EDITORIAL

The ‘three-legged stool’

A SYSTEM FOR SPINAL INFORMED CONSENT

Many hospitals do not have a structured process of consent, the attainment of which can often be rather ‘last-minute’ and somewhat chaotic. This is a surprising state of affairs as spinal surgery is a high-risk surgical specialty with potential for expensive litigation claims. More recently, the Montgomery ruling by the United Kingdom Supreme Court has placed the subject of informed consent into the spotlight.

There is a paucity of practical guidance on how a consent process can be achieved in a busy clinical setting. The British Association of Spinal Surgeons (BASS) has convened a working party to address this need. To our knowledge this is the first example of a national professional body, representing a single surgical specialty, taking such a fundamental initiative.

In a hard-pressed clinical environment, the ability to achieve admission reliably on the day of surgery, in patients at ease with their situation and with little likelihood of late cancellation, will be of great benefit. It will reduce litigation and improve the patient experience.

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Many hospitals across the English-speaking world have a consent process for spinal surgery in place. These may reflect local or national preferences, but what is common to them all is that they are functional, and demonstrate that a spinal surgeon has at least made an effort to inform his or her patient of the risks and benefits of a particular spinal procedure. The process and outcome of consent should be documented and readily retrievable. However, many hospitals have no structured process in place and the whole event can be rather ‘last-minute’ and somewhat chaotic. This is a surprising state of affairs as there is good evidence that spinal surgery is a surgical specialty at a high risk of litigation and claims of malpractice.

More recently, the Montgomery ruling by the United Kingdom Supreme Court has clarified the subject of informed consent - this was well described in Foy’s article in this journal in 2015, with all of its attendant ramifications.

There are specific tenets of English Law on the subject of informed consent, which have been the foundation for further advice given by the Department of Health, the General Medical Council, many of the medical malpractice indemnifiers and spinal surgeons’ own professional bodies. A surgeon has an ethical, legal and professional duty to inform his or her patient of the reasons for surgery, of the possible consequences of surgery, which must include both benefit and risk, and the likely outcome if surgery were not to be undertaken (i.e., the natural history of the underlying condition). The patient must also be guided on possible other treatment options and the comparative risk/benefit of these in order to make an informed choice.

A review by Lemaire outlines many of the difficulties in getting the right balance of giving too little, or too much information to patients. The surgeon should assess the needs of his or her patients at the level of a ‘reasonable’ patient, and must then offer further information to each individual patient according to their needs so that they can make an informed judgment on their particular care. The surgeon would take into account their intellect, employment, family circumstances and other factors, quite apart from their concurrent medical status. This is a patient-centred, rather than a paternalistic doctor-centred, approach. This is the central issue in the Montgomery ruling.

The academic literature and websites of spinal institutions and professional bodies in this country and abroad show that there is a wide range of systems available for the process of consent, but many examples are designed to fit in with the hospital, rather than the patient.
It is of interest that paragraphs and whole sections of consent forms are copied across institutions and countries, as one surgeon reasonably tries to seek the best of the available resources to meet an acceptable consent process in his or her own practice.

Although there are laws and good advice on surgeon/patient partnerships with respect to consent, there is a paucity of practical guidance on how this can be achieved in a busy clinical setting. The British Association of Spinal Surgeons (BASS) convened a working party in 2015 to address this issue and used as a working model, in the initial stages, a system that had been in place for many years at a busy spinal centre in the east of England. To our knowledge, this is the first example of a national professional body representing a single surgical specialty and taking such a fundamental initiative.

The informed consent process for elective spinal surgery should be a continuous and ongoing process, ideally with the operating surgeon seeing his or her patient at the time the decision to operate is made, and thereafter up to and beyond the time of surgery. In most modern healthcare systems, patients are usually admitted on the day of surgery, even when the case involves complex surgery. However, obtaining consent on the day of surgery is not best practice, as a patient cannot be assumed to be of sound mind at such a stressful time, and if a problem subsequently arose, patient competence to consent would be called into question. As a result, informed consent has to take place well ahead of the day of the operation.

In the consent model BASS has adopted, the consent process is a ‘three-legged stool’ in that there are three distinct aspects to consent, all of which support the whole, and none of which are of any value in isolation. These three pillars include firstly, the information booklets, written and illustrated at a level a reasonable patient can comprehend. The second is the ‘patient-centred’ dialogue including the risks of the proposed treatment, about which a reasonable patient would need and want to know. This dialogue must be documented and recorded in the patient’s position, would need and want to know.14 This dialogue must be documented and recorded in the hospital records and ideally a copy in letter form sent to the patient and General Practitioner. The third pillar of consent regards the specific procedure, and surgeon-guided consent form, along with the NHS or individual hospital form, and to gain consent for surgical outcome data to be sent to our national registry.

The procedure-specific booklets with full colour illustrative original artwork outlining the anatomy as well as the procedure, with advice on the natural history of the process involved, are central to the process of consent. Possible risks and complications specific to the spinal procedure and the more general risks of surgery are described, as well as rare, but highly significant risks, including the possibility of death, paralysis and blindness. Other essential information must include a realistic expectation of outcome and over what particular timescale. An example is the extended period of recovery following major lumbar deformity correction, meaning that patients cannot expect to feel the full benefit of the procedure for many months. However, more than anything, a patient must not be permitted to expect a ‘cure’, but rather a significant improvement with measurable and tangible outcomes, such as reduction in pain or an increase in walking distance. In this way, it is possible for both the surgeon and the patient to have a sensible dialogue about outcomes, which helps considerably to manage expectations.

Patient recall and assimilation of oral information in a clinical setting is reported to be poor. Lemaire12 describes and tabulates this in his overview of the studies conducted on patient recall of information given prior to surgery in various surgical specialties. Information should be provided with a level of detail which should be comprehended by the majority of patients. This can be challenging in many countries with diverse populations of differing socioeconomic groups, ethnic minorities and patients whose first language is not English. As a result, the information booklets and consent forms will in time be translated into the appropriate language alongside the original English. It is of paramount importance, therefore, that these booklets are well illustrated, given to the patient when the decision to operate is made, and have been proofread by groups that represent the patients. This will give time for a confidant to help a patient who might have language difficulties and attend the subsequent consent clinic with them.

Ideally, two to four weeks prior to surgery, the patient should have a pre-operative review by a trained nurse or similar, to consider their fitness to undergo surgery and to discuss, as required, any relevant issues with the anaesthetist. The patient will also have an appointment with the surgeon to go through the process of informed consent for the proposed surgery. Pragmatically, it is an opportunity to confirm that the patient has the same symptoms on which the decision to operate was based, and also to confirm imaging is relevant and up-to-date in countries where there are lengthy surgical waiting lists. There would also be time to make minor changes to the planned procedure as appropriate, and following a discussion with the patient. The surgeon has the chance to gauge the understanding the patient has of previous verbal, written and illustrated information given at the time of surgical listing.

Following on from the Montgomery judgment, a fundamentally different emphasis must be imparted on the dialogue for obtaining consent – this is no longer a paternalistic model, as might previously have been the case. It must be a ‘patient-centred’ dialogue as described earlier. Badenoch14 describes the need for the surgeon to advise on the risks of surgery that this patient would need and want to know in this position. He describes how it is necessary for the surgeon to consider his or her patient’s individual characteristics and situation in life, for example their social, physical, employment and intellectual status, in order to have more insight into personalising the disclosure further.
At this consent appointment, the operating surgeon will guide the patient through a series of key points, which will be signed off in turn. The consent forms are specific to procedure in the same manner as the information booklets, and are divided into a number of sections describing the components of the operation, as well as the potential risks. It is important that there is a pause after each consent item is signed to allow reflection by the patient, and for them to discuss any questions they might have. The consent form preamble stresses the importance of the patient’s understanding of the nature of the operative procedure, what to expect from the surgery, and the risks which may occur with the operation, as well as other rare but significant complications which have been known to occur. It is stated that the list is not exhaustive, and that other unforeseen complications can occur. It is made clear to the patient at this time that the consent process is not a ‘get-out clause’ for the surgeon in case of litigation, and that any adverse incident would be fully investigated. Rather, it is an opportunity for the surgeon and patient to meet and discuss the surgery openly in a friendly and informative way, without the stress of the expectation of immediate surgery.

One of the signed statements allows the pre- and post-operative outcome scores to be sent to the British Spinal Registry (BSR) on the understanding that these anonymous data will be used positively to assess the effectiveness of the operation and allow feedback to the surgeon for the purposes of local and national audit, which could inform a process of continuing technical and process-specific improvements.

The spinal consultants in our Spinal Unit, where this process has been in place since 2003, have found it to be a very positive psychological experience for the patient, and helps to form a bond between patient and surgeon. Frequently, it is the first time that a patient understands his or her surgeon’s apprehensions when considering the surgical decision-making process. Casey describes how the consent process is key to gaining patient trust and when well-documented, this closes the door on many legal ‘fishing trips’. In one spinal unit, over the 12-year period where this consent process has been in place, there has been no case of a patient withdrawing from surgery because of the risks which are both written down and described as suggested; these risks have included the possibility of death or paral-ysis. This experience is at odds with the conclusions drawn from the Law Lords in Chester versus Afshar, in which case, the plaintiff stated that she would not have proceeded to surgery on the day it was scheduled had she known of the small specific risk of post-operative cauda equina syndrome.

The informed consent process must be comprehensible to every patient with mental capacity. The Montgomery ruling places the onus on the surgeon to inform each patient of other factors the surgeon knows to be important for that patient to be able to make further judgment on their own health. In addition, there must be ready access and provision of detailed information in the event that patients require it. Ng and Gibson offer a comprehensive review of the risk factors for spinal procedures, following an exhaustive review of the Cochrane database. They sought to report accurate and documented complication rates rather than ‘guesstimates’ often provided by individual surgeons. In the United Kingdom, with increasing numbers of patients registered on the BSR, realistic information regarding complication rate will become available for patients and surgeons and the process of informed consent will, as a result, be improved.

The formation of the BASS working party to address and deliver an informed consent system to allow for a high-quality, informed consent process is a timely action, in light of recent legal rulings, and it will be highly practical. It will be a welcome tool for many new consultants just starting in post, and for those hospitals without an established system. In addition, experienced surgeons might see the benefits of a system supported by their professional body, within all legal and professional guidance that will be continually researched, updated and catalogued. It will demand, however, that time is set aside to enable the consent process effectively. In a hard-pressed clinical environment, the ability to achieve admission reliably on the day, even with complex surgery, in patients who are at ease with their situation and with little likelihood of late cancellation for unforeseen circumstances, will be of great benefit. It may well reduce litigation and should improve the patient experience.

The BASS working party does not want this system to be prescriptive to BASS members, particularly to those surgeons with a well-functioning service in place, but rather it will be a useful tool for those departments that fall short of this ideal. BASS would also like to emphasise that consent is an ongoing process which commences when surgery is first recommended, is patient-centred, and is not left to the immediate pre-operative stage.

References


