

CLINICAL GUIDELINES, PROFESSIONAL HORIZONS AND LEGAL REALITIES

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ABSTRACT

In medical negligence litigation, the standard for breach of duty is measured against the Bolam test which reflects accepted practice. Despite protracted debate and common law development, the Bolam standard remains the touchstone for litigation in this area. Clinical guidelines (CGs) are statements based upon best available medical evidence and are designed to facilitate clinical decision-making to optimise outcomes thereby reflecting expected practice. Nevertheless, there is little research that considers how CGs engage in litigation and their influence on judicial reasoning. Given the increasing pressures on the NHS amid rising costs of litigation, these are important issues. This study provides an original contribution to the literature on CGs in determining breach of duty in law. Using a mixed methods' approach, data from multiple sources have been gathered and analysed to assess the use of CGs by lawyers and the courts thereby adding to the discourse on the judicial shift away from deference to Bolam. It concludes by offering a conceptual basis for the use of CGs within a framework for reasonableness and promotes their principled use while avoiding constraints on expert testimony, experience, and exercise of clinical discretion. This study has relevance for academics, legal and medical practitioners, and policy makers.

KEYWORDS: breach of duty, clinical guidelines, doctors, negligence, reasonableness, standard of care

I. INTRODUCTION

The standard for breach of duty in medical negligence litigation is measured against the Bolam test in that a doctor ‘is not guilty of negligence if he has acted in accordance with [a] practice accepted as proper by a responsible body of medical men skilled in that particular art’.¹ Application of the Bolam test, alongside deference to medical expert testimony, has long been regarded as secession of judicial authority to doctors in setting the standard of care.²

A negligence test rooted in professional tradition is seen as outdated in today’s context, where accountability is largely guided by formal protocols and evidence-based standards. McNair J’s pronouncement that ‘a doctor is not negligent, if he is acting in accordance with ... a practice [accepted as proper by a responsible body of doctors], merely because there is a body of opinion that takes a contrary view’, seems to have created a traction that inhibits judicial challenge of expert opinion. In fact, it is commonly understood that where there are differing schools of thought, doctors cannot be negligent if a professional and responsible opinion considers their conduct to be acceptable even if it was rejected by the bulk of expert opinion.³

The advent of Bolitho promised some retrieval of judicial authority. In the only substantive speech, Lord Browne-Wilkinson stated (in relation to diagnosis and treatment) that the court must ‘be satisfied that the exponents of the body of opinion relied upon can demonstrate that such an opinion has a logical basis’.⁴ The concept of ‘logical basis’ has received considerable attention.⁵ The so-called ‘gloss’ that Bolitho applies to the Bolam standard has been interpreted as presaging a shift from unqualified acceptance of medical opinion, to one of a more inquisitorial approach by the court. This raises the question as to whether a set of objective standards might usefully provide the court with the knowledge and assurance of the standard expected against which breach of duty can be measured.

Clinical guidelines (CGs) are statements produced upon the best available evidence and are designed to assist clinicians to make optimal decisions about clinical care by promoting interventions of proven benefit. Evidence-based guidelines aim to promote consistency of clinical decision-making and narrow the gap between practice and best evidence from research.⁶ Their uptake and proliferation across the globe is testament to concerns shared by all contemporary healthcare systems: the ongoing variations in clinical care due to sub-optimal use

¹Bolam v Friern Hospital Management Committee [1957] 1 WLR 582, 587 (McNair J).

² H Teff, ‘The Standard of Care in Medical Negligence—Moving on from Bolam’ (1998) 18 OJLS 473; M Brazier and J Miola, ‘Bye-bye Bolam: A Medical Litigation Revolution?’ (2000) 8 Med LR 85–115.

³Teff, *ibid* 475.

⁴Bolitho v City & Hackney Health Authority [1997] 3 WLR 1151, 1159.

⁵ Brazier and Miola (n 2); H Teff, ‘Clinical Guidelines, Negligence and Medical Practice’ in M Freeman and A Lewis (eds), *Law and Medicine: Current Legal Issues Volume 3* (OUP 2000) 67–80.

⁶ SH Woolf and others, ‘Clinical Guidelines: Potential Benefits, Limitations, and Harms of Clinical Guidelines’ (1999) 318 (7182) *BMJ* 527–30.

of services or medical interventions, escalating costs of healthcare and increasing demands on capacity.

The literature remains relatively sparse on the impact of CGs in medical negligence litigation. Apparent inconsistencies in the way guidelines are used by the courts provided the impetus for our research. The courts are not unfamiliar with the potentially pivotal role of guidelines in asserting the expected standard of care. Nevertheless, their role may vary even within the same case at different stages of the litigation process. In *Montgomery*, for example, a case that concerned negligent disclosure of information, the Supreme Court had been influenced considerably by professional guidelines which promoted comprehensive standards of disclosure.⁷ Those guidelines were seen as more representative of contemporary standards which had outpaced current law.⁸ Earlier, in the same case, the Court of Session had been more equivocal about the role of guidelines. In the context of foetal distress, for example, even though CGs indicated that the foetal heart rate tracing demonstrated pathological lack of oxygen, this finding had to be considered by the doctor in its clinical context.⁹ While CGs were relevant in the exercise of clinical discretion they were not considered determinative of the course of action to be followed.¹⁰ Clinical guidelines were mere ‘indications of possible courses of action in particular circumstances’ and not set in stone.¹¹

It is not the purpose of this paper to rehearse well-trodden ground around *Bolam*, *Bolitho* and breach of duty, nor the theoretical basis underlying standards for developing CGs and arguments in favour of CGs in litigation. Some years ago, the *Bolitho* decision, alongside other socio-political developments led us to consider whether evidence-based CGs from authoritative bodies might begin to play a greater role in measuring the standard for breach of duty of care in medical negligence.¹² In the first published empirical study (in England) on the role of CGs in clinical negligence litigation,¹³ we concluded that a high proportion of lawyers were familiar with the use of CGs in litigation and that there was an expectation that their use would increase.¹⁴

⁷ *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871.

⁸ GMC, *Consent: Patients and Doctors Making Decisions Together* (GMC 2008); GMC, *Good Medical Practice* (GMC 2013); *Montgomery v Lanarkshire* [2015] UKSC 11, [77]: These guidelines were not referred to by the Inner Court of the House of Session.

⁹ *Montgomery v Lanarkshire Health Board* [2013] CSIH 3, [58].

¹⁰ *ibid* [59].

¹¹ *ibid*.

¹² A Samanta and J Samanta, ‘Legal Considerations of Guidelines: Will NICE Make a Difference?’ (2003) 96 *JRSM* 133; A “new” Professionalism Was Emerging: Safeguarding Patients: Lessons Learned from the Past—Proposals for the Future: 5th Report (Cmnd 6394, 2003) and the National Institute for Health and Care Excellence (NICE) was established on 1 April 1999. A significant part of its remit is the development of evidence-based clinical guidelines.

¹³ A Samanta and others, ‘The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the *Bolam* Standard?’ (2006) 14 *Med LR* 321–66.

¹⁴ *ibid*.

In this study,¹⁵ we explore how and why CGs are used in medical litigation in relation to: awareness and use by lawyers (a); deployment in the litigation process (b); use by the court (c); impact on judicial decision-making (d); settlement of claims (e); and potential barriers (f). Data are derived from multiple sources to provide a unique and meaningful insight into the evolving role of CGs in medical litigation.

We first describe the methods used to collect and analyse quantitative and qualitative data to provide headline metrics and key themes. We then discuss how guidelines are deployed in setting the standard for breach of duty, impact on judicial decision-making, settlement of claims, and perceived potential barriers to their use. We conclude that CGs can be instrumental in deciding whether to abandon or settle a claim at any stage in the litigation process. Cases may settle on the proposition that clinicians should follow authoritative guidance unless there are cogent reasons for not doing so. We propose that CGs should be used in litigation within a framework of reasonableness on a case by case basis.

The implications and impact of this original research is relevant for legal and medical practitioners, the courts, clinical governance and regulatory bodies, and healthcare policy-makers and is particularly germane at a time when costs of litigation and compensation are burgeoning.¹⁶

II. METHODS

A. Methodological Approach

The focus of this study was not to provide a quantifiable assessment of the use of CGs, but on how and why they are used in medical negligence litigation, and accordingly a 'mixed, multi-strategy' approach was used.¹⁷ The research design uses different sources to answer multiple questions within a complex environment¹⁸ and provides a deeper and more critical appreciation than a single strategy.¹⁹ We have used this technique successfully in the past²⁰ and consider this well-placed to capture the richness of the interaction between CGs and medical negligence litigation. Multi-source qualitative and quantitative data to explore issues under heads a–f described above were gathered from a questionnaire survey (a, b, c, d), six in-depth interviews (IDIs) (a, b, c, d), a CDG (consensus discussion group) (f), a detailed review of the literature and case law

¹⁵ Research ethics approval was granted by De Montfort University.

¹⁶ A Crawford, 'NHS Faces Huge Clinical Negligence Legal Fees Bill' NHS Resolution (21 January 2020) <<https://www.bbc.co.uk/news/health-51180944>> accessed 4 January 2021. The NHS in England faces legal fees of £4.3 billion to settle outstanding claims.

¹⁷ A Bryman, *Social Research Methods* (OUP 2001).

¹⁸ J Brannen, *Mixed Methods Research: A Discussion Paper* (ESRC National Centre for Research Methods 2005). <<http://eprints.ncrm.ac.uk/89/1/MethodsReviewPaperNCRM-005.pdf>> accessed 4 January 2021.

¹⁹ L Hurmerinta-Peltomaki and N Nummela, 'Mixed Methods in International Business Research: A Value Added Perspective' (2006) 46 *Man Int Rev* 439–59.

²⁰ J Samanta, A Samanta and O Madhloom, 'A Rights-Based Proposal for Managing Faith-Based Values and Expectations of Migrants at End-of-Life Illustrated by an Empirical Study Involving South Asians in the UK' (2018) 32 *Bioethics* 368–77.

(c, d), and metrics from NHS Resolution²¹ (e). Triangulation of data strengthened the validity of the study.²² For the reasons above, we believe that the evidence we have obtained from this project is robust and of value for providing useful insights into the areas of enquiry.

Following ethics approval, the study was undertaken in three phases: (i) an online survey of practising lawyers for self-reported use of CGs in medical negligence litigation; collection of data from NHS Resolution regarding medical litigation claims between 2007/08 and 2016/17²³; (ii) in-depth Skype or conference-call interviews with senior lawyers peer-recognised for their expertise in medical negligence, to explore how CGs are used currently in litigation; and (iii) a CDG between clinicians, lawyers and other healthcare professionals to examine perceptions of barriers to evidence-based CGs in practice.²⁴

B. Data Collection

A questionnaire similar to one used previously²⁵ was circulated to facilitate comparison with previous results,²⁶ and to ascertain change over time. The focus was on participants' actual or observed experiences of how CGs were used at all stages of the litigation process. Free-text boxes encouraged further elaboration of responses. Following a 'pilot', the questionnaire was refined²⁷ and conducted using SurveyMonkey which has been validated as a comprehensive and reliable tool.²⁸ Solicitors and barristers practising mainly in medical negligence in England and Wales were identified using Chambers UK Guide to the Legal Profession²⁹ and the Legal 500 Directory.³⁰ A representative sample of practising lawyers with significant experience was obtained from law firms' websites applying a filter of at least three or more new cases of medical negligence per year. A cover letter and questionnaire were emailed to 289 practising lawyers with reminders sent to non-responders at four and eight-week intervals.

²¹NHS Resolution is an arm's length body of the Department of Health and Social Care.

²² A Strauss and J Corbin, *Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory* (3rd edn, Sage Publications 1998); A O'Cathain, E Murphy, and J Nicholl, 'Three Techniques for Integrating Data in Mixed Methods Studies' (2010) 314 *BMJ* 1147–150.

²³ This period was chosen to approximate the date of our previous study to facilitate comparison of longitudinal change.

²⁴ Phase 3 took place during the second part of a national interdisciplinary conference. Delegates discussed key issues regarding potential barriers to the use of CGs.

²⁵ Samanta and others (n 13).

²⁶ We accept that the respondents were not the same as before. However, the survey was only one part of the study and the results have been triangulated with data from other sources.

²⁷ J Lumsden, 'Online Questionnaire Design Guidelines' in A Reynolds, R Woods, J Baker (eds), *Handbook of Research on Electronic Surveys and Measurements* (Idea Group Reference 2007) 44–64.

²⁸ C Hewson, 'Research Methods on the Internet' in JA Danowski and L Cantoni (eds) *Communication and Technology* (Boston De Gruyter 2015).

²⁹ Chambers UK Guide to the Legal Profession (2017) <<https://chambers.com>> accessed 4 January 2021.

³⁰ Legal 500 Directory (2017) <<https://www.legal500.com/books/l500/directory>>

A principal function of NHS Resolution pertains to claims for compensation brought against the NHS in England for negligent medical care.³⁰ NHS Resolution provided data on the total number of claims settled and numbers of (i) claims settled without proceedings, (ii) claims settled with proceedings, and (iii) claims settled with (or without) trial and the level of damages awarded (where relevant).³¹

Invitations to be interviewed were sent to ten participants identified through the survey on the basis of their expertise, size of medical negligence caseload, and six agreed.³² IDIs lasted between 45 and 90 min. These were semi-structured, audiorecorded, and conducted by at least two investigators.

Senior clinicians across several specialisms were canvassed to ascertain their perceptions as to the major hurdles to CGs in practice.³³ The following were most frequently raised: (i) limited resources; (ii) limited support and facilitation by employing organisations; and (iii) erosion of clinical autonomy. These areas were explored with sixteen participants (eight doctors, five lawyers, and three other health professionals) through a CDG.³⁴

C. Data Analysis and Results

1. Analysis

Quantitative data were analysed using Microsoft Excel and standard statistical tests. Chi-square analysis was used for bivariate associations, and Wilcoxon-type test to identify trends.³⁵ Qualitative data from unabridged transcripts were analysed independently by two researchers as the most rigorous approach³⁶ to limit potential bias.³⁷ Words and phrases were assigned to conceptual categories by frequency to develop themes systematically, with regular cross-over checking to assure consistency of process and calibration between investigators.

2. Results

Quantitative results and claims' metrics are shown as headline figures (Figures 1 and 2). Qualitative results showed the following emergent themes: deployment of CGs in litigation, CGs and the legal standard for breach of duty, impact of CGs

³⁰ NHS Resolution deals with over 90% of medical negligence claims and uses the services of several legal agencies in the country <<https://resolution.nhs.uk/services/claims-management/>> accessed 4 January 2021.

³¹ Raw data were kindly provided by NHS Resolution. Responsibility for collation, analysis, conclusions, and commentary lies with the authors.

³² Four barristers, two solicitors, and an obstetric claims expert.

³³ A.S., Personal communication with experienced health professionals.

³⁴ EJ Hill and others, 'Consensual Qualitative Research; An Update' (2005) 52 J Counsel Psychol 192–205.

³⁵ J Cuzick, 'A Wilcoxon-Type Test for Trend' (1985) 4 Stat Med 87–90; Statistically significant results are those that reject the null hypothesis (no difference between the comparison groups) and a probability level less than 5% that the result occurred purely by chance ($p < 0.05$).

³⁶ M Bloor and others, *Focus Groups and Social Research* (Sage 2001).

³⁷ Supplemented by a qualitative data analysis tool (NVivo) to input into the overall analysis.

on judicial decisions, CGs in settlement of claims, and potential barriers to CGs at the medical and legal interface. Direct quotations derived from IDI or survey free-text comments (SFTs) are used to illustrate the views expressed and the emergent themes within each domain.

III. DISCUSSION

A. Headline Figures

1. Survey Data

In the present survey³⁸ (compared with our previous study), a statistically significant higher proportion of barristers participated (65.5% v 35.5%, $p < 0.05$).³⁹ There was

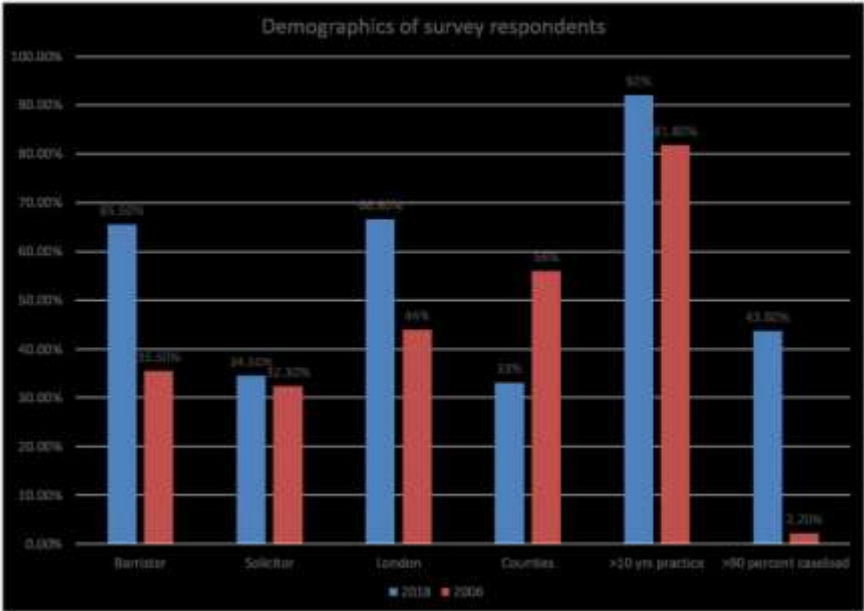


Figure 1: Respondent demographics.

³⁸ The response rate was 13.5% (39/289) (average response rates for on-line surveys 10–15%, peoplepulse.com). We use the results to illustrate changing trends and do not assert generalisability for individual cases.

³⁹ The ‘null hypothesis’ assumes no meaningful difference between values being compared. This is tested using a test for ‘significance’. The ‘p-value’ (probability value) is the statistical likelihood of obtaining results at least as extreme as the results found based on the default position that no relationship exists between the two phenomena. A value of $p < 0.05$ means there is a less than a 5% chance that the noted difference is random (there is 95% confidence that a ‘significant’ difference exists between the phenomena).

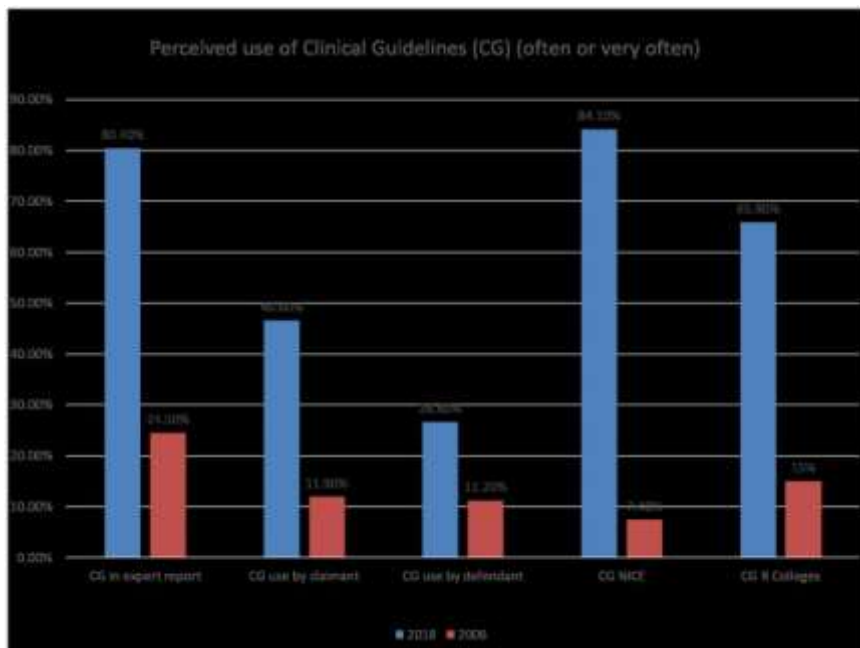


Figure 2: Use of clinical guidelines.

also a statistically significant higher proportion of respondents who reported that medical negligence accounted for more than 90% of their caseload (43.8% v 2.2%, $p < 0.01$). There was no statistically significant difference (between the surveys) in the proportions of solicitors, those in practice for over 10 years, or in respect of their place of work (London or the Counties).

The following significantly increasing trends were identified: CGs used in expert witness reports, 84.4% v 24.5% ($p < 0.05$); CGs used by claimants, 46.6% v 11.9% ($p < 0.05$); CGs used by defendants 26.6% v 11.2% ($p < 0.05$); use of CGs from NICE 84.1% v 7.4% ($p < 0.01$); use of CGs from the Royal Colleges 65.9% v to 15% ($p < 0.01$).

2. Claims

NHS Resolution data reveal several noteworthy trends. Between 2007/08 and 2016/17, the total number of claims against the NHS almost doubled, indicating a significant rise. Of these, approximately forty per cent of claims (at each time point) were either withdrawn or settled without award of damages. For cases settled out of court, or following some form of alternative dispute resolution, damages rose from £45.4 million (2007/08) to £97.5 million (2016/17). There was a significant trend for increased payment of damages (immediate payment plus periodical payments together with future estimates) for cases settled with court proceedings and/or following trial. This rose from £554.8 million to £1.34 billion over the same period.

B. Deployment of Clinical Guidelines in Medical Negligence Litigation

Clinical guidelines are developed on the basis of high-level scientific evidence and are used by clinicians, policy makers, and funders to make effective, cost-efficient decisions that promote optimal outcomes for patients.⁴⁰ It is not unreasonable therefore to expect that CGs will be followed and that failure to do so, without just cause, might have negative repercussions. Over the last few decades evidence-based guidance has proliferated significantly.⁴¹ Hence, CGs from an authoritative provenance can be expected to reflect the concept of reasonable and responsible medical care.⁴² This approach towards CGs being used as a matter of evidence was recognised by one participant:

When I started practice, lots of experts in meetings would say ‘well, they are only guidelines’ and that was the mantra ... but in the light of research and all the modelling that is done to improve healthcare and health generally, that argument does not hold much water now or in the future.⁴³

A unique dimension of this study is a comparison of current data with that obtained previously. The findings strongly reveal that use of CGs, by defendants as well as claimants, has increased significantly, principally guidelines from NICE and the Royal Colleges relating to obstetrics and cancer referral. Significantly more respondents used CGs ‘often, or very often’ during all stages of proceedings than previously:

We used to refer to teaching textbooks and published articles. Now it is far more common to refer to relevant NICE guidelines and other published guidelines, as well as online sources. This is increasing.⁴⁴

Drivers include quality improvement initiatives and modelling pathways designed to optimise healthcare delivery: ‘The use of guidelines will increase in the future because I can see the change has been the drive to improve governance, and the most accessible tool used is guidelines.’⁴⁵ To enhance quality assurance and governance the intrinsic robustness of CGs and the quality of the evidence-base was centrally important since: ‘There are orders of quality and relevance. Guidelines from national organisations will be very powerful pieces of evidence.’⁴⁶ The marked preference for protocols underpinned by recognised indicators of quality applied across the board from guidelines of national provenance to those produced at regional and local levels. Several participants suggested that the increased quality of the scientific and medical evidence-base

⁴⁰Woolf and others (n 6).

⁴¹Guidelines have proliferated and have global reach into multiple sectors.

⁴²Loveday v Renton [1990] 1 Med LR 1117.

⁴³Participant 2: (Barrister)(IDI).

⁴⁴Respondent 7: (Barrister)(SFT)

⁴⁵Respondent 5: (Solicitor)(SFT)

⁴⁶Participant 1: (Barrister)(IDI)

that underpinned CGs, together with more refined production and enhanced accountability, meant that their future use would be greater and therefore be more challenging for defendants to advance convincing arguments as to why they chose not to follow CGs in circumstances where their use appeared to be warranted. According to a leading Queen's Counsel specialising in Clinical Negligence, national CGs at the time of the index event in a negligence claim are likely to provide a useful barometer of the standard of care expected.⁴⁷ Since most NHS Trusts will have devised or adopted protocols or policies for many aspects of the management and treatment of patients, it is imperative that expert witnesses remain abreast of all relevant national and local guidance and be prepared to take these into account.⁴⁸

The resonance of findings from both quantitative and qualitative sources supports the contention that use of CGs in litigation has increased and is expected to grow. Nevertheless, total reliance on CGs could have its own drawbacks in that: 'Slavish reliance on guidelines can lead to [clinicians] losing the ability to think for themselves and failure to personalise treatment, which would not be in the best interests of patients.'⁴⁹ However, this evidential weight carries a double edge. As Coggon and colleagues warn, strict adherence to national protocols can stifle innovation and overlook the subtleties of clinical judgment, potentially disadvantaging pioneering treatments that fall outside established guidelines. Although routine, uncritical deployment of evidence-based guidance may be accompanied by more consistent practice this might be achieved only at the expense of curtailing delivery of individualised care that aligns with the needs of particular patients. This could diminish the presumption that non-compliance would *prima facie* represent evidence of breach of the standard of care and argue in favour of a more enquiring position for the court to undertake in each case.

C. Clinical Guidelines Used by the Court

1. Determinative?

Notable differences of opinion existed among interview participants who felt that CGs were determinative of the standard of care and others who disagreed. Some bold assertions were made: 'Deviation from guidelines is relied on as evidence as negligence'⁵⁰ and '[c]linical guidelines are essential in determining whether or not a clinician has met the expected standard.'⁵¹

The extent to which CGs were likely to be viewed as determinative was thought to be influenced significantly by pedigree and provenance: 'Generally speaking, if guidelines are from bodies such as NICE, the GMC or the Colleges, then judges are going to take notice of them.'⁵² '[The courts] ... place a high

⁴⁷ N Poole, *Clinical Negligence Made Clear* (Bath Publishing 2019) 184.

⁴⁸ *ibid.*

⁴⁹ Participant 6: (Claims expert)(IDI).

⁵⁰ Respondent 11: (Barrister)(SFT).

⁵¹ Respondent 21: (Barrister)(SFT).

⁵² Participant 4: (Barrister)(IDI).

reliance repeatedly on NICE or [Royal College] guidelines and occasionally on local guidelines ... although with the latter it is usually to say that local guidelines may not always align with national guidance.’⁵³ Whether relevant and high-ranking CGs had been followed, or not, was considered to be a major factor of influence as to whether a case was likely to settle at an early stage: ‘Most cases, probably 95%, don’t go to trial but when they do there is often a NICE guideline lurking somewhere in the background.’⁵⁴ More generally, ‘In practice, guidelines are often taken as determinative and if there has been a clear failure to follow a guideline, that case will usually settle.’⁵⁵

Participants who considered that guidelines should not be determinative of the standard of care based this on their opinion that guidelines represented only one reasonable body of opinion. From this perspective there might well be several other reasonable opinions that would need to be considered especially if there was evidence that those alternatives were also being followed by responsible and competent doctors: ‘I have seen (NICE) guidelines being used as a proxy for the standard of care when it is not always appropriate.’⁵⁶ In order to counter such arguments effectively expert witnesses had to be: ‘fully on top of the literature and be ready to deploy it’.⁵⁷

The courts have not, to date, gone so far as to say that CGs are expressly determinative of the legal standard for breach of duty of care. Guidelines may be used as ‘swords’ by claimants or as ‘shields’ by defendants. In *Arkless*,⁵⁸ for example, the claimant had been examined by Dr Atkins following her injury caused by hyper-extension of her wrist.⁵⁹ Dr Atkins was unable to state definitively how he had examined the claimant. He described how he habitually examined a wrist for injury to the scaphoid bone, and the procedure he usually adopted.⁶¹ The court suggested that assistance as to what constituted reasonable medical practice could be obtained from ‘Guidelines for the Management of Scaphoid fractures in the Emergency Department’ published by the College of Emergency Medicine in 2013. Although the guidance post-dated the index injury, it was accepted as authoritative by both experts in relation to clinical practice at the time of the index event. The judge found that based on the CGs, medical literature, and expert testimony, three specific tests ought to have been undertaken.⁶⁰ In failing to administer the tests required by the guidelines, the defendant had not met the standard of care required.

⁵³ Participant 3: (Barrister)(IDI).

⁵⁴ Participant 5: (Solicitor)(IDI).

⁵⁵ Respondent 32: (Barrister)(SFT).

⁵⁶ Participant 6: (Claims expert)(IDI).

⁵⁷ *ibid.*

⁵⁸ *Arkless v Betsi Cadwaladr University Local Health Board* [2016] EWHC 330 (QB).

⁵⁹ The backs of her fingers had touched her arm. 61

Arkless (n 59) 4.

⁶⁰ *ibid* 22.

Evidence of CGs being used as determinative of the standard of care can be seen across first instance and appellate decisions. In *Adshead*,⁶¹ a GP was found to be negligent after failing to follow unambiguous recommendations in Department of Health guidance to refer urgently where potentially life-threatening symptoms were present. The widower sued the GP for failing to refer his wife to a breast cancer specialist when she presented with a palpable lump and tenderness. In rejecting the suggestion that a body of medical opinion existed that would have supported the defendant's action, Gray J referred to the 'Two-Week Wait' referral to hospital for suspected malignancy (in accordance with Department of Health guidance in force at the material time) and stated:

This is not a case where there is room for application of the Bolam principle In the case of a patient who presents with a potentially life-threatening symptom, I do not accept that a responsible general practitioner would delay referring her, even for a short period, in circumstances where the recommendation made unambiguously in the guidelines is to refer immediately.⁶²

By comparison, compliance with Royal College guidance was used to exonerate the defendants in *Wells*,⁶³ where parents brought an action following their baby's death due to meconium aspiration. At trial, both sides had referred to guidance from NICE and the Royal College of Obstetricians and Gynaecologists.⁶⁴ The court held that taking foetal blood samples (FBS) had given doctors a far clearer idea of foetal condition so that an appropriate clinical decision could be made. *Dingmans J* held that taking FBS allowed doctors to have a much better idea of the condition of the fetus to ensure that optimal decisions could be made. Although the guidelines did not show that outcomes would be different following FBS did not mean that it was unreasonable to undertake these.⁶⁵ The Claimant's action was dismissed on the basis that NICE guidelines supported taking FBS in the circumstances, thereby substantiating the reasonableness of the defendant's action.

A recurrent concern of some participants that is also reflected in the literature is that guidelines have potential to stifle responsible clinical innovation and creativity. In *Ratty*,⁶⁶ however, the court's reliance on a standard practice guideline did not function to suppress responsible surgical discretion. The claimant sought to rely on 'Marnham's rule' a medical rule of thumb that asserts that there should be no abdomino-perineal surgery without histological proof of

⁶¹ *Adshead v Tottle* (1 November 2007, Lawtel).

⁶² *ibid*.

⁶³ *Wells and another v University Hospital Southampton NHS Foundation Trust* [2015] EWHC 2376 (QB).

⁶⁴ National Institute for Health and Care Excellence, *Intrapartum Care: Care of Healthy Women and Their Babies During Childbirth* (NICE 2007) and Royal College of Obstetricians and Gynaecologists, *The Use of Electronic Fetal Monitoring* (RCOG, 2001).

⁶⁵ *Wells* (n 65).

⁶⁶ *Ratty v Haringey Health Authority* [1993] WL 137259295 (CA).

cancer.⁶⁷ The claimant had been found to have a lesion of the colon which appeared clinically to be highly suggestive of cancer. An initial biopsy was negative (which is not, by itself, conclusive proof of the absence of malignancy). Subsequent radiological investigations were reported as showing a stricture which appeared to be carcinomatous. Notwithstanding ‘Marnham’s rule’, the surgeon had resected the lesion, which was later found to be non-malignant. The Court of Appeal held that although Marnham’s rule represented a useful guide, it had no greater persuasive authority than this. In respect of this (clinical) rule vis-a-vis the defendant’s action, the Court of Appeal held that ‘[This] is a rule of general application, and should only be departed from under circumstances which plainly and unarguably justify such a course.’⁶⁸ Since the defendant surgeon had deviated from this on sensible clinical grounds he had not been negligent. A careful balance must be struck between not overly constraining medical practice, and the courts being too ready to endorse expert opinion. The courts need to take a ‘hard look’ before endorsing deviation from standard professional practice as reasonable and responsible in law.

2. Not Determinative or Relevant?

Some participants believed that guidelines whilst useful as evidence were only one part of the litigant’s armamentarium: ‘Guidelines are part of and have always been part of a picture, but they are not definitive.’⁶⁹ For some, CGs were seen as a potential constraint: ‘[CGs] are guidelines and not tramlines, so their use is limited.’⁷⁰ One barrister believed that the rapid proliferation of guidelines effectively constrained their potential use since both parties were likely to be able to point to guidance that supported their cause: ‘They [clinical guidelines] are helpful but defendants cherry pick. They are not mandatory.’⁷¹ This position, to some extent, is reflective of how published works and the research base have always been used by parties to justify and support their own positions.

The potential of CGs to define and potentially constrain the standard of care in law has long been recognised by guideline producing consortia. Guidance produced by the Royal College of Obstetricians and Gynaecologists, for example, includes an express proviso that their recommendations do not ‘dictate an exclusive course of management or treatment’. Instead, ‘[t]hey must be evaluated with reference to individual patient needs’.⁷² The need for clinicians to take account of the specific needs of individual patients contextualised against resource constraints and institutional policy is emphasised similarly.

⁶⁷ B Hurwitz, *Clinical Guidelines and the Law: Negligence, Discretion and Judgement* (CRC Press, Taylor & Francis 2018).

⁶⁸Ratty (n 68) 8.

⁶⁹Respondent 17: (Solicitor)(SFT).

⁷⁰Respondent 35: (Solicitor)(SFT).

⁷¹Respondent 27: (Barrister)(SFT).

⁷² RCOG, *About RCOG Guidelines: Green-Top Guidelines* (2020) <<https://www.rcog.org.uk/en/guidelines-research-services/guidelines/about-rcog-guidelines/#gtg>> accessed 4 January 2021. ‘Green-top’ guidelines have the strongest evidential foundations.

Nevertheless, the extent to which caveats such of these will be effective is likely to depend on whether all, or at least a large body of responsible practitioners, are following that guidance. A defendant practitioner would then need to show just cause as to why that guidance had not been followed. Rather than protecting the practitioner, such provisos might reflect an attempt to limit the potential liability of guideline-producing consortia.

In Bayley,⁷³ the Claimant developed post-partum pain and swelling in her leg, which was diagnosed as a deep vein thrombosis (DVT). She was discharged and told to visit the clinic the following day. The allegation of negligence concerned the defendant's failure to provide the claimant with graduated compression stockings. The defendant's evidence was that provision of stockings would not have made any material difference to the outcome although on the balance of probability it would have reduced her pain. Reference was made to NICE guidance to justify the decision not to provide stockings to prevent post thrombotic syndrome or venous thrombotic recurrence after a proximal DVT. On scrutinising the guideline the court noted:

The addendum to the NICE Clinical guidelines 144 issued in November 2015 [534/21-31] ... recommends that elastic graduated compression stockings are not offered to prevent post thrombotic syndrome or for the prevention of venous thrombotic recurrence after a proximal DVT.⁷⁴

The court recognised that this particular guideline did not apply to compression stockings for the management of leg symptoms that presented after a DVT had occurred nor for the prevention of thrombosis. From the court's perspective, since the stockings were neither mandatory nor compulsory, failure to provide stockings was therefore not evidence of negligence.

3. A Starting Threshold?

Based on the interview data as well as the SFTs, CGs appear to hold an intermediate status between being determinative and non-determinative evidence for establishing the standard of care. Generally, CGs were seen as the 'starting point' or 'threshold' for informing the expected standard of care: 'Clinical guidelines are a good tool for starting to assess the standard of care....guidelines should not be applied rigidly.'⁷⁵ There was (almost) a *prima facie* presumption that guidelines reflected the benchmark against which practice could be measured, particularly national guidelines from authoritative bodies: 'Clinical guidance is always helpful in a case. The NICE guidelines especially are incredibly user friendly and detailed.'⁷⁶ Some participants suggested that 'compelling evidence' would be necessary to justify any deviation. It was

⁷³ Bayley v George Eliot Hospital [2017] EWHC 3398 (QB).

⁷⁴ para 15.

⁷⁵ Respondent 34: (Solicitor)(SFT).

⁷⁶ Respondent 42: (Solicitor)(SFT).

asserted that as a general rule, clinicians should not depart from evidence-based guidelines without cogent reason.

From the perspectives of participants, whilst CGs may not be determinative of the standard of care, they will almost certainly inform the standard of reasonableness and more likely than not act as a starting point to assess whether the threshold for the standard had been met. Nevertheless, it is often their use as supportive evidence that is the crux:

It is rare to come across a case where liability could be assessed by a lawyer or judge on the basis of applying clinical guidelines alone. The [clinical guidelines] sometimes form useful background material in support of arguments.⁷⁷

In similar vein, the courts recognise the usefulness of evidence-based guidance as a starting point. In *C v North Cumbria*,⁷⁸ a midwife was found not to have been negligent in administering a second dose of prostin (a drug used to stimulate contractions) during a difficult delivery. Green J held that nationally respected guidelines were intended to be relied upon. The defendant had acted in accordance with guidance from the Data Sheet of the drug as well as the British National Formulary that suggested a second dose could be given if labour was not ‘established’:

The Defendant points out that these guidelines have been approved by regulators and professional bodies. They are not merely informal documents produced by manufacturers. They are intended to be relied upon and should accordingly carry considerable weight in favour of a midwife who acts consistently with them.⁷⁹

After considering the facts fully, the judge stated:

In conclusion my view is that *prima facie* a midwife who acts in accordance with the guidelines should be safe from a charge of negligence. However, in the present case since it is common ground that in some regards the guidelines are not satisfactory I do not decide this case upon the basis that adhering to guidelines is sufficient. I consider that the fact that Midwife Bragg acted in accordance with the guidelines is a factor militating against negligence but I also assess Midwife Bragg’s conduct against the benchmark of the other surrounding facts and circumstances.⁸⁰

⁷⁷Participant 4: (Barrister)(IDI).

⁷⁸*C v North Cumbria* [2014] EWHC 61 (QB).

⁷⁹*ibid* 84.

⁸⁰ *ibid*.

One way might be for clinicians to seek further opinion from colleagues where there is clinical doubt, this might not be possible in every situation. In C the guidance was seen to represent the ‘starting point’ or threshold for a more detailed examination of the standard against which breach of duty would be measured and required ‘a balancing of risks and benefits such that if the guidelines are adhered to then that is inherently likely to reflect a properly balanced (reasonable) decision.’⁸¹ Acting in accordance with guidance was a factor mitigating negligence. However, other facts and circumstances had to be assessed against this benchmark guidance.⁸² This begs the question as to how a reasonable practitioner in the defendant’s position could be expected to know that the guidelines were ‘not satisfactory’. By definition medical negligence disputes are examined forensically only after the event and with the full benefit of hindsight and expert evidence.

Our study supports the contention that the unique facts of each case provide nuanced layers to the analysis of breach of duty. It was unlikely that CGs would replace expert witness testimony:

Guidelines might reflect only one reasonable body of opinion ... there might well be another reasonable body which is not represented on the drafting committee’⁸³ and, ‘Guidelines are evidence of appropriate standards, but they are no more than guidelines and can be departed from in any given case. Usually justification or explanation is required.’⁸⁴

Of particular interest was the presumption that failure to follow guidelines could be considered to be negligent unless there were strong reasons to deviate from that position because: ‘Authoritative guidelines usually provide a good indication of where the threshold for the standard of duty is likely to be.’⁸⁵

Recognition of the need for clinical discretion and flexibility to be able to respond to the needs of particular patients was clear: ‘A case cannot succeed just on the basis of guidelines as there will always be competent physicians who don’t follow it, which therefore defeats the concept of breach of duty.’⁸⁶ For this reason, one participant cautioned against the possibility that CGs might come to replace clinical discretion:

Nationally recognised clinical guidelines will, of course, inform the standard of care to be applied by the court. However, guidelines should not come to replace the standard of care or be the automatic standard.’⁸⁷

⁸¹ibid 84(i).

⁸²ibid 84(v).

⁸³ (n 44).

⁸⁴ (n 52).

⁸⁵ (n 54).

⁸⁶ (n 47).

⁸⁷ (n 73).

The need for cases to be considered on merit was particularly evident:

Most clinical negligence cases are fact-specific and it is rare to come across a case where liability could be assessed on the basis of applying clinical guidelines alone. They form useful background material in support of arguments.⁸⁸

The court's approach to guidance informing or representing the threshold for the standard of care can be seen in *Spencer*.⁸⁹ A successful claim was brought for personal injuries and consequential losses arising from the defendant's negligent failure to warn of the potentially life-threatening significance of symptoms of DVT. The court referred to NICE guidance published shortly before Mr Spencer's surgery⁹⁰ and acknowledged 'that the determination as to whether a given practice is in accordance with the NICE guidelines is not by itself determinative of negligence, but it is highly relevant'.⁹¹

The courts recognise the importance of applying clinical judgment to individual patients. As stated in *Velarde*,⁹² a case that concerned a neonatal brain injury allegedly caused by negligent restriction of fluids, Langstaff J noted that he was 'struck by the refrain of a number of experts ... who spoke of the need to consider the individual child... rather than protocol'.⁹³ It therefore seems that in litigation the courts will generally consider CGs in relation to the specific facts, rather than as an absolute standard. However, there may be certain circumstances in which CGs take greater dominance.

4. Greater Dominance in Specific Circumstances?

National evidence-based guidance may be expected to exert considerable influence in determining the legal standard in specific situations and specialities. Participants believed that there was an expectation that clinicians working in specialist areas ought to be aware of key guidance: 'NICE guidelines are particularly highly regarded on the basis that clinicians are expected to be familiar.'⁹⁴ One repeated example concerned national cancer guidance and the 'two-week' rule: 'We frequently see reference to the NICE guidelines for suspected cancer, evidencing circumstances where referral under the two week wait rule was not done.'⁹⁷ Similarly in primary care: 'NICE guidelines are very often used in the diagnosis of cancer cases, especially in relation to the two week wait referrals by GPs.'⁹⁵

⁸⁸ (n 72).

⁸⁹ *Spencer v Hillingdon* [2015] EWHC 1058 (QB).

⁹⁰ NICE Clinical Guideline 92: Venous thromboembolism: reducing the risk.

⁹¹ *ibid* 73.

⁹² *Velarde v Guy's and St Thomas NHS Foundation* [2017] EWHC 1250 (QB).

⁹³ *ibid* 69.

⁹⁴ Respondent 11: (Barrister)(SFT). 97

Respondent 9: (Solicitor)(SFT).

⁹⁵ Respondent 28: (Solicitor)(SFT).

National guidelines for obstetrics and gynaecology were considered to be highly relevant and often formed the basis of high value claims: '[Royal College of Obstetricians and Gynaecologists] guidelines are often referred to in obstetric cases, and we also refer to local guidelines about administration and forms of treatment.'⁹⁶ This tendency was shared by both solicitors and barristers: 'In my practice, I am frequently referred to the NICE guidelines which deal with foetal monitoring and the management of labour'¹⁰⁰; and, '[g]uidelines are more prevalent and influential in obstetric claims and more relevant to breach regarding delivery of care.'⁹⁷

Apart from oncology and obstetrics, specific guidance from other specialisms was also seen as relatively common: 'A good recent example is the use of NICE guidelines on the provision of graduated compression stockings following DVT.'⁹⁸ Another stated: 'Today I have referred to the 2004 NICE dyspepsia guidelines.'⁹⁹ The 'Sepsis Six' protocol that is subsumed within NICE Guideline 51¹⁰⁰ was similarly considered to play an important and influential role in negligence litigation by survey respondents.

In *Rose v Thanet*,¹⁰¹ a claim was brought against a Clinical Commissioning Group (CCG) against its decision not to fund treatment in contravention of clinical guidance. Although this case was a claim in public law and not decided on principles of negligence, it serves as a useful illustration. On the facts, relevant NICE guidelines stated that pre-menopausal women preparing for treatment likely to cause infertility should be offered oocyte cryopreservation (and be informed of its low success rate).¹⁰² Notwithstanding this guidance the policy of the CCG was to fund such treatment in exceptional circumstances only, which was considered not to apply in this particular case, and funding had been refused. The claimant contended that the policy of the CCG had failed to take into account NICE Guideline 156. The CCG argued that the guidelines were not mandatory. It was for each CCG to decide commissioning priorities for their population and how to best allocate resources. The court held that although NICE guidance did not have to be followed, a CCG was under an obligation in public law to have regard to relevant NICE guidance and provide clear reasons for any policy decision not to follow it. The court stated:

(1) a relevant body must have in place arrangements for making decisions and adopting policies on whether a particular health care intervention is to

⁹⁶ Respondent 26: (Solicitor)(SFT). 100
Participant 2: (Barrister)(IDI).

⁹⁷ Respondent 35: (Solicitor)(SFT).

⁹⁸ Respondent 23: (Barrister)(SFT).

⁹⁹ Respondent 23: (Barrister)(SFT).

¹⁰⁰ NICE Guideline (NG 51), Sepsis: recognition, diagnosis and early management (2016).

¹⁰¹ *Rose v Thanet CCG* [2014] EWHC 1182.

¹⁰² NICE guidance 156 (published February 2013).

107 *Rose* (n 105) 23.

be made available for persons for whom the relevant body has responsibility. (2) Arrangements under paragraph (1) must- (a) ensure that the relevant body complies with relevant NICE recommendations; and (b) include arrangements for the determination of any request for the funding of a health care intervention for a person, where there is no relevant NICE recommendation and the relevant body's general policy is not to fund that intervention.¹⁰⁷

Thanet CCG's only reason for not following the guidance was that it disagreed with its evidence on the effectiveness of oocyte cryostorage. The court held that CCGs might not legitimately disagree with NICE on matters concerning medical science. Since no rational basis or reasoning on grounds of exceptionality had been given it followed that the policy of the CCG had been unlawful.

Rose v Thanet involved the implications of failure to comply with national guidance. The case concerned a decision-making body and not an individual and was argued on public law rather than tort. On one view, the judgment could be perceived as an impingement on the discretion of the healthcare provider. Alternatively, grounds of exceptionality could have been argued, which could have formed justification for the CCG's decision. The Thanet judgment applied as an illustration to individual cases of negligence could have significant implications for determining the legal standard for reasonable care. However, as shown from our study, divergence from accepted national guidance may be tolerated if there are cogent reasons for doing so.

D. Impact of Clinical Guidelines on Judicial Decision-Making

1. Persuasiveness

Participants perceived guidelines as being particularly influential on judicial decisionmaking in areas such as obstetrics and cancer referral. Reasons for such persuasiveness were: first, the provenance of guidance was usually from nationally respected professional organisations and carried greater weight; secondly, the content of the guidance was perceived as either 'black or white'; thirdly, the presentation was in an easily understandable format. Clinical guidelines in these areas were typically seen by the judiciary as a benchmark for reasonable clinical care. There is a presumption that care which deviates from evidence-based guidelines would be substandard or negligent, and one needs compelling evidence to justify why a practitioner is still acting reasonably when deviating from the guideline.¹⁰³

The potentially persuasive nature of an evidence-based guideline was readily apparent:

¹⁰³ Participant 3: (Barrister)(IDI).

¹⁰⁹ Participant 5: (Solicitor)(IDI).

¹¹⁰ Participant 5: (Solicitor)(IDI).

If one expert is able to point to clinical guidance to support their position, particularly if produced by NICE or the Colleges, then that expert almost gets a casting vote ... it generates a sense of 'well, it's not just me that's saying this' and nine times out of ten a judge will have no experience of that particular area of medicine, and that would be seen as a pretty persuasive piece of evidence.¹⁰⁹

Others felt that the reason for their influence was due partly to the nature of law and the legal profession in that:

Lawyers are used to dealing with rules, and guidelines seem like rules, and you can confidently infer that evidence-based guidelines are based on research trials and experience. That's a nice easy presentation for a judge to understand.¹¹⁰

Nevertheless, while the considerable potential of supportive clinical guidance is readily apparent, potential problems caused by forensic dissection of clinical guidance, as though they were instruments of law, has been recognised.¹⁰⁴ Guidelines are written to assist clinicians to make evidence-based decisions rather than to assist judges to decide whether a treatment or intervention was clinically indicated. A further question concerns whether the courts are truly appropriately placed to adjudicate on matters of clinical judgment. Even after Bolitho opportunities for judicial intervention are limited to where clinical opinion is evidently illogical.¹⁰⁵

From the participants' perspective the source of guidance was considered to have principal relevance: 'Guidelines produced via NICE, the Royal Colleges and the GMC, will inevitably be seen by a judge as a marker of reasonable clinical care.'¹⁰⁶ Clinical guidelines were seen as part of an overall bundle of persuasive evidence to lay before the court: 'I don't think judges know very much about guidelines, and at the end of the day much depends upon the evidence that is produced in court.'¹⁰⁷ Nevertheless, lawyers had also seen evidence presented in guidelines as being more authoritative and persuasive compared with sworn in expert testimony in that sometimes:

a defendant expert will say that a certain treatment was defensible, even though it did not follow guidance. Those cases are often difficult because

¹⁰⁴ J Montgomery and E Montgomery, 'Montgomery on Informed Consent: An Inexpert Decision?' (2016) 42 JME 89-94.

¹⁰⁵ Bolitho (n 4).

¹⁰⁶ Respondent 7: (Barrister)(SFT).

¹⁰⁷ Respondent 17: (Solicitor)(SFT). 115

Participant 4:
(Barrister)(IDI).

judges can be better persuaded by the black and white content of a guideline.¹¹⁵

The potential risk of inequity was also observed:

If a defendant says ‘I followed the guidelines’ he is accused of slavishly following paper guidance; if he says he did not follow the guidelines, it is said that doctors should stop thinking that clinical judgement is better than those of the Guidelines Committee.¹⁰⁸

2. Admissability

Perhaps some lessons regarding evaluation of the admissibility of guidelines can be drawn from other jurisdictions. In *Daubert*,¹⁰⁹ the United States Supreme Court created standards for judicial evaluation of the reliability and authoritativeness of the scientific foundations that could be permitted as evidence. Solomon¹¹⁰ speculates that this might encourage the judiciary to scrutinise the development process behind the creation of guidelines as well as the credentials and motivations of their producers. He contends further that the National Guidance Clearing House (NGC) inclusion criteria might provide examples of the minimum set of criteria that should be required for guidelines to be admissible.¹¹¹ The NGC project highlighted the importance and centrality of evidence-based medicine. The US jurisprudence demonstrates that standards set down in clinical guidelines represent minimal standards and as such are not a sufficient determinant of reasonable care. In *Jewett*,¹¹² for example, it was argued that although the standard of care complied with that of guidance from the American College of Obstetricians and Gynaecologists, that standard was the very minimum and in the circumstances more should have been done by the defendant. The NGC also demonstrated the real potential for conflicting sets of professional guidelines. In *Levine*,¹²¹ for example, the claimant’s experts relied upon guidance of the American Cancer Society whereas the defendant’s experts raised those of the American College of Obstetricians and Gynaecologists. The court acknowledged that the views of competent bodies may differ. On the facts the defendant’s guidelines were considered more persuasive since the

¹⁰⁸ Respondent 31: (Barrister)(SFT).

¹⁰⁹ *Daubert v Merrell Dow Pharmaceuticals Inc* (1993) 509 US 579.

¹¹⁰ RP Solomon, ‘Guidelines in the United States: Perspectives on Law and Litigation’ in J Tingle and C Foster (eds) *Clinical Guidelines: Law, Policy and Practice* (Cavendish 2002) 137–59.

¹¹¹ In 1998 the National Guidelines Clearing House (NGC) was created. It aimed to provide healthcare providers and users with an accessible database to obtain objective, detailed information on CGs and to support their dissemination, implementation and usage. When it closed in 2018 the repository included over fivethousand guidelines and expert commentaries <www.guideline.gov> accessed 4 January 2021.

¹¹² *Jewett v Our Lady of Mercy Hospital* (1992) 82 Ohio App 3D 428 612 NE 2d 724. 121 *Levine v Rosen* (1992) 616 A 2d 623 (Pa).

defendant's conduct was strongly supported by respected professionals. It seems likely that in cases such as these expert opinion will always be required to assist the court to assess Daubert validity for the admissibility of guidelines.¹¹³ The consensus seems to be that use of guidelines in medical negligence litigation depends upon state evidential practices and decided case law.¹¹⁴ More recent calls have been made for the adoption of 'safe harbours' for clinicians who follow evidence-based guidance established through comparative effectiveness research,¹¹⁵ although exactly how CGs will be used in this process is not entirely clear.¹¹⁶

3. Expert Testimony or CGs

Participants agreed unanimously that experts referred to guidelines where these were available, as part of their evidence although this was not necessarily determinative of the outcome: 'Independent expert opinion is critical to success in clinical negligence cases. That opinion may in part refer to guidelines but that is not usually the deciding factor.'¹¹⁷ Guidelines were, however, regarded generally as being highly influential and likely to impact on judicial decision-making. One barrister stated that in his experience guidelines held little sway over the actual decision because judges could 'buy both arguments [following CGs or not] to find for the claimant'.¹¹⁸ It was recognised that on pragmatic grounds: 'There can be differences of opinion on guidelines. Experts may differ on their relevance.'¹¹⁹ Their potential as a 'deal breaker' was also recognised:

If the expert tells me the specific guidelines are (a) applicable to the scenario under consideration; and (b) that a responsible body of relevant clinicians would consider that the failure to comply with the said guidelines would amount to a breach of duty, then that is the end of the debate.¹²⁰

Common law reveals interesting developments as far as expert testimony is concerned. In *KR v Lanarkshire Health Board*¹²¹ allegations were raised in respect of medical negligence and failure to obtain informed consent prior to an emergency caesarean section. Following prolonged deceleration of foetal heart rate, the pursuer argued that the baby should have been delivered urgently and

¹¹³Samanta and others (n 13) 344.

¹¹⁴ LL LeCraw, 'Use of Clinical Practice Guidelines in Medical Malpractice Litigation' (2007) 3(5) J Oncol Pract 254.

¹¹⁵ P Orszag, 'Malpractice Methodology' New York Times (20 October 2010) <<http://www.nytimes.com/2010/10/21/opinion/21orszag.html>> accessed 4 January 2021.

¹¹⁶ TK Mackey and B Liang, 'The Role of Practice Guidelines in Medical Malpractice Litigation' (2011) 13(1) Virtual Mentor 36–41.

¹¹⁷Respondent 10: (Solicitor)(SFT).

¹¹⁸Respondent 31: (Barrister)(SFT).

¹¹⁹Respondent 31: (Barrister)(SFT).

¹²⁰Respondent 32: (Barrister)(SFT).

¹²¹*KR v Lanarkshire Health Board* [2016] CSOH 133

referred to guidelines published by NICE and the Royal College of Obstetricians in support of these arguments. Since the attendant Registrar had been aware of these guidelines it was argued that there was no just cause for not following them. While a more experienced doctor might reasonably use clinical discretion to divert from evidence-based guidelines, juniors ought not. The defendant argued that in determining whether there had been negligence, the court could not simply prefer one body of expert evidence over another; instead the court had to examine the defendant's evidence to decide whether or not it withstood logical analysis. In reaching these conclusions the court considered the status of NICE and RCOG guidelines, both of which recommended that in the presence of clear evidence of acute distress, the baby should have been delivered as a matter of urgency rather than taking FBSs. While recognising that guidelines were not mandatory and would always be subject to clinical discretion, both experts accepted that the extent to which these could be departed from would depend upon the experience of the doctor concerned. The registrar was relatively inexperienced and ought to have prepared for immediate assisted vaginal delivery. Instead, she had arranged for further blood samples to be taken in breach of current guidance. The court considered that the views of the defendant's experts lacked a logical basis since both parties accepted that the reasonableness of departing from the guidelines depended on clinical acumen and experience.¹²²

Standard practice presented in guidelines was departed from and yet the deviation was endorsed as reasonable care in *Vernon*,¹²³ a decision undoubtedly influenced by expert evidence. The Claimant had received considerably higher doses of a drug than those recommended by several authorities including the Product Datasheet, the British National Formulary, and Martindale's Extra Pharmacopoeia. The Claimant suffered bilateral vestibular damage and loss of balance as a result. The court heard compelling evidence from several experts with all but one agreeing that they would have prescribed at the same dose as the defendant. The judge accepted that the dosage was proper and that the doctors were not negligent in prescribing it. The court held that the manufacturers and prescribers' guidelines were too conservative and erred on the side of caution. It might be argued that manufacturers' guidelines or dosages indicated in pharmacopoeia might err on the side of caution for partisan reasons for purposes of limiting potential liability. Manufacturer guidance on dosage addressed to prescribers will normally discharge the duty of care to the patient where drugs are prescribed. Although difficult to determine retrospectively, in *Vernon* it was significant that expert witnesses were prepared to endorse the prescribing practice of the defendant. On the facts, it is not clear whether the judge had merely deferred to expert evidence. Alternatively, this decision need not be seen as deferential to expert evidence but as an assertive court utilising all available evidence and weighing the coherence of testimony. The experts and the defendant could explain their departure from the guidance. The court adjudged

¹²² The evidence therefore failed the Bolitho test.

¹²³ *Vernon v Bloomsbury Health Authority* (1995) 6 Med LR 297.

this to be reasonable in the circumstances and made a sophisticated ruling that did not overly constrain clinical discretion.

E. Settlement of Claims

All participants acknowledged that the reported case law represents only a very small subset of the totality of medical negligence disputes. Case law comprises the few disputes (of very many) that go to trial with judgment. Decisions to abandon or settle claims may be made by parties at any stage of the litigation process:

The vast majority of clinical negligence cases don't go to trial and guidelines are often relevant to the decision about whether to settle the case out of court, as well as about how to present the case in court.¹²⁴

Several participants believed that following evidence-based guidelines in relevant circumstances was an important factor behind decisions whether to settle early. Failure to follow CGs appeared to promote early settlement before, as well as during, court proceedings:

Clinical guidelines are not determinative but in practice they are often seen as determinative, and if there has been a clear failure to follow a guideline that case will usually settle.¹²⁵

Failure to follow authoritative guidance was perceived to be 'more serious' and potentially 'negligent' even though 'clinical common sense and practice' might support the defendant's action.¹²⁶

Even where the evidence was strong that treatment outside of guidance had been appropriate, such cases were not always defended, although it was recognised that 'regard must be had as to how longstanding the guideline is and whether any reasonable practitioner would have been aware of it'.¹²⁷ Unjustified assumptions about 'negligence' by some legal teams, whether defendant or claimant, particularly in the early stages of proceedings, meant that some claims were not considered to be worthy of defending: 'Cases tend to settle on the proposition that medical professionals should not depart from national guidelines without cogent reason.'¹³⁷ These situations were more likely to arise where evidence-based guidance from NICE or the Royal Colleges was available in obstetric cases and with delayed cancer referrals from primary care.

Our findings indicate a divergence in the way CGs are regarded in respect of the legal standard for breach of duty in law, compared to how CGs are regarded as a standard in practice for settling or defending a claim in the litigation process.

¹²⁴Participant 4: (Barrister)(IDI).

¹²⁵Participant 1: (Barrister)(IDI).

¹²⁶Respondent 11: (Barrister)(SFT).

¹²⁷ Participant 6: (Claims expert)(IDI).

¹³⁷ Respondent 32: (Barrister)(SFT).

In practice, there seems to be at least two important points. First, failure to follow guidance could prompt a ‘suspicion’ of negligence. The misgiving would seem stronger if the CG in question is an established or recognised guideline from an authoritative source such as NICE or the Royal Colleges. Secondly, there appears to be a reticence to defend a case if the defendant has not complied with a guideline. One reason for such reluctance may be because of advice from expert witnesses. Experts have often stated that they see their position as being somewhat compromised if CGs have not been followed, even though the basis for non-compliance may be perfectly plausible clinically (A.S., direct communications). They perceive themselves as being placed in an invidious position should proceedings progress. Such a view is unfortunate because it creates a requirement to comply with guidance, although such compliance will not necessarily vindicate the defendant in an action.

Analysis of the number of claims and quantum based on figures from NHS Resolution shows that between 2007/08 to 2016/17 the number of claims almost doubled. Although the proportion of claims settled with damages (approximately 60%) has not altered, damages paid for those settled with court proceedings/trial has risen nearly threefold from £554 million to £1.34 billion over this period. For cases settled without proceedings there has been an approximately two-fold rise from £45.4 million to £97.5 million.

The astronomical rise in quantum is on account of the considerably larger awards for cases at the ‘high end’ of medical negligence, particularly those that proceed to trial. For settlements without court proceedings, there was a twofold rise between 2007/08 and 2016/17. During this period there was a doubling of claims, but a constant proportion progressed to court proceedings or trial. Some of these cases (without court proceedings) may have been abandoned, or perhaps settled without compensation. They may have been disposed of through other channels. An unadjusted calculation would suggest that the per capita payment in this cohort would be roughly unaltered over an approximate ten-year period. It is therefore conceivable that the relative lack of rise per capita over a decade might seem an attractive proposition in litigation for the early settlement of cases characterised by non-compliance with CGs.

The frequency of the use of CGs as a determinant for the early settlement of cases is not a routine aspect of metric collection by NHS Resolution and would require qualitative analysis through scrutiny of files.¹²⁸ Based on data from our survey and interviews, CGs are used in the pre-trial stage and influence decisions to settle claims early if guidance was not complied with. The importance of this issue cannot be overstressed as it has relevance to cost containment in medical negligence litigation. Clinical guidelines may also play a role in decisions to settle through routes alternative to court proceedings. Since litigation in this area is costly, lengthy, and stressful with uncertain outcomes,¹²⁹ some form of

¹²⁸ We could not obtain case files as these were retained by solicitors instructed by NHS Resolution.

¹²⁹ J Hyde, ‘Jackson Backs New Clinical Negligence Liability Test to Allow More Claims’ *Gazette* (17 May 2019) <<https://www.lawgazette.co.uk/news/jackson-backs-new-clinical-negligence-liability-test-to-allowmore-claims/5070323.article>> accessed 4 January 2021.

alternative dispute resolution might be pursued with efficiency outcomes for all parties dependant on whether guidelines had been followed.

F. Potential Barriers to the Use of Clinical Guidelines

Direct communication and discussion¹³⁰ with experienced health professionals identified three principal potential barriers to the routine use of CGs. These were: limited resources, the need for employers to facilitate optimal use of CGs, and concerns about CGs constraining clinical autonomy. These themes were explored during a consensus discussion group (CDG) with participants from legal, medical, and other allied healthcare professions.

Participants considered that shortage of resources should not be considered as a blanket defence for decisions not to follow relevant guidance. Concern was expressed that limitation of resources, as a bona fide defence, might lead to a ubiquitous lowering of standards within clinical practice. The majority view was that resource limitations should be transparent and acknowledged, particularly where local guidelines had been developed to accommodate such constraints. Most thought that liability for negligence due to resource limited non-compliance with guidance should lie with organisations rather than individuals. This view chimes with the powerful dissent of Sir Nicolas Browne-Wilkinson V-C (as he then was) in *Wilsher* (in the Court of Appeal) who considered that

A health authority which so conducts its hospital that it fails to provide doctors of sufficient skill and experience to give the treatment offered at the hospital may be directly liable in negligence to the patient.¹³¹

Participants agreed that employing organizations should facilitate use of CGs by updating and making these readily accessible. Organisational accountability was considered to be of paramount importance for enabling practitioners to use guidelines more widely and consistently. Mediators for enablement included appropriate induction and education of staff, ease of accessibility, IT support, regular updating of guidelines, audit of use and dissemination strategies to share best practice.

Concern was expressed that guidelines might constrain clinical autonomy and discretion. Clinical autonomy, judgment, and discretion are essential prerequisites for personalised patient care, although the potentially stifling effect of CGs on clinical autonomy is often over-rated. As in *Hunter v Hanley*,¹³² there is ample scope for genuine differences of opinion in the delivery of responsible clinical care. A doctor is not prima facie negligent merely because her clinical decision differs from those of her peers. The law has no authority to force one expert's opinion over another where those opinions are responsible and honestly and truthfully held.¹³³ Evidence-based CGs can be useful evidence of expected

¹³⁰With A.S.

¹³¹*Wilsher v Essex AHA*, [1987] Q.B. 730 (1986) per Browne-Wilkinson 778 A-C.

¹³²*Hunter v Hanley* 1955 SC 200.

¹³³ *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634. 144 Brazier and Miola (n 2).

professional practice particularly where adopted by most reasonable and responsible practitioners. The court confronted by experts who disagree about good practice may be able to use evidence-based guidance as an indicator of a 'gold standard.'¹⁴⁴

An additional factor raised tangentially during the CDG, was that of the expertise and acumen of the guideline producing consortia and the quality of the underpinning research which is expected to be robust. At times, history has revealed that this cannot be taken for granted. Inaccurate reports have been published in high-profile and influential journals across the world even about critical global emergencies such as the Covid-19 pandemic.¹³⁴ Another example is the 2009 European Society of Cardiology guidelines that recommended the benefits of pre-operative beta blockade in patients with ischaemic heart disease, principally supported by two studies which were later discredited due to research misconduct.¹³⁵ It is estimated that over 10,000 deaths were caused due to the impact of this (mal) research on guidelines and national policies.¹³⁶ Leung cautions that by influencing evidence-based guidance, fraudulent, and misleading research findings could influence judicial decisions indirectly.¹³⁷

IV. CONCLUSION

The current study shows that CGs are used in a variety of ways across medical litigation, by claimants as well as defendants. Although not dispositive, CGs can be persuasive or influential upon judicial decision-making. Another key finding is that guidance can weight decisions about whether to abandon or settle a claim at an early stage. This is premised on the proposition that clinicians should follow nationally endorsed and authoritative guidelines unless there are cogent reasons for not doing so. A shift in the role of CGs engaging in pre-trial stages as well as at trial, and for settlements out of court, could have implications for clinical negligence litigation.

We acknowledge the limitations of our study. First, we have provided relatively little quantitative data on the role of CGs in medical litigation. Furthermore, although we invited over 300 practising lawyers to participate in the survey and sent two reminders, we achieved a modest response rate of 12%. However, the study design was to build an understanding of how guidelines are used in medical negligence litigation rather than focus on quantitative assessments. The survey results have been triangulated with qualitative data from IDIs, as well as from SFTs from the survey questionnaire. The methodology

¹³⁴ S Boseley and M Davey, 'Covid-19: Lancet Retracts Paper that Halted Hydroxychloroquine Trials' *Guardian* (4 June 2020) <<https://www.theguardian.com/world/2020/jun/04/covid-19-lancet-retracts-pa-per-that-halted-hydroxychloroquine-trials>> accessed 4 January 2021.

¹³⁵ GD Cole and DP Francis, 'Perioperative [Beta] Blockade: Guidelines Do not Reflect the Problems with the Evidence from the DECREASE Trials (2014) 349 *BMJ* g5210.

¹³⁶ G Vogel, 'Suspect Drug Research Blamed for Massive Death Toll' (2014) 343 *Science* 473–74.

¹³⁷ GKK Leung, 'Criminalizing Medical Research Fraud: Towards an Appropriate Legal Framework and Policy Response (2019) 19(1) *Med LI* 3–31.

underlying the qualitative data collection and analysis was rigorous and robust. Multisource data along with triangulation have strengthened assurance of validity. On these grounds we believe that the results are genuine as well as informative, although the generalisability of findings may be limited due to the small numbers involved.

Secondly, despite our best efforts, we were unable to access pre-trial files and records of claims (from NHS Resolution) for qualitative analysis. This was mainly because case files are maintained by defendant solicitors who are instructed on behalf of NHS Resolution. However, our analysis of claims' metrics provides numeric evidence that demonstrates the rise in the total number of claims and their settlement, pre-trial, or in court but pre-judgment, providing a snapshot of how this landscape has altered over the past decade and depending upon the defendant's non-compliance with guidelines.

Whilst CGs serve a useful purpose in medical negligence litigation, slavish reliance carries the risk that they might assume such an aura of authority that they are mistakenly perceived by lawyers and health practitioners to represent the 'law', thereby usurping medical expertise and expert testimony. The prescriptive use of CGs as a driver for systems quality improvement could elide the distinctions between political imperatives, guidelines as recommended standards, and legal rules. Yet casual disregard for CGs in the modern environment of evidence-based clinical practice is unwise. A balance is required.

The unifying thread for optimal use of guidelines in litigation is the principle of reasonableness. Reasonableness ties together the disparate elements of breach of duty of care, the Bolam and Bolitho tests, and the expected standard of care in the case litigated, into one coherent whole. As Montrose states 'the question of negligence should be one of what ought to be done in the circumstances, rather than what is done in similar circumstances by most, or even all people'.¹³⁸ Through the concept of reasonableness negligence imports into law an ethical command to encourage safe behaviour¹³⁹ which in our view provides a balance to the use of guidelines in negligence. We see two evident advantages. First, it gives the law flexibility to set the standard of care in relation to the particular demands of the case in question. Secondly, it allows the law the ability to arrange that standard dependent upon wider policy considerations. For example, it is well-recognised that the cost of compensation awards is rising exponentially and may not be sustainable in the future. There is some evidence from the data that CGs are being used in the early and pre-trial stages of litigation to decide whether cases should be settled. The position of the court regarding the use of guidelines may shape future policy aimed at reducing costs in this area.

In Bolitho, Lord Browne-Wilkinson expanded on 'logical basis' as cases involving 'the weighing of risks against benefits' and that before accepting a body of opinion as being responsible, reasonable, or respectable, the judge would

¹³⁸JL Montrose, 'Is Negligence an Ethical or Sociological Concept?' (1958) 21 MLR 259–264.

¹³⁹ K McK Norrie, 'Reasonable: the Keystone of Negligence' (1987) 13 JME 92–94. 151 Bolitho (n 4).

‘need to be satisfied that the experts have directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion on the matter’.¹⁵¹ We have previously suggested a conceptual basis of a framework for the use of guidelines in clinical litigation.¹⁴⁰ There are four stages to this model: first, is the defendant’s conduct Bolam-responsible; secondly, is it Bolitho-justifiable; thirdly, are the guidelines cited Daubert-valid in respect of admissibility as evidence; and fourthly, a consideration of how guidelines engage in the particulars of the case. We believe that these concepts form a paradigm for reasonableness in determination of the legal standard. The key questions in ascertaining whether the defendant’s conduct has met the requisite standard of care requires careful assessment of the defendant’s conduct as well as

TABLE 1: Analysis of the numbers of claims and compensation paid (figures provided by NHS Resolution)

	016/17		2007/08	
Total	11,518		6,018	
Withdrawn or settled (no damages)	4,4470	(38.8%)	2,540	(42.2%)
Settled, with damages				
No proceedings	3,696	(32.1%)	(62.2%) 1,717	(28.5%) (57.8%)
Proceedings	3,327	(28.9%)	1,748	(29.4%)
Trial	25	(0.2%)	13	(0.22%)
Damages				
No proceedings (settled with negotiation)	£97.5 million		£45.4 million	
With proceedings/trial (immediate payment, plus periodic payments and estimates for future)	£1,344.1 million (£1.34 billion)		£554.8 million	

punctilious scrutiny of relevant guideline recommendations in the case. A rounded analysis by the court of these parameters would then form the ‘logical basis’ for evaluating the legal standard for breach of duty.

Guidelines used in this manner and within a framework for reasonableness have the attraction of offering a principled basis for judicial use of evidence-based medical intelligence, while preventing the stifling of expert testimony,

¹⁴⁰Samanta and others (n 13).

experience, and the exercise of clinical discretion. We believe that this approach would promote consistency and fairness for litigants in medical negligence by reducing unpredictability caused by the malady of ‘*quot homines tot sententiae*’.¹⁴¹

¹⁴¹ ‘There are as many opinions as there are people.’ Terence; *Phormio*; line 454. Circa 161 BC.