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In clinical practice, when does suboptimal care become substandard care?

We all know from our own clinical practice and from attending multidisciplinary team (MDT) meetings that, not infrequently, a postoperative radiograph of a fracture fixation or arthroplasty is not perfect and could have been performed better. We also know that, as Voltaire told us, perfect is the enemy of good. As surgeons, we have to analyze these situations and learn from them in order to improve the performance of ourselves, our colleagues, and our trainees.

Increasingly frequently, these matters are being scrutinized with the benefit of 20/20 hindsight by the legal representatives of unhappy patients. There are some clear legal principles that guide both the legal profession and the medical profession in the assessment of these situations of which we should all be aware. The Bolam test still governs most investigations and treatment scenarios in medical practice. Therefore, if a similar position were taken by a reasonable body of the treating clinician's peers, it is held to be Bolam defensible unless (after Bolitho) it is logically indefensible. The recent Montgomery ruling on consent[1] has moved the goalposts somewhat. The Bolam test no longer applies to informed consent. The Montgomery Judgement (paragraph 87) emphasizes the importance of tailoring consent to the individual patient and also affirms the importance of following the General Medical Council's (GMC) guidelines.

Broadly speaking, there are four possible scenarios that can be visualized when assessing the quality of patient care:

1. Gold standard: Could not be faulted in any respect, the level we all strive to attain.
2. Reasonable: The level that satisfies Bolam, and therefore the Courts.
3. Suboptimal: Not quite right; within an acceptable level/margin of error but not a situation with which we would be entirely happy.
4. Substandard: Clearly below the reasonable and competent level that we would wish, as a minimum, to achieve. Not at a level that any reasonable or competent surgeon would consider to be acceptable.

As orthopaedic surgeons, we are at something of a disadvantage, as the results of many of our surgical procedures are visible to all and sundry by way of radiographs and scans. The varus/valgus angle of the femoral stem or tibial tray can be measured on radiograph or CT scan. The inclination of the acetabular component can be measured. The precise position of pedicle screws and interbody cages can be assessed. However, we know that radiographs that are suboptimal are frequently associated with a good clinical result. We also know that radiographs that appear to be gold standard are sometimes associated with a less than perfect result. In the future, analysis of data from the National Joint Registry and Spinal Registry may allow us to define tolerance limits better and their relation to outcomes more clearly than we are able to do at the present time.

The problem that challenges those of us who analyze or advise on clinical negligence cases is to decide at what point suboptimal care becomes substandard care. Some examples may be of assistance. When considering the quality of care provided in any clinical scenario, I would normally look at four distinct areas (if surgery was involved):

1. Was the decision to operate reasonable?
2. Was the information provided to the patient, including the consenting process, reasonable and did it follow GMC/Montgomery guidance?
3. Was the operation performed to a reasonable standard?
4. Was the postoperative care reasonable?

In all honesty, given the spectrum of opinion that exists among orthopaedic surgeons, it is usually difficult to criticize a decision to offer surgery in general or a particular choice of operation. We may all have different thresholds for advising surgery based on our training and clinical experience. Fortunately, the great majority of our time is spent dealing with matters involving quality, rather than quantity, of life. In spinal surgery in particular, the same patient may be given diametrically opposite opinions by two spinal surgeons (i.e. conservative treatment *versus* operation, both of which would be considered reasonable).

Given the recent meta-analysis by Thorlund et al,[2] which was picked up by the press, it is now more difficult to justify arthroscopic intervention in the middle-aged degenerate knee unless there are clear mechanical symptoms and demonstrable intra-articular pathology that fits with those symptoms. Therefore, surgeons may find themselves subject to scrutiny or criticism if recommending a 'ten-thousand mile service' on a degenerate knee in the 21st century, although Bollen[3] was not impressed with the veracity of the Thorlund meta-analysis. In a clinical negligence case, it was easier to decide that a decision to operate was substandard in a situation where a patient with normal knee radiographs has undergone two arthroscopies, total knee arthroplasty, and patellar resurfacing (four operations) before the hip arthritis was diagnosed and a hip arthroplasty was advised.

With regard to preoperative advice, information, and consenting, this is now an absolute minefield after the Montgomery ruling. You should be aware, if you are not already, that Montgomery can be invoked retrospectively. By that, I mean that patients can allege that they were not properly counselled about the risks and benefits of surgery for operations that took place before the Montgomery ruling was made. Increasingly, we see the claim that, "I would never have consented to the operation if I had known this could happen." Therefore, it is vital to document clearly in the outpatient letter the discussion of the natural history of the underlying condition without surgery, the surgical options available, and the potential risks and potential benefits of the available procedure(s). Even so, solicitors still try to argue on the basis of lack of understanding of the complication by their client when that complication occurs. A recent case comes to mind where, following anterior cervical discectomy and fusion (ACDF), a recurrent laryngeal nerve palsy occurred, resulting in hoarseness that did cause significant problems, as the patient's job required her to communicate verbally on a regular basis with fellow staff and clients. Recurrent laryngeal palsy was listed on the consent form and in the outpatient letter but the patient and her solicitor argued that she would not have consented to the procedure had she understood the functional implications of such an injury. This was despite conceding that she signed up for an operation that might paralyze her and she did understand the significance of this potential complication. The case was eventually dropped but not before running to quite an advanced stage. The documentation and position of the treating surgeon made the case defensible.

Care is also required preoperatively concerning the risk/benefit profile given to the patient for the intended procedure. This follows the Thefaut v. Johnston case,[4] where the surgeon was criticized for predicting a potential improvement of over 90% for relief of leg pain/sciatica following spinal decompression, whereas the experts involved in the case described it as closer to 85%. The judge described this as "a significant overstatement". Whether we would all agree that > 90% *vs* 85% represents a significant overstatement is debatable. However, it does illustrate the level of detail used in the final analysis before judgement by the court.

The concluding point I would make in this brief article about the complex subject of consent is that you should not tell a patient that an operation is mandatory unless it is (and it frequently isn't). I have come across a small number of claims where the surgeon has told a patient that a particular procedure is mandatory and therefore the preoperative consenting process focuses on nothing else but the recommended procedure. When a complication occurs and the patient is making a claim, their legal team forensically unpick the consenting process and they usually have little problem arguing that not all of the material facts were given to the patient and, had they been, he or she would not have gone ahead with the procedure at that time. The example of this that comes easily to mind is in the spinal surgery world. There would be little (if any) argument that a patient who presents with a massive disc prolapse requires emergency decompression, i.e. surgery is mandatory. Contrast this with the patient who has multilevel symptomatic spinal stenosis is told that it is mandatory to carry out a multiple level decompression and instrumented interbody fusion to decompress the nerves and restore sagittal alignment. While it is perfectly reasonable to recommend such an operation, it is certainly not mandatory and other options, including decompression alone or with posterolateral fusion, should be discussed. To describe an operation as mandatory implies to the patient (and their solicitor) that no reasonable and competent surgeon would adopt a different approach to the problem.

What is acceptable in the operating theatre in 2018? Starting with spinal surgery again, if a surgeon is carrying out a three- or four-level fixation with biplanar screening for trauma, or in conjunction with a degenerative decompression procedure, how many pedicle screws is he or she allowed to misplace before it moves from the reasonable end of the spectrum to the substandard end? It is generally accepted that pedicle screw insertion is associated with a 5% to 10% misplacement rate. Therefore, one misplaced screw would not raise any eyebrows. Two might be considered suboptimal but not substandard. Is more than two substandard or unlucky? There are no absolute guidelines and it is incumbent on experts in these cases to exert a degree of common sense when giving an opinion.

What about joint arthroplasty? As discussed above, all sorts of measurements can be made on postoperative radiographs and scans. Sizing of implants may be an issue. In knee arthroplasty, it seems to be accepted that significant undersizing should be avoided to minimize the risk of subsidence. There is some evidence from McArthur et al[5] that oversizing doesn't significantly affect outcomes, while Chau et al[6] suggest that, in unicompartmental knee arthroplasty, oversizing with more than 3 mm of overhang of the tibial tray is associated with poorer outcomes. In light of that knowledge, does that make oversizing of a tibial tray by more than 3 mm substandard or just suboptimal? With the duty of candour position promulgated by the GMC, are we duty-bound to point it out to a patient who is very happy with the result of the operation but has 3 mm or 4 mm of overhang on the postoperative radiograph?

In the postoperative period, it is frequently the failure to recognize and act upon complications, particularly infection, that causes patients to commence litigation. There seems to be a particular issue with the private sector, where patients undergo surgery and the treating consultant then goes on holiday or to a meeting, leaving a patient with a postoperative problem either on the ward or very recently discharged,

without a clear contingency plan for their ongoing investigation or management. If there is a continuing problem, it is obviously suboptimal to leave without organizing suitable cover and clearly documenting the arrangements in the inpatient record. It is easier to defend if the patient has been discharged as there is always the fallback of the National Health Service (NHS).

The biggest issue that I see in the postoperative period is the poorly chosen comment of the consultant asked for a second opinion following a poor outcome after an operation. I am not suggesting that we avoid being honest with patients, but comments such as, "the surgeon has made a complete mess of that," or, "I would never have advised you to have an operation," are usually unhelpful and lead to litigation where the likelihood of success is often low, and distracts the patient from continuing treatment and managing and/or accepting the ongoing problem. The former comment is usually made after fracture fixation or joint arthroplasty with poor outcome, and the latter after failed spinal surgery. In the former, the leg length inequality or relative malposition of the implants is often well within the tolerance that would be accepted by reasonable and competent surgeons practising in that field, i.e. suboptimal but not substandard. In the latter case, it is just not relevant to comment with the benefit of hindsight that surgery shouldn't have been recommended when it is clear that there would have been reasonable and competent spinal surgeons who would have recommended surgery. Therefore, I would suggest that, when asked for second opinions, a degree of humility is exercised with suboptimal radiographs and outcomes unless the situation is so obviously substandard that it is mandatory to tell the patient.

A case that comes to mind in that category is one where I was asked to see a patient a couple of years after a C5/6 anterior cervical discectomy and fusion (ACDF) who had a minor cord injury, poor outcome, and persisting symptoms. She had been radiographed twice postoperatively and then discharged by the registrar six to nine months after surgery. It was clear from the radiographs and scans that she had undergone a C6/7 ACDF rather than a C5/6 ACDF but either no one had realized this or they had simply failed to tell her. On that occasion, I felt that it was appropriate to tell the patient and I believe that litigation did follow.

In summary, I perhaps haven't answered the question posed in the title of this paper because, really, it is unanswerable. There is a grey area between reasonable and substandard care and, in that difficult area, each case has to be analyzed and judged on an individual basis. Analysis is not helped by experts who don't seem to understand their role in the process. Too many experts apply gold (rather than reasonable) standards and judge with the benefit of hindsight rather than putting themselves in the position of the treating clinician at the appropriate time. Too many experts also step outside their own area of expertise. Unrealistically favourable reports for claimants often lead to spurious, easily defensible claims that not only cost time and money, but can also lead to disappointment and anger on the claimant's part.

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