

The ill-informed: Consent to medical treatment and the therapeutic exception

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Abstract

Affirming the doctrine of informed consent, the UK Supreme Court in *Montgomery* v *Lanarkshire HB* belatedly followed the Australian decision of *Rogers* v *Whitaker*, decoupling the duty to inform patients about the material risks of medical treatment from *Bolam*. The underlying commitment to patient autonomy coincides with a wider body of medical law that protects the right of capacitous adult patients to make treatment decisions, even if others consider those decisions bizarre and even if they will cause the patient serious harm. It is seemingly anomalous, therefore, that the Supreme Court in *Montgomery* referred to a 'therapeutic exception' (TE), as this suggests an underlying paternalistic approach. Contrary to this view, international examples suggest that a TE does not necessarily conflict with commitment to patient autonomy. In some countries, the exception mitigates the effects of a broadly objective test of materiality by enabling clinicians in exceptional circumstances to protect the autonomy interests of the particular patient. In others, it protects those incapable of an autonomous decision from harm. In England and Wales, however, alternative mechanisms can be interpreted to protect such patients from harm. On this basis, it is argued that the TE is obfuscatory, unnecessary and unjustified.

Keywords

informed consent, materiality of risk, therapeutic privilege, therapeutic exception, Montgomery v Lanarkshire, negligence, Rogers v Whitaker

Introduction: Montgomery v Lanarkshire Health Board

In 2015, the UK Supreme Court in *Montgomery* v *Lanarkshire Health Board*¹ (*Montgomery*) appeared on one hand to strike down the long tradition of medical paternalism that allowed

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clinicians to decide what patients should be told and on the other to revive paternalism by granting sanction to the notion of therapeutic exception (TE). In the United States, Australia and Canada, the TE is also recognized in law, resulting in similar jurisprudential tensions. Exploring the origins and historical justifications of the TE, this article demonstrates that in England and Wales, it is no longer relevant or necessary.

In England and Wales, medical treatment without a valid consent constitutes a trespass to the person and a criminal law assault.² Validity depends on the patient being 'informed in broad terms of the nature of the procedure'.³ Less draconian implications flow from a failure to provide information on the risks and implications of treatment, which can result in a claim in negligence. Clinicians exercise clinical judgement in determining what treatment to recommend and are under no obligation to provide futile or overly burdensome treatment.⁴ Nor are they required to give the patient all the available information concerning the treatment and its alternatives.⁵ Rather, the clinician⁶ must take reasonable care to inform the patient of 'material risks'. What is considered material would on a utopian conception involve the courts asking whether patients were given the information that they required in the particular circumstances.⁷ At first, this was considered beyond the capacity of the law and a more objective test was settled upon. The test set out in *Bolam* v *Friern Hospital Management Committee* (Bolam), which governs the standard of care for professional persons, requires that clinicians act in a manner 'accepted as proper by a responsible body of medical men skilled in that particular art'.⁹

The relevance of the *Bolam* test to information disclosure has been the source of much academic (Brazier, 1987; Brazier and Miola, 2000; Jones, 1999; Miola, 2009) and judicial¹⁰ debate. In the 1985 House of Lords judgement of *Sidaway*,¹¹ the judges agreed that the appeal should be dismissed because an undisclosed risk was not considered material. However, they varied considerably in their views of what *constituted* a material risk. Lord Scarman alone contended that *Bolam* should not determine the issue; a view upheld in Australia, Canada, New Zealand and some states in the United States. In the seminal US Court of Appeals for the District of Columbia case of *Canterbury* v *Spence*,¹² the prudent professional test was rejected in favour of a rights-based approach that focused on the hypothetical reasonable patient. The Australian High Court in *Rogers* v *Whitaker*¹³ went further still, adding a subjective limb to the objective prudent patient test. This requires clinicians to disclose risks where they are aware or should be aware that the particular patient would find them significant.

In *Montgomery*,¹⁴ the Supreme Court considered liability in negligence for failure to disclosure material risks to patients as part of the process of informed consent. Nadine Montgomery was awarded £5.2 million compensation following birth complications. She was of small stature and had gestational diabetes and had expressed anxieties about vaginal delivery. Her obstetrician failed to warn of shoulder dystocia and her son was born with cerebral palsy. The Court found that had her son been born by elective caesarean section, it is more probable than not that he would have been born uninjured.¹⁵

In their joint judgement, Lords Kerr and Reed (with whom the other justices agreed¹⁶) distinguished between cases concerning errors in treatment and diagnosis where the test set down in *Bolam* will continue to apply, and cases concerning the disclosure of risk and treatment alternatives which, it was held, are not purely a matter of professional judgement and cannot be decided by reference to a responsible body of medical opinion.¹⁷ *Montgomery* asserts and cements a position that has for some time been adopted in practice.¹⁸ The Supreme Court declared that Lord Scarman in *Sidaway* had represented substantially the correct position, subject to the *Rogers* v *Whitaker* 'refinement'.¹⁹ Setting out a revised test, Lords Kerr and Reed stated:

The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.²⁰

Henceforth, unless patients do not want to be so informed,²¹ physicians must discuss the risks of treatment and make patients aware of alternatives. Gone is the single comprehensive legal standard that applied to both treatment and advice. *Montgomery* separates those aspects of medical decision-making that require expert knowledge (such as treatment) and those that do not (such as advice on the risks of treatment and its alternatives).

The new test is subject to two exceptions. The first is uncontroversial; a 'necessity exception' exists where urgent treatment is required and the patient is unable to make a decision.²² The second is more problematic. The 'TE' applies when disclosure would 'be seriously detrimental to the patient's health'.²³ While the newly articulated test for materiality has resulted in extensive academic commentary (Badenoch, 2016; Bagshaw, 2016; Beswick, 2015; Campbell, 2015; Heywood, 2015; Hobson, 2016; McGrath, 2015; Montgomery and Montgomery, 2016; Reid, 2015), the TE has received much less attention, despite its seemingly incongruous place in a judgement that professes to adopt a patient-focused position intended to uphold autonomy rights (*News*, 2015).²⁴

This article explores the ambits of the TE, considering the dicta in *Montgomery* and other domestic decisions and international comparisons. It does not consider the potential application of the TE in relation to prognosis and diagnosis (see Hodkinson, 2013: 121) or the use of placebos (see Chan, 2015), focusing instead on the role of the TE within the doctrine of informed consent and the revised test for materiality of risk.²⁵ The article begins with the influences and development of the TE, linking its justifications to a wider body of medical law and to the significance of patient autonomy. A change in nomenclature from therapeutic *privilege* (TP) to TE is, it is argued, indicative of a narrowing of its scope, but the purpose and limits of the TE await judicial clarification.

The second section considers the influence of other common law jurisdictions in the Supreme Court's revision of the test for materiality and acceptance of the TE.²⁶ It is argued that the apparent widespread acknowledgement of the TE disguises a restrictive approach to its application. In light of this, the third section sets out objections to the TE, including its propensity to obscure legal principle and confuse the operation of informed consent in practice. The final section concludes that there are two possible justifications for a TE which are consistent with modern-day formulations of patient autonomy. One exists where the legal system promulgates an objective test that prevents clinicians from paying due regard to the particular patient's preferences regarding risk disclosure. Another exists where the legal system cannot protect the interests of vulnerable people in circumstances where the disclosure of material information will render them unable to make an autonomous decision about treatment. It is argued that neither condition exists in England and Wales. On this basis, the TE is unnecessary, conceptually flawed and should be disallowed.

The article seeks to influence the domestic development of the TE in law and practice but also has broader relevance to debates around the limitations of the doctrine of informed consent to protect patient choice and its interaction with the mental capacity framework. It concerns a grey area common to many jurisdictions that struggle to protect from serious harm those who are considered vulnerable by virtue of their inability to make an autonomous choice, while

concurrently upholding legal commitment to the right of patients with mental capacity to make treatment decisions that others consider irrational.

The TE

Developing a TP in England and Wales. There is a lack of clarity in the terminology surrounding therapeutic justifications for non-disclosure. The term 'TP' was coined before the legal duty to disclosure was even established (President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982: 95, citing Meisel, 1977: 99). Its ambits differ across time and place, and some countries now refer instead to a therapeutic 'exception', for reasons that will become apparent in this section. In England and Wales, few cases refer to the TP, even fewer apply it and none have accepted it as a defence. This does not indicate that the privilege was never applied in clinical practice. That the courts paid so little attention to its development is understandable given that it was, at least initially, of dubious practical importance. After all, it formed only a small part of the wide paternalistic privileges bestowed on medical practitioners in law. Under what was initially accepted as the Sidaway test, doctors only had to tell patients what a responsible body of doctors would consider reasonable. There was considerable scope to exclude information that other doctors would consider detrimental to patients' best interests. Jones (1999: 113) has argued that the TP did not apply as an exception to the duty to disclose information but rather 'it is incorporated within the duty of disclosure itself applying *Sidaway*' (see also Grubb, 1988: 138). The privilege formed part of the broader issue of clinical judgement, which is dominated by beneficence. Current practitioner guidance exhorting doctors to 'treat each patient as an individual' (General Medical Council, 2013: para. 2), flows from the World Medical Association Declaration of Geneva, adopted in 1948.²⁷ The objective prudent professional standard potentially conflicted with this guidance when it was objectively reasonable to disclose a risk, but doing so would harm the particular patient. In other words, the clinician might reasonably believe that information that would enhance autonomy and choice in the average patient would cause acute anxiety and potentially result in the refusal of beneficial treatment in the particular patient. In such circumstances, the TP has historically justified withholding the harmful information. Thus, in McAllister v Lewisham & North Southwark Health Authority, 28 Rougier J held that the TP applied where:

a doctor may be genuinely and reasonably so convinced that a particular operation is in the patient's best interests that he is justified in being somewhat economical with the truth where recital of the dangers is concerned. Again that all comes within the umbrella of a question of clinical judgement.

This led to a tension, outlined by Jackson (2006: 281), because the objective approach to the standard of care was subject to a subjective (therapeutic) exception:

Why should doctors be entitled to take into account the patient's special sensibilities when deciding not to tell her about a particular risk, while her individual and perhaps idiosyncratic preferences do not determine whether the doctor should positively disclose information?

But the courts were reluctant to trespass on applications of clinical judgement that operated in patients' therapeutic interests. Patients held the power to decline information but

doctors could override patient autonomy where they felt it was in the patient's best interests to do so.

The dawn of patient autonomy. As the dominance of Sidaway diminished in practice, ²⁹ further contradictions emerged. On one hand, as dominant liberal philosophies increased emphasis on self-determination, a broad TP became increasingly difficult to justify. On the other hand, it was clear that while an objective prudent patient test would enhance deference to patient choice, it was not a panacea (Miola, 2009). Clinicians remained conflicted where their professional duty to disclose information that a reasonable average patient would desire would cause the particular patient harm. Thus, accompanying Lord Scarman's (minority) rights-based approach to risk disclosure was an overt recognition of the TP as an exception to the general rule³⁰ where it would be 'detrimental to the health (including, of course, the mental health) of his patient'.³¹ Later, in Chester v Afshar, Lord Steyn too recognized (obiter) that a TP might exceptionally apply where it is justified in the patient's best interests.³²

The best interests justification had troublesome implications. First and foremost, it blurs the boundary between capacitous and non-capacitous decisions. But it generates additional inconsistencies. If there is a duty to protect best interests, then it should arguably make no difference whether or not the patient asks for information about the risks which a reasonable patient (or professional) would consider material. And yet, the doctor's duty to respond to the patient's questions is explicit in *Sidaway*.³³ It is not clear how the legal right to know and the doctor's duty to disclose are dependent upon the patient *asking* for disclosure of material risks.³⁴ Also, if there is a duty to protect best interests, one might expect the courts to award damages for the communication of harmful information. While an argument might be made to establish a duty of care based on an assumption of responsibility (Fay, 2012), the courts have proved reluctant to allow a claim for insensitive communication of correct information.³⁵

The only domestic case to deal—if tangentially—with the TP, placed a restraint on the best interests approach. It made clear that best interests cannot be used as a blanket rationale to justify non-disclosure of information and recognized the value of information even where it causes distress and even if it might result in refusal of consent. The case in question—AB v Leeds Teaching Hospitals NHS Trust³⁶—did not involve treatment of a patient but retention of tissue from deceased children without parental consent. The public outcry following two public inquiries resulted in group litigation. The defendants argued that providing information about the retention of tissue would have caused unnecessary distress to parents that could result in psychiatric harm. In essence, the claim was that the TP applied. The claim was rejected. Gage J stated, 'In so far as it involved the exercise of a therapeutic judgment it was one which does not appear to have been exercised on a case by case basis'. ³⁷ As has now been confirmed in Montgomery, ³⁸ for the TE to apply, it must be considered separately in relation to each individual.

Current General Medical Council's (2008: paras 16–17) guidance goes further still in its restriction of the best interests approach, seizing on Lord Steyn's view in *Chester* v *Afshar* that the TP should only apply in exceptional circumstances. The guidance recognizes that information might be withheld 'where giving it would cause the patient serious harm. In this context "serious harm" means more than that the patient might become upset or decide to refuse treatment' (see also Department of Health, 2009: paras 19–21).

This position conforms with that taken in the Mental Capacity Act (MCA) 2005, which restricts the application of the best interests test to situations where the person (P) lacks capacity. ³⁹ Article 8 of the European Convention on Human Rights, which protects the right to

a private and family life, has been applied by the European Court of Human Rights to protect and uphold autonomy rights.⁴⁰ In domestic common law too, commitment to upholding adult patients' capacitous choice is clear. In *Re MB*, Butler-Sloss LJ stated:

A mentally competent patient has an absolute right to refuse to consent to medical treatment for any reason, rational or irrational, or for no reason at all, even where that decision may lead to his or her own death.⁴¹

As Jones (2008: 551) has stated, the right to refuse treatment exists 'even where there are overwhelming medical reasons in favour of the treatment'.

Montgomery and the TE. The TP is not referred to in Montgomery. Instead Lords Kerr and Reed carve out a limited therapeutic 'exception' to the duty to disclose material risks. The change in terminology was not explained and is unlikely to signal a complete disconnection from the case law outlining a TP. It is probable, however, that the Supreme Court justices sought to emphasize the limited scope of the exception and move away from the paternalistic perceptions of 'privilege' as an integral aspect of the duty of disclosure. 'Privilege' implied a special status for doctors that contrasted sharply with other professions. In common with professional guidance, Lords Kerr and Reed limit the exception to disclosures that are 'seriously detrimental to the patient's health', 'a cautioning that it 'cannot provide the basis of the general rule'. 'A The decision signals a death knell for a TP applied to protect the best interests of patients, making clear that the TE should not be used to prevent patients making informed choices 'which the doctor considers to be contrary to her best interests'. Departing from medical paternalism, '46 the judgement firmly upholds commitment to patient choice:

[S]ocial and legal developments...point away from a model based upon a view of the patient as being entirely dependent on information provided by the doctor. What they point towards is an approach to the law which...treats them so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risk, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices.⁴⁷

The Supreme Court asserts that 'patients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession'. Lady Hale recognizes that the pregnant woman 'cannot force her doctor to offer treatment which he or she considers futile or inappropriate. But she is at least entitled to the information which will enable her to take a proper part in that decision'.

Accordingly, there are three ways in which the uncertainties of the pre-*Montgomery* case law on the TP are ameliorated:

- The general rule on disclosure of risk exists to protect patient rights to autonomy and freedom to decide.⁵⁰
- 2. The name change from 'TP' to 'TE' implies a defence to a claim for non-disclosure rather than an aspect of the duty of disclosure.
- The TE will apply where the physician reasonably believes disclosure would cause serious detriment to the patient's health. It is a limited exception that must not be abused.⁵¹

However, several issues are left to future development. The exception was not relevant on the facts and the Supreme Court declined to further articulate its scope. ⁵² We cannot turn to the pre-*Montgomery* case law because, as we have seen, it is sparse, conceptually confused and is inextricably linked to the test for materiality which *Montgomery* subjected to change. At least three questions remain to be answered:

- 1. According to what standard will physicians who invoke the TE be judged?
- 2. What sort of serious harm will justify its use (see Hobson, 2016)?
- 3. What is its justification and is it really necessary?

Montgomery may have provided a 'very explicit and belated obituary' (Foster, 2015) to one aspect of medical paternalism, but it leaves another aspect up in the air.

International jurisprudence

It is common knowledge that the TE is relevant to a number of jurisdictions that adopt the prudent patient test.⁵³ It seems reasonable to assume that this was a relevant factor in the Supreme Court's decision to retain the exception. What is less well known is that the TE is not by any means an inevitable corollary of a prudent patient test and that its application is rare and constrained. This section examines the application of therapeutic justifications for non-disclosure of material risks in the United States, Canada and Australia and concludes that the defence is in its death throes.

In the United States, the TP has been recognized in one form or another since the 1800s.⁵⁴ In the 1960 case of *Natanson* v *Kline*,⁵⁵ the Supreme Court of Kansas recognized that 'Anglo-American law starts with the premise of thoroughgoing self-determination' but accepted certain exceptions:

There is probably a privilege on therapeutic grounds, to withhold the specific diagnosis where the disclosure of cancer or some other dread disease would seriously jeopardise the recovery of an unstable, temperamental or severely depressed patient.

Early cases emphasized the principle 'first, do no harm' allowing physicians considerable scope to decide when and how far to sacrifice truth for beneficence. For example, in *Wilkinson* v *Vessey*, the Supreme Court of Rhode Island accepted non-disclosure where 'the doctor makes an affirmative showing that the non-disclosure was in the best interests of the patient'. ⁵⁶ Other states were more cautious, limiting the scope of the TP out of recognition of the central importance of information to decision-making. In the 1957 *Salgo* case, where the term 'informed consent' was first coined, it was recognized that:

a physician violates his duty to his patient and subjects himself to liability if he withholds any facts...necessary to form the basis of an intelligent consent by the patient to the proposed treatment.⁵⁷

The Court recognized that the TP is relevant where disclosure would cloud decision-making capacity and where it would result in physical or psychological harm. Similarly, in the 1977 Maryland case of *Sard* v *Hardy*, ⁵⁸ it was held that the privilege applies:

in those cases where a complete and candid disclosure of possible alternatives and consequences might have a detrimental effect on the physical or psychological well-being of the patient, or where the patient is incapable of giving his consent by reason of mental disability or infancy, or has specifically requested that he not be told.

This approach was emulated in *Cornfeldt* v *Tongen*, ⁵⁹ where the Supreme Court of Minnesota recognized the relevance of the TP where disclosure would either complicate or hinder treatment, preclude a rational decision or cause psychological harm.

However, the social transformation of informed consent to reflect individualist values (Dolgin, 2010), the development of dedicated frameworks to protect patients who lack capacity and recognition that the right to consent and refuse treatment has constitutional foundations in the US Supreme Court decision in Cruzan v Director, Missouri Department of Health.⁶⁰ resulted in a more restrictive approach to the TP. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1982: 95) favoured circumscribing the TP so that it would apply where the disclosure itself would cause harm rather than to prevent refusals of beneficial treatment. At first, judicial warnings not to abuse the privilege sufficed. The Court in Canterbury v Spence proposed limitations and sound medical judgement to 'carefully circumscribe' the privilege, 'for otherwise it might devour the disclosure rule itself. 61 The TP would apply where disclosure posed a threat to the patient which made disclosure 'unfeasible or contraindicated from a medical point of view'. Although the term 'TP' endured, there are clear parallels with the TE in Montgomery, in that the therapeutic justification for non-disclosure was increasingly viewed as a limited exception to the general rule that material risks must be communicated, applying so as to avert a risk of serious harm.62

Today many states have codes governing informed consent and some of these incorporate a TE. For example, New York refers to four statutory defences to negligent non-disclosure of risk including common knowledge, refusal of proffered information, emergency and the TP.⁶³ The latter allows the doctor to adapt the 'manner and extent' of the disclosure to protect the patient from harm. Where the state has a relevant code and it does not expressly refer to a TE, it is unlikely the exception would apply. For example, in *LcCaze* v *Collier*, the Louisiana Supreme Court stated:

A physician withholding information under such a therapeutic privilege could never have a valid consent under the Uniform Consent Law if the withheld risk was covered in the statute. ⁶⁴

Those states that continue to recognize a form of TE do so in contravention of professional guidance from the American Medical Association (AMA) Council on Ethical and Judicial Affairs:

Withholding medical information from patients without their knowledge or consent is ethically unacceptable. Physicians should encourage patients to specify their preferences regarding communication of their medical information, preferably before the information becomes available. Moreover, physicians should honor patient requests not to be informed of certain medical information or to convey the information to a designated proxy, provided these requests appear to genuinely represent the patient's own wishes. (Bostick et al., 2006: 306)

The AMA (2016: ch. 2.1.3) encourages doctors to explore preferences regarding communication, to honour requests for non-disclosure and sometimes to delay disclosure but is

clear that truthfulness and openness are essential components of respect for autonomy and of trust.

A restrictive stance is also taken in Australia. As we have seen, *Rogers* v *Whitaker*⁶⁵ provided that physicians have a duty to warn patients of the material risks inherent in the proposed treatment. A risk is material if a reasonable person in the patient's position would likely attach significance to it if warned of that risk. The majority recognize the relevance of the TP, ⁶⁶ but Gaudron J in a separate addition to the *Rogers* v *Whitaker* judgement sought to limit its scope:

I see no basis for any exception or 'therapeutic privilege' which is not based in medical emergency or in considerations of the patient's ability to receive, understand or properly evaluate the significance of the information that would ordinarily be required with respect to his or her condition or the treatment proposed.⁶⁷

Since then there are, as far as I am aware, only two reported cases raising the TP. In *Tai* v *Saxon*, ⁶⁸ the Western Australian Supreme Court held that in a non-essential procedure, a failure to warn on grounds that it would cause the patient harm was not sufficient to invoke the TP. The TP was successfully argued in *Battersby* v *Tottman* where non-disclosure of information was thought necessary to avert the risk that treatment for suicidal thoughts would be rejected by the patient. ⁶⁹ It is suggested later in this article that in England and Wales, the same protection might be achieved utilizing the best interests framework set out in the MCA 2005.

The dicta of Gaudron J may have restricted the scope of the TP in Australia but a more restrictive stance still is taken in Canada. The Supreme Court of Canada addressed the issue of informed consent in *Reibl* v *Hughes*, ⁷⁰ setting out an objective test which considers whether a reasonable person in the circumstances of the plaintiff would have consented to the proposed treatment if all the risks had been disclosed. Hodkinson (2013) argues that an exception to the duty to disclose is implicit in the following statement in *Reibl* v *Hughes*:

it may be the case that a particular patient may, because of emotional factors, be unable to cope with facts relevant to recommended surgery or treatment and the doctor may, in such a case, be justified in withholding or generalizing information as to which he would otherwise be required to be more specific.⁷¹

However, though the Supreme Court recognized that disclosure may not be feasible in an emergency, it did not expressly adopt the TE. Nor does it appear to have been adopted in Codes on consent which some states and provinces have promulgated. In Ontario's Health Care Consent Act 1996, ⁷² for example, section 10 sets out the key principle of 'no treatment without consent'. This is subject only to a determination of incapacity or emergency. The latter applies both to patients lacking capacity (section 25(3)) and to those with capacity but who lack the ability to communicate due to language or disability and where time is of the essence (section 25(2)). In other cases, consent must be informed which means the person must receive information 'that a reasonable person in the same circumstances would require in order to make a decision about the treatment' (Health Care Consent Act 1996, s. 11(2)). In *Meyers Estate et al* v *Rogers*, ⁷³ Justice Maloney stated that 'the Supreme Court of Canada has not, in *Reibl*, adopted or even approved the therapeutic privilege exception in Canada'. And in *Pittman Estate* v *Bain*, ⁷⁴ the Ontario Court refused to accept the TE when a doctor failed to tell a patient that his wife had contracted HIV. Edwin (2008) argues that these cases show that 'the patient's right to be informed takes precedence over the doctor's exercise of discretion'. The restrictive

Canadian approach emphasizes the fiduciary nature of the doctor–patient relationship.⁷⁵ The fiduciary relationship flows from the dependence and trust patients put in the medical profession and contrasts with the contractual origins of the doctor–patient relationship in the United Kingdom and Australia.

In conclusion, the Australian, Canadian and US jurisdictions all recognize exceptions to the rule requiring disclosure of material risks (however that might be defined). The most widely recognized exception is the emergency exception, and most recognize that, when the emergency is over, the information should be relayed. Some jurisdictions also accept that obvious risks need not be disclosed, and most make clear that patients can decide not to be informed of material risks. In the United States, only around half of the states accepted the 'reasonable patient' approach put forward in *Canterbury* (Dolgin, 2010: 101).⁷⁶ Of those, not all accepted the TE. Rather the TE must be justified in light of the approach to patient choice, the adopted test for materiality and the provisions for protecting those unable to make a capacitous decision. The international moves to patient-centred standards of disclosure and more sophisticated frameworks governing mental capacity have restricted the number of cases in which the exception is successfully invoked. Some jurisdictions now avoid the term 'privilege' to distance the exception from a best interests justification. Conversely, by referring to 'privilege' rather than 'exception', some states may seek to ensure that the term is not employed as a defence or exception. Rather it refers to the physician's limited discretion to respond to emergencies and to protect the best interests of patients lacking capacity. In the United States, the AMA's strong stance is indicative of the international approach to a legal principle in its death throes. Trust and autonomy are not compatible with the withholding of information necessary to make an informed decision. They are compatible with beneficence that is maintained by sensitivity to the patient needs and adjustments in the way the information is disclosed.

The dangers of obfuscation

Restrictions in the scope of the TE in *Montgomery* and professional guidance make it unlikely that doctors will ride roughshod over patient rights to make informed treatment decisions. And yet, the scope and application of the TE matters for two principle reasons. First, the vague and poorly articulated defence is unfair to doctors. Consent is a dynamic process. The risk of a procedure and the possible consequences of having and not having it, and the alternatives to treatment and their relative risks and benefits, can remain static or change many times in the course of the doctor–patient discussions. What concerns doctors is the *mechanics* of obtaining consent and *Montgomery* has potential to enhance the fear of litigation. The vague TE does nothing to assuage this and may even exacerbate the problem. Neither the judgement nor the GMC gives adequate guidance on the meaning of serious harm in this context, and clinicians may rightly complain that the legal exhortations to put the individual patient first and to avoid causing serious harm while observing what is predominantly an objective and hypothetical standard of disclosure are both complex and obscure. The Royal College of Surgeons (2016: para. 4.2) warns that 'The possibility of this [therapeutic] exception presents significant legal difficulties for doctors'.

Legal conundrums. In law too, commitment to the TE is problematic for a number of reasons. The TE does not apply to other professions (see Pattinson, 2014: 4–029). Barristers cannot avoid telling their clients of the risk that the case will be lost although it will cause emotional

breakdown, just as well-meaning professors cannot withhold catastrophic marks from their students for fear that the news will exacerbate an underlying medical condition. Furthermore, the privilege has potential to result in an overly complicated legal approach. Lords Kerr and Reed recognized that the new test for disclosure may result in less certainty and more litigation.⁷⁷ Clinicians will find it harder to predict whether the Court will consider their decision not to disclose a risk unreasonable. In *Sidaway*, the four judgements differed considerably in their positions on the distinction between diagnosis/treatment and disclosure of risk (see Hoppe and Miola, 2014: 80). In subsequent cases,⁷⁸ Lord Diplock's position initially carried the day. This asserted that clinicians are under:

[A] single comprehensive duty . . . not subject to dissection into a number of component parts to which different criteria of what satisfy the duty of care apply, such as diagnosis, treatment and advice. ⁷⁹

Montgomery presents a more complicated picture, drawing distinctions between different aspects of practice. Montgomery and Montgomery (2016: 93–94) argue that the distinction is confused and confusing:

It is not clear what type of skill and judgement is being applied if it is not 'medical'. Nor does the Court explain what test is to be used to assess whether such non-medical skills and judgements have been exercised appropriately. There is a radical shift from the position that everything that doctors do needs to be seen as 'medical' (the position in *Sidaway*) to the position that unless every aspect of the decision is driven by 'medical science' it is not a matter of professional expertise.

The Court stated that unpredictability is an acceptable price to pay: 'respect for the dignity of patients requires no less. 80 But the existence of the TE adds a layer of obfuscation that is difficult to justify. One issue is that it is not clear who will bear the burden of proving that the exercise of TE was unreasonable. It seems unlikely that it will be the claimant. The change in terminology from 'privilege' to 'exception' supports the view that it is the clinician who must show that the withholding of information is a 'reasonable exercise of medical judgment'.81 Another issue is that the Court in *Montgomery* states that when deciding how to explain the risks, the judgement is not a matter for the Bolam test. 82 But where information is considered detrimental to the health of the patient, it is not clear how reasonableness would be determined. If the operation of the TE is seen as a matter of medical expertise, then it will require medical evidence. If so, the Court could not 'give effect to any preference it may have for one responsible body of professional opinion over another, provided that it is satisfied that both qualify as responsible bodies of medical opinion'. 83 In short, the Bolam test would apply. We have seen that, in Sidaway, Lord Scarman argued that a prudent patient test would be subject to the TP. Lord Scarman opined that the onus of proof would be on the clinician and that medical evidence would be necessary to judge its veracity:

[The therapeutic privilege's] true analysis is that it is a defence available to the doctor which, if he invokes it, he must prove. On both the test and the defence medical evidence will, of course, be of great importance. 84

There is persuasive authority for this position in certain US cases⁸⁵ and indeed Lords Kerr and Reed hint at a similar conclusion in *Montgomery* when they speak of withholding information as a 'reasonable exercise of medical judgment'.⁸⁶

However, it is not certain that a court would adopt this position. It is conceivable that some decisions about what information to withhold from a patient to protect them from serious harm might not require technical medical knowledge. There is no English case on point, but the Supreme Court of Hawai'i in *Barcai* v *Betwee*⁸⁷ accepted that the matter will turn on the facts. In *Barcai*, the Court at first instance accepted the application of the TE when risks associated with the administration of antipsychotic medication were not disclosed to a patient. The appeal court found that Dr Betwee's testimony had not established that the non-disclosure was based on considerations specific to Barcai's case. A new trial was required in which Dr Betwee could raise the TE. It was held that expert testimony is generally (though not universally) required to assess the relevance of the TE. This is because the jury (in this case) might lack the special knowledge and technical training to be able to determine the standard without expert evidence.

Thus, there is potential for *Bolam* to remain relevant to the assessment of the clinician's reasonableness in invoking the exception, at least in cases where the decision turns on expert medical knowledge. This would necessitate further legal differentiations between medical and non-medical judgement. Two problems flow from this. One relates to the ensuing legal complexity. While Lords Kerr and Reed argued that any lack of clarity resulting from the new test for materiality was necessary in order to uphold patient dignity, it is not clear that the justification extends to the TE. Insofar as the TE puts in the hands of clinicians the power to decide what is detrimental enough to warrant non-disclosure of material information that the courts have found necessary in order to equip patients to make an informed choice, the TE forms a potential contradiction to commitment to patient choice. Another problem is that however carefully the courts and professional guidance limit the extent of the TE, the warning in *Canterbury* v *Spence* that it 'might devour the disclosure rule itself' holds true insofar as raising the TE risks 'reBolamisation' of the test for materiality.

Principle. The TE was not relevant on the facts of *Montgomery* and so it is perhaps understandable that Lords Kerr and Reed did not set out a justification for its retention. They did however make clear that:

[The TE] is a limited exception to the general principle that the patient should make the decision whether to undergo a proposed course of treatment: it is not intended to subvert that principle by enabling the doctor to prevent the patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests. 90

It is clear then that the Court is not committed to a broad welfare-based exception to the duty to inform. It would not, for example, apply to allow non-disclosure when it seems likely that the patient will refuse necessary treatment because of an overriding fear that the disclosed risk will materialize. The TE is far removed from the TP outlined in *McAllister* above. Three other possible justifications are considered here.

The first is that the Court sought to protect patients suffering from certain conditions which could be exacerbated by the shock or worry caused by disclosure of information and result in serious harm. Consider the facts of a Hawaiian case, *Nishi* v *Hartwell*, ⁹¹ where the TE was successfully argued. There a patient suffering from chest pain was paralyzed due to an adverse reaction to drugs used in a radiological procedure to detect aneurysm. Clinicians had not informed him of the risk because he was already very frightened and suffered from hypertension. Disclosure might have led to serious harm. At the time the case was heard, it was accepted that the TE operates to protect the best interests of the patient. ⁹² As we have seen, this

is no longer the case in England and Wales. It is unlikely that the TE would be justified here, on similar facts. To do so would be to accept that clinicians can and arguably should withhold stress-inducing information from patients with a susceptibility to stress-related serious harm (such as heart attack and even depression). While there may be compelling cases where non-disclosure might be justified because the risks are severe, the treatment is urgently needed and the opportunities to disclose information sensitively are very limited, they could exceptionally be justified under the doctrine of necessity. ⁹³ This would depend upon P being unable to make an informed decision; it not being practicable to communicate the material information to P; and the action taken being no more than is immediately required in P's therapeutic interests.

Historically, the TE might have been justified on the basis that the objective nature of the test (whether prudent professional or prudent patient) prevented the clinician from acting in the best interests of the particular patient. In *Sidaway*, Lord Scarman justified the TP on this basis:

The 'prudent patient' cannot...always provide the answer for the obvious reason that he is a norm..., not a real person: and certainly not the patient himself. Hence there is the need that the doctor should have the opportunity of proving that he reasonably believed that disclosure of the risk would be damaging to his patient or contrary to his best interest. This is what the Americans call the doctor's therapeutic privilege.⁹⁵

In states that retain an objective test this reasoning might still apply, albeit usually with a higher threshold for the application of the TE based on prevention of serious harm. Thus, the New York Code recognizes that one application for the TE is to allow the clinician to adapt the way information is disclosed to avoid harm to the patient. Under a prudent patient standard as proposed by Lord Scarman in *Sidaway*, the test is fact sensitive but does not incorporate the characteristics of the individual patient. Jackson (2006: 281) has argued that the prudent patient test is an inadequate means of protecting patient self-determination:

Individual patients' interests in information will vary dramatically.... Giving all patients the information that the abstract reasonable patient in their position would require might be preferable to the *Bolam* standard of disclosure, but it will result in some patients being provided with information that they do not want, while others will have been deprived of facts about the proposed treatment that are of vital importance to them.

Considering this criticism, the TE would arguably serve an important ethical function, preserving the clinician's duty to the actual patient, at least to the extent that it facilitates the doctor's ability to respond to the particular patient's preferences.

But post-*Montgomery*, this reasoning no longer holds for two principal reasons. First, the Supreme Court makes clear that patients can now decide *not* to be informed of material risks. Although the legal requirements for waiver are not fully articulated, it seems that patients will need to know and understand the basic information necessary to give a valid consent (and for the clinician to avoid a claim in battery), but the patient has the power to limit the details to which they are party. The right not to know is a controversial corollary of the right to information (Ost, 1984), but the law now extends beyond the requirement that material risks are disclosed and also requires disclosure of material *information*. The importance of patient control over the relevance of particular information is demonstrated by a consideration of the 2011 North Carolina law that prohibited women from having an abortion until their doctor had displayed ultrasound images of the foetus and read a state-mandated text describing what the

pregnant woman was seeing. In *Stuart* v *Camnitz*, ⁹⁸ the US Court of Appeal held that this was a constitutional interference with doctors' expressive rights due to the failure to incorporate a TE. Doctors could not be coerced into voicing a message of childbirth over abortion, regardless of the therapeutic ill effects. In *Montgomery*, it was made clear that patients have a role to play in determining the relevance of the information to which they are subjected. There is perhaps more that professional bodies can do to make this abundantly clear to clinicians, patients and their families so that patients can exercise increased control over the (avoidance of) information that would be welcomed by the average patient but harmful to the particular patient.

Second, the Supreme Court in *Montgomery* refined the test for materiality, introducing a subjective element to the test and placing increased focus on patient understanding. In common with the Australian case of *Rogers*, 99 not only must clinicians provide information that a reasonable patient would consider relevant, but they must also disclose information where they are aware or ought reasonably to be aware that 'the particular patient would be likely to attach significance to it'. The significance of risk is now recognized as a nuanced and individualistic assessment:

The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, 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 available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, *and sensitive also to the characteristics of the patient*. ¹⁰¹ (italics added)

Henceforth, not only must clinicians provide information on the material risks of the proposed treatment, they must also inform the patient of the risks and benefits of 'reasonable alternative or variant treatments' and the seriousness of the patient's condition. The test is no longer one of 'material risk' but extends now to 'material *information*'. The revised test does not simply require *more* information. Rather it is a matter of tailoring information to the reasonably ascertainable needs of the patient. A checklist approach is inappropriate. Consent must be bespoke. Dialogue between clinician and patient is essential. On this conception, the *Montgomery* test for materiality gives clinicians scope to adapt the information to the needs of the particular patient. Clinicians who insensitively communicate material risk in a manner that causes harm risk censure. But unless the patient lacks capacity or waives the right to disclosure, clinicians must make clear the material information needed for the patient to give informed consent.

Consider a hypothetical example posed by Brazier and Cave (2016: 146), 'Would a surgeon be able to justify withholding from a very elderly patient the frightening information about the risk of impotence in an operation the surgeon judged to be essential to maintain the patient's independent living?' Assuming the patient retains capacity, under *Bolam*, it might have been argued that a reasonably prudent professional would withhold such information in the best interests of the patient; under Lord Scarman's test, it is likely that the prudent patient with the particular patient's condition would find this information material in which case withholding the information would only be justified if the clinician reasonably believed it would be contrary to the best interests of the elderly patient. Under *Montgomery*, however, the reasonable patient would attach significance to the risk but if the clinician had specific knowledge that the nature of the risk would be unlikely to adversely affect the patient but that the provision of information would frighten the patient and therefore obfuscate the decision, then there is scope to limit or adapt the information. Section 2(3) of the MCA makes clear that such 'knowledge' must not

flow from unreasonable assumptions based on the patient's age or other characteristics, but it might come from the patient himself. It might be, for example, that a family member or carer suggests that this information would alarm the patient in which case the clinician can explore this with the patient if there is a sense that disclosure would risk serious harm. Provided clinicians carefully recorded this in the patient's notes, they should have nothing to fear from the law of negligence or professional regulation. There is no need in these circumstances to invoke the TE: the test for materiality is now sufficiently nuanced to allow clinicians limited scope to adapt the information to suit the needs of the particular patient. The scope is admittedly narrow, but this, it is submitted, is fitting given the emphasis in law and in *Montgomery* on preserving self-determination of adults with capacity to make decisions based on what in law is considered material information.

Another possible justification of the TE is that it might protect from serious harm those for whom disclosure would render them incapable of a rational decision. For example, there is legal authority for the proposition that a severe needle phobia can result in an inability to make a decision that can, in an emergency, justify treatment without consent. Might the phobia also justify non-disclosure of material information (e.g. that post-operative catheterization will be necessary), if mention of this information is likely to result in an irrational refusal of treatment that the patient otherwise desires? If the evidence suggests that, but for this information, the patient could make an autonomous treatment decision, withholding information might ostensibly *enhance* rational autonomy. Nonetheless, it is suggested in this section that such a conception would be inherently problematic.

A distinction can be drawn between situations when disclosure of information will result in a decision that clinicians view to be irrational and disclosures that will destroy the patient's capability for rational thought. As we have seen, it was made clear in *Montgomery* that the TE no longer extends to the former category. The decision is rational according to the individual's value system but irrational from an external viewpoint. But might the existence of the TE in *Montgomery* aim to allow clinicians scope for non-disclosure when the information is likely to cause such a reaction as to render P incapable of a rational decision?

McLean (2009: 19) has recognized that 'Irrespective of those philosophical approaches which seek to make autonomy a richer concept, it is the decision-making aspect of autonomy that dominates in law'. Coggon and Miola (2011: 538) agree that the law on information disclosure has traditionally upheld a liberal conception of free choice but argue that it inadequately protected patient autonomy. They cite *Al Hamwi v Johnston and Another*¹⁰⁸ as an example. There it was held that doctors providing the requisite information were not, on the facts, responsible for the patient's failure to understand it. The law was interpreted to focus on the mechanics of providing material information rather than its effectiveness in equipping the patient to make an autonomous decision. Coggon and Miola argue that this emphasizes ostensible rather than substantive autonomy.

The subjective refinement of the prudent patient test and reference to the patient's characteristics in *Montgomery* implies commitment to patient autonomy rather than a purely liberal conception of informed consent that focuses on mere provision of information. Clinicians are now required to engage in 'dialogue, the aim of which is to ensure that the patient understands' the material information. This represents a positive development, distancing the law on informed consent from a mechanical checklist approach and demanding meaningful engagement with the patient. Nevertheless, insofar as the judgement hints at a substantive model of autonomy, the corollary of protecting the substantive autonomy rights of those capable of engaging in the consent process is that those who are rendered incapable might be

deemed worthy of paternalistic protection. Beneficence in the form of the TE might be utilized to safeguard the welfare interests of those patients whom clinicians reasonably believe would be rendered incapable of a rational decision and subjected to serious harm if the material risk is disclosed. If so, this marks a divergent approach from the MCA 2005 which utilizes *incapacity* as the benchmark for best interests decision-making. Admittedly, such divergence is evident in recent developments of the inherent jurisdiction of the High Court to protect people from harmful involuntary decisions (Cave, 2017). But the application of the inherent jurisdiction is judicial rather than clinical; it would be more difficult in the case of the TE to ensure that its application is facilitative of autonomy rights so as to enhance (rather than limit) commitment to Article 8 of the European Convention on Human Rights. 111

Is the TP obsolete?

Rejection of the TE on the basis of the procedural difficulties it causes and the dangers of medical paternalism would not leave vulnerable patients without protection. In addition to the safety nets of necessity, the right to decline information and the professional duty to provide information in a sensitive manner, the MCA sets out a scheme to protect patients incapable of a capacitous decision. This section will argue that the MCA is relevant to decisions around information disclosure and that its best interests framework serves to protect those who lack capacity. It is submitted therefore that the TE is obsolete and that its existence has potential to contradict the principles of the MCA by subjecting those capable of a capacitous decision to a best interests framework because they are at risk of serious harm, without appropriate safeguards.

Section 1(2) of the MCA establishes an assumption of capacity that can only be rebutted if the individual is unable to make a decision due to an 'impairment of, or a disturbance in the functioning of, the mind or brain' (section 2(1)) that renders him unable:

to understand the information relevant to the decision,

to retain that information,

to use or weigh that information as part of the process of making the decision or to communicate his decision (whether by talking, using sign language or any other means; section 3(1)).

If P meets the diagnostic threshold and lacks the requisite understanding, then section 4 sets out a scheme for making decisions in P's best interests, where possible with P's participation. In such a case, the duty to disclose would be influenced by the test for materiality but dominated by the best interests test. There would be no duty to disclose material risks that cause the patient serious harm. Where the MCA applies, there is no need to rely on the TE. But the extent of the Act's application in the context of information disclosure is unclear. The Act provides a model for decision-making rather than information provision.

Can a capacitous decision be made without disclosure of material risks? The first issue is that it is not immediately clear from the Act what information must be understood, retained, used or weighed and communicated in order that the decision be considered capacitous. The remit of the Act extends beyond medical treatment to residence and welfare decisions. It is no surprise therefore that section 3 does not map neatly onto the laws of battery and negligence. In requiring that P 'understand the information relevant to the decision' in order to make the

decision, then as a minimum, the basic information necessary for a valid consent must be communicated and understood. If this is all that is required, then the TE might have a legitimate role in those cases where the patient understands enough to make a valid, capacitous consent but lacks the ability to understand material risks and cannot therefore make an *informed* consent. But does the Act suggest such a conception? Section 3(2) accepts that the quality of information might be adapted to suit the needs of the individual. But section 3(2) concerns the delivery of the information rather than its content. Section 3(4) provides:

The information relevant to a decision includes information about the reasonably foreseeable consequences of—(a) deciding one way or another, or (b) failing to make the decision.

The Code of Practice (Department for Constitutional Affairs, 2007: para. 3.9) requires that risks and benefits are explained and that 'important information' is not omitted. This goes beyond the basic information required to avoid a claim in battery. Case law confirms that while P is not necessarily required to understand, retain, use or weigh and communicate *all* the information that is provided in order to be considered capacitous, P must be able to process the 'salient factors'. ¹¹³ P must understand the 'relevant information' and given that informed consent is now 'firmly part of English law', ¹¹⁴ this must logically include the material risks. Lords Kerr and Reed make clear that:

An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.¹¹⁵

It seems consistent to assume that 'sound mind' is synonymous with 'capacity', a term which Lady Hale employs specifically. The conclusion is that, subject to the TE, all adult patients with capacity are entitled to material information. Those who lack capacity are still entitled to participate 'as fully as possible' (Mental Capacity Act 2005, s. 4(4)), but this is a determination that is to be made by the decision maker in the reasonable belief that the decision is in P's best interests (Mental Capacity Act 2005, s. 4(9)). In other words, best interests and not the law on battery or clinical negligence governs the risks that must be disclosed to a patient who lacks capacity.

Does the MCA require provision of information before a decision is reached about capacity? This section argues that there are circumstances in which the MCA can apply to protect P from harmful information on the basis that P lacks mental capacity and that this renders the TE unnecessary.

The application of the best interests framework relies on the clinician being able to establish that P lacks capacity. Can clinicians make an *ex ante* decision that the patient lacks capacity before the information is provided? Section 2(3) guards against assumptions about capacity on the basis of a person's behaviour or condition. And the Code of Practice (Department for Constitutional Affairs, 2007: para. 4.16) makes clear that, 'It is important not to assess someone's understanding before they have had information'. On the other hand, consent is a dynamic process. If it is apparent that P cannot understand certain salient information, there is no obligation to provide further, potentially harmful information if it is not in P's best interests

to do so. In other words, an ex ante determination of capacity is not ruled out in all circumstances.

Section 3(1)(c) requires that in order to have capacity, P must be able to weigh the information and use it to make a decision. If an impairment renders the person unable to weigh certain aspects of information and those aspects are necessary in order for the decision to be informed, then that person can be said to lack capacity. The Code of Practice (Department for Constitutional Affairs, 2007: para. 4.21) gives the example of a person with an eating disorder who might be able to understand information about the consequences of not eating but unable to weigh that information in order to make the specific decision because of their eating disorder.

Returning to the above example of a patient with a severe needle phobia who is likely to withhold consent to an operation she/he desires if told the material information that post-operative catheterization will be necessary, it was submitted that there are dangers in using the TE to justify non-disclosure due to the potential for medical paternalism. However, if it is reasonably believed that in relation to this specific issue, P lacks capacity to use or weigh the material information that is required in order for P to make an informed consent, then there is an argument that P lacks capacity.

The threshold is high: To use Hedley J's articulation, P might be shown to lack 'the capacity actually to engage in the decision-making process itself and to be able to see the various parts of the argument and to relate the one to another'. In Re SB, 119 a woman with bipolar disorder did not lack capacity to decide to have an abortion at 24 weeks despite psychiatric evidence that she could not use and weigh information concerning the support that her husband and mother would provide, due to paranoid thoughts. She was able to rationally use and weigh other information that was sufficient to enable her to make a capacitous decision. Indeed 'She perfectly understands any risks to her from undergoing a termination, which have been fully explained to her by the doctor...' 120

SB can be contrasted with *Cambridge University Hospitals NHS Foundation Trust* v *BF*, ¹²¹ where McDonald J held that a person with paranoid schizophrenia lacked capacity to consent to or to refuse medical treatment for ovarian cancer:

[I]n order to understand, and in order to use or weigh information relevant to the decision in issue a person has to have some capacity for rational thought regarding that information. Where a person labours under a condition that substantially deprives them of control of their thought process such that rational considerations concerning the relevant information are overpowered by involuntary irrational considerations . . . it is difficult to see how that person may be said to be able to understand or to use or weigh information relevant to the decision in question.

Consider *Dooley* v *Skodnek*, ¹²² one of the few cases internationally where the TE was successfully raised. A New York appellate court held that disclosure of information about treatment for a psychiatric condition might be withheld, at least temporarily where the patient suffered an acute phase of illness. In England and Wales, it seems that non-disclosure in such a case might potentially be justifiable under the MCA. Another example is the Australian case of *Battersby* v *Tottman*, ¹²³ where a patient suffering from psychosis was not warned that the drug Mellaril had potential to damage her eyesight. Had the clinician explained the risks, it was likely that Mrs Battersby would have stopped taking the medication, in which case she would have been at a significant risk of committing suicide. The TP was accepted in defence of the decision not to disclose the risk. If clinicians faced a similar situation in England and Wales,

there is scope to argue that the claimant lacked capacity to make the decision. Provided this belief was reasonable, P could be furnished with all the information that is in her best interests and a decision made with her participation.

Where a person's impairment of the mind results in them being unable to understand, use or weigh the information about material risks, they lack capacity to make a decision. Similarly, there may be circumstances where the clinician reasonably believes that the disclosure of a material risk would render a patient with an impairment of the mind or brain unable to make a decision, so justifying withholding the information on the ground that P lacks capacity. The TE, I would argue, is redundant in such circumstances. While it might seem heavy-handed to deny such a person capacity, recall first that capacity is decision specific. It is only this decision that the patient in all the circumstances is incapable of making. Also, recall that incapacity does not mean that P should not take as full a role as possible in the decision. Finally, one might argue that the Court of Protection is a more suitable setting in which to adjudicate questions about the patient's ability to understand and the clinician's duty to disclose than pursuing fault-based litigation in the compensation-orientated High Court. Decisions to withhold information should be discussed with the person's family or carers so that they can inform the decision about what information is in the best interests of the patient and can refer the case to the Court of Protection in the event of dispute.

As was made clear in *Montgomery*, patient autonomy is relevant not only to the acceptance or refusal of treatment offered by clinicians but also to the process of informed consent. If P lacks capacity to engage in that process, then it is right and proper that the MCA best interest framework is engaged. Equally, I would submit that if P does not lack capacity; treatment is not urgently required to avoid serious harm; and P has not waived the right to information, then P has a right to the sensitively portrayed information required to make an informed decision.

Conclusion

Disclosure of information to patients can serve several purposes. It might have therapeutic benefits designed to allay fears and promote well-being. It can also serve the patient's interests in self-determination. This article is concerned with the latter. Medical law in England and Wales upholds the right of adults with capacity to consent to or refuse medical treatment, irrespective of the rationality of the decision and its potential to cause the patient harm. Without pertinent information, patients are robbed of the ability to reason and make their own decisions whether to undergo the recommended treatment. Nor do England and Wales stand alone in protecting and promoting patient choice. The Council of Europe's Oviedo Biomedicine convention 1997, signed by 35 states (though not the United Kingdom¹²⁴), represents a minimum standard of harmonization. Article 5 requires that medical interventions are only carried out once free and informed consent has been given and that the patient is furnished with 'appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks'.

Montgomery embraces a more substantive version of autonomy than was previously accommodated in the law on informed consent. Clinicians should engage in dialogue designed to ensure that patients understand¹²⁵ material information including information about risks and alternatives¹²⁶ that is 'fact-sensitive, and sensitive also to the characteristics of the patient'. This is not an edict requiring clinicians to provide patients with more and more information; it is a requirement that, where practicable, patients' individual needs should be accommodated so as to make their choices meaningful. The effects of Montgomery should not

be exaggerated. It does not create a freestanding claim for breach of duty to make an informed choice ¹²⁸ and it has not led to a huge increase in successful claims for negligent information disclosure. ¹²⁹ It *does* recognize that material information is needed in order to make an informed decision and that informed consent is firmly part of law. Yet, in common with a number of jurisdictions, the Supreme Court judgement in *Montgomery* recognized that the duty to disclose material information before obtaining patient consent is subject to a TE. Articulation of the precise scope of the TE and its justification was left to future decisions. This article has analysed the legal development of the TE in England and Wales and made comparisons with the United States, Australia and Canada, so as to provide new insights on the relationships between informed consent and mental capacity, patient autonomy and medical beneficence. In light of this, it has been suggested that in England and Wales, the TE is unnecessary and unjustified and that its existence is problematic in law and principle.

The TE was not relevant on the facts of *Montgomery*, and the Court's acceptance of its existence was possibly influenced by domestic and international precedent. In fact, the domestic application is of little relevance because previous assertions of the 'TP' reacted to limitations of the objective materiality test to protect the interests of the particular patient. *Montgomery* incorporates a subjective component into the prudent patient test and in doing so removes one possible justification for the TE. ¹³⁰ In international jurisprudence, the existence of the TE may be widespread, but its application is rare. Even in Australia where the objective and subjective limbs to the test for materiality most closely map onto the *Montgomery* test, Mulheron (2003) has said:

[The TE] was specifically endorsed as part of Australian law by the High Court in *Rogers v Whitaker* (1992) 175 CLR 479. However, there has been negligible application of the defence since that endorsement....[T]he defence has been so narrowly interpreted since, such that it has come to occupy an almost untenable position in Australia's medical jurisprudence.

Lords Kerr and Reed limited the scope of the TE, framing it as an 'exception' rather than a 'privilege' and distancing it from a broad best interests application. In doing so, they removed another potential justification for the TE: the paternalistic protection of patient welfare.

Nor would it be consistent for the TE to apply whenever disclosure could exacerbate a medical condition and cause harm. To do so would create a wide exception and potentially even a duty to limit material information where the patient has a particular sensitivity (e.g. hypertension) which might result in harm (e.g. heart attack) if disclosure causes undue stress. Montgomery itself makes clear that the information should be adapted to the characteristics of the patient ¹³¹ and sensitively portrayed. ¹³² Exceptions will apply where the patient waives the right to certain information, and potentially if the treatment is very urgent and the patient cannot consent in which case non-disclosure may be justified under the doctrine of necessity. An exception might also exist if the patient has an anxiety disorder or other 'impairment' so as to satisfy section 2(1) of the MCA 2005. If the patient is incapable of understanding the material information, the best interests framework will apply on the basis that the patient lacks capacity. But there are questions about the potential application of the MCA to information disclosure and the suitability of the MCA's best interests framework to adequately protect those who are rendered incapable of rational decision-making by the disclosure of information. If the legal system cannot protect vulnerable patients in circumstances where the disclosure of material information will render them unable to make an autonomous decision about treatment, then the TE might serve a useful function.

The MCA sets out a scheme to protect those incapable of autonomous decision-making but there is ambiguity regarding the information that must be understood as part of the section 3 test. I have argued that the 'salient information' in the case of a person consenting to treatment is the information about risks and benefits that is in law considered 'material'. Difficulty also surrounds those cases where clinicians might seek to avoid serious harm that will result before a person can reasonably be considered to lack capacity. This is because the Act ostensibly requires that a person is furnished with the information upon which to make a decision before clinicians determine that the person lacks capacity. However, I have argued that in the dynamic process of consent, an apparent inability to understand does not require clinicians to blithely recite risks and benefits that the patient cannot take in, regardless of the confusion and harm it will cause. There is therefore scope within the terms of the Act to prevent serious harm caused by disclosure when it is apparent that the patient is incapable of using or weighing the particular information, in which case beneficent protection is appropriate according to section 4 of the Act.

The result is that, while the TE might be justifiable in some jurisdictions to protect the autonomy interests of certain patients and the best interests of non-autonomous patients, it is not required in England and Wales. Future cases governing the extent of the TE present two options. One is to recognize that, in the specific context of information disclosure, the TE is necessary because the MCA does not adequately protect those who are unable to make an autonomous decision. This would continue a trend established in the recent development of the inherent jurisdiction to protect those who have capacity but lack the ability to make a voluntary decision (Cave, 2017). Conversely, this article has suggested that the MCA's protective scheme extends to such patients, in which case a principled justification for the TE is lacking. In England and Wales, the existence of the TE raises the potential for the *Bolam* test to remain relevant to information disclosure cases. In the context of risk disclosure, it is unnecessary and anomalous. It sacrifices coherence and clarity and will constitute a source of confusion for practitioners (Royal College of Surgeons, 2016: para 4.2).

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Notes

- 1. [2015] UKSC 11, [2015] 2 WLR 768. (Montgomery).
- 2. Chatterton v Gerson [1981] 1 All ER 257.
- 3. Ibid. at [265].
- 4. Aintree University Hospitals NHS Foundation Trust v James [2013] UKSC 67, at [40] per Lady Hale; Montgomery n. 1 at [115] per Lady Hale.

5. Sidaway v Bethlem Royal Hospital Governors [1985] AC 871, at [904] per Lord Templeman (Sidaway); See also Montgomery n. 1 at [90] per Lords Kerr and Reed.

- Note that reference to 'clinicians', 'physicians' or 'doctors' is simply shorthand for any healthcare professional responsible for obtaining informed consent.
- 7. Sidaway n. 5 at [888], per Lord Scarman.
- 8. Bolam v Friern Hospital Management Committee [1957] 1 WLR 582.
- 9. Ibid. at [586].
- See in particular Sidaway n. 5; Smith v Tunbridge Wells Health Authority [1994] 5 Med LR 334;
 Pearce v United Bristol Healthcare NHS Trust [1998] 48 BMLR 118.
- 11. Sidaway n. 5; See Montgomery [2015 UKSC 11, at [86].
- 12. Canterbury v Spence 464 F 2d 772, 789 (DC Ci 1972).
- 13. Rogers v Whitaker (1992) 175 CLR 479, at [490]. See also Rosenberg v Percival [2001] HCA 18.
- 14. Montgomery [2015] UKSC 11.
- 15. Ibid. at [22].
- 16. Lady Hale's judgement makes additional observations about the context of childbirth. Unless stated otherwise, references in this article to *Montgomery* are to Lords Kerr and Reed's joint judgement.
- 17. Montgomery [2015] UKSC 11, at [86].
- 18. Ibid. at [70] citing General Medical Council, *Good Medical Practice* (2013). See also [78] citing GMC, *Consent: Patients and Doctors Making Decisions Together* (2008), para 5.
- 19. Ibid. at [86]-[87].
- 20. Ibid. at [87].
- 21. Ibid. at [85].
- 22. Ibid. at [88].
- 23. Ibid. at [88] and see [85] and [91].
- 24. Ibid. at [68], [80], [81], [108].
- 25. Ibid. at [80].
- 26. See Ibid. at [70]–[73].
- 27. WMA, *Declaration of Geneva* (1948), as amended, 'The health of my patient will be my first consideration'.
- 28. McAllister v Lewisham & North Southwark Health Authority [1994] 5 Med LR 343.
- 29. See *Montgomery* [2015] UKSC 11, at [68].
- 30. *Sidaway* n. 5 at [889]: 'Its true analysis is that it is a defence available to the doctor which, if he invokes it, he must prove'.
- 31. Ibid. at [888].
- 32. Chester v Afshar [2004] UKHL 41, at [16]: 'there may be wholly exceptional cases where objectively in the best interests of the patient the surgeon may be excused from giving a warning'. See also Pearce v United Bristol Healthcare BHS Trust 48 BMLR 118, per Lord Woolf MR.
- 33. Sidaway n. 5 at [902] per Lord Templeman: 'In my opinion if a patient knows that a major operation may entail serious consequences, the patient cannot complain of lack of information unless the patient asks in vain for more information'. And per Lord Bridge at 898: '[W]hen questioned specifically by a patient of apparently sound mind about risks involved in a particular treatment proposed, the doctor's duty must, in my opinion be to answer both truthfully and as fully as the questioner requires'. And see Pearce v United Bristol Healthcare NHS Trust [1998] 48 BMLR 118 per Lord Woolf MR '[I]f a patient askes a doctor about the risk, then the doctor is required to give an honest answer'.
- 34. See Rogers v Whitaker n. 13 at p 11 per Mason CJ, Brennan, Dawson, Toohey and McHugh JJ:

One consequence of the application of the *Bolam* principle to cases involving the provision of advice or information is that, even if a patient asks a direct question about the possible risks or complications, the making of that inquiry would logically be of little or no significance; medical opinion determines whether the risk should or should not be disclosed and the express desire of a particular patient for information or advice does not alter that opinion or the legal significance of that opinion. The fact that the various majority opinions in *Sidaway* (n. 5 at, [895], [898], [902]–[903]), for example, suggest that, over and above the opinion of a respectable body of medical practitioners, the questions of a patient should truthfully be answered (subject to the therapeutic privilege) indicates a shortcoming in the *Bolam* approach.

- 35. AB v Tameside and Glossop HA [1997] 8 Med LR 91, at [93] per Brook LJ, 'There appears to have been no previous reported English case in which liability in negligence has been imposed on someone for communicating accurate, but distressing, news in a careless manner'.
- 36. AB v Leeds Teaching Hospitals NHS Trust (Re Organ Retention Group Litigation) [2004] EWHC 644 (OB).
- 37. [2004] EWHC 644 (QB), at [237]. See also Hawaiian authority on the same point: *Barcai* v *Betwee*, 98 Haw 470, 50 P 3d 946 (2002), Supreme Court of Hawai'i; *Nishi* v *Hartwell* 473 P 2d 116 (1970), Supreme Court of Hawai'i; *Carr* v *Strode* 79 Hawai'i 475, 904 P 2d 489 (1995) Supreme Court of Hawai'i; *Barnard* v *Char* 79 Hawai'i 371, 903 P 2d 676 (1995) Intermediate Court of Appeals of Hawai'i.
- 38. Montgomery n. 1 at [95] per Lords Kerr and Reed.
- 39. Mental Capacity Act 2005, s. 1(4) and s. 2(3). See *Aintree University Hospitals NHS Foundation Trust* v *James* n. 4 at [23] per Lady Hale: 'A person who has the capacity to decide for himself can of course make decisions which are not in his own best interests and no doubt frequently does so'.
- 40. See Pretty v UK (2002) 35 EHRR 1, at [61]; Ternovszky v Hungary (Application no. 67545/09, Judgement of 10 December 2010, at [22]; KH and Others v Slovakia (Application no. 32881/04), Judgement of 28 April 2009; Jehovah's Witnesses of Moscow and Others v Russia (Application no. 302/02), Judgement of 10 June 2010; Schneiter v Switzerland (Application no. 63063/00), Judgement of 31 March 2005; X v Finland (Application no. 34806/04), Judgement of 3 July 2012.
- 41. Re MB (An Adult: Medical Treatment) [1997] 2 FLR 427. And see Sidaway n. 5 per Lord Templeman p 904–905; Re T (An Adult) (Consent to Medical Treatment) [1993] Fam 95 per Lord Donaldson MR p 102; Re B (Consent to Treatment: Capacity) [2002] 1 FLR 1090, per Dame Butler-Sloss, 1095.
- 42. Montgomery n. 1 at [91].
- 43. Ibid. at [88].
- 44. Ibid. at [85].
- 45. Ibid. at [91]. Contrast with McAllister v Lewisham & North Southwark Health Authority [1994] 5 Med LR 343 examined above.
- 46. Ibid. at [81].
- 47. Ibid. at [81].
- 48. Ibid. at [75].
- 49. Ibid. at [115].
- 50. Ibid. at [68], [75], [80], [108].
- 51. Ibid. at [88], [90].
- 52. Ibid. at [88]: 'It is unnecessary for the purposes of this case to consider in detail the scope of those exceptions'.

53. See *Canterbury v Spence* n. 12 at [789]; *Sidaway* n. 5 at 889, per Lord Scarman; *Battersby* v *Tottman* (1985) 37 SASR 524, at [527]–[528], [534]–[535].

- 54. American Medical Association, *Code of Medical Ethics* (1847): Doctors have a 'sacred duty...to avoid all things which have a tendency to discourage the patient and depress his spirits'. And see *Twombly* v *Leach* 65 Mass (11 Cush) 397, at [405]–[406] (1853): 'Upon the question whether it be good medical practice to withhold from a patient in a particular emergency, or under given or supposed circumstances a knowledge of the extent and danger of his disease, the testimony of educated and experienced medical practitioners is material and peculiarly appropriate'.
- 55. 186 Kan 393, 350 P 2d 1093 (1960), Supreme Court of Kansas.
- 56. 110 RI 606, 295 A 2d 676, 687–688, 69 ALR 3d 1202 (1972). And see Scott v Bradford, 1979 OK 165, 606 P 2d 554 (Okla 1979), reh'g denied:

the primary duty of a physician is to do what is best for his patient and where full disclosure would be detrimental to a patient's total care and best interests a physician may withhold such a disclosure, for example, where disclosure would alarm an emotionally upset or apprehensive patient.

- 57. Salgo v Leland Stanford Jr, University Board of Trustees, 154 Cal App 2d 560, 317 P 2d 170 (1957).
- 58. 281 M 432, 379 A 2d 1014 (1977) Court of Appeals of Maryland.
- 59. 262 NW 2d 684 (1977), Supreme Court of Minnesota.
- 60. 497 US 261 (1990).
- 61. 464 F 2d 772, 789 (DC Ci 1972).
- 62. For example, Pennsylvania provided an exception where 'furnishing the information... to the patient would have resulted in a seriously adverse effect on the patient or on the therapeutic process to the material detriment of the patient's health.' 40 Pa Stat Ann, section 1301.103 (repealed by 2002, March 20, PL 154, No 13, section 5104(a)(3), eff 1 January 2004); Delaware provides an exception where 'further disclosure could be expected to affect, adversely and substantially, the [patient's] condition, or the outcome of the treatment, procedure or surgery'. 18 Del Code, section 6852(b)(3).
- 63. NY Public Health Laws, section 2805-d(4)(d) (2014).
- 64. 434 So 2d 1039 (La 1983).
- 65. [1992] 175 CLR 479.
- 66. Ibid. at [16] per Mason CJ, Brennan, Dawson, Toohey and McHugh JJ.
- 67. Ibid. at [8].
- 68. [1996] No 23/95, Western Australian Supreme Court (unreported).
- 69. [1985] 37 SASR 524.
- 70. [1980] 2 SCR 880. Referred to in *Montgomery* n. 1 at [51], [52], and [70].
- 71. [1980] 114 DLR (3d) 1, 895 per Chief Justice of Canada.
- 72. SO 1996, c2, Schedule A (Ontario).
- 73. (1991), 78 DLR (4th) 307 (Ont GD), 312.
- 74. (1994), 112 DLR (4th) 257 (Ont GD).
- 75. McInerney v MacDonald (1992) 93 DLR (4th) 415 (SCC).
- 76. Dolgin (2010: 101) notes that while many adopt a professional standard 'in practice, however, the two standards are less different than it might seem because the medical profession has integrated the informed consent doctrine into its own understanding of ethical practice'.
- 77. Montgomery n. 1 at [93].
- 78. Blyth v Bloomsbury Health Authority [1993] 4 Med LR 151; Gold v Haringey Heath Authority [1988] 1 QB 481.

- 79. Sidaway n. 5 at p 893.
- 80. Montgomery n. 1 at [93].
- 81. Ibid. at [85].
- 82. Ibid. at [85]. And see recent application in Webster (A Child) v Burton Hospitals NHS Foundation [2017] EWCA Civ 62.
- 83. Sidaway n. 5 at p 895B, per Lord Diplock, recently cited with approval in Stucken v East Kent Hospitals University NHS Foundation Trust [2016] EWHC 1057, [89] per Jay J.
- 84. Sidaway n. 5 at [889]. And at [889]:

If the doctor admits or the court finds that on the prudent patient test he should have disclosed the risk, he has available the defence that he reasonably believed it to be against the best interest of his patient to disclose it.... The doctor himself will normally be an essential witness: and the reasonableness of his assessment may well need the support of independent medical testimony.

- 85. Canterbury v Spence n. 12 at 791; and see Woolley v Henderson 418 A 2d 1123 (1980) Supreme Judicial Court of Maine.
- 86. Montgomery n. 1 at [85].
- 87. Barcai v Betwee, n. 37.
- 88. Ibid. at [962]:

If the jury could evaluate the defendant physician's testimony without specialized expert knowledge, no such expert testimony is needed and the jury should be instructed on the informed consent issue... It is only when the particular facts associated with the physician's rationale for withholding disclosure involve 'medical facts' that expert testimony will be required to rebut the claim and allow the jury to consider an informed consent claim.

- 89. Canterbury v Spence, n. 12.
- 90. Montgomery n. 1 at [91].
- 91. 473 P 2d 116 (1970), Supreme Court of Hawai'i, overruled on other grounds by *Carr* v *Strode* 904 P 2d 489 (Haw 1995).
- 92. Salgo v Leland Stanford Jr University Board of Trustees, supra; Watson v Clutts, 262 NC 153, 136 SE2d 617 (1964) where it was stated:

Difficulty arises in attempting to state any hard and fast rule as to the extent of the disclosure required. The doctor's primary duty is to do what is best for the patient. Any conflict between this duty and that of a frightening disclosure ordinarily should be resolved in favor of the primary duty.

- 93. See *Montgomery* n. 1 at [88]: 'The doctor is also excused from conferring with the patient in circumstances of necessity, as for example where the patient requires treatment urgently but is unconscious or otherwise unable to make a decision'. And see discussion above of Canadian Health Care Consent Act 1996, s. 25(2) which recognizes an exception to the duty to disclose where P lacks the ability to communicate due to language or disability and where time is of the essence.
- 94. Re F (Mental Patient Sterilisation) [1990] 2 AC 1, per Lord Goff:

We are searching for a principle upon which, in limited circumstances, recognition may be given to a need, in the interests of the patient, that treatment should be given to him in circumstances where he is (temporarily or permanently) disabled from consenting to it. It is this criterion of a need which points to the principle of necessity as providing justification.

95. Sidaway n. 5 at [889].

- 96. Montgomery n. 1 at [85].
- 97. If this information is refused, capacity should be assessed under the Mental Capacity Act 2005.
- 98. Stuart v Camnitz 774 F 3d 238 (2014) US Court of Appeals, 4th Circuit.

'Therapeutic privilege,...permits physicians to decline or at least wait to convey relevant information as part of informed consent because in their professional judgement delivering the information to the patient at a particular time would result in serious psychological or physical harm.... It is an important privilege, albeit a limited one to be used sparingly.... It protects the health of particularly vulnerable or fragile patients, and permits the physician to uphold his ethical obligations of benevolence.

- 99. Rogers v Whitaker n. 13 at [490]; Montgomery n. 1 at [72].
- 100. Montgomery n. 1 at [87] and [73].
- 101. Ibid. at [89].
- 102. Ibid. at [87]. And see application in *Holdsworth* v *Luton & Dunstable University Hospitals NHS FT* [2016] EWHC 3347 (QB).
- 103. Ibid. at [89].
- 104. Contrary to alarmist media reports. See, for example, H Bodkin and L Donnelly, 'The end of doctor knows best as medics are told to let patients make their own decision about treatment,' *The Telegraph*, 27 October 2016, which says: '... clinicians should take patients through every possible option...'.
- 105. *Montgomery* n. 1 at [73]: '[T]he doctor's duty of care takes its precise content from the needs, concerns and circumstances of the individual patient'.
- 106. Ibid. at [90].
- 107. Re MB (Adult: Medical Treatment) [1997] 2 FLR 426.
- 108. Al Hamwi v Johnston and Another [2005] EWHC 206.
- 109. *Montgomery* n. 1 at [90]: 'The doctor's duty is not...fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form'.
- 110. See DL v A Local Authority & Others [2012] EWCA Civ 253.
- 111. Ibid. at [67]. And see LBL v RYJ and VJ [2010] EWHC 2665 (COP), [62].
- 112. Mental Capacity Act 2005, s. 3(2): A person is not to be regarded as unable to understand the information relevant to a decision if he is able to understand an explanation of it given to him in a way that is appropriate to his circumstances (using simple language, visual aids or any other means).
- 113. *LBJ* v *RYJ* [2010] EWHC 2664 (Fam); *CC* v *KK* [2012] EWHC 2136 (COP), [69]; *WBC* v *Z* [2016] EWCOP 4.
- 114. Montgomery n. 1 at [107] per Lady Hale.
- 115. Ibid. at [87].
- 116. Ibid. at [115] and [116].
- 117. And see CC v KK & STCC [2012] EWHC 2136, [68] per Baker J:

The person under evaluation must be presented with detailed options so that their capacity to weigh up those options can be fairly assessed... before a person can be treated as lacking capacity to make a decision, it must be shown that all practicable steps have been taken to help her to do so. As the Code of Practice makes clear, each person whose capacity is under scrutiny must be given 'relevant information' including 'what the likely consequences of a decision would be (the possible effects of deciding one way or another).

- 118. PCT v P, AH & the Local Authority [2009] EW Misc 10 (COP), [35].
- 119. Re SB [2013] EWHC 1417 (COP).

- 120. Ibid. at [34] per Holman J.
- 121. Cambridge University Hospitals NHS Foundation Trust v BF (by her litigation friend, the Official Solicitor) [2016] EWCOP 26.
- 122. Dooley v Skodnek 138 AD 2d 102, 529 NYS 2d 569, 570-571 (2d Dep't 1988).
- 123. Battersby v Tottman (1985) 37 SASR 524.
- 124. But referred to in Montgomery n. 1 at [88].
- 125. Ibid. at [90]. Although doctors are not expected to ensure that the patient understands: *Al Hamwi* v *Johnston and Another* [2005] EWHC 206.
- 126. Ibid. at [87].
- 127. Ibid. at [89].
- 128. Shaw v Kovac [2015] EWHC 3335, [30], per Berkley QC.
- 129. See, for example, unsuccessful claims in *Grimstone* v *Epsom and St Helier University Hospitals NHS Trust* [2015] EWHC 3756; *MC* v *Birmingham Women's NHS Foundation Trust* [2016] EWHC 1334 (QB); *XYZ* v *Warrington and Halton NHS Foundation Trust* [2016] EWHC 331. In *A* v *East Kent Hospitals NHS Foundation Trust* [2015] EWHC 1038 it was held that risks do not need to be communicated to a patient if they are 'theoretical', 'negligible' or 'background' [69] per Dingemans J. and see *Tasmin* v *Barts Health NHS Trust* [2015] EWHC 3135 (QB). It has however been extended beyond pre-operative information: *Spencer* v *Hillingdon Hospital NHS Trust* [2015] EWHC 1058. It has also applied outside the medical context: See *O'Hare* v *Coutts & Co* [2016] EWHC 2224 (QB) on financial risk per Kerr J at [206]: 'The reasoning in Montgomery is not, in my judgement, irrelevant outside the medical context' and see *Baird* v *Hastings* [2015] NICA 22 on solicitor's negligence.
- 130 Montgomery n. 1 at [87].
- 131. Ibid. at [89].
- 132. Ibid. at [85].

References

- American Medical Association (2016) *Code of Medical Ethics* AMA. Available at: https://www.ama-assn.org/about-us/code-medical-ethics (accessed 5 January 2017).
- Badenoch J (2016) A doctor's duty of disclosure and the decline of "the Bolam test": A dramatic change in the law on patient consent. *Medico-Legal Journal* 84(1): 5–17.
- Bagshaw R (2016) Modernising the doctor's duty to disclose risks of treatment. *Law Quarterly Review* 132(2): 182–186.
- Beswick J (2015) Devo-(wo)man? A move in respect of personal sovereignty and decision-making in health care? *Medical Law Review* 23(4): 683–693.
- Bostick NA, Sade R, McMahon JW, et al. (2006) Report of the American Medical Association Council on Ethical and Judicial Affairs: Withholding information from patients: Rethinking the propriety of 'therapeutic privilege'. *The Journal of Clinical Ethics* 17(4): 302–306.
- Brazier M (1987) Patient autonomy and consent to treatment: The role of the law. *Legal Studies* 7: 169–193.
- Brazier M and Cave E (2016) *Medicine, Patients and the Law*. 6th ed. Manchester: Manchester University Press.
- Brazier M and Miola J (2000) Bye-bye bolam: A medical litigation revolution? *Medical Law Review* 8(1): 85–114.
- Campbell M (2015) Montgomery v Lanarkshire health board. *Common Law World Review* 44(3): 222—228.

Cave E (2017) Protecting patients from their bad decisions: Rebalancing rights, relationships and risk. *Medical Law Review*. DOI: 10.1093/medlaw/fww046.

- Chan TE (2015) Regulating the placebo effect in clinical practice. Medical Law Review 23(1): 1–26.
- Coggon J and Miola J (2011) Autonomy, liberty and medical decision-making. Cambridge Law Journal 70(3): 523–547.
- Department for Constitutional Affairs (2007) Mental Capacity Act 2005 Code of Practice. London: TSO.
- Department of Health (2009) Reference Guide to Consent for Examination or Treatment. 2nd ed. London: DoH.
- Dolgin JL (2010) The legal development of the informed consent doctrine: Past and present. *Cambridge Quarterly of Healthcare Ethics* 19(1): 97–109.
- Edwin AK (2008) Don't lie but don't tell the whole truth: The therapeutic privilege is it ever justified?' *Ghana Medical Journal* 42(4): 156–161.
- Fay M (2012) Negligence and the communication of neonatal genetic information to parents. *Medical Law Review* 20(4): 604–630.
- Foster C (2015) The Last Word on Consent? *New Law Journal*. 2 April 2015. Available at: https://www.newlawjournal.co.uk/content/last-word-consent (accessed 5 January 2017).
- General Medical Council (2008) Consent, Patients and Doctors Making Decisions Together. London: GMC.
- General Medical Council (2013) Good Medical Practice. London: GMC.
- Grubb A (1988) Conceiving A new cause of action. In: Freeman M (ed.) *Medicine, Ethics and the Law: Current Legal Problems.* London: Stevens, pp. 130–145.
- Heywood H (2015) RIP Sidaway: Patient-oriented disclosure a standard worth waiting for? *Medical Law Review* 23(3): 455–466.
- Hobson C (2016) No (,) more bolam please: Montgomery v Lanarkshire health board. *Modern Law Review* 79(3): 488–503.
- Hodkinson K (2013) The need to know-therapeutic privilege: A way forward. *Health Care Analysis* 21(2): 105–129.
- Hoppe N and Miola J (2014) Medical Law and Medical Ethics. Cambridge: Cambridge University Press.
- Jackson E (2006) 'Informed consent' to medical treatment and the impotence of tort. In: McLean S (ed.) First Do No Harm: Law, Ethics and Healthcare. Aldershot: Ashgate, pp. 273–287.
- Jones M (1999) Informed consent and other fairy stories. Medical Law Review 7(2): 103-134.
- Jones M (2008) Medical Negligence. 4th ed. London: Sweet and Maxwell.
- McGrath CP (2015) 'Trust me, I'm a patient...': Disclosure standards and the patient's right to decide. Cambridge Law Journal 74(2): 211–214.
- McLean S (2009) Autonomy, Consent and the Law. Abingdon: Routledge-Cavendish.
- Meisel A (1977) The expansion of liability for medical accidents: From negligence to strict liability by way of informed consent. *Nebraska Law Review* 56: 51–152.
- Miola J (2009) On the materiality of risk: Paper tigers and panaceas. Medical Law Review 17(1): 76-108.
- Montgomery J and Montgomery E (2016) Montgomery on informed consent: An inexpert decision? Journal of Medical Ethics 42: 89–94.
- Mulheron R (2003) The defence of therapeutic privilege in Australia. *Journal of Law and Medicine* 11(2): 201–213.
- News (2015) End of 'medical paternalism'. *New Law Journal* 7645. 13 March 2015. Available at: https://www.newlawjournal.co.uk/content/end-medical-paternalism (accessed 5 January 2017).
- Ost DE (1984) The 'right' not to know. Journal of Medical Philosophy 9(3): 301-312.
- Pattinson S (2014) Medical Law and Ethics. 4th ed. London: Sweet and Maxwell.

- President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1982) *Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship.* Washington: The Commission.
- Reid E (2015) Montgomery v Lanarkshire Health Board and the rights of the reasonable patient. *Edinburgh Law Review* 19(3): 360–366.
- Royal College of Surgeons (2016) Consent: Supported Decision-Making A Good Practice Guide. London: RCS.