

patient's diagnosis and treatment. The use of trainees (residents in the USA) should be included within the consent.⁴ Patients were less inclined to sue in legal actions when properly consented, having been informed of the risks from gastrointestinal surgery.¹⁰

Despite the need to observe the principle of first, do no harm, a balance between the benefit that surgical management will provide and risks arising is important. Such benefits should extend the patient's quality of life, which then leads to an ethical principle: respect for patient autonomy.¹¹

The first podiatric review on invasive surgery (patient satisfaction) included consent and risks divided into two components; (a) information about the procedure and (b) complications and risks.¹²

What of evidence in different specialties to provide consent?

Great variation was identified in consent practice following a review of 120 consent forms for common ENT procedures. Poor correlation was shown compared to published risk incidence for many of the procedures.¹³ In a meta-study, 6 of 44 studies (from a total of 2083) selected covered orthopaedics, with only one related to the foot. Conclusions suggested that written information was important and must be provided in addition to verbal discussion. Written information does not constitute valid informed consent alone.¹⁴

In a Ugandan study, a questionnaire targeted 371 patients where 80% of participants reported having been given explanations on the indication for their surgery. Seventeen percent did not know the type of operation they had undergone, and another 17% did not give their consent for the operation. Only 23.7% were able to identify the person who obtained consent from them. The need to improve explanation about a patient's treatment options arose from the study.¹⁵

Risks appear the common denominator if not a pre-requisite. In the original podiatric surgery audit study, the Patient Satisfaction Questionnaire (PSQ-10)^{12,16,17} involved 10 questions broken into 4 domains.^{18,19} When it came to information about the procedure, most patients (89%) thought that they had been given sufficient information. Three percent felt that they

did not want to know details, while 6% criticised the clarity of details offered. Two-percent felt insufficient information had been given.

Complications & risks

Complications and risks were discussed before the operation. Forty-six percent indicated that they were provided with good explanation concerning risks, 35% said that some explanation was provided, 10% could not remember, but thought that some explanation was given, and 9% said that no explanation of risks and complications had been given. Written information was received by 70% patients before surgery, and 97% of respondents admitted adequate post operative instructions. Furthermore, if a post surgical problem arose, 89% knew what to do, while 11% were unsure.¹²

Since 2010, 50 components of sequellae and complications have been audited annually.¹⁹ Two reports¹⁸⁻¹⁹ are compared contrast with an independent orthopaedic source where 15.7% were reported illiterate.²⁰ The rationale for using PSQ-10 in the orthopaedic report was explained as; 'being clearer for patients to identify their expectations', but more importantly it would provide 'a basis to guide pre-operative education,' the key to consent.

How much information to disclose?

The guesswork can be taken out of the question posed, predicated by legal tests. In practice, surgeons sometimes leave out critically relevant information.⁵ As information technology has increased so has the patient's thirst for medical information, often linked to social media forums.

The phrase 'serious or frequently occurring risks' while common to most UK consent forms⁷⁻⁹ is open to interpretation. A judgement in the Court of Appeal concluded that consent should include any 'significant risk which would affect the judgment of a reasonable patient.'²¹ Internationally, the guidance on consent requires surgeons to consider which risks a patient should be informed about. While *Bolam* (1957)²² and *Sidaway* (1985)²³ have formed case law in the UK, where such terms have influenced the judging of hospitals and surgeons. Most clinicians follow a practical view of what is important. The Sidaway principle cannot be applied to all cases.²⁴ The

principles of elective surgery have been modified guiding legal interpretation.²⁵

‘...In modern law medical paternalism no longer rules and a patient has a prima facie right to be informed by a surgeon of a small, but well-established, risk of serious injury as a result of surgery.’⁷ This subtle change now has made a major impact on all forms of consent where the act of treatment has consequences.

When Nadine Montgomery gave birth in Lanarkshire to a severely disabled baby in 1999 from birth complications, another legal test evolved that impacted upon disclosure of information about risks. The decision in *Montgomery (2015)* makes it more likely that a claimant will be able to demonstrate that such failure amounts to a breach of duty.

Risks inherent in a proposed procedure need to be considered relative to the benefits and risks attaching to an alternative course of action. This implies the clinician requires more consideration when balancing options when treating a patient if possible by providing similar assistance, but with lower chances of sequelae or complications. A number of useful points raised from *Montgomery v Lanarkshire* can be summarised.²

- ‘The discharge of the doctor’s duty in this regard is not simply a matter of information disclosure, but rather places the doctor in an ‘advisory role [that] involves dialogue’ so that the patient ‘is then in a position to make an informed decision’.
- Questions over the materiality of a risk, and whether it needs to be disclosed and explained, must, of course, take into account the magnitude of the risk. But, post *Montgomery* it is not the only relevant point. Moreover, the threshold for disclosing a risk is not a static one, but rather one that may vary depending on what a doctor is aware, or should be aware, the patient would want to know. The test for breach of duty therefore incorporates an element of patient subjectivity.
- The decision in *Montgomery* makes it more likely that a claimant will be able to demonstrate that a failure to disclose information about risks amounts to a breach of duty. It may be of particular assistance to a claimant where the risks inherent in a

proposed procedure need to be considered relative to the benefits and risks attaching to an alternative course of action.’

The element of risk put into perspective

Initially eight operative complications were cited¹²; swelling /haematoma, infection, scarring, necrosis, DVT, reflex sympathetic dystrophy (now CRPS), pulmonary thrombosis and operation complication. The latter was rather broad but later refined in successive versions of a database audit system that became to be known as PASCOM-10.

The process of reporting complications, especially infection, is well supported in surgical literature.¹¹

The reaction of patients to information containing risk can vary, but surprisingly many will show less reaction even when confronted with stark suggestions of morbidity, or even mortality for minor elective surgery. The overall incidence of postoperative wound complications in elective orthopaedic surgery is low; 0.07%-6.5% taken from four sources.²⁶

A *complication* can be defined as ‘any undesirable, unintended, and direct result of an operation affecting the patient, which would not have occurred had the operation gone as well as could reasonably be hoped’.¹¹ The term post operative *sequella* has been used in lieu of complication to include events that can arise with more frequency and are easily resolvable.¹⁶ The boundaries become less clear when the perioperative problem is not easily resolvable or arises outside usual expectations. Risk as part of consent still forms a critical element of the process, but poses problems. It is important that the clinician presents an accurate if not realistic chance of a problem arising. A US court warned against requiring statistical disclosure as a standard for obtaining informed consent. In addition, the court noted that such exaggeration would have to significantly increase the risk of the procedure in order for it to affect a reasonably prudent patient.²⁷ It is unlikely that this will be at variance in British Courts.

A risk from a minor concern may be easy to manage with few ill effects but may occur more frequently than a rarer risk that imposes a greater degree of morbidity. Conditions such as complex regional pain syndrome (CRPS), necrotising fasciitis

and deep thrombosis (DVT) take longer to manage than relatively smaller sequellae such as delays in wound healing (dehiscence). Using the Montgomery rule these small risks cannot be reduced in their magnitude by citing low percentages. The Supreme Court in the case of *Montgomery v Lanarkshire* made it clear ‘that the assessment of whether a risk is material cannot be reduced to percentages’.^{2,28} While factors that can influence risk have been studied²⁶, much discussion in depth is unrealistic within a consultation where part of the process is about reassuring patients that they will benefit for surgical intervention. The choice now arises where low chance of sequellae will have to be included with less regard for the effect on patient’s reactions, despite appearing ‘overkill’.

New concepts to improve consent

Visual interpretation of best case v worst case

A novel process for incorporating this discussion in the informed consent was recently proposed.²⁹ In this model, patients are provided with a visual drawing of the options available, for example, surgery versus palliative care. The surgeon writes the “best-case” and “worst-case” possible outcomes of each option on a linear continuum, as well as how likely these are for the particular patient before them. This includes explicit discussion of the quality of life that the patient can expect in each scenario. The patient can then visually determine how their personal preferences fit into the best or worst possible outcomes. While this approach takes additional time, the potential benefit of avoiding the post-operative conflicts discussed above is tremendous.

Patient Negative Impact Score

This type of information informs the patient about IMPACT and thus critical discussion with patients over;

- (i) risk - the likelihood of something happening versus
- (ii) impact - where the effect of a sequella following surgery leads to changes in the patients’ progress to such a degree that the patient is worse off, or even incapacitated.

Table 1
Impact scores associated with the effects of foot surgery¹⁹ Adapted for patient information sheets. Click here for [larger image](#)

Impact level	1	2	3	4	5
	minimal risk, no effect	slight risk minor effect	moderate but correctable but inconvenient	notable recovery longer than expected	significant with permanent effects

Previously referred to as a [Negative Performance Indicator \(NPI\)](#), it is suggested that this term might be reformed as the level of impact, or Patient Impact Score (Table 1). From the database PASCUM-10 [30] the objective of establishing the types of sequellae for the incidence of risk, frequency of that risk and the impact of such a risk comply with modern consent³¹. Compliance with the need for adequate and reasonable disclosure was proposed to meet the tests of *Chester v Asfar* and *Montgomery v Lanarkshire*.²⁸ In August 2018 The College of Podiatry updated their criteria and continually look to validate the scores. Guidance on consent and risk is published on the [author’s website](#) and covers the impact score. PASCUM and factsheets are available to the public as this is open access information.

Data has been provided in this format for several podiatric conditions. A five level matrix colour coded index (Table 1) grades post operative sequelae into different categories. The scores associated with levels 1-5 represent a subjective impression of how a surgical event, mild, intermediate or severe will impact on a patient. It is proposed this aspect of evidence could be used objectively, allowing the patient to understand the percentage incidence, but also the effect on the quality of life.

Currently the College of Podiatry is one of few professional bodies to offer this level of information and the database currently holds above 114,000 patient-episodes for the podiatric surgical community covering a wide range of surgical interventions representing the professional body.

The original NPI was formed by a working party without any specific intention to meet legal tests and to date has not been endorsed in wider practice although was discussed at the National Glasgow Conference in 2012. From the current literature and changing patterns since *Bolam*, *Sidaway*, *Asfar*, *Montgomery* cases, the need to

information that complies with autonomous clinician-patient as effective disclosure now influences podiatric cases.

Having provided a draft book on neuroma risks [31] to patients, the author found the quality of their comprehension increased with the effect that 1 out of 5 patients issued with impact information withdrew from treatment

The reliance on risk alone influencing decision making can fail when supporting patients during consent taking. Protecting patients is paramount and enshrined within good ethics. However, for caring clinicians trying to help their patients, the enthusiasm to provide care can omit some components. A clinician having done what they felt best is no longer supported by signing a piece of paper, whether it includes every risk known or not. If the patient has not had the benefit of all treatment choices, or is unable to consider the facts outside the clinical environment, or not unaware of the impact of a risk, despite being low, the risk of successful judgement against the podiatrist is very likely.

Conclusion

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The material presented is derived from complex cases not always dealt with at the first court hearing (lower court). The cases of Chester v Asfar and Montgomery v Lanarkshire have provided new interpretations. Lower courts will have to strike a balance between two interested parties. On the one hand the *clinician* is required to disclose and explain material risks, and on the other hand the *patient* wishes to know the relevant risks to incorporate information to assist the decision-making process.

Consent needs time, consistency within a process and the patient must be involved as much as possible. The use of the Patient Negative Impact Score is presented as a viable option to key into surgical informed consent to minimise poor patient comprehension in an impartial way supported by the collegiate body in podiatry.

The focus of consent may well continue to change but the use of incidence of risk is fraught with problems of ambiguity and should be used in conjunction with an impact score and perhaps “best-case” and “worst-case” possible outcomes for each options.

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