“Advice, not Orders”? The evolving legal status of clinical guidelines

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DM holds degrees in medicine and law. He is a clinical researcher in emergency medicine interested in clinical decision making. CP is a retired customer experience professional with a particular interest in social inclusion and consumer rights. JH is an academic lawyer with an interest in medical law.

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Healthcare professionals are expected to deliver care that is consistent with clinical guidelines. In this article, we show that the English courts are increasingly willing to be persuaded by written guidelines when determining the standard of care in cases of alleged clinical negligence. This reflects a wider shift in the approach taken by courts in a number of common law jurisdictions around the world. However, we argue that written guidelines are still only one element that courts should consider when determining the standard of care. It is possible to deliver perfect care that deviates from professional guidelines and even to deliver negligent care by uncritically following a guideline that is flawed. We further argue that written guidelines are relevant beyond defining the accepted standard of care. This is because the decision to deviate from a guideline suggests the existence of multiple approaches that should be discussed with patients as part of ensuring informed consent. It is therefore likely that written guidelines will become an even more prominent feature of the medicolegal landscape in future years.

Clinical guidelines aim to reduce unnecessary variation, help clinicians make evidence-based decisions, and ultimately improve patient outcomes[1]. However, clinical practice often diverges from recommendations made by professional bodies[2 3].

Possible reasons for low guideline uptake include logistical barriers, local policies, clinician preference, varying interpretations of study data, and the availability of multiple acceptable solutions to a single problem. A further possibility is a lack of capacity to keep abreast of all guidelines[1]. The former NHS Library, for example listed 152 individual publishers of clinical guidelines one of which has published over 100 guidelines[2] and full guidelines produced by the National Institute for Health and Care Excellence (NICE) can run to almost 1,000 pages[4 5]. It is also possible, however, that clinicians consider professional guidelines to be mere recommendations: "*advice, not orders*"[6]. This article argues that such a view is being steadily eroded by developments in English common law, which reflects a wider change in approach by courts around the world. Nevertheless, guidelines are fallible and should only be treated as another type of evidence by those tasked with determining the standard of care in any given set of circumstances. They may however pose implications for shared decision making and the process of obtaining informed consent before embarking on a treatment strategy. Clinicians should be aware of these developments when choosing how best to incorporate written guidelines into their practice.

The global reach of common law

Common law describes a body of judicial decisions reached by earlier courts. It is based on the concept of *stare decisis* ("to stand by things decided") and aims to achieve consistency between cases and certainty within the law. Up to a third of countries operate legal systems within the common law tradition. While each country is naturally free to develop its own approach, courts in common law jurisdictions are often influenced by persuasive judgments from those in other countries[7 8]. The approach of the English courts, for example, has been influenced by the judgments of foreign courts. Similarly, a single judicial approach may be recognised as arising across countries as geographically and culturally distinct as the UK, Singapore, India, and Australia[8].

Determining the standard of care in clinical negligence

The pre-eminence of written guidelines is an inevitable consequence of the judicial move towards viewing the standard of care as a question of law to be determined by the court rather than by expert witnesses.

Liability for negligence in English law requires (1) a duty of care, (2) breach of that duty, (3) that the breach caused harm and (4) that the harm was not too remote a consequence of that breach[9].

Whether a duty of care is breached depends on whether or not the plaintiff's actions fell below the relevant "standard of care". Historically, the minimum standard of care in English tort law has been determined by recourse to accepted medical practice and not written guidelines[10]. In *Bolam* (1957), Mr Justice McNair found that a claim of negligence must fail if a clinician "*acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art*"[11]. Under *Bolam*, a doctor could freely depart from guidelines as long as he could find expert witnesses willing to state that this was acceptable behaviour[10]. In this respect, the courts were reluctant to privilege written guidelines over the views of expert witnesses. For example, in *Loveday* (1991), Lord Justice Stuart-Smith ruled that published guidelines "*cannot be relied upon as though it was evidence of qualified experts not called in witness*"[12].

However, *Bolam* has been revised over the last 20 years, most notably by *Bolitho* (1996) in which the House of Lords found that the minimum standard of care is a question of *law* to be determined by the court rather than other doctors[13]. According to Lord Brown-Wilkinson, "*the court has to subject the expert medical evidence to scrutiny and to decide whether the practice is reasonable... the issue of reasonableness is for the court and not the medical profession*"[13]. This move towards an objective test for determining the minimum standard of care has enhanced the significance of clinical guidelines. The courts have since shown increasing willingness to follow national guidelines when determining the legal standard of care, for example in *Re C* (1998)[14], *Penney* (2000)[15] and *Fotedar* (2005)[16]. In *Fotedar*, the court assigned greater weight to guidance from the Royal College of Obstetricians and Gynaecologists (RCOG) than to expert witnesses when determining whether it was acceptable to perform a vacuum extraction delivery before the cervix was fully dilated. In explaining his decision, Mr Justice Gray said "*protocols such as these appear to me to give valuable guidance as to what is and what is not acceptable practice*". Unsurprisingly, there is an increasing tendency for claimants to argue that divergence from guidelines is *prima facie* evidence of negligence[17].

The fallibility of clinical guidelines

Although written guidelines are increasingly used in defining the standard of care, their role may still be understood within the context of *Bolam*. Guidelines are considered as representing "*a practice accepted as proper by a responsible body of medical men skilled in that particular art*"[11]. For example, in *Bland* (1993), Lord Goff said "*if a doctor… acts in accordance with the medical practice now being evolved by the Medical Ethics Committee of the BMA, he will be acting with the benefit of guidance from a responsible and competent body of professional opinion, as required by the Bolam test*"[18]. The Court of Appeal adopted a similar position in relation to GMC guidance in *Burke*[19].

However, it is also clear that the courts are unwilling to accept written guidelines uncritically and that such documents are subject to judicial scrutiny in the same way as evidence from expert witnesses. In *Bolitho*, Lord Browne-Wilkinson said: "*if it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible"*[13]. It is therefore beholden on clinicians to act in a way that is "reasonable and responsible" regardless of whether or not they are following clinical guidelines. The courts have shown considerable willingness to reach conclusions that diverge from professional evidence. For example, in *Marriott* (1999), the judge at first instance stated "*I have concluded that if there is a body of opinion which supports the course… then such an approach is not reasonably prudent"*[20]. Similarly, although Lord Goff accepted guidance published by the Medical Ethics Committee of the BMA in *Bland*, he did not accept this at face value and instead preceded his endorsement of the guideline with the words "*study of this document left me in no doubt that…*"[18]. The courts – and not expert witnesses or published guidelines – remain the final arbiter or what is "reasonable and responsible".

This caveat is important for clinicians faced with conflicting guidelines and recommendations to pursue actions that may prove to be unlawful. During the COVID-19 pandemic, the BMA published ethical guidance for doctors faced with making triage decisions to protect overwhelmed critical care resources[21]. However, significant concerns have been raised that this guidance did not give due consideration to doctors' legal obligations and could expose doctors to both civil and criminal liability[22].

NICE issued a rapid guideline on critical care during the COVID-19 pandemic, which recommended that all adult patients be assessed for frailty on admission to hospital using the 9-point Clinical Frailty Scale (CFS). This assessment would then inform whether or not patients were likely to survive (and so should be prioritised for) admission to intensive care units. It was quickly pointed out that a tool designed to measure a physiological process related to ageing should not be applied to people with long-term stable disabilities. Legal challenges claimed that NICE published its guideline in breach of the public sector equality duty (s.149 Equality Act 2010), without consulting with disabled people, and irrationally applied an inappropriate tool without caveat across the whole adult population. NICE subsequently amended this guideline[23], but it will continue to serve as a reminder to clinicians that their duties extend beyond uncritical acquiescence to written guidelines.

It is likely that the weight accorded by the courts to a written guideline will be influenced by its origin and the process by which recommendations were developed. For example, it has been proposed that NICE recommendations occupy a special tier in the hierarchy of written guidance because of their central authority, wide reach, and the extensive guideline development process[24].

NICE guidelines are usually developed over a period measured in years and involve a wide range of experts and stakeholders[25]. Other commentators have suggested that documents published by the government, NHS and professional regulators may carry more legal weight than those issued by organisations such as the BMA[22].

However, it is likely that the courts will continue to consider each written guideline on its own merits in the same way that the evidence of an expert witness is not accepted purely on the basis of qualifications and eminence. NICE might usually be an authoritative source of guidance but its "rapid guideline" on COVID-19 was challenged for failing to consult with disabled people and so overlooking their needs[22 23]. This important omission might not have occurred had the document been developed over the usual timescale associated with NICE guidelines. Similarly, although some commentators have suggested that guidelines issued by the BMA are "unauthoritative" by virtue of their origin with a professional association[22], Lord Goff was clearly impressed by the standard of BMA guidance in *Bolitho*[13].

Although clinicians will often be able to take "short-cuts" by trusting guidelines published by reputable sources, they should be aware that this will not be sufficient under all circumstances.

Implications for informed consent

Guidelines may be fallible and only another line of evidence available to courts tasked with determining the relevant standard of care. However, one respect in which the legal importance of written guidelines has been understated is their role in establishing informed consent. Even the most sensible and carefully documented decision to follow or depart from written guidance could expose a clinician to risk of a claim if consent to treatment is obtained negligently.

The standard of care required of a doctor taking consent from a patient has historically been defined by *Bolam*; an approach re-affirmed by the House of Lords in *Sidaway* (1985)[26]. In *Sidaway*, Lord Diplock warned that a frank discussion with the patient about alternative treatments could risk "*deterring the patient from undergoing the treatment which in the expert opinion of the doctor it is in the patient's interest to undergo... to decide what risks the existence of which a patient should be voluntarily warned... is as much an exercise of professional skill and judgment as any other part of the doctor's comprehensive duty of care to the individual patient*". Perhaps unsurprisingly, the paternalistic approach in *Sidaway* did not survive. Increasing health literacy and the modern emphases on patient autonomy and shared decision making coupled with the weakening impact of a number of earlier judgments saw *Sidaway* finally overruled by their lordships in *Montgomery* (2015)[27].

In *Montgomery*, the claimant, a pregnant woman of small stature and with diabetes was not warned about the risk of shoulder dystocia from a vaginal birth because her surgeon did not believe that the alternative mode of delivery (i.e. caesarean section) was justified. The delivery was subsequently complicated by shoulder dystocia and, during instrumented delivery, the child suffered hypoxic injury and cerebral palsy. The claimant argued that she would have pursued a caesarean section had she been warned that there was even a small risk of this outcome from a vaginal delivery. This was despite the fact that written guidance from the Royal College of Obstetricians and Gynaecologists indicated that caesarean section was not clinically indicated in the claimant's case[28]. In their judgment, Lords Kerr and Reid wrote that "*the doctor is... under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments*". They added that the test of "materiality" was "*whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach a significant risk, or the doctor is or should be aware that the particular patient would be likely to attach significance to it*". Although this definition of materiality was formulated in relation to risk, it seems likely that the same test would be used to determine whether a patient should be informed about alternative treatments[29]. This could lead to a negligence claim if the patient then came to harm and successfully argued that they would have pursued a different course had been made sufficiently aware and had the time to consider the available options.

When a clinician recommends an approach that is contrary to written guidance, this suggests the existence of at least two acceptable approaches to managing the patient's presentation. The same is true in the event of a clinician proposing an approach in the presence of conflicting guidelines. *Montgomery* has enshrined shared decision making in law and obliges clinicians to discuss alternative approaches with patients. As a result, it may often be insufficient to simply apply written guidelines without a documented discussion with the patient about alternative approaches as part of a process of informed consent.

Conclusion

Clinical guidelines will become increasingly important over the coming years as a result of developments in English common law. As these judgments have been cited approvingly by courts in a range of countries, including Singapore, India, and Australia[30-32], this represents a global paradigm shift towards an environment in which courts prefer to use clinical guidelines when determining the standard of care and whether or not consent was obtained appropriately. However, written guidelines are not infallible and should only be used to help courts determine the relevant standard of care that should be applied in each case. This situation may leave clinicians in an unenviable position but one

that may be more comfortable when clinical decisions – including alternative treatment approaches – are shared with the patient.

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