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Clinical guidelines: must we follow them?

Controversy about clinical guidelines is not new. Hurwitz (1999)[1] described how, in the fourth century BC, Plato explored the difference between skills grounded in practical expertise and those based solely on following instructions or obeying rules. Plato was of the opinion that flexible responsiveness and 'improvisatory ability' were endangered by the use of guidelines. Plato's view was that the ritual following of guidelines debased medical practice because guidelines presuppose an average patient rather than the particular patient that the doctor is treating. He also believed that the knowledge/analysis that goes into the development of guidelines is not with the treating clinician, but with guideline developers distant from the clinical situation.

The legal profession seem to like guidelines and protocols; it gives them something to judge us by. The question we need to ask in clinical practice is, how do we stand legally if we don't follow NICE guidelines or hospital/departmental protocols? Is it a mandatory requirement that we do so? If not, why have they been drafted in the first place? Gupta and Warner[2] helpfully summarise the rubric of the NICE guidelines, pointing out that NICE concede that they are not a replacement for clinical knowledge and judgement, and do not take the place of the individual responsibility of healthcare professionals to make appropriate decisions.

NICE itself indicates that clinical guidelines recommend the ways in which healthcare professionals should care for people with specific conditions and encourage best practice. However, Tingle[3] describes how, in 1996, the Department of Health[4] indicated that the guidelines should be constructed in such a way that permits deviation and initiative, which has the potential to result in improvements. The point is also made by Tingle that clinical guidelines are not a cookery book and clinical judgement is not suspended when they are used.

In our day-to-day clinical practice we are generally judged on the basis of the Bolam principle or test, after the case of Bolam *v* Friern Hospital Management Committee (1957).[5] Judge McNair opined in this case, "A doctor is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical men skilled in that particular art. Putting it another way round, a doctor is not negligent if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view."

Since that time, our professional practice has been judged on the basis of clinicians performing to a reasonable and competent standard that would be supported by their peers. While doctors should clearly strive to achieve 'best practice' the Bolam principle is based on reasonable and competent practice rather than Olympian or gold standard practice. The Bolam test was modified to a degree by the Bolitho judgement in 1996 which held that the position taken by the treating doctor had to be logically defensible, even if Bolam-compliant.

Following the recent Montgomery ruling, the Bolam principle has of course been further attacked and overturned as far as it applies to informed consent.[6] James Badenoch,[7] senior counsel in the presentation of the Montgomery appeal to the Supreme Court, argues that in all areas of medical litigation, "the writing is on the wall" for Bolam and, "the law should go further and remove Bolam from its pedestal altogether."

In orthopaedics-related medical negligence practice, the author has recently been asked to advise on cases where failure to adhere to the NICE guidelines on DVT thromboprophylaxis in joint arthroplasty surgery, and failure to follow pre-operative rehabilitation protocols prior to surgical management of low back pain, have been raised as an important issue by claimants solicitors in support of their clients' claim for substandard treatment. Samanta et al[8] described the use of guidelines in a group of litigation cases in the USA. They found that they were only used in 7% of the cases, more usually by the defence team (the sword) but also on occasions by the claimants legal team (the shield.)

The theme was further developed in the UK by Samanta et al in 2006,[9] in a detailed review of the awareness and use of guidelines by solicitors and barristers in their medical negligence practice in England and Wales. They contacted 372 lawyers (220 solicitors and 152 barristers) of which only 110 (71 solicitors and 39 barristers) responded. Despite the poor response rate (30%), the results are of interest. Eighty-nine per cent of the respondents reported that they or someone in their team had used clinical guidelines in clinical negligence cases in which they had been involved in the previous three years. They found that guidelines were brought into the case more often by expert witnesses, rather than having been introduced by the legal teams. There was a significant majority view amongst the legal responders (85%) that the remit of NICE would increase the use of clinical guidelines in future negligence cases. It appears that at the time the survey was carried out, the use of guidelines was more prevalent in negligence litigation in England and Wales than in the United States, although the study cited by Samanta et al in 2003[8] is not strictly comparable with that reported in England and Wales in 2006.

Samanta et al proposed a four stage conceptual model for the use and utilisation of guidelines in negligence litigation:

- Is the decision made by the treating clinician, as far as it applies to the use (or avoidance of use) of the guideline, Bolam defensible?
- Is the decision by the treating clinician, as far as it applies to the use (or avoidance of use) of the guideline, Bolitho justifiable?
- Is there scientific validity behind the quoted guideline or protocol?
- How does the guideline apply to the particular circumstances of the matter under consideration, i.e. the case-specific application?

Clearly in any negligence case if the position taken by the treating doctor in relation to the use of the guideline in question is not Bolam defensible, then the court would conclude that no reasonable practitioner would have behaved in that manner and the duty of care owed to the patient has been breached.

If the position is Bolam defensible, is it Bolitho justifiable? In the Bolitho case[10] Lord Browne-Wilkinson opined, "The court has to be satisfied that the exponents of the body of opinion relied upon can demonstrate that such opinion has a logical basis. In particular, in cases involving, as they often do, the weighing of risks against benefits, the judge, before accepting a body of opinion as being responsible, reasonable or respectable, will need to be satisfied that in forming their views, the experts have directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion on the matter." Therefore the individual doctor or Trust needs to be able to demonstrate to the court's satisfaction that their adherence to or avoidance of the guideline in question has a logical and scientifically justifiable basis.

The third stage would be to decide whether or not the particular guideline was admissible as evidence. Guidelines arise from a variety of sources ranging from NICE, the Royal Colleges, other professional bodies and private insurance companies. There may be differing recommendations between guidelines. Consideration may have to be given by the court to the principles and methodology used in formulation of the guidelines together with their reliability and relevance. Guidelines developed using rigorous, evidence-based methodology are unlikely to be regarded as unreliable.

Indeed, the emphasis between the NICE guidelines on venous thromboembolism (VTE) prophylaxis following total joint arthroplasty and the 'living document' on the BOA website[11] is one area where guideline recommendations are not strictly in alignment. The BOA document praises the efforts of NICE in formulating their guidance, but also presents compelling evidence from Barrack,[12] the American College of Chest Physicians (ACCP) and the American Academy of Orthopaedic Surgeons (AAOS) for the use of aspirin as equally effective to other forms of chemoprophylaxis against VTE. There is reference to the 2013 report of the National Joint Registry (NJR) which shows, for example, that 8% of patients undergoing total hip or knee arthroplasty in 2012 were given aspirin as VTE prophylaxis. This amounted to 12 692 patients treated outside NICE VTE guidelines. Does the position taken by the treating surgeons amount to reasonable and competent practice in light of the ACCP and AAOS evidence? Is it logically justifiable from a judicial perspective? I believe so, but until it is tested in the legal arena we will not know for certain.

The final stage suggested is application of the guidelines to the specific facts of the case under consideration. This would usually involve consideration of a narrow range of issues including whether the guidelines had been followed (a matter of fact), and whether the conduct of the practitioner in these circumstances fell below what would be expected of a reasonable doctor in that situation. The latter would still require expert witness opinion.

They suggest that their proposed approach is a halfway house between the traditional Bolam test and the position where guidelines define the standard of care. They believe that the model blends a scientific evidence-based approach with clinical autonomy which is an inherent component of medical practice which would provide a structured approach to judicial decision-making.

I believe that the suggestions made by Samanta et al[9] are sensible and logical in relation to the position of guidelines in medical negligence cases. In reality, very few negligence cases get to court. Guidelines are introduced sporadically and are often used as shields or swords in the early skirmishes, and (subject to the veracity of the expert evidence on each side) no doubt are one piece of the jigsaw that the legal teams use in deciding whether to settle or proceed with the claim.

Therefore what are we to make of all this in our day-to-day management of patients? If we take a decision not to follow a guideline or protocol, we need to have a reasoned argument for taking that decision. This applies whether the decision is taken on an individual patient basis or if we have a fundamental issue with the recommendations made within the guideline or the reasoning behind it. After all, guidelines are just guidelines, not mandates, aren't they? However, in light of Montgomery it would be important to explain to the patient the rationale behind the departure from a NICE guideline or standard hospital protocol.

As long as Bolam continues to be recognised by the law, we may (I think) rely on Foster's argument:[13] "Clinicians are worried about protocols because they think that failure to follow them will necessarily connote negligence. This is nonsense. The Bolam test does not cease to apply simply because a protocol has been drafted." However, given the evolving state of medical negligence litigation in 2016 and the Montgomery assault on Bolam, we would also need to ensure that our position was Bolitho logically and scientifically supportable from a judicial perspective.

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