review, 2018c, p14-16, s.2.3.3). One patient directly attributed the harm that many had suffered to practitioner conflict of interest, stating that "I am … tired of doctors inserting this product, … so many … know the harm that mesh is causing, but they still choose to implant it … [as] … it is much more lucrative to carry on" (Independent Medicines and Medical Devices Safety Review, 2018c, p29). A further concern raised by the IMMDSR was that influential practitioners – who are subject to conflict of interest – can adopt harmful practices which then have a detrimental 'knock-on' effect upon the practice of other practitioners. The modern practitioner-patient relationship is now consumed within wider multi-disciplinary teams which oversee the meso-level of patient care. It is at this level that guidelines and policies are often drafted which subsequently shape the practice of other practitioners when they come to select treatments for their own patients (Montgomery & Lipworth, 2019). Therefore, the financial interests which affect an influential practitioner, can have an indirect impact upon a wider body of medical opinion; thus, shaping treatment choices for the patients of other practitioners. In 2019, influential cardiologist Dr Gregg Stone and his colleagues published findings of their EXCEL study in the New England Journal of Medicine. The study suggested that stents were a more effective and safer alternative to coronary artery bypass grafts (CABG) for left main coronary artery disease (Stone et al., 2019). However, the clinicians involved had been sponsored by large American stent manufacturer Abbot and, as a result, the findings were subject to substantial conflict of interest (Cohen & Brown, 2019). Before the conflict of interest came to light, the guidelines were endorsed by the European Association for Cardio-Thoracic Surgery (EACTS) and subsequently formed the basis for the 2019 European Revascularisation Guidelines (Neumann et al., 2018; Stone

[1]Note that the US Federal Drug and Food Administration (FDA) had given the first warning on mesh safety in 2008 – it was not until 2014 that transvaginal use was suspended in Scotland, though its use continued in England until 2017.

et al., 2019). The conflict of interest had influenced the researchers to heavily manipulate the data so that it appeared that the stents were safer, when in fact they posed an 80% higher risk of heart attack (Cohen & Brown, 2020). This illustrates that the harm deriving from financial interest can radiate throughout medical practice to inflict harm on larger numbers of patients. Such harm is likely to be the most difficult to link to financial interests, as Rowlands attests, and so would be unlikely to concern issues of materiality in informed consent (Rowland, 2020). It is for this reason that the proposed expansion of disclosable risk be supported by further measures – such as a mandated financial interest register and more stringent adherence to journal codes of conduct – so as to mitigate against the wider harm derived from financial interests (Cumberlege, 2020 at 2.56, 2.67).

Erosion of trust

Such conflict of interest and its potential to promote harmful practice patterns also carries the potential for eroding patient trust. In his sentencing of Paterson, Justice Baker explained that the surgeon had purposefully exaggerated the risk of cancer to gain patient trust and confidence to consent to the surgery, and in doing so had "deceived" patients (Regina v Paterson, 2017 at 45). A key theme throughout Justice Baker's sentencing of Ian Paterson was the absolute trust his patients had in him, due to his position as a consultant surgeon. In addition to the financial, physical, and psychological harm sustained by his patients, Justice Baker described how they had all experienced a loss of trust in the medical profession at large (Regina v Paterson, 2017 at 61, 62). Justice Baker describes the victim impact statements as describing the "profound" physical and psychological effect from the over-treatment (Regina v Paterson, 2017 at 47) and that they were "left feeling violated and vulnerable" (Regina v Paterson, 2017 at 59) with psychological harm including "post-traumatic stress disorder, anxiety and depression" – all of which contributed to eroding trust in the profession (Regina v Paterson, 2017 at 59). In one impact statement patient Carole Johnson described how she had "lost a lot of trust in medical professionals" as a whole (Dyer, 2017, p. 1). The subsequent Inquiry heard that Paterson's incentivization of local GPs had further contributed to the loss of trust in the medical profession (James, 2020, p120). There was a similar theme throughout the evidence presented to the IMMDR pertaining to mesh. Evidence presented to the IMMDR considered that there had been "a gross abuse of trust" (Independent Medicines and Medical Devices Safety Review, 2018c, p172, s. 5.13.3). Such loss of trust has important implications for healthcare outcomes as the practitioner-patient relationship requires trust in order to facilitate open discussions for the purposes of both diagnosis and subsequent consent to medical treatment. Therefore, loss of trust can indirectly result in harm to patient care (Birkäuer et al., 2017).

EMPIRICAL EVIDENCE

Empirical evidence for financial interests leading to harmful changes in practice

Robertson and colleagues describe several studies which provide empirical evidence of practitioner practice changing "for the worse" (Robertson et al., 2012, p. 456) when subject to financial interests. In a study by Mitchell and Scott in JAMA, patient referrals to practitioner-owned centers were up to 45% higher compared to those of from practitioners holding no such financial interest (Mitchell & Scott, 1992 as cited in Robertson et al., 2012, p. 455). Studies also show that financial interests are associated with higher rates of diagnostic investigations. Swedlow and colleagues' study of a Californian employee compensation scheme found that almost 40% of Magnetic Resonance Imaging (MRI) scans ordered by self-referring practitioners who held a financial interest in the testing facility were "medically inappropriate"; indicating that practitioner behavior had changed "for the worse" where financial interests were at play (Swedlow et al., 1992, p. 1504 in Robertson et al., 2012 at p455, 456). Shah and colleagues presented similar "highly significant" findings which indicate that where financial interests exist, rates of medically inappropriate and harmful investigations are heightened, despite

being contrary to relevant clinical guidelines (Shah et al., 2011 in Robertson et al., 2012, p. 454). From a sample size of 17,847 patients, Shah et al found that rates of diagnostic cardiac nuclear stress test referrals were 2.3 times higher when practitioners had a financial interest in billing, compared to those practitioners who did not (Shah et al., 2011, p. 1997). Such tests are not routinely indicated for investigative purposes due to their poor specificity, risk of false positives – which can trigger further unnecessary investigations – and the risk of harm from ionizing radiation (Shah et al., 2011 in Robertson et al., 2012, p. 454). Even greater "disparity in practice patterns" was noted in relation to stress echocardiography – an investigation which is also not indicated for routine use – with rates of referral 12.8 times higher amongst practitioners with financial interest (Shah et al., 2011, p. 1997 in Robertson et al., 2012, p. 454). Empirical evidence of inappropriate investigations linked to financial interest even extended to invasive procedures such as biopsies. Mitchell demonstrated, through a regression analysis of Medicare data, that amongst self-referring urologists the billing rate for prostate biopsies was 72% higher and was associated with lower rates of cancer detection (J. Mitchell, 2012 in Robertson et al., 2012, p. 455). This indicates that patients "unlikely to have prostate cancer" were undergoing prostate biopsies (J. Mitchell, 2012, in Robertson et al., 2012, p. 455). UK charity Prostate Cancer UK describe side effects of prostate biopsies as including pain, discomfort, bleeding, infection, acute urinary retention and erectile dysfunction (Prostate Cancer UK, 2019). There are also likely to be psychological implications associated with undergoing investigations for cancer which could constitute harm. This indicates that patients were subject to unnecessary and harmful investigations (J. Mitchell, 2012, in Robertson et al., 2012, p. 455). In another study from 2008, Mitchell also demonstrated that individual practitioner behavior changed *following* acquisition of private medical facilities, stating that the "relative odds" that a patient would receive more complex – and costly – surgery was 65 times higher after a practitioner had taken ownership (J.M. Mitchell, 2008, at p735 in Robertson et al., 2012 at p456).

These findings add empirical value in support of the mostly observational findings of the UK's Paterson Inquiry and IMMDSR; both of which are likely indicative of more widespread issues in the UK (James, 2020; Independent Medicines and Medical Devices Safety Review, 2018c, p29). Such evidence can help bridge the connection between financial interests, detrimental changes in practice and patient harm. The Paterson Inquiry was subject to an overall lack of empirical evidence (James, 2020; Rowland, 2019 s.5p5). The inquiry failed to expose the extent of Paterson's financial interest in the UK private sector – which would have strengthened the case for causal link between his interests and resultant harm – although the CHPI suggest the figure could run into millions of pounds (CHPI at s9, p.2; s26, p4). Furthermore, the true extent of Paterson's 'over-treatment' of patients remains unknown, however it is also likely that the 740 patients said to have been harmed from 1997 to 2011 represents a gross underestimation[2] due to the insufficiencies in patient recall (James, 2020, p1, para 2; Rowland, 2019 s.5p5). By comparison, there is more evidence relating to the use of pelvic mesh, although data are still lacking. A 2018 study by Gornall offers some empirical evidence that the widespread use of transvaginal mesh in the UK *was* derived from financial interest. Gornall describes that from 1998 to 99 only 214 women in England were treated for SUI, yet in the subsequent decade rates rose dramatically so that by 2009 up to 12,000 mesh implantations were performed annually in England alone (Gornall, 2018a). Notably, such findings correspond with a 1998 study by Ulmsten – which was subject to a $1 million Ethicon sponsorship in return for "favourable" results (Ulmsten et al., 1998; Gornall, 2018a, p. 2). A recent class action trial found that Ethicon's parent company Johnson and Johnson had actively suppressed knowledge that their mesh maimed patients (Emmett et al v Ethicon Women's Health & Urology, 2019). Ethicon's widespread courting of the medical profession through conference and educational sponsorship, a practice which may be been linked to brand loyalty, also correlates with UK surgeon's 'eagerly adopting' the practice (Gornall, 2018a, p. 1; Hall & Jones, 2007). Treatment bias in favor of mesh is evident and is suggestive of – at the very least – a tentative link between financial interests and changes in practice

[2]Note, James (2020, p1 para 2) describes the "[t]housands of people . . . still living with the consequences of what happened."

patterns. The studies collated by Robertson and colleagues provide a firm empirical foundation which further supports the link between financial interest and harmful changes in treatment practice.

Empirical evidence for erosion of trust

The practitioner-patient relationship is fiduciary relationship founded upon trust, which may be undermined by conflict of interest. Spece and colleagues provide empirical evidence that financial interests, which promote harmful practice patterns, erode such patient trust in both the practitioner and in their treatment recommendations (Spece et al., 2014). The 2014 randomized vignette-based experiment undertaken enlisted 691 mock patients who were asked to put themselves into the position of a patient due to undergo a cardiac stent procedure upon the recommendation of a cardiologist. The researchers then controlled the information given to the participants relating to the appropriateness of the treatment – in terms of the risk of *not* undergoing the procedure – and, according to the degree of financial disclosure made by the fictional practitioner in relation to hospital ownership. Degrees of disclosure ranged from non-disclosure, to standard and enhanced disclosure. Standard disclosure informed patients of the hospital ownership, whilst enhanced disclosure gave notice of links between such conflict of interest and treatment recommendation bias. Participants were asked whether they agreed or disagreed with the statement "the cardiologist has only my interests in mind in making this recommendation" which was an operationalization of the notion of trust (Spece et al., 2014, p. 270). The study found that disclosure "significantly and substantially increased the probability" that simulated patients would refuse treatment, irrespective of whether the disclosure was standard or enhanced (Spece et al., 2014, p. 270). The findings indicate that the "existence of disclosure as opposed to the strength of disclosure" had "swayed" patients and that this was likely due to doubts as to whether the practitioner continued to uphold their best interests (Spece et al., 2014, p. 270). Notably, trust was only reduced when the patient had a low-risk condition therefore patients at high risk are more likely to continue to trust their practitioner. One limitation of the study was that it lacked real-world context as mock patients may act differently to real patients whose own health is at stake (Spece et al., 2014, pp. 268–269).

Another study by Rose and colleagues which did involve real-world context suggests that financial interest disclosure does not erode patient trust, but that failure to disclose conflict of interest could. Investigators mailed 'conflict of interest' disclosure notifications to 1903 patients alongside their appointment letters for Cleveland Clinic in 2015 (Rose et al., in press). Twenty-seven practitioners participated, disclosing payments of $20,000 or more from companies whose products they used in their practice. The study demonstrated that the disclosure "significantly" improved patients' knowledge of practitioner financial conflict of interest with 56% of patients correctly acknowledging their practitioner's interest. Such knowledge was found to have a "significant association" with trust ($p < .003$). Trust was highest amongst patients who erroneously believed that their practitioner had no financial conflict of interest. In comparison with this cohort, trust was significantly lower amongst patients with uncertainty over a practitioner conflict of interest ($p = .001$). Most tellingly, the results also indicate that there was no statistical difference between patients who correctly believed their practitioner held a conflict of interest and those who falsely believed there was no conflict of interest ($p = .22$). The study was subject to some limitations, such as the acknowledgment that since patients already had appointments they may have been "motivated to continue to trust their physicians" rather than search for an alternative (Rose et al., in press, p. 10). The authors also note that the findings may not be generalizable as trust in the sample hospital, for example, was particularly high. Nonetheless, whilst the study appears to contradict the findings of Spece and colleagues, the authors support the general premise that disclosure of information is important for "encourag[ing] patients to play a more active role in their healthcare decisions" through informed consent (Rose et al., in press, p. 3). The findings indicate that knowledge of conflict of interest – rather than the disclosure – has a "significant association" with patient trust (Rose et al., in press, p. 10). Therefore, we can surmise, that a *failure* to disclose information and, the associated lack of transparency, could erode trust.

For the purposes of this study, it is suggested that the study by Spece and colleagues most readily reflects the informed consent process in the UK, which usually involves a discussion with the practitioner rather than the provision of written information. Furthermore, the study by Spece relates directly to acceptance of treatment, whereas the study by Rose and colleagues does not specify whether patients subsequently accepted treatment or whether they attended a consultation only (Rose et al., in press; Spece et al., 2014). Nonetheless, it is preferrable that further research be undertaken in this area. One consideration could be whether the provision of a letter offers sufficient comparison to the verbal provision of information afforded in the study by Spece and colleagues (Spece et al., 2014). Spece and colleagues argue that "a substantial portion of patients appear likely to behave differently once given . . . information" about practitioners' financial interest and so patients appear to attach significance to such information (Spece et al., 2014, p. 271). Notably, Rose and colleagues also found patient *knowledge* of financial interest to have a significant association with trust (Rose et al., in press). It is to this end that Spece and colleagues therefore assert that such information is "material to [patient's] decisions" and that disclosure of "potent" financial conflicts of interest should be "added to the list of presumptively required disclosures" or should be "interpreted as falling within the existing category of 'risks' that presumptively must be required" (Spece et al., 2014, pp. 271, 273). Accordingly, the case will be made that potent financial interests – namely those which are likely to have great influence over treatment decisions – would be disclosable under existing UK common law relating to disclosure of material risks (Spece et al., 2014, p. 271; Montgomery v Lanarkshire Health Board, 2015).

PHYSICIAN DISCLOSURE DURING CONSENT TO CLINICAL CARE

The law pertaining to consent to medical treatment in the UK more commonly lies in the tort of negligence than in the tort of battery, since the consent process has become a routine part of practice. Cases which concern pre-treatment advice tend to relate to whether the practitioner provided sufficient information to allow the patient to make an informed decision and whether causation can be established (see Table 1).

UK case law: pre-Montgomery

Bolam (1957)

Responsible Body of Medical Opinion Standard. In the mid-1950s, the case of *Bolam v Friern Hospital Management Committee* explored the extent of the practitioner's duty of care at law. Mr Bolam had not been given muscle relaxants during a course of electro-convulsive therapy for treatment of mental illness, and subsequently suffered severe acetabular fractures. The court found that the practitioner had not failed in their duty of care owed to Mr. Bolam. The House of Lords recognized that whilst some practitioners offered muscle relaxants, the practice not to offer them was also

Table 1. Summary of Montgomery v Lanarkshire Health Board (2015) **UKSC 11.**

Summary of Montgomery v Lanarkshire Health Board (2015) UKSC 11	
Roles	
The Doctor	To take into account medical considerations and exercise professional skill and judgment in choice of investigatory or treatment options (p27)
The Patient	To enact the "entitlement to decide on the risks" (p27)
The Court	Takes "responsibility for determining the nature of a person's rights"(p27)
Duty	"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" (p28)
Materiality	"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." (p28) (See also p.89; significance includes "magnitude" plus additional factors).
Causation	"If the patient had been informed of all material risks. . .if she had known the probability and magnitude (Severity) of the risks. . .would she have made a difference choice, thereby avoiding harm?" (p105)

accepted. Nair J stated that the practitioner was not negligent because they had acted "in accordance with a practice accepted as proper by a responsible body of medical men skilled in the particular art" and that negligence is not established "merely because there is a body of opinion who would take a contrary view" (Bolam v Friern Hospital Management Committee, 1957 at 587). To some extent, this was a policy decision which gave recognition to the existence of differences of opinion in medical science. Yet it was also reflective of the prevailing paternalism of the time with the case determining that a body of medical opinion would also decide what information on risk patients should be told, rather than giving consideration to what patients believe they need to know in order to fully exercise their rights of self-determination (Bolam v Friern Hospital Management Committee, 1957, at 583; Devaney & Holm, 2018). Legal academics have described the ruling as overtly deferential to the medical profession (Poole, 2019) and as one which facilitates a degree of self-regulation therein (Devaney & Holm, 2018).

Sidaway v Board of Governors (1985)

In Sidaway v Board of Governors of the Bethlem Royal Hospital (1985) Mrs Sidaway, was unsuccessful in her claim for negligent pre-treatment advice. Her neurosurgeon had failed to warn her of a 1–2% risk of spinal cord damage arising from a surgical procedure to treat neck pain – a risk which subsequently materialized. The case was brought before the House of Lords where there were divergent views on whether *Bolam* remained the correct test to apply in determining the legal standard of pre-treatment advice.

The Prudent Patient. Lord Scarman contemplated that patient decision-making was reliant upon a broad range of considerations including "circumstances, objectives and values which [the patient] may not make known to the doctor but which may lead him to a different decision from that suggested by a purely medical opinion" (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985 at 886). He therefore proposed a 'prudent patient test' be applied in order to recognize the patient's right to make their own decisions, stating that "[i]deally, the court should ask itself whether in the particular circumstances the risk was such that this particular patient would think it significant if he was told it existed" (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985 at 888). This statement introduced early considerations of 'significance' and the 'particular patient.' Lord Scarman reasoned that if a patient could suffer harm resulting from an undisclosed risk, then such risk should have been disclosed by a doctor (or practitioner) exercising reasonable care in fulfilling their duty of care toward said patient.

The Responsible Doctor. Lord Diplock dissented and, in theorizing that disclosure of unsolicited information could deter patients from undergoing treatments which were in their best interests, asserted that the standard of information disclosure should be judged according to a body of medical opinion in line with the Bolam standard (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985, at 891).

The Prudent Doctor, Prudent Patient. Lord Templeman proposed a midway solution by way of the 'prudent doctor, prudent patient' approach. An objective test of professional judgment according to the Bolam test, set alongside a subjective test which is applied to the individual patient. Accordingly, there may be greater disclosure if the patient "asks in vain for more information or . . . there is some danger which . . . requires to be taken into account" so as to ensure the practitioner provides "sufficient information to enable the patient to reach a balanced judgment" (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985, at 902). This, however, placed the burden upon the patient to ask the relevant questions as Lord Templeman believed that "[a]n obligation to give a patient all the information . . . [would be] inconsistent with the doctor's contractual obligation to have regards to the patient's best interests" (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985 at 904).

Reasonably Prudent Doctor. In offering judgment – and ultimately dismissing Mrs Sidaway's claim – Lord Bridge applied a 'qualified' Bolam test to establish that the standard of information required was a matter of clinical judgment, and so was reflective of a 'reasonably prudent doctor test.' Lord Bridge rejected the claim that patients should be warned of all risks (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985 at 897). He did however accepted that it was not necessary to "hand over to the medical profession the entire question of the scope of the duty of disclosure" and so a qualified Bolam Test should be applied with the stipulation that the court adopt an oversight role and that doctors must provide honest answers when asked specific questions pertaining to their treatment (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985 at 900).

Bolitho v City and Hackney Health Authority (1998)

The case of Bolitho v City and Hackney Health Authority (1998) relates to negligent failure to treat and causation rather than negligent non-disclosure, yet its judgment is illustrative of the dominance *Bolam* maintained even some forty years later. The House of Lords considered the case concerning two-year-old Patrick Bolitho admitted to hospital with breathing difficulties. A doctor who was called via pager did not attend and the child subsequently died. His mother brought a claim in negligence against the practitioner claiming that had he been intubated his life would have been saved. It was established that the doctor failed in their duty of care by not attending Patrick, however the decision turned on the issue of causation. The doctor argued that, but for the failure to attend, Patrick would still have died as she would not have intubated him. Such a decision was in line with practice considered acceptable by a responsible body of medical opinion as per *Bolam* the Standard (Bolam v Friern Hospital Management Committee, 1957, at 587). The Law Lords sought to address the apparent deficiencies in the *Bolam* standard by adding additional qualifications of logic and reasonableness. Lord Browne-Wilkinson stated "if . . . it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible" (Bolitho v City and Hackney Health Authority, 1998 at 243) Nevertheless, the subsequent application of *Bolitho* qualification to the *Bolam* test has been inconsistent (Samanta & Samanta, 2003) .

Pearce v United Bristol Healthcare Trust(1998)

Shortly after the ruling in *Bolitho*, the first inkling that the sands were shifting away from the prevailing paternalistic standard of *Bolam* became evident in the case of (Pearce v United Bristol Healthcare NHS Trust, 1998). The case was heard in the lower Court of Appeal where Lord Woolf first introduced the concept of a 'reasonable patient' and their right to be informed of 'significant' risk. The case concerned Mrs Pearce, who had requested labor induction to advance the delivery of her overdue baby. She was instead advised to await a natural onset of labor and the baby was subsequently stillborn.

Toward the reasonable patient standard

In bringing a claim for negligent pre-treatment advice, the court considered that the risk associated with the advice was in the region of 0.1–0.2%. In offering his judgment, Lord Woolf MR considered the 'reasonable patient' in stating that "if there is significant risk which would affect the judgement of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk" (Pearce v United Bristol Healthcare NHS Trust, 1998 at 124 as per Woolf MR). On the interpretation of 'significant risk' Woolf MR stated that "it is not possible to take in precise percentages" (Pearce v United Bristol Healthcare NHS Trust, 1998 at 124 as per Woolf MR) and that such risk would be determined by taking account of "all the relevant considerations" (Pearce v United Bristol Healthcare NHS Trust, 1998 at 125). The appeal was ultimately dismissed on the grounds that it

could not be established that the risk posed by the additional passage of time represented a significant, and therefore disclosable risk (Pearce v United Bristol Healthcare NHS Trust, 1998, at 125 as per Woolf MR).

Chester v Afshar (2004)

The case of Chester v Afshar (2004) explored the complexities of causation, a hurdle which many cases pertaining to information disclosure fail to overcome. On causation, the focus shifts from examining the practitioner's standard of care to addressing what the patient would have done had they been in possession of the non-disclosed information. In this case, Miss Chester, a young woman suffering from lower back pain, was referred to neurologist Dr Afshar. Surgical intervention was proposed however Miss Chester was not informed of a 1–2% risk of cauda equina syndrome, which materialized. She argued that had she known the risk; she would not have consented to undergo the treatment some three days later.

Causation in medical negligence

Lords Hoffman and Bingham powerfully rejected Miss Chester's claim. Lord Bingham argued that Miss Chester had not satisfied the court that, 'but for' the failure to inform, she would never had undergone the surgery, only that she would not have consented at that time and therefore undergone the surgery on the specified day. He explained that whilst the 'but for' test was an ordinary test of causation, it was "generally accepted that . . . [it] does not provide a comprehensive or exclusive test of causation in the law of tort [as too often] . . . it gives too expansive an answer," thus highlighting that additional tests of causation may be applied (Chester v Afshar, 2004 at 8). Lord Hoffman also agreed that the ordinary test of causation was not satisfied and held that there were no grounds for a special rule to be applied in this case. However, the three remaining Law Lords disagreed, finding that a departure from the ordinary test was required on policy grounds so that a practitioner's duty to inform would not become a hollow one. Lord Steyn said

> I have come to the conclusion that, as a result of the surgeon's failure to warn the patient, she cannot be said to have given informed consent to the surgery in the full legal sense. Her right to autonomy and dignity can and ought to be vindicated by a narrow and modest departure from traditional causation principles (Chester v Afshar, 2004 at 24)

The case illustrates that in some circumstances, the contextual difficulties associated with applying an ordinary test of causation will require adjustments be made to the test; such as by the application of a series of 'but for' tests or by applying a test of 'material contribution' (Poole, 2019, pp. 129, 135).[3] However, the decision to depart from the ordinary test of causation in Chester was controversial (Mason & Laurie, 2011) suggest that whilst *Chester* sought to address the paternalism of Bolam, it perhaps "swings too far in the other direction" as the harm sustained was more in line with "hurt . . . feelings – than . . . actual physical injury" (Mason & Laurie, 2011, s4.138, p 120; Chester v Afshar, 2004). Conversely, it may also be argued that the departure from the ordinary test which was applied in *Chester* offers broad consideration of the effect that non-disclosure of material information has on harm suffered. On such grounds, non-disclosure of potent – and therefore material – financial interests could arguably satisfy a test of causation under UK law.

[3]For example, in Bailey v The Ministry of Defence & Anor (2008) EWCA Civ 883, a question of 'material contribution' was applied instead.

Montgomery v Lanarkshire (2015)

The case of Montgomery v Lanarkshire Health Board (2015) marked a landmark departure from the paternalistic *Bolam* standard toward a more patient-centric approach to medical decision-making (Bolam v Friern Hospital Management Committee, 1957). Mrs Montgomery brought a claim for negligent non-disclosure to the Supreme Court. The claim centered on the failure to disclose the 9–10% risk of shoulder dystocia associated with vaginal delivery that Mrs Montgomery was subject to as a type 1 diabetic mother (Montgomery v Lanarkshire Health Board, 2015 at 13). The information had not been disclosed despite Mrs Montgomery raising explicit concerns relating to complications associated with her diabetes, nor had she been informed of the option of a cesarean section (Montgomery v Lanarkshire Health Board, 2015 at 2; 17). The risk of shoulder dystocia materialized, resulting in a traumatic vaginal birth during which her son was starved of oxygen and suffered permanent brain damage. In bringing the case on his behalf, the mother argued that had she been advised of this risk, she would have elected for a cesarean section and the brain damage her son subsequently sustained would have been avoided.

The 'prudent patient' standard

The Supreme Court Justices rejected the stance taken in *Sidaway* which placed the burden on the patient to ask the doctor the necessary questions so as to be informed, describing the proposition as "profoundly unsatisfactory" (Montgomery v Lanarkshire Health Board, 2015 at 58). It was recognized that such a standard was deficient as the patient may not be aware of what questions they need to ask and thus be placed at a disadvantage. To this end, patients were no longer to be treated as placing themselves in doctors' hands but, instead, as autonomous adults capable of understanding that decision-making involves consideration of risk (Montgomery v Lanarkshire Health Board, 2015 at 91). This set a new standard which recognized that doctors are under a duty to;

> [t]ake 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 treatment. 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 Health Board, 2015, at 87)

The case established that a 'prudent patient' test – which gives consideration to materiality and significance – should be used in determining disclosable information for the purposes of informed consent (Lee, 2017). The Supreme Court justices again emphasized that material risks "cannot be reduced to percentages" as decision-making is often multi-factorial (Montgomery v Lanarkshire Health Board, 2015, at 89). Baroness Hale asserted that patients are "entitled to take into account [their] own values, [their] own assessment of the comparative merits [of a treatment option]" and in doing so make an assessment "of comparative merits" of treatment (Montgomery v Lanarkshire Health Board, 2015, at 115) . In order to establish the factors relevant to an individual patient there must be dialogue – a concept which has given rise to shared, or supported, decision-making models (Montgomery v Lanarkshire Health Board, 2015 at 90; General Medical Council, 2020; Royal College of Surgeons, 2018). This redefined legal duty sought to facilitate greater respect for patients' rights of self-determination and autonomy by enabling them to make informed choices about their treatment.

Causation

On the matter of causation, *Montgomery* successfully applied the ordinary rule of causation without need to adopt the approach in *Chester* (Montgomery v Lanarkshire Health Board, 2015, at 105). The Supreme Court ruled that it would be wrong to determine the issue of causation according to the claimants "supposed reaction . . . if she had been advised of the minimal risk of a grave consequence" and instead causation should be determined according to her "likely reactions if she had been told of the risk of shoulder dystocia" (Montgomery v Lanarkshire Health Board, 2015, at 103). The court considered that, had during discussion between patient and practitioner, the patient been informed of

the risks, "dispassionately" and without coercion to adopt the practitioner's recommended course, then she "would probably have elected to be delivered of her baby by caesarean section [and upon those grounds] is not in dispute that the baby would then have been born unharmed" (Montgomery v Lanarkshire Health Board, 2015 at 104) Evidence in support of this decision – namely that the doctor admitted that Mrs Montgomery would have elected for cesarean section – had been discounted in the lower courts (Montgomery v Lanarkshire Health Board, 2015 at 101–102). The Justices also considered the likely response from other "women in her position" would be to opt for a cesarean section (Montgomery v Lanarkshire Health Board, 2015 at 101; 104). This approach to causation was also adopted in case of Webster v Burton Hospital NHS Foundation Trust (2017). The claimant's baby – delivered after 40 weeks' gestation – suffered neurological harm which could have been avoided had the birth been induced at term. In applying the approach to causation adopted in *Montgomery*, the Court of Appeal asked whether the mother had been advised of the risks and benefits associated with managing the latter stages of pregnancy at the 34-week scan, including the option to induce labor. In finding that the harm sustained could have been avoided, the case re-affirmed the decision in *Montgomery* and successfully established causation (Montgomery v Lanarkshire Health Board, 2015; Webster v Burton Hospital NHS Foundation Trust, 2017).

ESSENTIAL ELEMENTS OF INFORMED CONSENT AFTER MONTGOMERY

The key outcomes of the Montgomery ruling (as outlined in Table 1) were considered in the subsequent case of Duce v Worcestershire Acute Hospitals NHS Trust (2018). The case explored the scope of *Montgomery's* prudent patient test and offered further clarification on the applicability of *Chester* in establishing causation in "failure to warn" cases (Chester v Afshar, 2004; Montgomery v Lanarkshire Health Board, 2015). As evidenced by development of the current standard of informed consent, it is evident that the burden of proof in such cases remain high (see case law summary in Table 2).

Mrs Duce brought a case for negligent non-disclosure of risk. The claimant, having suffered from dysmenorrhea and menorrhagia for several years, elected to undergo a total hysterectomy and bilateral salpingoophorectomy, yet claimed not to have been informed of the risk of nerve damage and subsequent chronic pain. The complication materialized and she brought her claim in negligence before the Court of Appeal. Hamblen LJ made the "fundamental distinction" between the doctor's role in considering suitable medical treatment and their subsequent role in disclosing information to the patient for the purposes of consent, so clarifying informed consent as a *two-stage test* (Duce v Worcestershire Acute Hospitals NHS Trust, 2018 at 30, 33). The clarification acknowledged that, within medicine, there may be different schools of thought (Montgomery v Lanarkshire Health Board, 2015). As such, selection of investigations and treatment would be considered an exercise of "professional skill and judgment" for which the *Bolam* test should apply (Duce v Worcestershire Acute Hospitals NHS Trust, 2018, at 33; Bolam v Friern Hospital Management Committee, 1957). Subsequent information disclosure during pre-treatment advice would be considered according to Montgomery's Reasonable Person Standard (Duce v Worcestershire Acute Hospitals NHS Trust, 2018, at 33). Duce further clarified additional factors relevant to materiality, such as "the odds of the risk materializing; the nature of the risk; the effect its occurrence would have on the life of the patient; the importance to the patient of the benefits sought by the treatment; the alternatives available and the risks associated with them" (Duce v Worcestershire Acute Hospitals NHS Trust, 2018 at 35). This clarification of materiality includes 'the odds of the risk materialising' which could expand the criteria for materially relevant, disclosable information.

SUMMARY OF RELEVANT UK CASE LAW

UK case law (as outlined in Table 2) demonstrates judicial precedence in setting a strict threshold for medical negligence cases pertaining to standards of treatment and pre-treatment advice. There are, however, signs that the tide is continuing to turn – albeit slowly – toward greater patient-centricity on

Table 2. Summary of relevant UK case law on medical negligence relating to treatment and pre-treatment advice.

Summary of Relevant UK Case Law on Medical Negligence	
Bolam v Friern Hospital Management Committee (1957) **1 WLR 582**	
Facts	Claim of negligent non-disclosure of information pertaining to risk and treatment options
Ruling	To adopt a 'Responsible body of medical opinion' standard in relation to duty of care.
Key Points	• A practitioner is "not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that art" (at p585) • Standard of care and information disclosure determined by body of medical opinion and not consideration of the patient.
Sidaway v Board of Governors of the Bethlem Royal Hospital (1985) **A.C. 871**	
Facts	Claim of negligent non-disclosure of information pertaining to 1–2% risk from surgery
Ruling	To adopt a 'qualified' Bolam standard
Key Points	• Lord Scarman dissented, preferring a prudent patient standard be applied (p888, 889) • However, Lord Bridge delivered the judgment of a "reasonably prudent doctor" standard (p900) • Burden upon patients to ask the right questions pertaining to risk • Disclosable risk is that which is considered to be a substantial risk of grave and adverse consequence (at p898)
Bolitho v City and Hackney Health Authority (1998)**, p. 2 AC 232**	
Facts	Claim of negligent failure to treat linked to causation
Ruling	To maintain the Bolam Standard with qualifications of reason and logic. Link between the failure to act and harm sustained could not be established, so case failed on causation (p243)
Key Points	• The Bolam standard prevails with qualification as to whether a body of opinion is logical and reasonable. • Ordinary test for causation applied.
Pearce v United Bristol Healthcare NHS Trust (1998)**, p. 48 BMLR 118**	
Facts	Claim of negligent non-disclosure of information pertaining to 0.1–0.2% risk of harm
Ruling	The case was unsuccessful however the concept of significant risk and the reasonable patient were introduced. Significant risk cannot be determined according to precise percentages (p124)
Key Points	Lord Woolf reconsidered the qualified Bolam Test asserting that "if there is a significant risk which would affect the judgment of a reasonable patient, then it is. . .the responsibility of a doctor to inform the patient" (p124)
Chester v Afshar (2004) **UKHL 41**	
Facts	Claim of negligent non-disclosure of information pertaining to 1–2% risk which was linked to causation
Ruling	To adapt the ordinary test for causation
Key Points	The ordinary 'but for' test of causation can be adapted to meet the complexities of the circumstances
Montgomery v Lanarkshire Health Board (2015) **UKSC 11**	
Facts	Claim of negligent non-disclosure of information pertaining risk and treatment options
Ruling	**New precedence**: To adopt the "reasonable person" and "particular patient" standard in determining materiality of risk in informed consent (p87)
Key Points	• Patients to be informed of material risks • Materiality is that which a reasonable person would attach significance to or what the doctor should reasonably be aware that a particular patient attaches significance to • Reasonable person and particular patient standard • Material and significant risk (p87) • **Causation**: considered that had the patient been aware of the risk, and not the minimal risk of grave consequence would she have reacted differently
Duce v Worcestershire Acute Hospitals NHS Trust (2018) **EWCA Civ 1307**	
Facts	Claim of negligent non-disclosure of risk
Ruling	Clarified the extent of Montgomery's reach; to be applied only to information disclosure and not treatment selection
Key Points	Established a **two-part test to informed consent**. • Standard of care in treatment (and alternative treatment) selection is to be determined according to Bolam • Information disclosure to be determined in accordance with Montgomery (p33) **Causation** the court suggests that the departure from the original test of causation in *Chester* would be the exception rather than the rule – the ordinary test should prevail.

matters of both materiality and causation. The clarification of materiality in *Duce* built upon *Montgomery* to suggest that where it can be proven that a risk is more likely to occur – such as through the provision of empirical evidence – then materiality can be confirmed (Duce v Worcestershire Acute Hospitals NHS Trust, 2018; Montgomery v Lanarkshire Health Board, 2015). Such empirical evidence could be derived from studies such as those undertaken by Robertson and colleagues which demonstrate harmful changes to treatment patterns derive from financial interests and subsequently cause harm to patients (Robertson et al., 2012). To then establish causation in negligent pre-treatment advice, the question should turn *not* what the doctors would have

decided to disclose, rather on the advice which *should* have been disclosed and what the patient would subsequently have decided to do (Poole, 2019). This affords greater consideration of the patient; however, the standard is often difficult for claimants to establish. The courts recognize that it is easy in hindsight to say one would not have made a certain decision and so they look for "compelling evidence" that the claimant would have refused such treatment (Poole, 2019, p. 134). The aforementioned study by Spece and colleagues suggest that disclosure of conflict of interest changes the patient's likelihood of consenting, indicating that they attach significance to that information for the purposes of informed consent – a key argument which could help establish causation linked to non-disclosure of financial interests (Spece et al., 2014 at 273).

COMPARISON OF COMMON LAW STANDARD WITH GMC GUIDANCE POST-MONTGOMERY

Montgomery's test of materiality stipulates that the practitioner is under a legal duty to ensure that the patient is made aware of any material risks, with the test of such materiality being whether a reasonable person in that situation would attach significance to such risk or, whether the practitioner should reasonably have awareness that the particular patient would attach significance to it (Montgomery v Lanarkshire Health Board, 2015 at 87). However, recent GMC guidance, outlined in the publication 'Decision making and Consent,' appears to be at odds with this legal standard, both in relation to the prudent patient test and the test of materiality (General Medical Council, 2020).

Materiality in relation to the reasonable person and the particular patient

The reasonable person

Recent guidance from the GMC could reflect a lower threshold for information disclosure than that which is set out in *Montgomery* (General Medical Council, 2020; Montgomery v Lanarkshire Health Board, 2015). The GMC guidance refers to information which "*a patient*" or *"the patient"* would want to know, rather than *Montgomery's* specific reference to the "reasonable person" or "particular patient" (General Medical Council, 2020; Montgomery v Lanarkshire Health Board, 2015 at 87). The GMC advise practitioners that, in providing information for the purposes of consent;

> You should not rely on assumptions about
>
> (a) The information a patient might want or need
> (b) The factors a patient might consider significant
> (c) The importance a patient might attach to different outcomes" (General Medical Council, 2020, page 12)"

The contemplation of what "a patient" might want, need, or consider significant appears ambiguous. Under UK law, the 'reasonable person' standard is applied. It was first described during the libel case of McQuire v Western Morning News (1903) as relating to the "man on the Clapham omnibus"; a standard which has served as a point of reference in English law ever since (McQuire v Western Morning News, 1903, at 109 as per Collins MR). The 'man on the Clapham omnibus' is the theoretical ordinary man, representative of the person on the street who is reasonable in his judgments and therefore provides a benchmark against which reasonable action can be measured. Lord Scarman likened his proposed 'prudent patient' to 'the man on the Clapham omnibus' in *Sidaway*, thus setting the reasonable standard of information as that which the reasonable person would expect to be given (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985 AC at 889). However, Lord Kerr and Reed diverged from this approach in *Montgomery* when they asserted that in exercising reasonable care in determining which information pertaining to risk should be disclosed, it should be recognized 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 Health

Board, 2015, at 94). In considering the collective views of women, there was a subtle yet important evolution of the reasonable person standard. In continuing the analogy, the Supreme Court Justices appear to determine reasonableness according to the collective 'passengers on the Clapham omnibus' standard, rather than that of the individual 'man on the Clapham omnibus' (Dunn et al., 2019, p. 117; McQuire v Western Morning News, 1903 at 109; Montgomery v Lanarkshire Health Board, 2015, at 94). This could represent a majority assessment of reasonableness. Indeed, Baroness Hale also considers a majority view in stating that "[t]hese are risks that any reasonable mother would wish to take into account in [decision-making] . . . in order to balance said risks against benefits in relation to each eventuality," highlighting a wider interpretation that goes beyond the individual (Montgomery v Lanarkshire Health Board, 2015, at 121). Such majority assessments could be determined according to empirical evidence of what information patients would expect to know in the given circumstances. Whilst such an approach has yet to be adopted by courts – as they remain cautious about retaining the right to go against 'unreasonable' popular opinion – Spece and colleagues argue that the use of empirical evidence could "shed light on the question of materiality" (Dunn et al., 2019, p. 117; Spece et al., 2014 at p273). Instead, the GMC's consideration of what 'a patient' might want, need, or consider significant could reflect the outdated 'man on the Clapham omnibus' standard, thus failing to encapsulate the intricacies of the current legal standard *its* potential to be interpreted in its broadest terms (General Medical Council, 2020).

The particular patient

One may argue that the GMC's reference to 'a patient' could, instead, be interpreted as reflecting the 'particular patient' standard which was also referred to in *Montgomery* yet this too is a deficient interpretation of the legal standard (Montgomery v Lanarkshire Health Board, 2015 at 87). The 'particular patient' caveat requires that practitioners tailor according to the particular patient. Such information would likely relate to the patient's own values and the impact such risk would have upon their life (Montgomery v Lanarkshire Health Board, 2015 at 87). In a subsequent section, the GMC goes on to refer to 'the patient' in advising practitioners that;

> You should usually include the following information when discussing benefits and harms;
> a. Recognized risks of harms that you believe anyone in the patient's position would want to know
> c. Risks of harm and potential benefits that the patient would consider significant for any reason
> d. Any risk of serious harm, however unlikely it is to occur (General Medical Council, 2020, p. 15)."

This may give strength to the argument that the GMC's guidance be interpreted as reflecting Montgomery's 'particular patient' caveat. Yet, whilst this is undeniably an important aspect of the test of materiality – indeed, it was further emphasized in *Duce*, when the court asserted that practitioners should consider the "effect . . . [that a risk] would have on the life of the patient" (Duce v Worcestershire Acute Hospitals NHS Trust, 2018 at 35) – it must also be noted that it may undermine patient autonomy (Dunn et al., 2019). Dunn and colleagues caution that the limitation that practitioners need only have a 'reasonable awareness of what a particular patient would attach significance to' could be interpreted as placing the onus on patients to make their practitioner aware of values or concerns that they consider significant (Dunn et al., 2019, p. 115). Relational constructs of autonomy call for dialogue and discussion (MacLean, 2006, p. 328) whereas 'reasonable awareness' calls for no such duty to actively develop relationships with patients in order to determine their values (Dunn et al., 2019, p. 115). The reasonableness caveat in represents a policy decision by the courts to protect practitioners from "limitless liability" for non-disclosures of apparently insignificant risk (King & Moulton, 2006, p. 452). Similarly, the "reasonable awareness of the particular patient' caveat may also limit the patient's ability to receive the information they may need to make an informed decision. It is therefore pertinent that the Montgomery test be read in its entirety, giving recognition to the "reasonable person' and 'particular patient' standards in their broadest forms (Montgomery v Lanarkshire Health Board, 2015, p. 87). To this end, the GMC guidance represents an insufficient interpretation of the legal standard which leaves ample room for misinterpretation which could undermine the intent of *Montgomery*. Notably, there is a sharp contrast between the GMC's guidance

and that from Royal College of Surgeons (RCS) which does reflect the legal standard (General Medical Council, 2020; Royal College of Surgeons, 2018) . The RCS guidance on 'Supported (or shared) Decision Making' emphasizes the relational nature of informed consent. It asserts that surgeons are "no longer the sole arbiter of determining what risks are material to their patients," instead, "what will constitute a material risk will vary from patient to patient … [therefore] consent has to be patient-specific" (Royal College of Surgeons, 2018, pp. 3, p14). The guidance continues by stating that "the discussion has to be tailored to the individual patient … [which] … requires time to get to know the patient well enough to understand their views and values" (Royal College of Surgeons, 2018, p. 4). Ultimately, this guidance better reflects the focus of *Montgomery* which is to facilitate the exchange of information between patient and practitioner so that consent be truly informed and valid.

The reasonable person-particular patient standard

In appeasing the reasonable person-particular patient elements of consent, King & Moutlon 2006 suggest that a two-stage approach to materiality be adopted. Initially, the reasonable person standard could be used to define the 'base line' standard of information to be disclosed to patients relating to a particular risk (King & Moulton, 2006). An empirical assessment could be used to determine the nature of such base line of information. Following this disclosure, King asserts that practitioners should then engage in a discussion with the patient which would allow them to identify and "satisfy [their] subjective needs" (King & Moulton, 2006, p. 452). Such an approach is supported by the results of a patient survey conducted by Feldman-Stewart and colleagues. The findings demonstrate that, within a collective of 'reasonable people,' there were diverging views which are likely attributable to differences in personal values and in perception and acceptability of risk (Feldman-Stewart et al., 2000). Therefore, both aspects of the test are required to ensure individual patients are sufficiently informed; and empirical evidence could play an important role in facilitating this.

FROM MATERIAL RISK BACK TO SIGNIFICANT RISK?

The GMC's reference to 'significant factors' and the 'importance of outcomes' rather than materiality, may also be at odds with the legal standard (General Medical Council, 2020, pp. 12, p15) (Montgomery v Lanarkshire Health Board, 2015, p. 87). Whilst terminology such as 'significant,' 'important' and 'material' may be interchangeable in general linguistical terms, at law a careful distinction must be made, as demonstrated by the case law whereby the courts have considered 'substantial,' 'significant' and 'material' harm (see Table 2) (General Medical Council, 2020, pp. 12, 15). 'Material' may be defined in non-legal terms as that which is "significant" (Oxford English Dictionary, 2021) or has "an important effect" (Cambridge Dictionary, 2021). In legal terms it may defined as "important … having influence … [or] … [of being] … relevant" (Black's Law Dictionary, 2021). By comparison, the definition of 'significant' tends to align with empirical factors. Definitions include that which " [is] likely to have a major effect," is "fairly large in amount of quantity" or that which describes the "statistics of, or relating to, observations or occurrences … " (The Free Dictionary, 2021). In exploring the tautology of materiality and significance, (Madden, 2015) describes a spectrum of legal interpretations of 'significance' which ranges from "degree or amount, [to] probability, and even near certainty" (Madden, 2015, p. 233). Therefore, 'significance' may be interpreted as a form of measurement which distinguishes it from materiality and its incorporation of additional factors such as importance and relevance. The uncertainty surrounding the term 'significance' has been cause for extensive judicial consideration as is summarized in Table 2.

In *Sidaway* the court described a disclosable risk as that which was "so great that the doctor should have appreciated that it would be considered a significant risk" (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985 at 900 as per Lord Bridge). Lord Bridge preferred the adjective 'substantial,' instructing practitioners to inform patients of "substantial risk of grave and adverse consequence," such as that which fell in the region of 10% (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985 at 900). Current GMC guidance – that patients should be informed of

"[r]ecognised risks of harms that you [the practitioner] believe anyone in the patient's position would want to know" (General Medical Council, 2020 at p15) – could be interpreted as reflecting the *Sidaway* standard. The guidance creates ambiguity on two fronts. Firstly, it relates to 'recognised risk' rather than 'material' or 'significant' risk – which could arguably be interpreted as risks which are 'recognised' as important by the surgeon. Secondly, it relates back to the aforementioned 'reasonable person' (in the patient's position) standard which does not consider the 'particular patient.' This appears to set a standard which is determined by the practitioner and therefore may promote a standardized form of disclosure. Notably this position is no longer considered good law as practitioners and patients may diverge on what is considered a substantial, or even significant, risk. In Wyatt v Curtis (2003), it was Sedley LJ recognized that:

> what is substantial and what is grave are questions on which the doctor's and the patient's perception may differ. To the doctor … [a 1% chance that] … the patient's chickenpox may produce an abnormality in the foetus may … be [neither substantial nor grave]. To the patient … [such] risk of a potentially catastrophic abnormality may … be both substantial and grave (Wyatt v Curtis (2003) at 16)

This acknowledgment that a disclosable risk should not be that which is determined by according to the practitioner's interpretation of significance marked a judicial shift from *Sidaway* (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985). The Supreme Court justices in *Montgomery* built upon this concept in asserting that risk is not purely related to a patient's perception of magnitude nor a *doctor's* assessment of significance (Montgomery v Lanarkshire Health Board, 2015). In addressing the relevant standard, the Supreme Court recognized that 'significant' and 'substantial' have "different shades of meaning" (Montgomery v Lanarkshire Health Board, 2015 at 66). Ultimately rejecting the adjective 'substantial,' 'significant' was considered to be the more fitting adjective when subsumed within the wider concept of 'materiality.' Material risk considers that "a reasonable person in the *patient's* position [or the particular patient] would be likely to attach significance to the risk" (Montgomery v Lanarkshire Health Board, 2015 at 87). Therefore, the GMC guidance to disclose that which the practitioner *believes* the patient would want to know also reflects an inadequate interpretation of the prevailing legal standard (General Medical Council, 2020, p. 15). In a subsequent subsection of GMC guidance it appears that greater consideration of the patient is afforded. However, in instructing that that information should usually include "[r]isks of harm … that the patient would consider significant for any reason," the GMC fails to mention disclosure of material risk, thus maintaining a narrow interpretation of risk which fails to reflect the legal standard (General Medical Council, 2020, p. 15). The Supreme Justices in *Montgomery* distinguished materiality as that which "cannot be reduced to percentages" in the way which significance has in the past (Montgomery v Lanarkshire Health Board, 2015, at 89). This conclusion reflects earlier judicial consideration of Lord Scarman's speech in *Sidaway* whereby he explained that patient decision-making goes beyond medical fact – and therefore beyond empirical considerations of 'significance.' Instead, it incorporates broader "circumstances, objectives, and values [which may not be] … known to the doctor but which may lead [the patient] to a different decision" than one which is based upon clinical considerations alone (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985 at 886; Montgomery v Lanarkshire Health Board, 2015 at 45). Accordingly, material risk is both "fact-sensitive, and sensitive to the characteristics of the patient" (Montgomery v Lanarkshire Health Board, 2015 at 89). Material risk affords 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 Health Board, 2015 at 89). Therefore, the GMC's reference to 'significant risk' alone fails to incorporate those wider patient-sensitive factors which are required for medical decision-making. Ultimately, the language employed throughout the GMC guidance fails to reflect the patient-centric approach which Montgomery sought to promote through considerations such as the 'reasonable person,' the 'particular patient,' 'materiality' and "significance." Legal materiality reflects an umbrella terms which incorporates factors such as the importance or relevance information has to

a patient, in addition to significance as interpreted in its broadest form (General Medical Council, 2020, pp. 12, 15). Whilst the legal standard has been re-defined in favor of greater patient-centricity; the GMC guidance suggests this has not yet fully descended into practice. "Whilst the legal standard has been re-defined in favor of greater patient-centricity; the GMC guidance suggests this has not yet fully descended into practice. The GMC's failure to articulate the current legal standard leaves practitioners with the erroneous impression that paternalism continues to prevail. The GMC's reference to 'significant' factors and the 'recognised risks' of harm which the *practitioner* believes the patient would want to know stands in direct contrast to Montgomery's materiality rule which requires consideration of the risks that the particular *patient* would want to know. To this end, the current GMC guidelines are insufficient and require strengthening, particularly since the legal standard is unlikely to be sufficient in solving this problem alone."

SUMMARY

Financial interests as significant and material

In the UK. informed consent to medical treatment remains focused upon disclosure of clinical information despite increasing evidence that many non-clinical factors influence patient decision-making (Sawicki, 2016). Indeed, financial interests, which are not of a clinical nature, have been shown to impact upon clinical decision-making and clinical outcomes (Robertson et al., 2012). It is upon these grounds that Berg and colleagues argue that it would be "fundamentally unfair to deprive patients of information concerning the financial pressures that may influence their physician's treatment decisions" (Berg et al., 2001, at 212). If the 'reasonable person' standard in *Montgomery* is interpreted as adopting a majority view of materiality, then empirical evidence could be assumed in cases of non-disclosure (Montgomery v Lanarkshire Health Board, 2015). Existing empirical evidence presents a strong case for 'potent' financial interests representing a disclosable material risk under current UK common law standards. Evidence has shown that financial interests influence practitioners' patterns of behavior "for the worse" (Robertson et al., 2012, p. 456). This includes the provision of inappropriate and unnecessary treatments. Further evidence suggests that a "substantial portion" of patients change their behavior when in receipt of such information and so may be said to attach significance to it (Spece et al., 2014, p. 271). On these grounds, such evidence could be interpreted as representing a majority view that potent financial interests are material to decision-making. As per King & Moutlon 2006, such a majority view – in satisfying the reasonable person standard of Montgomery – could then form the core information required for disclosure. Building upon this, practitioners should then tailor information to the 'particular patient,' bearing in mind that materiality goes beyond percentages – and therefore empirical evidence alone. Such dialogue requires the practitioner acquire patient-sensitive knowledge to evaluate any additional disclosable information, which would be facilitated by shared decision-making. Notably, since the non-disclosure of financial interests was found to be associated with erosion of trust, it may be argued that increased disclosure of financial interest could potentially re-build trust in the medical profession (Rose et al., in press).

Directions for future research

The conflicting findings relating to patient behavior following disclosure of financial interests indicate that further research is required in this area. Such research would be critical in enhancing arguments pertaining to both materiality and causation. Spece and colleagues suggests that a substantial proportion of patients will refuse treatment following a potent financial interest disclosure, whereas Rose and colleagues found that in the real-world setting, patients retained their appointments (Rose et al., in press; Spece et al., 2014). On the matter of causation, if the findings by Spece and colleagues were accepted they could provide "compelling evidence" (Poole, 2019, p. 134) for an ordinary test of causation (Poole, 2019). It could then be argued that 'but for' the failure to disclose potent financial

interests, the patient would not have been likely to consent to treatment and the harm would not have been sustained. As previously explored, in negligent non-disclosure cases, the question of causation often turns on what information should have been disclosed, yet in *Montgomery* causation was determined according to the "likely reactions [of the claimant] if she had been told of the risk" which was determined by giving consideration to the reaction of women in general (Montgomery v Lanarkshire Health Board, 2015 at 103). This approach could, similarly, reflect a majority approach to causation. The experimental vignette adopted by Spece and colleagues could be adapted to the given case in order to support causation by offering an estimation of whether disclosure would have changed the patient's decision to accept treatment (Spece et al., 2014, p. 272). Spece and colleagues suggest employing the expert witnesses to conduct experimental vignettes which reflect the individual decision the patient was presented with could represent a "promising reform" (Spece et al., 2014, p. 273). UK cases such as *Chester* and *Montgomery* have demonstrated that causation often turns on whether disclosure would have avoided the harm sustained (Chester v Afshar, 2004; Montgomery v Lanarkshire Health Board, 2015). If the patient could successfully demonstrate that the disclosure of financial risk would have led them to delay treatment, seek a second opinion or an alternative treatment, then causation may be established (Chester v Afshar, 2004; Montgomery v Lanarkshire Health Board, 2015). Such empirical evidence could support the claim of causation, rather than setting the burden of proof purely at the patient's door. Whilst in lieu of a test case, uncertainty remains as to how the courts would view such cases, in the US the courts have recognized a practitioner's duty to disclosure information which is not strictly medical-related whereby it represents a factor which may influence the practitioner's medical judgment (Moore v Regents of Univ. of California, as cited in Sawicki, 2016, p. 25) . However, it is pertinent to note that the data from Rose and colleagues suggest that in the real-world context patient behavior does not change – at least in terms of appointment attendance – following disclosure. Yet whilst their data suggests that patients continued to trust that their hospital would "give [them] all the information [they] need about treatment," there is no evidence to suggest that patients actually elected to then undergo treatment following their consultations (Rose et al., in press, p. 5). Expanding this research to consider whether patients then underwent treatment would be beneficial. Of further interest is whether patient's behavior changes if information is disclosed verbally compared to receiving the information in a letter, thus comparing the findings of the two studies (Rose et al., in press; Spece et al., 2014).

It must also be considered as to how far informed consent can be relied upon as a 'risk-management mechanism.' On one hand, it may be argued that once practitioners disclose financial interests and obtain consent in light of a heightened risk that there may, in practice, be a lowering of the standard of care to which the practitioner is held. Arguably, however, the *Bolam* standard – which holds that the standard of care should be that which is in line with a body of medical opinion – should mitigate against instances whereby care deviates beyond the norm, such was the case with Paterson and his cleavage-saving mastectomies (Bolam v Friern Hospital Management Committee, 1957; James, 2020). It is suggested that should financial interests be accepted as disclosable material risks, then future empirical research be directed toward establishing whether, or to what extent, such disclosures mitigate against potential harms. One further limitation of this study lies in the diverse nature of financial interests. As outlined, it is likely that only those deemed 'potent' would be disclosable, with potency relating to those interests which are likely to have most influence over patterns of practice. It is likely that, even with such a definition, uncertainty will remain and therefore future research should also aim to clarify which financial interests which should be directly disclosed for the purposes of informed consent. However, caution must be employed in defining potency as, if interpreted too widely, therein lies the risk that patients could be bombarded with irrelevant information. Lord Templeman's cautioned that the standard of information disclosure should not transcend into a deluge of information for the purposes of discharging a duty (Sidaway v Board of Governors of the Bethlem Royal Hospital, 1985 at 904). Ultimately, a balance must be struck so as not to overwhelm the decision-making process and undermine the intent of informed consent.

Finally, as Rose and colleagues highlight, when patients are in the process of arranging or attending an appointment the 'cost' of making alternative arrangements may prove influential (Rose et al., in press). In the UK, many patients already face long waiting times for NHS treatment, therefore patients may feel they have little choice to accept treatment from the practitioner they are assigned. However, the impact of the recent scandals which have hit UK healthcare should not be discounted. Therein lies a strong argument in favor of greater transparency through enhanced information disclosure for informed consent. At the very least, such transparency may help to rebuild trust, which has been shown to improve healthcare outcomes (Birkäuer et al., 2017). Furthermore, it is not anticipated that informed consent is the cure-all solution for the harmful influence of financial interests in healthcare. It should, instead, be read alongside the recommended mandatory disclosure and device registries outlined by the Cumberlege Report (Cumberlege, 2020). Since such practitioner registries in the US have failed to sufficiently inform patients of financial interests, it is anticipated that the recognition of potent financial interests as disclosable material risks would strengthen any legislative provisions introduced into the UK (Cumberlege, 2020)

CONCLUSION

The current common law standard pertaining to informed consent, as set out in the case of (Montgomery v Lanarkshire Health Board, 2015), holds that patients must be informed of the material risks of treatment. The Montgomery test of materiality – which asks whether in the circumstances, a reasonable person in the patient's position would attach significance to the risk – incorporates consideration of various factors, including the magnitude of the risk. This test of materiality is considered appropriate and should be followed by practitioners, medical authorities and future courts however its applicability may be broader than is currently appreciated. Traditionally, only the risks which are inherent to the treatment are considered disclosable for the purposes of informed consent yet, evidence suggests that potent financial interests may also be considered material – and therefore disclosable – under current common law provisions. Whilst practitioners should uphold the patient's best interest as their primary concern in discharging their professional duties, secondary financial interests have been shown to take precedence in some cases. Empirical evidence supports the theory that financial interests can change practice patterns for the worse and result in harm to the patient.

It is also anticipated that the Montgomery materiality rule will bolster the case for causation in a court of law by considering whether the patient would have reacted differently if they had been in possession of this information. There is evidence to suggest that patients *would* consider such information to be significant for the purposes of informed consent to treatment and would refuse treatment which was subject to the influence of potent financial interests – a crucial consideration in establishing causation. A test case is likely required on several points; to determine whether UK courts would interpret the law as such; to explore whether the courts would be willing to adopt empirical evidence to support their reasoning on matters of materiality and causation and, to consider whether the expert witness role could be expanded to incorporate the undertaking of experimental vignettes. It may be surmised that, since the courts have demonstrated an evolution toward greater patient-centricity in recent years, that such an approach may be adopted in future to determine the materiality of conflict of interest in informed consent to medical treatment.

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I have no known conflict of interest to disclose.

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