**Consent to Innovative Treatment**

Tina Cockburna\* and Michael Fayb

a Associate Professor, Co-Director Australian Centre for Health Law Research School of Law, Queensland University of Technology, Brisbane, Australia; b Lecturer in Law, Centre for Law, Ethics and Society, School of Law, Keele University, Keele, Staffordshire, United Kingdom.

\*[t.cockburn@qut.edu.au](mailto:t.cockburn@qut.edu.au). We would like to thank Tsachi Keren-Paz, Jose Miola, Gregory Keating and Bill Madden for their very helpful comments on previous drafts.

**Consent to Innovative Treatment**

Much political, media and academic attention has focused on: 1) the legal test for evaluating whether there has been a breach of duty in the provision of innovative treatment; and 2) the extent to which the law reform proposed by Lord Saatchi in the *Medical Innovation Bill* (*MIB*) was necessary or desirable to relieve doctors of (perceived) legal strictures preventing innovative treatments. However, comparatively little attention focused on the requirement that patients must provide consent to innovative treatment. In this paper we argue that the English and Australian law relating to consent is capable of application in the context of innovative treatment so as to provide certainty for health professionals and promote patient autonomy.

Keywords: medical negligence, medical trespass, consent, innovative treatment

In conceiving the *Medical Innovation Bill*, Lord Saatchi argued: ‘there will be no cure for cancer until real doctors with real patients in real hospitals can attempt some kind of innovation, and that is not possible under current law’.[[1]](#footnote-1) His perception of the chilling effect of the law remains disputed. This hyperbole also missed that patients must provide valid consent to innovative treatment, which not only encompasses ‘the patient being advised in broad terms of the nature of the procedure to be performed,’[[2]](#footnote-2) to defeat a trespass claim, but also requires the provision of information about material risks.[[3]](#footnote-3) It is unclear how this would have intersected with the Bill’s proposed peer-review defence, which is why overlooking consent in drafting the *MIB* was surprising.

The *MIB* originally stated in s1(3)(d) that doctors would perform innovative treatments after ‘obtaining any consents required by law’. At Committee stage[[4]](#footnote-4) this was amended to ‘informed consent’ but reverted to ‘obtain any consents required by law.’[[5]](#footnote-5) The Bill was silent on when consent should be sought – before or after the peer-review process – or as a continuous dialogue. Although in desperate situations willingness to undergo innovative treatment may not be swayed by a peer review, the Bill failed to explain whether its intended effect was to introduce a requirement that a successful peer review outcome was a pre-requisite to valid consent.[[6]](#footnote-6) Nor did it consider the possibility that a successful peer-review outcome might influence patients’ decision making. If a patient is told by his doctor that a professional colleague has been consulted, and agrees the proposed treatment is responsible innovation and clinically appropriate, this of itself may be the determining factor in the patient’s decision to agree to treatment, particularly for a patient already subject to optimism bias.[[7]](#footnote-7) However, in medical contexts, most patient decisions are influenced in some way by doctors’ explanations, particularly of consequences of not receiving treatment.[[8]](#footnote-8) Also not considered was the possibility of conflicts of interest: between the interests of doctors and their patients, such as when doctors will gain commercially by developing or adopting innovative treatments; and also between future and present patients, including how society's interest in learning through innovative treatments should be handled as a conflict of interest. A final omission was how to deal with unknown risks; a significant issue in innovation because the actual consequences of a treatment or procedure may be unclear for months, years or even decades. Unknowns are inherent in medical innovation, therefore failure to consider the importance of communicating unknowns to patients was a significant drafting oversight.

This paper addresses the lack of discussion on consent in the *MIB* debate by examining how the rules for obtaining valid consent in the UK and Australia engage with innovative therapies. It considers consent in two legal contexts: (1) broad consent to defeat a trespass claim for wrongful treatment, and (2) the duty to disclose material risks.

**Two Doctrines of Consent**

Obtaining valid consent from patients has two civil law consequences for doctors: firstly, to avoid[[9]](#footnote-9) a trespass claim; and, secondly, in the context of negligence, it fulfils the duty to disclose material risks. Consent is a ‘flak jacket’[[10]](#footnote-10) that insulates medical professionals from criminal[[11]](#footnote-11) and civil consequences of physically interfering with another’s body, although this does not simply involve obtaining permission, as negligently obtained consent also has consequences.[[12]](#footnote-12) This distinction was drawn in *Chatteron v Gerson*:

once the patient is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is realm and the cause of action on which to base a claim for failure to go into risks and implications is negligence, not trespass.[[13]](#footnote-13)

Avoiding liability for trespass requires a doctor to inform a patient of the broad nature of the procedure (a synthetic tracheal transplant and why necessary), whereas to discharge the duty in negligence a doctor must disclose the material risks of the operation and its alternatives (risks of a synthetic trachea and the alternative of a living tracheal transplant). In other words, the patient needs to understand the broad nature of the interference with their bodily integrity to authorise physical contact that would otherwise be a battery. This paper first considers consent to innovative treatment in relation to trespass and then turns to negligence.

**Consent, Medical Trespass and Innovation**

When medical treatment is provided without consent, a trespass claim for battery may arise.[[14]](#footnote-14) Battery is ‘invasion of the physical person of the [claimant]’,[[15]](#footnote-15) exceeding ‘physical contact which is generally acceptable in the ordinary conduct of daily life’.[[16]](#footnote-16) Consent ‘transforms what would otherwise be unlawful into acceptable.’[[17]](#footnote-17) In medical trespass, the significance of protecting bodily integrity and patient self-determination is the ability to refuse treatment. If a doctor conducts a procedure a competent patient refuses, even where treatment is, objectively, in their best interests, ‘it is unlawful for doctors to administer that treatment.’[[18]](#footnote-18) Patients can therefore choose to accept or reject innovative treatments and, in doing so, control whether they adopt the role of ‘Guinea Pig.’[[19]](#footnote-19)

Assuming basic information is provided about the proposed procedure, for consent to be valid, the patient must have capacity,[[20]](#footnote-20) consent must be voluntary, and relate to the actual treatment performed. Consent may be vitiated by misrepresentation about the nature of the procedure (for example where the treatment is not objectively capable of addressing the patient’s condition).[[21]](#footnote-21)

Where the proposed treatment is capable of therapeutic effect, to determine the effects of misrepresentation, the core elements defining the nature of the procedure must be distinguished from peripheral elements like risk discussion – absent or wrong advice about risks will not vitiate consent, but may be negligent.[[22]](#footnote-22) If a patient consents to one procedure but a different procedure is undertaken, consent is absent because it is not the act consented to.[[23]](#footnote-23) An innovative treatment cannot therefore be performed under the auspices of another therapeutic intervention. This would undermine a patient’s control of their bodily integrity. Understanding one procedure in broad terms (traditional mastectomy to treat cancer), and giving valid consent, does not mean a patient has consented to a different treatment for the same disease (cleavage-sparing mastectomy to treat cancer with cosmetic-improving outcome).

Whether failing to explain that a treatment is innovative in itself invalidates consent is not so clear, because to defeat a trespass claim consent must be to the broad nature of the intended treatment, not the risks and implications inherent in the procedure. However, if the fact a treatment is innovative is deliberately withheld in bad faith, possibly ‘the consent will be vitiated by fraud’.[[24]](#footnote-24) The question is whether a procedure’s innovative status qualifies as part of its broad nature or the associated risks. If the latter, failure to disclose risks will not invalidate patients’ consent, but may be a breach of duty actionable in negligence. But where treatment is carried out for solely non-therapeutic reasons, or ulterior motives such as financial gain due to conflict of interest, there will be no valid consent. [[25]](#footnote-25)

The UK case of *R v Paterson*[[26]](#footnote-26) may provide an example of consent being vitiated in the context of innovative cancer treatment. Paterson, a breast surgeon, used an ‘unrecognised and unapproved procedure’[[27]](#footnote-27) described as a ‘cleavage sparing’ mastectomy (which he developed and performed contrary to specialist guidelines; tumours were removed but potentially cancerous tissue left behind for better cosmetic results, leaving patients prone to cancer returning).[[28]](#footnote-28) This cleavage sparing treatment was innovative[[29]](#footnote-29) because it was a significant departure from standard treatment; there was no evidence to support its safety and efficacy. Paterson also exaggerated or invented the risk of cancer, causing patients to undergo unnecessary surgery. He was convicted of wounding with intent to perform ‘extensive, life-changing operations for no medically justifiable reason’ which ‘no responsible body of duly qualified and experienced breast surgeons would have advised, because none of the procedures was necessary to maintain their [the patients’] health.’[[30]](#footnote-30) In sentencing remarks Baker J said Paterson lost sight of what he was doing in part due to pursuit of his ‘own self-aggrandisement’ and the material rewards from private practice.[[31]](#footnote-31) The Court of Appeal echoed this, stating that Paterson’s motivation included ‘greed, self-aggrandisement and power.’[[32]](#footnote-32)

Paterson’s name was erased from the medical register.[[33]](#footnote-33) Civil claims have reportedly settled.[[34]](#footnote-34) While the full spectrum of Paterson’s motivation may never be known,[[35]](#footnote-35) if a trespass claim was brought it is arguable that consent would be invalidated because the innovative procedures were medically unnecessary and for financial gain. Like *Appleton* and *Dean*, it is arguable that the nature of the procedures was misrepresented to patients;[[36]](#footnote-36) and that Paterson deliberately ‘withheld the information that the treatment was unnecessary because he knew that they would not have consented if they knew the true position’.[[37]](#footnote-37) As patient consent was based on exaggerated or false information about the risk of cancer, it is arguable that such consent would be vitiated by fraud because information was withheld in bad faith.[[38]](#footnote-38)

Where a medical practitioner has financial interests in innovative treatments, complex questions arise in relation to consent. If treatment is necessary, and the innovation is not undertaken solely for financial benefit or self-gain, but rather patient benefit, it is unlikely that consent will be vitiated.[[39]](#footnote-39) However, financial interest and a desire to advance medical knowledge may lead to optimism bias on the part of the doctor[[40]](#footnote-40) and therefore should be disclosed as a material risk, with a referral for independent advice.[[41]](#footnote-41) For example, an Australian study found clinicians involved in developing innovative techniques may fail to list alternative treatment options, or place undue pressure on patients to consent, which is more concerning ‘in relation to a new and potentially risky intervention than if the conflict of interest is associated with something established as safe.’[[42]](#footnote-42)

However, if an innovative treatment is recommended above others because of financial interests (withheld from the patient) consent may be invalidated. The patient, like in *Appleton* and *Dean*, may not understand the true position, namely that the doctor is recommending a therapy based on personal financial benefit. In *Dean,* an Australian case, Basten JA said:

… the motive of the practitioner in seeking consent to proposed 'treatment' may establish that what was proposed was not intended to be treatment at all, so that the nature of the act to which consent was ostensibly given was not the act carried out. Thus, although the conduct was objectively capable of constituting therapeutic treatment, if it were in fact undertaken solely for a non-therapeutic purpose not revealed to the patient, there will be no relevant consent.[[43]](#footnote-43)

Though the patient must only be apprised of the procedure’s broad nature for consent to be ‘real’, this logically includes the basis for conducting the procedure. Typically, this is the necessity for treatment, and consent will be valid, but where the true motive is financial gain[[44]](#footnote-44) consent may be vitiated. Consent may also be vitiated due to conflict of interests if the purpose of treatment is to test a new therapy (by increasing uptake to improve data),[[45]](#footnote-45) which may benefit future patients and also advance the doctor’s financial interests.

The General Medical Council (GMC) requires transparency about financial interests. Practitioners must be honest with patients about any interests which may affect their treatment.[[46]](#footnote-46) They must not attempt to influence patients’ treatment choices for their own benefit,[[47]](#footnote-47) and disclose to patients any financial interests in organisations to which they make referrals.[[48]](#footnote-48) In *Good Medical Practice*, the GMC is clear that:

If you are faced with a conflict of interest, you must be open about the conflict, declaring your interest formally, and you should be prepared to exclude yourself from decision making.[[49]](#footnote-49)

Conflict of interests issues arose in *Hall v Petros,*[[50]](#footnote-50) an Australian case. The defendant gynaecologist undertook a repair of an enterocele and intra vaginal slingplasty (IVS) on the claimant. The procedure used a technique pioneered by the defendant and a colleague.[[51]](#footnote-51) The defendant invented the delivery instrument and received a royalty per instrument.[[52]](#footnote-52) Patients undergoing the IVS operation were eligible for Health Insurance benefits.[[53]](#footnote-53) The claimant was not told about a risk of tape rejection or infection. This risk eventuated, and a claim for negligence (failure to disclose material risks) was brought.

The possibility of optimism bias by the defendant doctor was raised during cross-examination; he was asked if he accepted that he may have been ‘somewhat blinded as to the adverse elements associated with it’.[[54]](#footnote-54) He rejected this stating the ‘role of the scientist is to seek the truth, whether it’s good or bad.’[[55]](#footnote-55) The trial judge observed the defendant ‘impressed me as having a proprietary attitude towards the IVS procedure, as well as great pride in events associated with its development.’[[56]](#footnote-56) He was:

satisfied that the defendant in his dealings with the plaintiff at least was concerned to extol what he perceived to be the many advantages of the IVS procedure rather than to point out, in a balanced and neutral manner, both possible beneficial and adverse outcomes and the risks.[[57]](#footnote-57)

Further, the defendant ‘did not … believe there was or is any real detriment associated with “his” procedure.’[[58]](#footnote-58) There was no argument consent was invalidated in relation to battery – it was not suggested that: the treatment lacked therapeutic benefit; financial gain was the sole motivation; or the patient was deliberately misled about the defendant’s interest.[[59]](#footnote-59) The trial judge held that the there was a duty to disclose material risks and the patient would not have undergone surgery if warned. *Hall* thus highlights how it is possible to avoid liability for battery yet still fail to meet the negligence risk disclosure requirements, including that the “procedure was not a standard procedure … and was not employed by a majority … that there were alternative procedures available.”[[60]](#footnote-60) It emphasises the need for transparency when conducting innovative treatments if doctors are to completely avoid liability.

**Material Risks and Innovation**

Once a patient is apprised of the broad terms of the intended procedure, the issue is no longer trespass since consent is ‘real’.[[61]](#footnote-61) Where there is no complaint of absence of consent, but rather a failure to explain risks and implications, the matter concerns negligence. In *Montgomery*, the UK Supreme Court explained the doctor’s duty to disclose material risks, citing *Rogers* with approval.[[62]](#footnote-62) The doctor’s duty of care is:

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.[[63]](#footnote-63)

This duty has both objective and subjective components.[[64]](#footnote-64) The objective element considers material risks from the perspective of a reasonable person in the patient’s position.[[65]](#footnote-65) As to the subjective element, Lords Reed and Kerr explained that this was ‘undoubtedly right’ as ‘the doctor’s duty of care takes its precise content from the needs, concerns and circumstances of the individual patient, to the extent that they are or ought to be known to the doctor.’[[66]](#footnote-66) Discharging this duty may also include consideration of non-medical factors,[[67]](#footnote-67) which is reflected in studies indicating that other values such as hope and fear play a part in patients’ decision making about undertaking high risk medical procedures.[[68]](#footnote-68)

Innovative treatments have distinctive features which give rise to unique issues in relation to the provision of information about material risks, particularly communicating uncertainty and the possibility of unknown risks; potential conflicts of interests (between doctors and patients, and between present and future patients); [[69]](#footnote-69) and the likelihood of optimism bias in decision making (for both doctors and patients).[[70]](#footnote-70) In the context of innovative therapies, consent therefore

acquires greater importance given the feature of greater uncertainty regarding the risks and benefits of proposed innovative therapy, and the possibility of a greater divergence of interests on the part of the physician when compared with the administration of standard therapy.[[71]](#footnote-71)

It has been suggested that patients may ‘not be in the best position to size up the medical complexities and uncertain risks, and are thus more vulnerable to false hopes and overly optimistic assessments of the worth of innovative therapy.’[[72]](#footnote-72) However, as recognised in *Montgomery,* ‘social and legal developments … point away from a model of the relationship between the doctor and the patient based upon medical paternalism,’[[73]](#footnote-73) therefore ‘[r]esponsibility for determining the nature and extent of a person’s rights rests with the courts, not with the medical professions.’[[74]](#footnote-74) Accordingly, the ‘patient-centred analysis of reasonable disclosure based on materiality’[[75]](#footnote-75) adopted in *Montgomery* and *Rogers* provides an appropriate and practical framework within which to evaluate disclosure obligations in the context of innovative treatment. As Richards and Hutchinson conclude,

the concerns around consent to innovative surgery are valid, but not unique. The innovative nature of a treatment is an important feature of the pre-treatment discussion, but while being relevant to the application of the law, it does not require a specific legal test. Indeed, the current test can be expanded to apply to the specific issues that arise in the context of innovative treatment.[[76]](#footnote-76)

***Material Risks***

In *Montgomery*,the UK Supreme Court emphasised that materiality is not restricted to a statistical analysis of risk but reflects the characteristics of the case and patient, encompassing:

1. the nature of the risk;
2. the effect of its occurrence on the life of the patient;
3. the importance to the patient of the benefits of the treatment;
4. any possible alternatives available; and
5. the risks of those alternatives.[[77]](#footnote-77)

*Montgomery* emphasises that the doctor’s role is to engage in a meaningful dialogue with the patient:

the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible. The doctor’s duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp.[[78]](#footnote-78)

Beyond not bombarding the patient with technical information, the law has not defined the steps necessary to engender understanding, except to explain what a doctor’s duty does not include. [[79]](#footnote-79) In *Al Hamwi* *v Johnston,*[[80]](#footnote-80) the UK Court of Appeal held that a doctor is not required to ensure understanding, but must take reasonable (unspecified) steps to check understanding.[[81]](#footnote-81) The extent to which a doctor must help patients comprehend information is therefore unclear.

***Deducing Material Risks in Innovation***

The cases of Charlie Gard,[[82]](#footnote-82) Alfie Evans[[83]](#footnote-83) and Layla,[[84]](#footnote-84) the Paulo Macchiarini synthetic trachea transplants scandal,[[85]](#footnote-85) and Paterson’s ‘cleavage sparing’ mastectomies,[[86]](#footnote-86) provide useful examples for considering consent in innovation. *Montgomery*’s materiality test will be used as a framework for this analysis, drawing upon case law from UK and Australia.

*Nature of the Risk*

The nature of the risk is a starting point and must be seen as defining the type of harm a patient risks by consenting to a procedure. Risk is defined by reference to the circumstances in which injury could occur, the likelihood of injury occurring, and the extent or severity of potential injury. Material risks in innovative treatment must be considered in terms other than raw statistics and percentages particularly because of the possible unknowns. In Australia these factors are ‘considered from the point of view of what a reasonable medical practitioner in the position of the defendant ought to have foreseen at the time’. [[87]](#footnote-87) Essentially, the question is whether the reasonable practitioner ought to be aware of the risk at the time of the operation. Similarly, in the UK, ‘a clinician is not required to warn of a risk of which he cannot reasonably be taken to be aware’.[[88]](#footnote-88) For example, in *Duce*, a claim that doctors failed to warn the hysterectomy patient of the risk of Chronic Post-Surgical Pain failed[[89]](#footnote-89) because there was no proof that gynaecologists knew or should have known of the relevant risks at the time. *Duce* suggests that there is no duty under *Montgomery* to disclose risks that doctors are unaware of, but a distinction can be drawn between established and innovative therapies. In the case of innovative treatments, the risk of unknown complications is foreseeable; doctors should be aware that unknown risks are inherent in untested interventions. The innovative character of the treatment, and the fact that there may be unknowns, would likely be material, requiring communication to the patient.[[90]](#footnote-90) It has also been suggested that disclosure should extend to the ‘particular physician’s individual experience with the procedure, given its novelty,’[[91]](#footnote-91) although this is subject to debate.[[92]](#footnote-92)

The description of the treatment as being ‘innovative’ is argued to be a material risk for two key reasons. First, because it informs patients that the suggested treatment is new and not standard; second, because it may also be linguistically significant. Labelling a treatment as ‘innovative’ sounds positive in comparison to describing a treatment as ‘unproven’ or ‘untested’.[[93]](#footnote-93)

A US study on informed consent and innovative surgical procedures (developed outside of clinical trials without regulatory oversight) found 60 per cent of patients ‘considered it essential to have a clear statement that the proposed robotic procedure was new rather than standard,’ suggesting patients want doctors to be transparent about innovations when obtaining consent.[[94]](#footnote-94) Patients reported they would be unable to make a treatment decision without such information. This compared with only 20 per cent of doctors who ‘considered the procedure’s technical details essential to discuss with patients’.[[95]](#footnote-95) An Australian study discovered the existence of medical paternalism in not necessarily telling patients they are trying a new approach because ‘patients may fail to recognise the significance of details that are disclosed because they represent an innovation’.[[96]](#footnote-96) The doctors’ view in these studies appear to echo earlier arguments advanced by Parchomovsky and Stein, who contended: ‘the need to label the new treatment “experimental” is likely to frighten away some patients by undermining their confidence in the treatment’; and doctors ‘should not be required to indiscriminately attach the “unknown” label to all risks and benefits associated with innovative treatments’.[[97]](#footnote-97) But these views are inconsistent with a legal framework emphasising patient self-determination.[[98]](#footnote-98) *Montgomery* makes it clear that withholding relevant information to influence patient decision-making is not acceptable,[[99]](#footnote-99) thus it is not legitimate to hide relevant information – that the treatment is innovative – to increase patients’ participation. Patients are not to be treated as ‘placing themselves in the hands of doctors’ but ‘as adults who are capable of understanding’.[[100]](#footnote-100) The Society of University Surgeons guidelines on developing and introducing medical innovations into practice explain consent ‘should include discussion of the innovative aspect of the procedure’ and ‘its novelty should be described to the patient as an integral part of the informed consent process.’[[101]](#footnote-101)

In an Australian disciplinary case, *Health Care Complaints Commission v Bours* *(No 1)*, a patient complained that consent was inadequately obtained for minimally invasive techniques, considered ‘controversial’ by other podiatric and orthopaedic surgeons. [[102]](#footnote-102) The complaint was not proven as the patient knew the proposed procedure was ‘not mainstream.’[[103]](#footnote-103) The Tribunal commented:

there is a range of opinion about whether MIS is controversial, novel, experimental, evolutionary or topical. Whether that of itself leads to a conclusion that the technique is controversial is a reasonable question to ask.[[104]](#footnote-104)

As with established treatments, the nature of risk in innovative treatment may be fatal,[[105]](#footnote-105) non-fatal or profoundly disabling.[[106]](#footnote-106) However, for innovative treatment, risk may not be defined – the incidence of some risks may be unknown, and some risks may be unknown altogether. While by definition it is impossible to quantify unknowns as statistical risks, ensuring the patient realises that s/he is effectively rolling the dice by undergoing innovative treatment is an important aspect of obtaining consent. In Layla’s case the unknowns inherent in the treatment were encapsulated by her father, who said ‘it was scary to think the treatment had never been used in a human before’.[[107]](#footnote-107) Here consent may have been negligent if the treatment’s innovative nature, and possibility of unknown risks, was not disclosed. Doctors are required to warn of risks of which they are reasonably aware,[[108]](#footnote-108) and because ‘the benefits and risks from innovative therapies are largely unknown’,[[109]](#footnote-109) these unknowns are ‘a relevant fact that should be brought to the patient’s attention.’[[110]](#footnote-110) Courts in other jurisdictions have grappled with disclosure of unknowns inherent in innovation for some time, with inconsistent conclusions.[[111]](#footnote-111)

Exploring the relevance of unknown risks in innovative surgical procedures to patients, a US study found 75% of patients thought it essential to know about possible unknown risks when considering an innovative robotic procedure, which suggests ‘surgeons should openly address this uncertainty.’[[112]](#footnote-112) An Australian study found unknown risks were a source of concern for practitioners, ‘being in tension with health professionals’ (particularly surgeons’) perceived position as authoritative “knowers”.’[[113]](#footnote-113) Participants:

felt that unknown risks could not be addressed in patient information – that it was difficult or immoral to tell patients that there were unknowns associated with a new procedure because it might lead to fear, or diminished confidence in the surgeon … They also noted that it was impossible to tell patients about risks that might not yet have been discovered or described in the literature: ‘[If] I don’t know about it, then I can’t explain it to them’ (Participant 14).[[114]](#footnote-114)

Concern was also expressed that risks could manifest ‘long after an intervention is accepted as routine practice (“a lot of risks, they might be really long term”) (Participant 11)’.[[115]](#footnote-115) A number of participants explicitly referred to thalidomide as an example.[[116]](#footnote-116) In such cases ‘medical “adventurism” needs to be balanced by ensuring that individual patient’s concerns and interests are not ignored or downplayed … particularly when all risks associated with the innovation will unequivocally be borne by the patient, not the physician.’[[117]](#footnote-117) The concerns for doctors are whether offering the treatment without notifying the patient of unknown risks is negligent or not, or if unknown complications with long latency periods could lead to liability years later. But if the doctors explain the possibility of unknown complications to the patient when obtaining consent, it is unlikely a court would find them in breach of duty, since the material risk (unknown complications) was disclosed to the patient.

The issue of how to deal with unknowns when obtaining consent arose in *Grimstone v Epsom and St Helier University Hospitals NHS Trust.*[[118]](#footnote-118) The claimant, who suffered pain and stiffness in both hips, was referred to a specialist orthopaedic surgeon, who operated. Afterwards she began experiencing issues requiring further intervention which caused significant pain and suffering. Suing in negligence, she alleged: she was inadequately advised of her surgical options; informed consent was not obtained for the operation undertaken; and she was not advised of the alleged lack of data about failure and survival rates of the components used in the procedure. McGowan J identified four questions, key among them: ‘Was he [the doctor] obliged to tell her about the limited data available on the device used?’[[119]](#footnote-119) McGowan J concluded:

The “concern” expressed by the Claimant's expert … that the data or lack of it was not explained to the patient cannot outweigh the view of the equally expert witness called by the Defendant … that a reasonable body of doctors in the same position would not have given such information to a patient.[[120]](#footnote-120)

This case has been criticised because McGowan J seems to apply the *Bolam* standard of a responsible body of medical opinion instead of the *Montgomery* materiality test, despite discussing *Montgomery*.[[121]](#footnote-121) Information about success and failure rates for the new hip implants was information about risk, thus the *Montgomery* test should have applied. As explained in *Montgomery,* communicating with patients is not a skill ‘with which the *Bolam* test is concerned’[[122]](#footnote-122) and ‘[t]here is no reason to perpetuate the application of the *Bolam* test in this context any longer.’[[123]](#footnote-123) On this basis it was arguably open to find on the *Montgomery* materiality test that the availability of limited data was a material risk which should have been disclosed.[[124]](#footnote-124)

Guidance may also be provided by *Penney v East Kent Health Authority*,[[125]](#footnote-125) where smear tests with abnormalities were not referred for further screening, and the patient told her results were negative. The defendant was negligent because a reasonable doctor would have referred the slides for further examination upon discovering abnormalities. While not a consent or innovative therapy case, a major issue in *Penny* was that the claimant was advised she was negative for cancer, when this was actually uncertain, and it later transpired she had cancer. The case partially turned on failure to disclose (and act upon) the uncertainty of her results. What might be extrapolated is that uncertainties should be communicated to patients when significant, often life altering, decisions rest upon being able to make an informed choice. The unknown risks inherent in undergoing innovative therapies, by their amorphous nature, cannot be described as ‘theoretical, negligible or background’[[126]](#footnote-126) and so cannot fall below the threshold of materiality. In fact, their unknown or perhaps even unknowable nature must make them material risks because of the unpredictability of consequences that may befall the patient contemplating innovative intervention.[[127]](#footnote-127) Regardless of whether a doctor finds it ‘difficult or immoral to tell patients that there were unknowns associated with a new procedure’,[[128]](#footnote-128) *Montgomery* makes it clear that the need for skill and judgment in communicating risks ‘does not entail that the question whether to explain the risks at all is normally a matter for the judgment of the doctor.’[[129]](#footnote-129)

*The Effect of the occurrence of the risk on the life of the patient*

This factor focuses more specifically on the effect on the patient, by reference to both objective and subjective considerations. In *A v East Kent*[[130]](#footnote-130) Dingemans J re-emphasised the view in *Montgomery* that ‘a material risk cannot be reduced to percentages, is fact sensitive and sensitive to the characteristics of the patient.’[[131]](#footnote-131) He recognised that GMC guidance made it clear that it was important to disclose a small but well established risk of serious adverse outcome when obtaining consent.[[132]](#footnote-132) But the risk of chromosomal abnormality of the claimant’s foetus (1 in 1,000) was considered ‘theoretical, negligible or background’.[[133]](#footnote-133) Comparing the risk of abnormality with the risk of premature delivery inherent in undergoing an amniocentesis (1 in 100) the judge concluded:

there was nothing to suggest that was a risk to which a reasonable patient … would have attached any significance … because the risks of having a disabled baby would have been greater from amniocentesis than from continuing with the pregnancy.[[134]](#footnote-134)

Certain risks might fall below the materiality threshold, but this is unlikely in the context of innovative treatment. The risks inherent in the modified immune cells given to Layla[[135]](#footnote-135) did not drop below the threshold of materiality despite the significant benefit of the therapy to her. Nor would the higher risks of cancer reoccurring after Paterson’s ‘cleavage sparing’ mastectomies be background or theoretical. It does not affect the materiality of a risk that no other treatment options are available, as in Layla’s case, because it is still open to a patient (or her parents in this example) to choose not to receive treatment. It would undermine *Montgomery*’s respect for bodily integrity and self-determination if the standard of disclosure was reduced in circumstances where an innovative therapy was the patient’s only remaining treatment option.

*The importance to the patient of the benefits of treatment*

The nature of the risk and effect on the patient must be considered in light of the importance to the patient of the benefits of treatment, although it is unlikely the benefits of treatment would weigh against disclosure of risks, especially given the limited contemporary role for therapeutic privilege.[[136]](#footnote-136) For example, disclosure of the risk of physical injury during ECT in *Bolam*[[137]](#footnote-137) would now unlikely be countervailed by the argument it was beneficial to the patient to undergo treatment. However, where risks are background or theoretical like in *A v East Kent Hospitals*, the importance of the treatment would clearly outweigh the benefits of disclosing such a risk because it is immaterial. This would appear to make this criterion somewhat redundant, as if risks are immaterial they do not need to be disclosed, and material risks cannot be withheld from patients even if the treatment is, medically, in their best interests. Thus the importance of treatment criterion could be understood as playing a larger role where doctors are applying therapeutic privilege, as in psychiatry (where over-information can lead to disengagement with treatment by a vulnerable patient) than in mainstream clinical practice.[[138]](#footnote-138)

The therapeutic exception is not intended to subvert the principle that the patient should make the decision whether to undergo a proposed course of treatment ‘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.’[[139]](#footnote-139) In *Morocz* it was held that the duty to provide information did not include telling the patient that they are not a suitable candidate for the surgery or that it would be unwise for them to proceed.[[140]](#footnote-140)

Identifying the relevant risk, the extent or severity of the potential injury, and the likelihood of this injury occurring, must be balanced against the patient’s circumstances. In *Rosenberg*, the court noted the ‘patient's need for the operation is important, as is the existence of reasonably available and satisfactory alternative treatments.’[[141]](#footnote-141) Furthermore, a ‘patient may be more likely to attach significance to a risk if the procedure is elective rather than life saving.’[[142]](#footnote-142) But even when the benefit of innovative treatment is potentially lifesaving, like the modified immune cells in Layla’s case, the positive outcome cannot make risks immaterial. Material risks would be countervailed by potentially lifesaving innovations; for example, the unknown risk of modified immune cells would remain material even in the face of the patient’s death. The risk of unknown harms in a procedure not previously used to treat a human being is not background or theoretical,[[143]](#footnote-143) even when balanced against death. An informed decision could not be made without knowing that accepting treatment is a leap into the unknown. Equally, where established alternatives to innovation are available, like with ‘cleavage sparing’ mastectomies, the fact there are unknown risks in the procedure would be critical to obtaining consent, as the risks in the established procedure are known and could be mitigated. It would be inconsistent with *Montgomery* to allow risks to be withheld because the patient has no other options.

*Possible Alternatives Available*

Possible alternatives are relevant when obtaining consent, especially when an established treatment poses a lower risk to the patient. In both *Montgomery* and *Pearce*, argument focused on the alternative provision of a C-section which carried a lower risk of harm to the child (hypoxic brain damage from shoulder dystocia in *Montgomery* and death in *Pearce*) than vaginal birth. *Birch* also centred on disclosure of lower risk alternatives, with the claimant undergoing a catheter-angiogram which carried a risk of a stroke while an alternative diagnostic process was available (MRI). Accordingly, valid consent to innovation should include disclosure of alternatives to the proposed innovative treatment, including no treatment, provided the threshold of materiality is met and risks are not merely theoretical or background. In Layla’s case conventional treatments had failed and no alternative treatments existed, therefore the risks of no further treatment were to be balanced against the risks of using modified immune cells. But the availability of a typical mastectomy alongside the ‘cleavage sparing’ mastectomy offered by Paterson, and the associated risks of the cancer recurring, would need to be disclosed when obtaining consent. The purpose of disclosing alternatives is to validate and empower patients to make their own choice, rather than being steered into particular choices to enable the testing of a theory. This risk of doctors championing their ‘baby’ was raised in *Hall*, where the doctor had pioneered the technique used. Concerns were also raised around the financial interest of Professor Hirano in *Gard*.[[144]](#footnote-144) Further, the disclosure of alternatives was important in Paterson’s ‘cleavage sparing’ mastectomies and Paulo Macchiarini’s pioneering of synthetic tracheal transplants. In the latter case, where surgical implantation of a donated trachea was an alternative to using synthetic trachea, it was necessary to disclose this to obtain valid consent. It may be that Macchiarini’s patients were aware of this obvious alternative prior to agreeing to his innovative treatment, with the lengthy wait for a transplants influencing their decisions to agree to synthetic implants. In any event, it is fundamental that established alternate treatments be discussed.

*The Risks of Available Alternatives*

Beyond the existence of alternatives, the risks of those alternatives must also be discussed. In *Birch*, it was held necessary to disclose the alternative of an MRI and that this posed a lower risk to the patient than a catheter-angiogram. In the context of innovative treatments, Layla, Paterson and Macchiarini again illuminate the complexities of obtaining consent. While Layla’s parents had no alternate treatment available for their daughter, alternatives were available to both Paterson’s and Macchiarini’s patients. Paterson’s patients could have opted for a typical mastectomy, removing the majority of breast tissue; the typical procedure involves a lower risk of cancer recurring but involves complete removal of the breast, whereas the ‘cleavage sparing’ operation is cosmetically advantageous but incurs a higher risk of cancer returning. In Macchiarini’s case, his patients could have waited for a donor trachea, which meant hoping that a donor match was found before the condition caused serious harm or death. In these circumstances the risks of the established alternative were of treatment not occurring in time, alongside the complexities of revascularisation of a donor trachea, and a possibility of donor rejection.[[145]](#footnote-145) In weighing these risks against the risks of innovative synthetic tracheas, the attraction of the innovative therapy is easy to discern, and in this respect the proposed innovation stood to achieve something positive. But the equation put to the patients and their families was imbalanced by a lack of information about the risks inherent in the synthetic trachea. Critically, the procedure had not been tested in animal studies, which arguably increased the risks inherent in the innovation due to the lack of knowledge around the synthetic tracheas; withholding such information from patients is almost certainly an example of negligently obtained consent.

**Conclusion**

Consent is central to medical treatment but was overlooked within the debate on innovative medical treatments fueled by the *Medical Innovation Bill*. The two doctrines of consent considered within this paper are significant considerations for doctors practising innovative therapies to avoid liability for trespass or negligently obtained consent. Key UK and Australian trespass cases set the standard of consent to provide a ‘flak jacket’ against liability as informing the patient about the broad nature of the proposed procedure. Thus where a patient is offered a synthetic tracheal transplant, for example, provided the broad nature of the operation is explained, the innovative therapy would not constitute actionable battery. The exception is where the true reason for the procedure is not therapeutic (for example the treatment is not necessary) and possibly where practitioners with financial and commercial interests in innovative treatments try to influence patient choice or personally gain (because consent is obtained on a false pretense). The Paterson case illustrates this for, although not brought in trespass, the ‘cleavage sparing’ mastectomies were in some cases not necessary.

The duty to disclose material risks is also a significant consideration when offering innovative treatments. The leading UK and Australian cases define a risk as material when a reasonable person in the patient’s position would likely attach significance to that risk, or the doctor should reasonably be aware that a particular patient would likely attach significance to it. Unknown risks have been considered and it is argued these are material and must be disclosed by doctors practising innovative therapies. The importance of the treatment to the patient is also crucial and a distinction drawn between innovation where conventional treatment has failed, such as Layla’s case, and where innovative therapies are arguably unnecessary because lower risk alternatives exist, like with Paterson’s ‘cleavage sparing’ mastectomies. Where alternatives might include long waits, such as tracheal transplants, discussion of the known and potentially unknown risks of the innovative therapy is a necessity.

In *Montgomery*, Lords Read and Kerr explained that patients are ‘capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices.’[[146]](#footnote-146) Nowhere is the need to disclose risks and prospects of uncertain success more important than within medical innovation. As in Layla’s case, people are willing to accept medical uncertainty, but consent should be real and valid to respect patients’ interests and protect doctors from litigation. That the *MIB* all but ignored consent was a significant omission in the debate on law, medicine and innovation.

1. Steve Connor, ‘Lord Saatchi: Let new cures be tried out on cancer patients’ *The Independent*, 12 October 2013 https://www.independent.co.uk/news/people/profiles/lord-saatchi-let-new-cures-be-tried-out-on-cancer-patients-8876504.html. [↑](#footnote-ref-1)
2. *Chatterton v Gerson* [1981] QB 432 (QBD); *Rogers v Whitaker* (1992) 175 CLR 479. [↑](#footnote-ref-2)
3. *Montgomery v Lanarkshire Health Board* [2015] UKSC 11; *Rogers* (n2). [↑](#footnote-ref-3)
4. 21 October 2014. [↑](#footnote-ref-4)
5. Bill as brought from the Lords, 27 January 2015. [↑](#footnote-ref-5)
6. The purpose of the *MIB* was to encourage responsible innovation; if a peer-review was unsuccessful, the innovation was prima facie irresponsible. A pertinent, unresolved question was whether the *MIB* allowed patients to give valid consent to ‘irresponsible’ innovations, or whether it was negligent to practice ‘irresponsible’ innovation, even if consent was obtained. [↑](#footnote-ref-6)
7. See Keren-Paz’ contribution in this special issue. [↑](#footnote-ref-7)
8. *Re T* [1993] Fam 95 (CA) (Staughton LJ). [↑](#footnote-ref-8)
9. There is debate about whether the claimant must prove no consent as an element of trespass, or the defendant must establish consent as a defence. In England lack of consent is an element: *Freeman v Home Office* (No 2) [1984] QB 524. Australian cases suggest consent is a defence: *Secretary, Department of Health and Community Services (NT) v JWB (Marion’s case)* (1992) 175 CLR 218, 310-311; *Dean v Phung* [2012] NSWCA 223; White v Johnston [2015] NSWCA 18. [↑](#footnote-ref-9)
10. *Re W* [1992] 4 All ER 627, 633. [↑](#footnote-ref-10)
11. *R v Ian Paterson* [2017] EWCA Crim 1625; *Reeves v R* [2013] HCA 57. This paper focuses on civil liability; detailed analysis of criminal cases is beyond scope. [↑](#footnote-ref-11)
12. *Chester v Afshar* [2004] UKHL 41; *Montgomery* (n3); *Rogers* (n2); *Rosenberg v Percival* (2001) 205 CLR 434*; Wallace v Kam* (2013) 250 CLR 375*.* [↑](#footnote-ref-12)
13. (n2) 443 (Bristow J). See also Rogers (n2) 490. [↑](#footnote-ref-13)
14. Discussed in Tina Cockburn and Bill Madden, ‘Intentional torts claims in medical cases’ (2006*)* 13(3) Journal of Law and Medicine 311. [↑](#footnote-ref-14)
15. *Wainwright v Home Office* [2003] UKHL 53, [67] (Lord Hoffman). [↑](#footnote-ref-15)
16. *Collins v Wilcock* [1984] 1 WLR 1172, 1177. [↑](#footnote-ref-16)
17. *Marion’s* case (n9) 233; *Dean* (n9) [48]. [↑](#footnote-ref-17)
18. *R (Burke) v GMC* [2005] EWCA Civ 1003. [↑](#footnote-ref-18)
19. See Gregory Keating’s contribution to this special issue. [↑](#footnote-ref-19)
20. Alternatively, consent may be given by parents, substitute decision makers or the Court. [↑](#footnote-ref-20)
21. *Appleton v Garratt* [1997] 8 Med LR 75 (consent vitiated in respect of teeth not requiring treatment because patients would not have consented if made aware of true purpose of treatment - battery established). See also *Dean* (n9) [61] (within about 12 months, dentist carried out root canal treatment and fitted crowns on all claimant’s teeth, during 53 consultations costing $73,640. Battery established because defendant ‘probably did not believe at the time he carried out the treatment that it was reasonably necessary’: [47]). [↑](#footnote-ref-21)
22. *Dean* (n9) [62]. [↑](#footnote-ref-22)
23. *Williamson v East London & City HA* (1998) 41 BMLR 85 (consent to remove leaky breast implant but a subcutaneous mastectomy performed.) See also *Chatterton* (n2) 443; White (n9) [60]. [↑](#footnote-ref-23)
24. *Chatterton* (n2) 442-443. [↑](#footnote-ref-24)
25. *Appleton* (n21); *Dean* (n9) cf. *White* (n9). [↑](#footnote-ref-25)
26. (n11). [↑](#footnote-ref-26)
27. Heart of England, NHS Foundation Trust, *Surgical Outcomes and Practice* <http://www.heartofengland.nhs.uk/wp-content/uploads/Surgical-Outcomes-and-Practice-FINAL.pdf> (accessed 9 October 2018). [↑](#footnote-ref-27)
28. *General Medical Council v Paterson* [2014] EWHC 201, [4]-[6]. [↑](#footnote-ref-28)
29. Evans Chan, ‘Legal and Regulatory Responses to Innovative Treatment’ (2013) 21 *Med Law Rev* 92, 94. [↑](#footnote-ref-29)
30. *R v Ian Paterson* (31 May 2017, Nottingham Crown Court) Baker J; <https://www.judiciary.uk/wp-content/uploads/2017/05/r-v-paterson-sentencing-remarks-mr-justice-jeremy-baker-20170531.pdf> (accessed 9 October 2018). [↑](#footnote-ref-30)
31. *Paterson* (n30). [↑](#footnote-ref-31)
32. *Paterson* (n11) [42]. [↑](#footnote-ref-32)
33. *GMC v Paterson* – Medical Practitioners Tribunal, 25 July 2017; https://www.gmc-uk.org/news/news-archive/comment-on-the-decision-to-strike-off-dr-ian-paterson (accessed 9 October 2018). [↑](#footnote-ref-33)
34. Alexandra Topping, ‘NHS pays out millions to patients of surgeon convicted of needless breast operations’ *The Guardian* 29 April 2017 <https://www.theguardian.com/society/2017/apr/28/cancer-surgeon-convicted-of-performing-needless-breast-surgery> (accessed 9 October 2018). [↑](#footnote-ref-34)
35. *Paterson* (n30) [62]. [↑](#footnote-ref-35)
36. *Dean* (n9) [61]-[64]. [↑](#footnote-ref-36)
37. *Appleton* (n21) [79]. [↑](#footnote-ref-37)
38. *Chatterton* (n2) 442-443. [↑](#footnote-ref-38)
39. *White* (n9). (claim alleging dental treatment carried out without knowledge it was unnecessary and ineffective failed on appeal because no evidence that treatment wholly unnecessary and conducted to extract government money, not treat patient. Retrial confined to negligence claim, which had not been argued at first instance.) Cf. *Appleton* (n21)*; Dean* (n9). [↑](#footnote-ref-39)
40. Dieter Giesen, ‘Civil Liability of Physicians for New Methods of Treatment and Experimentation: a Comparative Examination’ (1995) *Med Law Rev* 22. See also Keren-Paz’s contribution in this special issue. [↑](#footnote-ref-40)
41. *Moore v Regents University of California* (1990) 793 P.2d 479; Chan (n29) 118. [↑](#footnote-ref-41)
42. Bernadette Richards and Katrina Hutchinson, ‘Consent to innovative treatment: No need for a new legal test’ (2016) 23 *Journal of Law and Medicine* 938, 943. [↑](#footnote-ref-42)
43. *Dean* (n9) [63]. [↑](#footnote-ref-43)
44. Financial gain could include interests in the development and sale of pharmaceuticals or innovative therapies, but could also be ‘payment of “incentives” to doctors in return for referrals to private hospital groups.’ Kate Adlington, Kamran Abbasi, and Fiona Godlee, ‘The General Medical Council and Doctors’ Financial Interests’ (2015) *BMJ* 350. [↑](#footnote-ref-44)
45. Chan (n29) 110, 117-118, 120. [↑](#footnote-ref-45)
46. GMC (2013), *Financial and Commercial Arrangements and Conflicts of Interest* [14] <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/financial-and-commercial-arrangements-and-conflicts-of-interest/financial-and-commercial-arrangements-and-conflicts-of-interest#paragraph-10> (accessed 9 October 2018). [↑](#footnote-ref-46)
47. Ibid [15]. [↑](#footnote-ref-47)
48. Ibid [17]. [↑](#footnote-ref-48)
49. GMC (2013) [79]. See also *Good Medical Practice: A Code of Conduct for Doctors in Australia*,

    https://www.medicalboard.gov.au/codes-guidelines-policies/code-of-conduct.aspx (accessed 9 October). [↑](#footnote-ref-49)
50. [2004] WADC 87. [↑](#footnote-ref-50)
51. Ibid [4]. [↑](#footnote-ref-51)
52. Ibid [127]-[129]. [↑](#footnote-ref-52)
53. Ibid [130]. [↑](#footnote-ref-53)
54. Ibid [195]. [↑](#footnote-ref-54)
55. Ibid [195]. [↑](#footnote-ref-55)
56. Ibid [299]. [↑](#footnote-ref-56)
57. Ibid [301]. [↑](#footnote-ref-57)
58. Ibid [303]. [↑](#footnote-ref-58)
59. The proforma consent letter included: ‘The operation discussed with you has been developed over the last seven years, in association with the world renowned Urogynaecology Department…’: Ibid [36]. [↑](#footnote-ref-59)
60. Ibid [348]. [↑](#footnote-ref-60)
61. *Chatterton* (n2) 442. [↑](#footnote-ref-61)
62. *Montgomery* (n3) [87]. [↑](#footnote-ref-62)
63. Ibid. See *Rogers* (n2) [16]. In Australia, non-uniform legislation has been enacted in several jurisdictions, which generally reflects the common law duty to disclose material risks: *Civil Liability Act 2003* (Qld) s 21; *Civil Liability Act 2002* (Tas) s 21; *Wrongs Act 1958 (Vic)* s 50. [↑](#footnote-ref-63)
64. See, for example: Susan J Lee Char, et al, ‘Informed consent for innovative surgery: A survey of patients and surgeons’ (2013) April 153(4) *Surgery* 473. [↑](#footnote-ref-64)
65. *Montgomery* (n3) [87]. [↑](#footnote-ref-65)
66. Ibid [73]. [↑](#footnote-ref-66)
67. *Montgomery* (n3) [82], [83]; [FM Hajjaj](https://www.ncbi.nlm.nih.gov/pubmed/?term=Hajjaj%20F%5BAuthor%5D&cauthor=true&cauthor_uid=20436026) et al, ‘Non-clinical influences on clinical decision-making: a major challenge to evidence-based practice’ (2010) 103(5) *Journal of the Royal Society of Medicine* 178. [↑](#footnote-ref-67)
68. Camilla Scanlan, Cameron Stewart & Ian Kerridge, ‘Decision Making in the Shadow of Death’ (2016) 16 *American Journal of Biothethics* 23. [↑](#footnote-ref-68)
69. Discussed above. [↑](#footnote-ref-69)
70. Chan (n29) 94-96. See also Keren-Paz in this special issue. [↑](#footnote-ref-70)
71. Chan ibid 116. See also Richards and Hutchinson (n41) 938. [↑](#footnote-ref-71)
72. Chan ibid 93. For general critiques of the limits of informed consent, see Johan Bester and Eric Kodish, ‘The Limits of Informed Consent for an Overwhelmed Patient: Clinicians’ Role in Protecting Patients and Preventing Overwhelm’ (2016) 18(9) AMA J Ethics 869; Onora O’Neill, ‘Some limits of informed consent.’ (2003) 29 *J Med Ethics* 4; Ann Kelly “Research and the Subject: The Practice of Informed Consent” (2003) 26 *Political and Legal Anthropology Review* 182; Peter Schuck, ‘Rethinking Informed Consent’ (1994) 103 *Yale LJ* 899. [↑](#footnote-ref-72)
73. *Montgomery* (n3) [81]. [↑](#footnote-ref-73)
74. Ibid [83]. [↑](#footnote-ref-74)
75. Chan (n29) 117-118. [↑](#footnote-ref-75)
76. (n41) 939. [↑](#footnote-ref-76)
77. *Montgomery* (n3) [89]. By comparison, in *Rogers* (n2) 493, the Australian High Court pointed to the more general factors identified by King CJ in *F v R* (1983) 33 SASR 189, 192-193 namely: the nature of the matter to be disclosed; the nature of the treatment; the desire of the patient for information; the temperament and health of the patient; and the general surrounding circumstances. [↑](#footnote-ref-77)
78. *Montgomery* (n3) [90]. See also *Rogers* (n2) [14]; *Morocz v Marshman* [2015] NSWC 325, [102]. [↑](#footnote-ref-78)
79. Guidelines are however available: GMC, *Good Medical Practice* (2014) <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice> (access 9 October 2018). In Australia see: National Health and Medical Research Council (NHMRC) ‘General Guidelines for Medical Practitioners on Providing Information to Patients’, (2004) <https://www.nhmrc.gov.au/guidelines-publications/e57>; NHMRC ‘Communicating with Patients: Advice for Medical Practitioners’, (2004) <https://www.nhmrc.gov.au/guidelines-publications/e58>. [↑](#footnote-ref-79)
80. [2005] EWHC 206. [↑](#footnote-ref-80)
81. Whether *Al Hamwi* remains good law after *Montgomery* is uncertain. How understanding in negligence overlaps with understanding in the *Mental Capacity Act 2005* (UK) is also under-considered. For more detailed discussion, see Michael Fay and Claire Melia, ‘Beyond Montgomery: doctor-patient relations and the legal standard of effective communication’ (forthcoming). In Australia, at least for non-English speaking patients, it has been held that the duty requires doctors to ‘take reasonable care to ensure that the material risks attending the surgical procedure were conveyed to the claimant’ and need for translation may make it ‘necessary for the practitioners to satisfy themselves that the substance of the information conveyed’: *Biggs v George* [2016] NSWCA 113, [28]. [↑](#footnote-ref-81)
82. [*Great Ormond Street Hospital v Yates & Gard*](https://www.judiciary.gov.uk/wp-content/uploads/2017/07/gosh-v-gard-24072017.pdf) [2017] EWHC 1909 (Fam). See Montgomery’s contribution to this special issue. [↑](#footnote-ref-82)
83. *Evans v Alder Hey* [2018] EWCA 984 (Civ). [↑](#footnote-ref-83)
84. Layla was successfully treated for lymphoblastic leukemia using a novel, untested therapy (involving an infusion of another person’s immune cells which had been [genetically altered](https://www.telegraph.co.uk/news/science/11840216/Once-we-start-editing-our-genes-where-do-we-stop.html)): [Sara Reardon](https://www.nature.com/news/leukaemia-success-heralds-wave-of-gene-editing-therapies-1.18737#auth-1), ‘Leukaemia success heralds wave of gene-editing therapies’ (2015) 527 *Nature* 146. [↑](#footnote-ref-84)
85. William Kremer, ‘Paolo Macchiarini: A surgeon’s downfall’. BBC News, 10 September 2016 <http://www.bbc.com/news/magazine-37311038> . [↑](#footnote-ref-85)
86. (n27). [↑](#footnote-ref-86)
87. *Rosenberg* (n9) [61]; [69]. [↑](#footnote-ref-87)
88. *Duce v Worcestershire Acute Hospitals NHS Trust*[2018] EWCA Civ 1307, [43]. [↑](#footnote-ref-88)
89. Ibid. [↑](#footnote-ref-89)
90. Chan (n29) 117. [↑](#footnote-ref-90)
91. *Morocz* (n77). [↑](#footnote-ref-91)
92. In Australia, in *Morocz* ibid [193], Justice Harrison held that the surgeon was not obliged to inform his patient about ‘his particular surgical history or experience with the performance of … (the procedure) or to discuss complications … that had been experienced by patients upon whom that procedure had been performed by him.’ Conversely, more recently in *Jambrovic v Day* [2017] NSWSC 1468, [116] the experts agreed that the defendant should have disclosed that this was the first time he would had performed such surgery. [↑](#footnote-ref-92)
93. The precise language which ought to be used when obtaining consent is beyond the scope of this article. [↑](#footnote-ref-93)
94. Char et al (n63) 5. [↑](#footnote-ref-94)
95. Ibid. [↑](#footnote-ref-95)
96. Richards and Hutchinson (n41) 942. [↑](#footnote-ref-96)
97. Gideon Parchomovsky and Alex Stein, ‘Torts and innovation’ (2008) *Mich Law Rev* 107, 285. [↑](#footnote-ref-97)
98. *Montgomery* (n3) [91]; *Rogers* (n2) [16] (limited scope of therapeutic exception). [↑](#footnote-ref-98)
99. [114]. [↑](#footnote-ref-99)
100. *Montgomery* (n3) [81]. [↑](#footnote-ref-100)
101. Walter Biffl et al. ‘Responsible development and application of surgical innovations: a position statement of the Society of University Surgeons’ J Am Coll Surg. 2008;206:1204–9. [↑](#footnote-ref-101)
102. (2014) NSWCATOD 113, [235]. [↑](#footnote-ref-102)
103. Ibid [257]. [↑](#footnote-ref-103)
104. Ibid [250]. [↑](#footnote-ref-104)
105. Pearce *v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118 (to the unborn child). [↑](#footnote-ref-105)
106. Sidaway *v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871 (spinal injury); *Birch v University College London Hopital NHS Trust* 2008] EWHC 2237 (QB);(stroke); *Rogers* (n2) (blindness). [↑](#footnote-ref-106)
107. GOSH Press Release, ‘World first use of gene-edited immune cells to treat ‘incurable’ leukaemia’ 5 November 2015, <https://www.gosh.nhs.uk/news/latest-press-releases/2015-press-release-archive/world-first-use-gene-edited-immune-cells-treat-incurable-leukaemia>. [↑](#footnote-ref-107)
108. *Duce* (n82) [43]. [↑](#footnote-ref-108)
109. Tsachi Keren-Paz and Alica El Haj, ‘Liability versus Innovation: The Legal Case for Regenerative Medicine’ (2014) *Tissue Engineering, Part A*:DOI: 10.1089/ten.tea.2013.0324,2. [↑](#footnote-ref-109)
110. Ibid. [↑](#footnote-ref-110)
111. E.g., *Estrada v Jaques* 321 S.E.2d 240 (N.C. Ct. App. 1984) (The Court held doctors ‘had a duty to disclose the novel nature of “relatively new” procedures and “any uncertainty regarding the risks” associated with such procedures.’). Cf. *Osburn v Danek Medical Inc* 520 S.E.2d 88 (N.C. Ct. App.1999 (same Court refused to follow *Estrada*, stating it unnecessary to require a doctor ‘to inform patients in every instance that a procedure is experimental in nature’). [↑](#footnote-ref-111)
112. Char et al (n63) 5-6. [↑](#footnote-ref-112)
113. Richards and Hutchinson (n41) 942. [↑](#footnote-ref-113)
114. Ibid. [↑](#footnote-ref-114)
115. Ibid. See the discussion of SIROT by Keren-Paz in this special issue. [↑](#footnote-ref-115)
116. Ibid. [↑](#footnote-ref-116)
117. Chan (n29) 119-120. [↑](#footnote-ref-117)
118. [2015] EWHC 3756. [↑](#footnote-ref-118)
119. Ibid [4]. [↑](#footnote-ref-119)
120. Ibid [12]. [↑](#footnote-ref-120)
121. Louise Austin, ‘*Grimstone v Epsom and St Helier University Hospitals NHS Trust*: (It’s Not) Hip to be Square’ (2017) *Medical Law Review*, fwx053, <https://doi.org/10.1093/medlaw/fwx053>. [↑](#footnote-ref-121)
122. *Montgomery* (n3) [85]. [↑](#footnote-ref-122)
123. Ibid [86]. [↑](#footnote-ref-123)
124. The claim may have failed on causation, given the finding she would have had surgery in any event, unless the modification in *Chester v Afshar* applied: *Grimstone* (n108) [12]. [↑](#footnote-ref-124)
125. [1999] EWCA Civ 3005. [↑](#footnote-ref-125)
126. *A v East Kent University NHS Foundation Trust* [2015] EWHC 1038 (QB), [84]. [↑](#footnote-ref-126)
127. Foreseeability of risk, known unknowns and unknown unknowns and relevance to reasonableness of treatment (in addition to consent) are discussed by Keren-Paz in his contribution to this special edition. [↑](#footnote-ref-127)
128. Richards and Hutchinson (n41) 942. [↑](#footnote-ref-128)
129. *Montgomer*y (n3) [85]. [↑](#footnote-ref-129)
130. (n127). [↑](#footnote-ref-130)
131. Ibid [64]. [↑](#footnote-ref-131)
132. Ibid. [↑](#footnote-ref-132)
133. Ibid [84]. [↑](#footnote-ref-133)
134. Ibid [101]-[102]. [↑](#footnote-ref-134)
135. (n87). [↑](#footnote-ref-135)
136. *Montgomery* (n3); *Rogers* (n2). [↑](#footnote-ref-136)
137. *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582. [↑](#footnote-ref-137)
138. Johan Bester and Eric Kodish, ‘The Limits of Informed Consent for an Overwhelmed Patient: Clinicians’ Role in Protecting Patients and Preventing Overwhelm’ (2016) 18(9) AMA J Ethics 869 [↑](#footnote-ref-138)
139. *Montgomery* (n3) 91. [↑](#footnote-ref-139)
140. (n77) [167]. [↑](#footnote-ref-140)
141. *Rosenberg* (n12) [78]. [↑](#footnote-ref-141)
142. Ibid [78] [↑](#footnote-ref-142)
143. *A v East Kent* (n130) [84]. [↑](#footnote-ref-143)
144. (n82). [↑](#footnote-ref-144)
145. For an overview of alternatives to synthetic tracheal transplants, see Pierre Delaere and Dirk Van Raemdonck ‘Tracheal Replacement’ J Thorac Dis. 2016 Mar; 8 (Suppl 2): S186–S196. [↑](#footnote-ref-145)
146. Ibid [81]. [↑](#footnote-ref-146)