Clinical guidelines and the standard of care: Part 2

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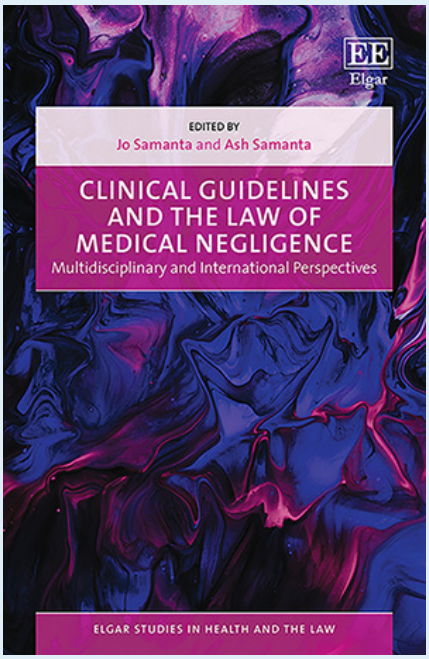


This article is based on the following book chapter: **Clinical Guidelines in Trauma and Orthopaedic Surgery.** Britten S, in Jo Samanta and Ash Samanta (eds). *Clinical Guidelines and the Law of Medical Negligence: Multidisciplinary and International Perspectives* (Edward Elgar Publishing, Cheltenham, UK & Northampton, MA, USA, October 2021). All excerpts reproduced with kind permission of the publisher.

Part 1 CORRIGENDUM
The fourth paragraph on the last page of Part 1 in the June edition of JTO should have read:

"This wide range of applications of BOAST guidelines, including in day to day clinical practice, as concise revision aids for trainee orthopaedic surgeons, and through to their use as reference tools in the national monitoring and audit of major injury, demonstrates their considerable usefulness and functionality."

Simon Britten

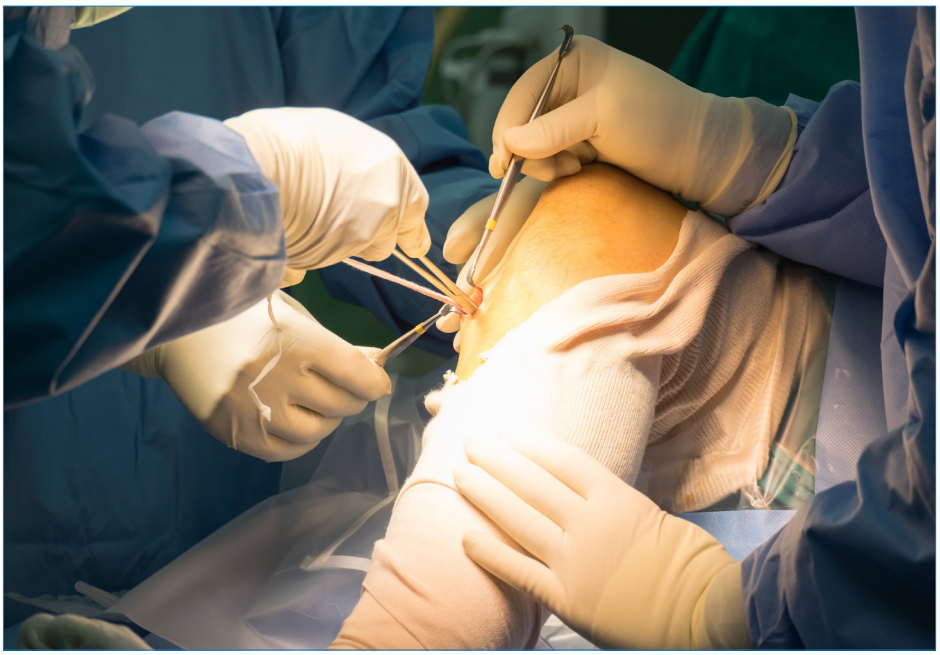
Mr Britten is grateful for the assistance of Bob Handley and Chris Moran, who both gave up time to discuss the origins, formulation and ethos of BOAST guidelines.

In Part 1, I noted that many clinical negligence lawyers have seen some use of clinical guidelines in their cases to assist the court in determining what constitutes reasonable care[1].

I suggested that when considering the standard of treatment from both the clinical and medico-legal perspectives, the surgeon may wish to take into account the relevant clinical guidelines; consider any circumstances specific to the individual case which may influence treatment options; appreciate that rigid adherence to guidelines may occasionally be unwise and potentially negligent; and recognise that intentional deviation from existing guidelines may be reasonable if there are case-specific factors which warrant departure from the guidelines. That is to say, each individual case should be considered on its own merits.

I began to discuss several sources of clinical guidelines of relevance to trauma and orthopaedic practice in the UK, and focused in detail on British Orthopaedic Association Standards in Trauma and Orthopaedics (BOAST) guidelines[2], and the BOA/BAPRAS (British Association of Plastic, Aesthetic and Reconstructive Surgeons) clinical guidelines on the orthoplastic management of open fractures[3].

I would now like to consider other useful sources of guidelines with which the orthopaedic surgeon should be familiar, both from the clinical and medico-legal perspectives.



National Institute for Health and Care Excellence (NICE)

In the case of *Price v Cwm Taf University Health Board*[4] at trial and on appeal, the court chose to set aside guidance from NICE as to what constituted reasonable treatment, preferring instead to go with the evidence of the expert instructed by the Defendant, Mr Weale. The NICE guidelines for knee arthroscopy in osteoarthritis[5] recommended arthroscopy and washout if a clear history of mechanical locking was given, while the Claimant argued that he merely had a sensation of catching within his knee.

Regarding departure from the relevant NICE guideline, at the original trial the judge accepted the expert evidence of Mr Weale, in finding that: "Overall, while [the surgeon] was not in the mainstream view in carrying out a further arthroscopy on the Claimant, bearing in mind the NICE Guidelines, he was within a reasonable body of orthopaedic surgeons who would reasonably have carried out such a procedure[6]." At appeal, Birss J found that the original trial judge had been entitled to reach that conclusion, representing a direct application of *Bolam* test.

At the original trial, there had been consideration of the difference between a clear history of mechanical locking of the knee versus the described symptom of catching within the knee. As the original trial judge had held that [the surgeon] had been wrong to equate the knee symptom of catching with that of true locking, the claimant's counsel submitted that essentially [the surgeon] carried out the second arthroscopy as a treatment of osteoarthritis contrary to the relevant NICE guidelines. In considering this point, Birss J noted: "… as the [original trial] judge recognised … the Guidelines also make clear that while they have been arrived at after careful consideration, they do not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the original patient. After noting that they do not override the need for appropriate individual decisions, the judge then made the statement which is challenged on appeal: 'nor is failing to follow the guidelines *prima facie* evidence of negligence[7]'."

> "GIRFT (Getting It Right First Time) emphasises the interrelationship between failure to follow clinical guidelines and the potential for litigation as a result."

In his blog, barrister Mike Hill of Parklane Plowden Chambers ran through a summary of *Price*, noting that inconsistencies between care given and NICE guidelines are often pleaded as evidence of a breach of duty or vitiation of the consent process, and pointing out that invariably the matter is defended by arguing that they are guidelines only[8]. Hill went on to state the view of NICE itself: "Your responsibility … This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account… The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer." Hill concludes by observing that Birss J and NICE are in agreement, noting that all cases are fact-sensitive, so that in some cases clinical guidelines should be observed and/or communicated, while in others not.

Rockwood and Green

Rockwood and Green's Fractures in Adults[9] is a widely accepted and respected text, the scope of which covers the entirety of fracture treatment of the upper and lower limbs, pelvis and spine. While not primarily a source for clinical guidelines per se, each chapter is written by a recognised international expert and includes a review of the relevant peer reviewed literature written on specific injuries. It is useful to treating clinicians and can also add significant weight to an orthopaedic expert's evidence on the standard of care provided in clinical negligence cases, augmenting the expert's own clinical experience.

From the author's own medico-legal experience is another instructional clinical negligence case which demonstrates the use of the relevant chapter in *Rockwood and Green*'s to back up the expert evidence provided.

A 'reverse oblique' unstable subtrochanteric femur fracture in a 68-year-old man was fixed using a 'sliding' or dynamic hip screw (DHS), rather than with the biomechanically more stable intramedullary nail (IMN). Soon after surgery, the DHS fixation failed and the fracture site collapsed, leading to a symptomatic non-union of the proximal femur with marked limb shortening and disability. Revision surgery was precluded by the development of an unrelated abdominal problem.

The author was instructed by the Claimant's solicitors and took the view that it had been unreasonable to use a DHS in this case. This was on the basis that the biomechanics of the DHS are known to be disadvantageous >>

to the sound fixation of reverse oblique subtrochanteric fractures and the medical literature does not support the use of a DHS in such fractures; indeed, the literature actively warns against using a DHS in fractures with such geometry – the relevant edition of Rockwood which was in print at the time surgery had been performed stated: "Reverse Obliquity Fractures. A sliding hip screw is not indicated for stabilisation of reverse obliquity fracture patterns … telescoping of the implant can promote fracture separation rather than impaction. This leads to an unacceptably high failure rate when a conventional sliding hip screw is used to treat this fracture pattern. Reverse obliquity intertrochanteric fractures are best stabilised with a cephalomedullary nail[10]."

The expert instructed by the Defendant stated that at the time the surgery was performed, in his experience a responsible body of orthopaedic surgeons would have used a DHS to fix such a fracture as a reasonable fixation option. The case settled in the Claimant's favour before trial for a six-figure sum without admission of liability. There were no obvious case-specific factors to justify using the biomechanically inferior implant contrary to guidance in Rockwood. This case illustrates the potential strength of one's clinical experience being backed up by a standard text such as Rockwood and Green when acting as an expert witness, provided that the edition quoted is contemporaneous with the case being considered. It also illustrates the importance of not disposing of old editions of standard textbooks, as they may come in handy when casting an eye over retrospective potential negligence cases.

Getting It Right First Time

GIRFT emphasises the interrelationship between failure to follow clinical guidelines and the potential for litigation as a result.

An NHS Resolution and GIRFT working party has produced professional standards guidance for hip and knee arthroplasty documentation[11]. These clinical guidelines have been produced in collaboration with contributors from the British Hip Society and British Association for Surgery of the Knee, the British Orthopaedic Association, NHS Patient Safety, NHS panel law firms, Claimant law firms, expert witnesses and the medical defence organisations. The documents were produced following analysis of medical negligence cases notified to NHS Resolution by leading orthopaedic medico-legal experts and viewed in light of existing clinical guidelines. GIRFT states the aim of the guidance is as follows: "… to promote good clinical practice based on lessons learnt from previous claims and to ensure that practice is clearly documented so that in the event that a claim was brought against good clinical practice, there would be sufficient documentation for the NHS to defend it in an efficient and cost-effective manner. In the future other high-volume areas for claims will be reviewed based on the feedback from this guidance[12]." The two documents provide detailed guidance as to the extensive operation note required to safely document a total hip or knee arthroplasty in such a way as to minimise the risks of action for clinical negligence.

The two GIRFT clinical guidelines in hip and knee arthroplasty documentation were published in 2019. As yet, there is no reference to them apparent in published case law. On the one hand, the full guidelines provide the orthopaedic surgeon with a cornucopia of opportunities to document the excellence of their arthroplasty practice, but it remains to be seen whether the gold standard level of detail required will prove to be difficult to attain in its entirety and then leave the reasonable surgeon open to censure and on the receiving end of a successful claim for clinical negligence.

Clinical guidelines in the COVID-19 era

From spring 2020 with the worldwide COVID-19 pandemic approaching the United Kingdom, novel clinical guidelines emerged covering two separate areas of potential relevance to orthopaedic surgeons' jeopardy and clinical negligence.

Guidelines were developed to advise orthopaedic surgeons on how to treat respiratory patients outwith their usual area of expertise, including guidance on oxygen therapy for patients with COVID-19 and escalation of respiratory support for such patients. No examples of orthopaedic surgeons acting as medical registrars during COVID-19 times have yet made it into medical negligence case law. This could be due to the delays to court proceedings introduced by lockdown during the pandemic, the expected time lag from initiating a clinical negligence claim to its conclusion, or alternatively a factor of the innate ability of orthopaedic surgeons to improvise and turn their hand successfully to most things!

An additional genre of guidelines were devised in how to treat a wide range of acute limb injuries non-operatively, without the need for the services of an anaesthetist, bearing in mind that prior to the pandemic many common injuries were treated operatively in order to restore normal anatomy and maximise functional outcomes for injured patients. The BOA produced a set of COVID-19 BOASTs, in anticipation of loss of anaesthetic capacity, the need to protect patients from exposure to disease (including in hospitals with COVID-19 inpatients) and the need to protect the NHS from unnecessary hospital admissions[13].

It remains to be seen how much litigation will follow, covering such matters as inadequate follow up and rehabilitation, failure to provide the indicated operative treatment leading to poorer outcome, and even 'unnecessary and avoidable' early amputation in a potentially salvageable limb. All this will have to be weighed against the very real danger during 2020 of simply being an in-patient in a hospital with many COVID-19-positive patients and the risk of nosocomial hospital-acquired transmission.

Conclusion

In recent years, a burgeoning list of sources for clinical guidelines has emerged covering a range of traumatic and elective conditions in orthopaedic surgery, with NICE and the BOA leading the way. Orthopaedic surgeons need to have a working knowledge of the guidelines relevant to their area of practice to aid sound decision making in their clinical work. If they choose also to engage in medico-legal practice, such working knowledge of the relevant guidelines is even more essential, in conjunction with their clinical experience, to help fashion their expert opinion.

It has to be appreciated by both the orthopaedic expert and the lawyers that there may be some ambiguity as to whether a specific guideline represents the gold standard of care (desirable), the reasonable standard (essential), or the auditable standard (quantifiable). In the author's experience, orthopaedic experts may occasionally lose sight of the fact that to avoid care provided being deemed negligent, the care provided merely has to be reasonable.

However, guidelines are exactly that – guidelines. The view of NICE is clear, that when making clinical decisions the healthcare professional must take fully into account any available clinical guidelines; but they must also appreciate that all cases are fact-sensitive, and care provided must take into consideration the patient's individual circumstances of relevance. Accepting that there will be cases in which there are specific individual factors to consider carefully, rigid adherence to clinical guidelines may not protect the orthopaedic surgeon from censure, while intentional deviation from clinical guidelines may be considered entirely reasonable. Depending on the specific circumstances, in some cases guidelines should be observed, while in others not. If the care provided deviates significantly from current clinical guidelines, then both the deviation and the reasoning for the deviation should be communicated with the patient whenever possible. ■

References

References can be found online at www.boa.ac.uk/publications/JTO.