■ ANNOTATION

The cost of consent: why healthcare providers must be compliant with the Montgomery principles

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The cost of clinical negligence in the UK has continued to rise despite no increase in claims numbers from 2016 to 2019. In the US, medical malpractice claim rates have fallen each year since 2001 and the payout rate has stabilized. In Germany, malpractice claim rates for spinal surgery fell yearly from 2012 to 2017, despite the number of spinal operations increasing. In Australia, public healthcare claim rates were largely static from 2008 to 2013, but private claims rose marginally. The cost of claims rose during the period. UK and Australian trends are therefore out of alignment with other international comparisons. Many of the claims in orthopaedics occur as a result of "failure to warn", i.e. lack of adequately documented and appropriate consent. The UK and USA have similar rates (26% and 24% respectively), but in Germany the rate is 14% and in Australia only 2%. This paper considers the drivers for the increased cost of clinical negligence claims in the UK compared to the USA, Germany and Australia, from a spinal and orthopaedic point of view, with a focus on "failure to warn" and lack of compliance with the principles established in February 2015 in the Supreme Court in the case of Montgomery v Lanarkshire Health Board. The article provides a description of the prevailing medico-legal situation in the UK and also calculates, from publicly available data, the cost to the public purse of the failure to comply with the principles established. It shows that compliance with the Montgomery principles would have an immediate and lasting positive impact on the sums paid by NHS Resolution to settle negligence cases in a way that has already been established in the USA.

Cite this article: ***Bone Joint J*** **2020;102-B(5):550–555.**

In August 2017, The Medical Defence Union (MDU) withdrew indemnity cover for private spinal surgery in the UK in response to a prohibitive rise in compensation payments.[1] In October 2018, Machin et al[2] warned of an existential threat to spinal surgery in England because of an unsustainable rise in clinical negligence claims. However, in its 2018/19 annual report, NHS Resolution[3] recorded a stable pattern of clinical negligence claims for the preceding three years, although there was an increase in the proportion of cases that involved consent and "failure to warn". The link between these three separate reports is the ongoing failure of clinicians to provide patients with adequate information as well as "time and space" to reflect on that information, during the process of informed consent.[4]

Informed consent to treatment is crucial to the surgeon/patient relationship. Complications of treatment may be uncommon, but they can be life-changing, especially in the high-risk surgical specialties (such as cranial neurosurgery, cardiac surgery, and spinal surgery). Patients may have difficulty in understanding the risks of, and alternatives to, surgery. It is the clinician's duty to take sufficient time and make enough effort to understand what is important to their patient and to explain all relevant matters to them in a way they can understand and, very importantly, to record the process. The first two decades of the 21st century have seen an evolution of the process and form of consent in the UK. Consent to treatment has changed from a position of medical paternalism to a rights-centred approach whereby the autonomy of the patient to accept or reject treatment is paramount.[5]

In 2004, in Chester,[6] the traditional principles of causation were bypassed in the interests of "corrective justice" and patient autonomy (Lord Steyn; Box 1). This has come to be seen as a transitional case in the sense that prior to 2004, the Bolam test[7] in England and the Hunter v Hanley test[8] in Scotland determined what should be disclosed as part of consent (Box 2). These tests allow variation in standards of consent and treatment provided there

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doi:10.1302/0301-620X.102B5.BJJ-2019-1759 $2.00

Bone Joint J 2020;102-B(5):550–555.

Box 1: Summary of Chester v Afshar case (2004).

Mr Afshar saw Ms Chester in his rooms and offered her a multiple level lumbar decompression for her presenting spinal symptoms. The surgery took place three days later in a private hospital in London, UK.

Mr Afshar failed to warn Ms Chester that cauda equina syndrome was a known, but rare, risk of the surgery (1% to 2% chance).

Ms Chester sustained a cauda equina injury that was in itself deemed non-negligent, but the failure to warn was found to be negligent.

The case was eventually settled in the House of Lords with a 3:2 judgement in her favour.

It was held that had Ms Chester known of the risk of cauda equina syndrome she would not have gone ahead with the surgery on that day or necessarily in that place.

Had she undergone surgery at another time the complication would not, on balance, have occurred.

The legal principles quoted by Lord Steyn referred to a similar case in Australia: "At the very least, however, this Australian case reveals two fundamentally different approaches, the one favouring firm adherence to traditionalist causation techniques and the other a greater emphasis on policy and corrective justice".

Box 2: Previously relevant legal tests regarding consent in England, Wales, and Scotland.

The Bolam Test (Bolam v Friern Hospital Management Committee 1957)

A doctor is not negligent if the treatment provided is "in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.... Putting it another way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view." McNair J

The Hunter v Hanley Test (Hunter v Hanley 1955)

It must be proved that there is "usual and normal practice";

It must be proved that the defendant has not adopted that practice; and

It must be established that the course the professional adopted is one which no professional person of ordinary skill would have taken if he/she had been acting with ordinary care.

is a reasonable body of opinion to support the actions of the doctor.

After 2004, communication that respected patient autonomy started to become increasingly important, although this was not universally supported by the Courts. In Al Hamwi[9] the judge found that, "Clinicians should take reasonable and appropriate steps to satisfy themselves that the patient has understood the information which has been provided; but the obligation does not extend to ensuring the patient has understood."

In Jones,[10] informed choice, particularly regarding the right of the patient to choose who carried out the treatment, was emphasized. The case demonstrated that consent taken by one specialist does not transfer to another automatically and that in general the consent process would need to be repeated if a different clinician from the original doctor came to deliver the treatment. In the same year, the General Medical Council (GMC)[11] set out guidance for doctors taking consent, including working in partnership with patients and establishing effective communication to ensure that patients were provided with sufficient information in a form they could understand.

By 2014, the medico-legal and ethical landscape had moved considerably from medical paternalism towards autonomy and rights-based shared decision making,[12] but the principles had not yet been formally defined in law.

In 2015, the landmark Supreme Court case, Montgomery,[5] established that in taking consent, doctors have to make a concerted effort to understand their patient and to recognize what is important to them so that patients are aware of any "material risks" involved in the treatment (Box 3). Since that judgement, doctors have been legally required to provide information to patients regarding not only the risks and benefits of surgery but also alternatives to surgery including the natural history of the condition.

Crossman[13] in 2016 provided one of the first tests of Montgomery and was also seen as an extension of the principle of causation established in Chester. In Crossman, the claimant was considered to be vulnerable with limited ability to express himself. The case reinforced the Montgomery principles that the doctor needs to understand the patient and to provide information in a way that is relevant to them so they can make an informed choice. Chan et al.[14] found in 2017 that, "Doctors at the coalface have received little official direction on how their practice should change in the light of the ruling. We have heard anecdotally that some hospitals are in the process of updating their procedures on informed consent, but few have completed this."

Thefaut[15] in 2017 tested a number of the Montgomery principles. It established that there should be "adequate time and space" for communication/dialogue between the doctor and the patient. It reiterated that medical language should be "de-jargonised" and that the doctor's duty is not fulfilled by bombarding the patient with technical information. The routine demand of a signature on a consent form did not in itself mean anything in terms of consent. Finally, the judge was critical of the clinician for overstating the benefit and minimising the risks of surgery. Clinicians therefore need to give realistic estimates of the risk/benefit balance and to avoid "over-egging the pudding".

In 2018, Mrs Hassell successfully sued Hillingdon Hospital NHS trust following a cervical spine operation that led to damage to her spinal cord leaving her with paralysis.[16] Her contention was that she had not been consented regarding this complication, and had the surgeon warned her of the risk of paralysis, she would have declined surgery as her condition was not so severe as to require an operation with such a life changing risk attached to it. The judge in the case criticized the surgeon, stating that whatever his "strengths as a surgeon when carrying out the operation... he was not a good communicator about the risk of operations". Furthermore, the judge found that Mrs Hassell had signed a consent form which discussed the risks of paralysis, but it was on the day of surgery and she was therefore rushed into doing so and that did not constitute informed consent. The case again demonstrated how important it is that clinicians fully discuss the risks of surgery together with less invasive options for

Box 3: Principles of consent established by the Montgomery judgement.

1. Autonomy

Doctors must respect the right of the patient to decide what is best for them. The doctor must assist the patient by providing all of the relevant information in a form that the patient understands, and the process should be recorded.

2. Individualism

Doctors should respect the fact that patients are individuals and their particular characteristics and circumstances should be taken into consideration when taking consent. The process of consent is one of shared decision-making which cannot be effective unless a doctor knows quite a lot about their patient. To achieve this, doctors have to spend time with their patients and consent cannot be rushed unless the circumstances are exceptional, such as when offering life-saving treatment.

3. Materiality

A risk is material if a reasonable person thinks that it might be important. It is not for the doctor to assume they automatically know what level of importance a reasonable person would attach to a particular risk. When advising patients regarding treatment, doctors need to understand enough about their patient so they can establish what that patient would consider to be material.

4. Risks

Risks that are specific to both the condition and the patient should be explained and it is not acceptable to quote generic risks for different types of surgery. Risks should be specific for the treatment being offered and should reflect the doctor's practice for that particular procedure. This means that doctors ought to have such information available. The process of appraisal and revalidation, overseen by the GMC, requires reflective practice. As part of that reflection, which helps to understand what the outcomes of treatment by an individual doctor are, it is important that data is kept regarding the number of procedures carried out as well as their outcomes in terms of success and failure particularly with regard to complications. Such information can then be used to assist patients in making their decisions regarding treatment.

5. Clarity of communication

Doctors have a duty to explain treatments and their risks in plain language that does not use jargon. The terms used should be understandable by a reasonable person and it is not acceptable for clinicians to hide behind obscure medical terminology. Doctors have to be good communicators and to be able to explain to patients, often quite complex concepts, in plain English.

6. Patient information

Information provided verbally or via electronic or print media should be specific to that patient and the treatment that they are being consented for. It is not acceptable that sources of patient information contain a discussion of many different pathologies and procedures or that the language used is beyond the ability of a reasonable person to understand.

treatment should they exist, and that they should record they have done so. It is not enough to simply say that it would be a surgeon's "usual practice to discuss those risks", they should be able to show they actually did so, or informed consent is unlikely to be established.

The precedent set in Chester has been widely debated in medico-legal circles because of the controversial nature of some of the opinions that form the majority judgement. However, the trajectory of legal opinion following that judgement, as far as Montgomery in 2015 was of increasing rejection of medical paternalism and acceptance of the autonomy and human rights of the patient. However, in 2015 a previous decision in the High Court in the case of Shaw[17] was appealed, which saw a measure of pull-back. The case hinged on whether additional compensation should be paid after a settlement for clinical negligence had been agreed, if it is also found that there was failure to warn of a material risk. The Court of Appeal was of the opinion that the case represented an important and developing area of law and medical ethics. The appeal was heard in 2017 and was opposed by the trust on the basis that appropriate compensation had already been awarded and if further compensation for failure to warn of a complication was granted, this would open the floodgates to patients who had been provided with excellent care but there had been an accidental omission of warning of a risk during the consent process. The Court of Appeal found for the trust.

In Duce,[18] the Court considered the risks that a doctor needed to warn the patient of, and when a failure to warn might have caused loss. Mrs Duce had a history of painful and heavy periods and had sought opinions from a number of specialists. She wanted a hysterectomy, despite advice to have more conservative treatment. The treating surgeon did not warn her of chronic postsurgical pain, which she developed following the operation. She said if she had been warned she would not have had surgery. The judgement was that there had been a failure to warn of the risk, but it was not negligent because at the time of the operation the condition was largely unknown. Also, Mrs Duce had actively sought an operation instead of less invasive treatment and there was no evidence that she would have not gone ahead even had she been warned. She appealed to the Court of Appeal and the appeal failed. The question of consent in Duce was found to be different from Chester on the basis that had Mrs Chester known of the possible risk of cauda equina syndrome, she would not necessarily have gone ahead with the spinal operation at that time and in that place. Had the operation be done at a different time, she would not have suffered the same complication. The Court of Appeal rejected this as an argument for Mrs Duce's case, not only because the judges might have had legal concerns regarding the original Chester judgement, but also because they were not convinced that Mrs Duce would not have opted for surgery had she be warned of the complication. In this case, hindsight bias was considered to be relevant. If claimants are to persuade the court that they would have changed their mind regarding treatment that had a particular risk, but it had not been explained to them, hindsight bias will need to be excluded as a trigger for a claim. From a medical

Table I. Annual number of open spinal cases performed in England and Wales according to Hospital Episodes Statistics (HES) data.

Year	Number of procedures
2011 to 12	49,118
2012 to 13	47,861
2013 to 14	49,444
2014 to 15	48,668
2015 to 16	44,026
2016 to 17	43,275
2017 to 18	47,138

perspective, this is achievable through the simple expediency of documentation that shows the doctor is compliant with the Montgomery principles.

In terms of consent, the test established in Bolam, that treatment is reasonable if there is a body of medical opinion that would support it, was finally laid to rest by the Court of Appeal in Webster.[19] Sebastian Webster was small for dates and was born with cerebral palsy after a period of umbilical cord compression during labour. The Trust admitted breach of duty because the obstetrician did not monitor the pregnancy by ultrasound sufficiently closely, namely every two weeks. The first judgement applied the Bolam test to consent and found there was expert evidence to support the obstetrician's management. The consultant gave evidence to the effect that even had there been more regular antenatal monitoring, he would not have changed his treatment plan and the brain injury was therefore inevitable. On appeal, the Court determined that Montgomery, not Bolam, should be applied, i.e. the material risks of the treatment to be explained were those that not only a reasonable person would attach significance to, but the particular patient would as well. Sebastian's mother gave evidence that the Court accepted, that had the material risks been explained to her, she would have opted for an early delivery and on that basis all of Sebastian's injuries would have been avoided. The decision of the lower court was overturned, and the appeal allowed. The courts, when applying Montgomery, regarding the significance of a risk and whether it is material to a particular patient, will take into consideration a wide range of factors including education, conduct through the relevant treatment and evidence given during the legal case. Hindsight bias might play a part in such a determination, since the evidence a claimant gives in court might not have been available to the doctor at the time of taking consent. However, this judgement reinforces the now established duty that doctors have to make efforts to understand a particular patient and their personal concerns and consider how those factors influence the provision of advice regarding treatment risks.

Providers of healthcare in the UK must adopt the Montgomery principles and also provide resources that allow "time and space" for effective consent for every treatment that carries risk. For low-risk, high-volume treatments such as endoscopy and outpatient biopsies, the requirements should not be onerous. However, for high-risk specialties resources have to be set aside to allow the patient time and space to consider their options. Following the lead of the spinal unit in Ipswich, UK, the British Association of Spinal Surgeons (BASS) has adopted a "three-legged stool" model for consent.[20] The first leg consists of the agreement between the patient and clinician at the outpatient clinic that a surgical procedure is the preferred option. The clinician explains the natural history of the condition, the range of treatment options and the risks attached to all of the options. The patient is free, but not mandated, to ask any question that is of relevance to them, i.e. to be provided with information that is material to them. Information is provided for them to study at their leisure either as a patient information leaflet or via online resources. The second leg of the stool is a consent clinic at least one week ahead of the admission date when the clinician and patient meet again to go over the procedure including reviewing risks and benefits and ensuring that the patient has sufficient information to make a fully-informed decision. The third leg of the stool is the signing of a consent form on the day of surgery. At each stage, the process should be fully documented. Todd and Birch[21] have proposed that in spinal surgery, a formal checklist should be used to ensure that all aspects of the consent process have been satisfactorily completed prior to the patient undergoing the planned operation. Completion of such a checklist would go a long way to preventing hindsight bias from triggering potential negligence claims. The recommendations of BASS and the Spinal Surgery Checklist reinforce guidance provided by the Royal College of Surgeons of England in 2016,[22] in which the practical hurdles of fulfilling the principles enshrined in Montgomery are recognized: "Gaining the patient's consent and documenting this sufficiently is an issue that often presents difficulties and the recent changes in case law have highlighted even more the need to tailor information to the patient's individual needs". The guidance also acknowledges that there are risks in non-compliance: "An inadequate consent process can damage the surgeon-patient relationship and also result in legal challenges and litigation". The British Hip and Knee Societies, in conjunction with the Get It Right First Time (GIRFT) programme and the British Orthopaedic Association have explicitly recognized the need for clear documentation of the process involved in major joint arthroplasty.[23,24] All other surgical specialties will need to follow this lead to ensure compliance and minimize the risk of litigation arising from inadequate documentation of the consent process.

Adoption of the three-legged stool approach adds about 30 minutes of outpatient time to the preoperative meetings between the clinician and the patient for complex specialties. For less complex procedures, such as much upper limb orthopaedic surgery, hernia repair, and some urological procedures, it would probably add about 20 minutes of extra outpatient time. We received feedback from clinicians working in NHS Trusts at the BASS 2019 annual meeting following a keynote address on the matter of consent, that the additional time required to become fully compliant with Montgomery is not available in routine NHS clinical practice without significant reorganization of clinic resources. Some trusts have instituted dedicated consent clinics as the three-legged stool recommends, but many have not. In private practice, individual surgeons, supported by the private hospital groups, need to arrange extra sessions to allow the time for consent clinics, but face the difficulty that such consultations might not be remunerated by the medical insurers.

Table II. Major arthroplasty cases performed in England and Wales in 2017 to 2018, according to Hospital Episodes Statistics data.

		Total	Emergency	Waiting list	Planned
W37	Total prosthetic arthroplasty of hip joint using cement	30,789	3,526	25,904	235
W38	Total prosthetic arthroplasty of hip joint not using cement	30,822	1,414	28,561	186
W39	Other total prosthetic arthroplasty of hip joint	6,191	4,337	1,235	22
W40	Total prosthetic arthroplasty of knee joint using cement	80,627	375	79,052	537
W41	Total prosthetic arthroplasty of knee joint not using cement	2,672	43	2,571	18
W42	Other total prosthetic arthroplasty of knee joint	2,411	331	1,815	37
W93	Hybrid prosthetic arthroplasty of hip joint using cemented acetabular component	2,761	196	2,487	12
W94	Hybrid prosthetic arthroplasty of hip joint using cemented femoral component	20,107	1,343	18,177	190
W95	Hybrid prosthetic arthroplasty of hip joint using cement	756	114	593	15
W96	Total prosthetic arthroplasty of shoulder joint using cement	1,881	151	1,601	59
W97	Total prosthetic arthroplasty of shoulder joint not using cement	3,014	64	2,850	64
W98	Total prosthetic arthroplasty of shoulder joint	730	60	618	24
Total		**182,761**	**11,954**	**165,464**	**1,399**

Analysis of the cases described by Machin at al[2] and a number of NHSR Freedom of Information (FOI) data requests shows that it is in the interest of all NHS Trusts and private providers to allocate the time needed to become compliant with Montgomery as it very likely to be cost-effective.

Relating to spinal surgery, 80 of 978 cases described by Machin et al involved failure to consent adequately. On a pro rata basis, had these entirely preventable cases not occurred there would have been a saving to the public purse of £43.8 million. However, consent cases have disproportionately high settlement levels as in Hassell, where there was a settlement of £4.4 million. If the true proportion of costs due to the failure to consent properly is as high as 20% the consequences are that NHSR would have paid around £100 million for such claims in the last five years.

Hospital Episode Statistics (HES) data considering procedural codes for spinal surgery in England (V22 to V46; V49; V51 & V52; V56 to V60; V66 to V68) from 2011/12 to 2017/18[25] (Table I) show that, on average, 47,076 spinal cases were completed within NHS facilities (including those outsourced to private hospitals) yearly since 2011/12. The extra time needed to ensure a fully Montgomery-compliant consent process for spinal surgery is in place, would cost Trusts around £4.7 million per year (47,000+ spinal cases per year; 30 minutes per case; £200 per hour outpatient costs). This would therefore represent a potential saving of around £15 million per year in this sub-specialty alone.

Further data from FOI requests to NHSR[26,27] show that between 2004 and 2019, "failure to warn" i.e. inadequate consent, was implicated in 26% of orthopaedic claims. This is a very similar figure to the USA,[28,29] but higher than in Germany where the rate is 14%[30] and much higher than in Australia (2% in 2012/13).[31] From 2009 to 2018, across all acute NHS Trusts, 7,548 surgical claims were settled for £1.091 billion. In 2017/18 alone, 994 orthopaedic claims were settled for £170.5 million reflecting a rising trend over the decade. Between 2003 and 2014 in the USA the rate of paid claims in orthopaedics fell by 28%,[32] attributed in part to tort law reform in many states, but this fall also likely reflects the earlier adoption of patient-centred, rights-based consent processes in the country.

Had clinicians in the UK been compliant with the 2008 GMC consent recommendations, which mirrored what came later in 2015 in Montgomery, in all surgical cases between 2009 and 2018, the saving to the public purse could have been in the region of £251 million. In the USA, where there is a much greater compliance with Montgomery-type consent processes, from 2004 to 2014, on a pro rata basis there was an estimated reduction in paid claims resulting from failure to warn of $259 million.[28,30]

Complex operations such as major joint arthroplasty account for the greatest proportion of successful claims. HES data (Table II) shows that almost 167,000 hip, knee, and shoulder arthroplasty cases were performed in 2017/18. If 30 minutes extra is required per case to ensure Montgomery compliance, this adds in the region of £17 million to the NHS budget per year. Available NHSR FOI data does not allow a granular analysis according to the primary operative procedure, but if it is estimated that all other orthopaedic cases account for about 50% of the risk and the added cost per consultation is similar, the total added cost to become compliant would be about £35 million – a potential annual saving of around £10 million.

In 2018, across all specialties, NHSR received 10,678 new clinical negligence claims, a trend that has remained flat for three years. It paid compensation for clinical errors totalling £2,360 million[4] an increase of £650 million compared to 2016, and £130 million on 2017 despite no increase in claim numbers (the latter increase largely due to a change in the Personal Injury Discount Rate (PIDR)). If the cost of failure to consent adequately, considering spinal and orthopaedic surgery, is in the region of £30 million a year; this entirely preventable cost represents over 1% of the total annual settlement amount of NHSR. Multiplied across all of the surgical specialties, it can be estimated that between 4% and 5% of the compensation paid by NHSR could be prevented by universal adoption of a fully Montgomery-compliant consent process.

Currently, and for the foreseeable future, the Montgomery test relating to consent is the standard by which clinicians and trusts will be judged in cases of potential clinical negligence. Failure to comply with all of the components of the test leaves clinical teams vulnerable. Achieving compliance is not

complicated but the process must be followed and properly documented. The components that are required to achieve it could be incorporated into teaching curricula at undergraduate and training levels without great difficulty to ensure it becomes embedded in clinician behaviour early in doctors' careers. For senior staff, specific training, particularly with regard to deconstructing established patterns of behaviour, to allow adoption of the new paradigm, may be needed.

A worthwhile reduction in the cost of UK clinical negligence claims would accrue by universal adoption of Montgomery-compliant consent processes which could be implemented in the short to medium-term. For longer-term reductions in NHSR costs, reform of tort law will be required as has been the case in the US.

There is an urgent need for the widespread uptake of appropriate clinical processes, with adequate documentation, that allow all medical staff performing procedures that require consent to be compliant with the principles defined by Montgomery. Once this has been achieved, there should be a significant and lasting reduction in the costs associated with clinical negligence in the UK.

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Funding statement:
The author or authors choose not to respond to the statements.

ICMJE COI statement:
N. Birch reports consultancy from Orthoson, employment and expert testimony by East Midlands Spine, royalties from Medicrea International, and travel/accommodation/meeting expenses from *The Bone and Joint Journal* editorial board, all of which are unrelated to this article.

This article was primary edited by J. Scott.