

THE ROLE OF CLINICAL GUIDELINES IN MEDICAL NEGLIGENCE LITIGATION: A SHIFT FROM THE *BOLAM* STANDARD?

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I. INTRODUCTION

In medical negligence litigation, a key step is for the claimant to prove that the physician failed to meet the required standard of care. The traditional test in law in such cases remains the *Bolam* test: a doctor is not negligent if what he has done would be endorsed by a responsible body of medical opinion in the relevant speciality at the material time.¹ The standard has been seen by some commentators as one set by the medical profession and evidenced by expert testimony, with minimal court scrutiny, and it has been suggested that stricter evaluation of such opinion would be welcome.² The decision in *Bolitho*³ suggests that the court should adopt a more interventionist stance in assessing expert evidence and in setting the standard of care. One such approach towards a more objective measure in determining the legal standard of care could be through the use of clinical guidelines ('guidelines').

Guidelines are consensus statements developed to assist clinicians in making decisions about treatment for specific conditions.⁴ They are

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¹ *Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582.

² H. Teff, 'The Standard of Care in Medical Negligence—Moving on From *Bolam*?' (1998) 18 *Oxford Journal of Legal Studies* 473.

³ *Bolitho v. City and Hackney Health Authority* [1997] 4 All ER 771.

⁴ Department of Health, *The New NHS: Modern, Dependable* (HMSO 1997).

systematically developed on the basis of evidence⁵ and aim to promote effectiveness and efficiency of healthcare delivery.⁶ It has been argued that evidence-based practice could be used to develop a framework that ensures consistent access to services and quality of care across the country, an approach espoused by the Department of Health.⁷ To promote the development and use of guidelines, the government created the National Institute for Health and Clinical Excellence (NICE).⁸ The Healthcare Commission (HC), also created as part of this government agenda for quality, has a duty to monitor the implementation of such guidelines.⁹ Some, however, believe that guidelines might fetter clinical discretion and autonomy and define too inflexible or unrealistic a standard for clinical practice.¹⁰ Discretion lies at the heart of clinical judgment and has to take into account a number of competing influences relevant to individual patient circumstances and clinical care. It has been argued, therefore, that guidelines should not constitute a *de facto* legal standard that is applied rigidly in every case.¹¹

The precise role of guidelines in determining the legal standard of care is uncertain. A plethora of academic commentary exists in the legal and medical literature analysing the theoretical basis as to why guidelines should, or should not, set the legal standard of care in clinical negligence litigation.¹² To the best of our knowledge, there are no empirical data on the actual or perceived use of guidelines in medical litigation in the UK. We embarked on a study with the aim of filling this lacuna through a survey to determine practising lawyers' perceptions of the use of guidelines in medical negligence litigation in England and Wales.

The survey results show that a high proportion of respondent barristers and solicitors were familiar with guidelines and had used them as

⁵ G. Feder, M. Eccles, R. Groll, C. Griffiths and J. Grimshaw, 'Guidelines: Using Guidelines' (1999) 318 B.M.J. 728

⁶ J H. Wilson, *Integrated Care Management: the Path to Success* (Butterworth Heinemann 1999) and *NHS Executive, Guidelines* (HMSO 1996).

⁷ *Supra*, n. 4

⁸ NICE was established on 1st April 1999 as a special health authority created by means of a statutory instrument (S.I. 1999 No. 220) under the provisions of s. 11 of the National Health Service Act 1977. NICE has direct responsibility to the Secretary of State.

⁹ S. 19 of the Health Act 1999 established the Commission for Health Improvement (CHI), which in April 2002 became the Commission for Healthcare Audit and Inspection (CHAI) and has now been subsumed under the HC.

¹⁰ D. Black, 'The Limitations of Evidence' (1998) 32 *Journal of the Royal College of Physicians of London* 23.

¹¹ B. Hurwitz, 'How Does Evidence Based Guidance Influence Determinations of Medical Negligence?' (2004) 329 B.M.J. 1024.

¹² For a general discussion of guidelines in the context of medicine and law, see J. Tingle and C. Foster (eds). *Guidelines: Law, Policy and Practice* (Cavendish 2002).

part of trial strategy. In addition, they expected that guidelines would play a greater role in medical litigation in the future. On the basis of our findings, we argue that guidelines might serve to inform the legal standard of care more proactively by representing a shift from the traditional *Bolam* standard. Clinicians should consider well-established guidelines in their practice and should be prepared to justify in court any departure, if so required. This paper does not purport to provide a comprehensive review of clinical guidelines in law or to rehearse the rich corpus of arguments that underlies the philosophical basis of using guidelines to determine the standard of care in medical litigation.¹³ Instead the paper focuses on the practical application of guidelines based upon empirical observations. We discuss the current use of guidelines in the English jurisdiction and factors that might either promote or deter the greater use of guidelines in medical litigation in the future, drawing upon experience from the USA to inform our discussion. We propose a four-stage conceptual model for using guidelines to inform the standard of care in clinical negligence litigation.

II. BACKGROUND

Several cumulative pressures have fuelled the need for transparent accountability of clinical judgment. The result is that the traditional concept of clinical autonomy has become constrained to a greater degree and medical practice is becoming both manipulated and influenced by a range of diverse factors. Social, political, professional, legal and consumer empowerment levers are key features behind recent changes.¹⁴

A. Socio-political Context

1. Government Agenda

Section 18 of the Health Act 1999 imposes a statutory duty of quality on all NHS and Primary Care Trusts to operate alongside the common law duty of care already owed to patients. The statute requires that high quality health care be provided on a uniform basis. Guidelines mesh with this goal because the rationale underlying guidelines is that systematic use of high-level empirical evidence will facilitate best

¹³ See, for example, H. Teff, 'Clinical Guidelines, Negligence and Medical Practice' in M. Freeman and A. Lewis (eds). *Law and Medicine Current Legal Issues Volume 3* (Oxford University Press 2000) at 67–80; V. Harpwood, 'The Manipulation of Medical Practice', *ibid.* at 47–66.

¹⁴ For a more detailed view on the manipulation of medical practice, see V. Harpwood, *supra*, n. 13.

practice.¹⁵ Consequently, there has been a strong political drive to promote the use of guidelines in order to assure the achievement and maintenance of cost-effective quality in healthcare provision.¹⁶ NICE formulates guidelines using an evidence-based approach with a view to furthering the goal of commitment to uniformity of healthcare quality throughout the country and there is an expectation that such guidance will be implemented consistently across the National Health Service.¹⁷ The HC has a harder-edged function of inspection, as well as the auditing of healthcare providers,¹⁸ and will probably have a greater impetus in ensuring that guidance from NICE is followed.¹⁹

The focus on quality in the NHS has resulted in considerable investment in the healthcare system. Conceptually, 'quality' covers a range of areas.²⁰ Towards the end of the last decade, the government articulated the agenda for quality in the NHS as 'doing the right things, at the right time, for the right people, and doing them right—first time'.²¹ Later, this vision was developed to incorporate a commitment to implement quality assurance and quality improvement programmes using opportunities to involve patients and their representatives in decisions about their healthcare and in designing services, working with all stakeholders in determining clinical priorities and providing valid and reliable information about standards of clinical care.²² An open and participative

¹⁵ For a detailed discussion on the formulation of guidelines and their development, see S.H. Woolf, 'An Organised Analytical Framework for Practice Guideline Development: Using Analytical Logic as a Guide for Reviewing Evidence, Developing Recommendations and Explaining the Rationale' in K. McCormick, S.R. Moore and R. Segal (eds). *Methodology Perspectives* (United States Department of Health & Human Services Agency for Health Care Policy and Research 1994) 105.

¹⁶ Department of Health, *Using Clinical Guidelines to Improve Patient Care Within the NHS* (HMSO 1996); Department of Health, *The New NHS*, *supra*, n. 4; Department of Health, *An Organisation With a Memory* (HMSO 2000); Department of Health, *Making Amends: A Consultation Paper Setting out Proposals for Reforming the Approach to Clinical Negligence in the NHS* (HMSO 2003); Department of Health, *NHS Redress: Statement of Policy* (HMSO 2005).

¹⁷ Department of Health, *A First Class Service: Quality in the New NHS* (HMSO 1998).

¹⁸ S. Dewar and B. Finlayson, 'The I in the new CHAI.' (2002) 325 B.M.J. 848.

¹⁹ This paper does not focus on NICE guidance in particular, but offers these arguments as background to the socio-political environment which might elevate guidelines as being representative of the expected standard of care. For a discussion on the extent to which NICE guidelines might influence the legal standard of care, see A. Samanta, J. Samanta and M. Gunn, 'Legal Considerations of Guidelines: will NICE Make a Difference?' (2003) 96 *Journal of the Royal Society of Medicine* 133.

²⁰ S. Leatherman and K. Sutherland, 'Evolving Quality in the New NHS: Policy, Process and Pragmatic Considerations' (1998) 7 (supplement) *Quality in Healthcare* 54.

²¹ *Supra*, n. 17.

²² Department of Health, *A Commitment to Quality, a Quest for Excellence* (HMSO 2001).

culture within the NHS aims to provide transparent accountability at all levels of service provision.²³ Wide and consistent use of guidelines might serve as a tool for individual and managerial accountability at a local level, as well as in the formulation of policy at a national level.²⁴

2. A New Professionalism

The General Medical Council (GMC) and Royal Colleges have concurred that good practice should be measured against established guidelines and have stressed the importance of robust mechanisms to identify and maintain high standards in medical care.²⁵ The GMC has emphasised that in order to promote the required standards of professional practice, there must be effective quality assurance and clear professional accountability.²⁶ To ensure good practice, doctors must remain responsible for their own performance and conduct and should share responsibility for the quality of care provided by their team. An effective team must be well-led and managed and needs to be committed to provide high-quality service. There is an expectation that in the process of quality improvement clinical teams will normally use recommended guidelines and that the approach taken by the team should go hand-in-hand with the proposed NHS arrangements for modernisation.²⁷ Standards to be followed are those set by the GMC and the Royal Colleges,²⁸ as well as by NICE.

The findings of the Bristol Inquiry shook public confidence and called into question standards within the NHS.²⁹ The fifth report of the Shipman Inquiry highlighted that it is not sufficient for guidance to be implicit in the context and circumstances of clinical practice.³⁰ The lack of explicit standards may result in inconsistent and widely varying decisions, as well as tragic consequences for patients and their families. The development of specific and detailed standards is a necessity in order to define cohesively the relationship between doctors and

²³ *Supra*, n. 17.

²⁴ *Supra*, n. 22.

²⁵ General Medical Council, *Good Medical Practice* (GMC 2001); Federation of Royal Colleges of Physicians, *Good Medical Practice for Physicians* (RCP 2001). There are, as yet, no new versions of these documents, although the GMC guidance is presently being reviewed.

²⁶ General Medical Council, *'Maintaining Good Medical Practice'* (GMC 1998).

²⁷ *Supra*, n. 7.

²⁸ *Supra*, n. 25.

²⁹ *Learning from Bristol: the Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984–95* (Cmnd. 5207 2001) at http://www.bristol-inquiry.org.uk/final_report/index.htm, accessed on 11 April 2006.

³⁰ *Safeguarding Patients: Lessons Learned From the Past—Proposals for the Future. Fifth Report* (Cmnd. 6394 2004) at <http://www.the-shipman-enquiry.org.uk/fifthreport.asp>, accessed on 11 April 2006.

patients.³¹ Clear standards with component terms would provide the basis for medical professionalism.³² A transparent synthesis of evidence and opinion is essential to gain public approval. Evidence-based practice might be expected to promote public confidence. Fitness-to-practise criteria should include not only standards of conduct, but also those that define professional performance. Clinical guidelines may prove useful in identifying and addressing problems of physician under-performance.

The NHS Reform and Healthcare Professions Act 2002 introduced a further layer of regulatory control over healthcare quality. This Act established the Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence), a body that represents patients and the public in circumstances in which a professional regulatory body is perceived to have been overly lenient in the exercise of its regulatory functions. In the context of professional regulation, established guidelines might help define the expected standard of practice. Knowledge transformation and consumer empowerment might raise a societal expectation that good practice hinges on following established guidelines where clinically appropriate.³³

B. Doctrinal Shifts

1. The *Bolitho* Judgment

The House of Lords ruling in *Bolitho* may promote a shift away from *Bolam*.³⁴ It may no longer be sufficient that the standard of care proclaimed by a defendant doctor is satisfied because it is endorsed by a responsible body of peers. In *obiter* comments in *Bolitho*, it was emphasised that the word 'responsible' in the traditional formulation of the *Bolam* test meant that responsible practice is that which withstands the scrutiny of 'logical analysis' from a judicial perspective.³⁵ Clinical practice, however prevalent within the medical profession, would

³¹ R. Rosen and S. Dewar, 'On Being a Doctor. Redefining Medical Professionalism for Better Patient Care' (King's Fund 2004); S. 46 of Health & Social Care (Community Health & Standards) Act 2003 sets out the legislative basis for health care standards.

³² R. Baker, 'Developing Standards, Criteria and Thresholds to Assess Fitness to Practice' (2006) 332 B.M.J. 230.

³³ It must be remembered that the value of guidelines is dependent upon how they are developed and on the synthesis of the available evidence. See, for example, P.G. Shekelle, S.H. Woolf, M. Eccles and J. Grimshaw, 'Guidelines: Developing Guidelines' (1999) 318 B.M.J. 593; and D.J. Cook, C.D. Mulrow and R.B. Haynes, 'Systematic Reviews: Synthesis of Best Evidence for Clinical Practice' (1997) 126 *Annals of Internal Medicine* 376.

³⁴ See, for example, M. Brazier and J. Miola, 'Bye Bye *Bolam*: a Medical Litigation Revolution?' (2000) 8 Med. L.R. 85; A. Samanta and J. Samanta, 'Legal Standard of Care: a Shift From the Traditional *Bolam* Test' (2003) 3 *Clinical Medicine* 443.

³⁵ See the analysis of Lord Browne-Wilkinson *supra*, n. 3 at 778.

perhaps be unlikely to withstand logical scrutiny if that practice is contrary to a clear consensus emerging from the evidence base. Lord Browne-Wilkinson indicated that experts should direct their minds to the question of comparative risks and benefits in order to reach a defensible conclusion on the matter in question.³⁶ A clinical conclusion which does not have risk analysis at its heart is not likely to be deemed a responsible conclusion. *Bolitho* has called attention to this issue and will therefore take effect not only in determining the logical basis of the course of action offered by the defendant, but also by engaging more forcefully in assessing risk analysis.³⁷ Properly considered clinical guidelines will similarly weigh risks and benefits. This consonance with doctrinal changes may be a further factor for evidence-based guidelines to play a greater part in medical litigation proceedings.³⁸

2. Civil Procedure Rules

The Civil Procedure Rules 1998 (CPR)³⁹ have radically transformed the rules of court that govern clinical negligence actions. Practice directions orchestrate clinical negligence claims and pre-action protocols. The overriding objective of the CPR is the early, efficient and cost-effective resolution of claims.⁴⁰ The rules require the use of alternative methods to resolve disputes as a key component in keeping with the overriding objective.

The need for compliance with the CPR may serve to expand the use of guidelines and related documentation in several ways. First, practising lawyers may have no option but to consider guidelines seriously when making a preliminary assessment of the viability of clinical negligence cases. Second, guidelines may come to play an important part in pre-trial resolution where the alleged negligence has involved a departure from guidelines or where the defendant's actions conform with accepted guidelines (or, more rarely, where allegations relate to a failure to lay down or implement guidance). Third, the CPR requires strict conformity with response times at clearly defined stages of a claim with a view to early closure of proceedings wherever possible. These rules may encourage complaints managers, lawyers and doctors to place a heavier reliance on guidelines in the resolution of disputes.⁴¹

Guidelines are also implicated by CPR disclosure rules. The pre-action protocol aims to encourage a 'cards on the table' approach as

³⁶ *Ibid.*

³⁷ This argument is developed further in section C of the discussion.

³⁸ C. Foster, 'Bolam: Consolidation and Clarification' (1998) 4 *Healthcare Risk Report* 5.

³⁹ The CPR came into effect on 26 April 1999.

⁴⁰ C. Foster, 'Civil Procedure, Trial Issues and Guidelines' in *Guidelines: Law, Policy and Practice*, *supra*, n.12, at 111–20.

⁴¹ See V. Harpwood, *supra*, n. 13.

early as possible. Standard disclosure⁴² requires a party to disclose only the documents on which the party relies, the documents which adversely affect his own case or adversely affect another party's case or supports another party's case and documents which are required to be disclosed by a relevant practice direction. This default position may be varied⁴³ if the parties agree or if the court orders variance from the standard obligation. Clinical guidelines will be disclosable⁴⁴ where the alleged negligence involves a departure from guidelines, or alternatively where guidelines are used to exculpate the defendant by showing adherence to conduct that falls within the guidelines. If the preliminary letter written on behalf of the claimant raises issues as to which guidelines are relevant, then in the absence of an agreement of variance order, it is unclear whether in such circumstances the guidelines *must* be disclosed. It has been postulated that, absent general caveats to the basic rule of disclosure, such as public interest immunity or confidential communications, failure to disclose the guidelines is likely to be viewed dimly by courts.⁴⁵ This potential for the use of guidelines in the context of the CPR might eventually result in a greater reliance on guidelines in court.

In summary, a number of socio-political, doctrinal and procedural developments have raised the profile of clinical guidelines in clinical negligence litigation. We surveyed practising solicitors and barristers to ascertain the extent to which guidelines are perceived as being used in litigation and their potential future use.

III. SURVEY AND RESULTS

A. Survey

A two-page questionnaire was developed based on our knowledge of guidelines currently in use in clinical medicine in the UK and previous literature regarding the use of guidelines in medical litigation. A pilot was undertaken and the questionnaire was refined. After revision, the questionnaire contained 14 multipart questions covering respondent demographics and practice characteristics, familiarity with specific guidelines and awareness and attitudes towards the use of guidelines for evidentiary purposes in medical malpractice litigation. Specific enquiries were made about four types of guidelines: those emanating from the Royal Colleges, the National Societies, NICE and the Scottish Intercollegiate Guidelines Network (SIGN). Responses to most questions were structured as a three or four-point Likert scale.

⁴² See Part 31.6 of the CPR.

⁴³ *Ibid* at Part 31.5.

⁴⁴ *Ibid* at Part 31.6.

⁴⁵ *Supra*, n. 40.

The principal solicitors and barristers practising in clinical negligence in England and Wales were identified from the Chambers UK Guide to the Legal Profession 2004 and the Legal 500 Directory 2004. The questionnaire and a cover letter were mailed to 372 lawyers (220 solicitors and 152 barristers).⁴⁶ A total of 110 lawyers completed the survey (71 solicitors and 39 barristers).⁴⁷ The data were analysed descriptively and several respondent subgroup comparisons were tested.⁴⁸

B. Results

1. Respondent Characteristics

Approximately two-thirds of the respondents were solicitors and one-third were barristers (Table 1). Forty-four per cent were based in London. Seventy-four per cent of respondents represented claimants more than they did defendants. Respondents were experienced in terms of both duration of practice and handling of clinical negligence cases. Eighty-three per cent had been in legal practice for 11 years or more, 81 per cent had clinical negligence cases as more than half of their personal caseload and 75 per cent handled more than 15 new clinical negligence cases per year.

2. Familiarity with Guidelines

A high percentage of respondents reported that they were somewhat familiar with each of several major guidelines, although a relatively small proportion described themselves as being very familiar with them (Table 2). Overall, 80 per cent of respondents were very familiar or somewhat familiar with guidelines from various Royal Colleges, 75 per cent were familiar with NICE guidelines and 46 per cent were familiar with guidelines from learned national societies. Solicitors were more familiar than barristers with guidelines from NICE ($p < 0.01$).

⁴⁶ Questionnaires were identified by numeric identifiers only in order to preserve respondents' confidentiality. No monetary incentives were offered to participants. A reminder was mailed to non-responders after 8 weeks.

⁴⁷ The unadjusted response rate was 30 per cent.

⁴⁸ A research assistant manually entered coded responses onto an Excel spreadsheet. One of the investigators analysed the data using the Stata 8.2 statistical package. Bivariate associations were examined using chi-square analysis and Cuzick's extension of the Wilcoxon rank-sum test for trend across ordered responses. See J.A. Cuzick, 'Wilcoxon-type Test for Trend' (1985) 4 *Statistics in Medicine* 87. Results described as 'statistically significant' are those for which the test statistic rejected the null hypothesis of no difference between the comparison groups at a p -value of <0.05 or smaller. A p -value, or probability value, of <0.05 indicates that there is less than a 5 per cent chance that the result occurred purely by chance.

Table 1. Demographic Features of Respondent ($n = 110$)[†]

	<i>n</i>	%
Legal practice type		
Barrister	39	35.5
Solicitor	71	32.3
Proportion of own caseload accounted for by clinical negligence cases (%)		
<10	5	4.5
11–25	3	2.8
26–50	13	11.9
51–75	22	20.2
76–90	21	19.3
>90	45	41.3
Years practicing law		
<5	1	0.9
6–10	18	16.5
11–20	40	36.7
>20	50	45.8
Proportion of firm's caseload accounted for by clinical negligence cases (%)		
<10	33	35.9
11–25	24	26.1
26–50	6	6.5
57–75	20	21.7
76–90	7	7.6
>90	2	2.2
Annual number of new clinical negligence cases personally handled		
0	1	0.9
1–5	5	4.6
6–10	8	7.3
11–15	13	11.8
16–20	20	18.2
>20	63	57.3
Annual number of new clinical negligence cases handled by firm		
0–5	0	0
6–10	1	1.1
11–15	4	4.4
16–20	0	0
>20	87	94.6

[†]Percentage of completed responses. Percentages may not be rounded off to 100.

Table 2. Lawyers' Familiarity with Clinical Guidelines ($n = 110$)[†]

How familiar are you with guidelines from ...	%		
	Very familiar	Somewhat familiar	Not at all familiar
The Royal Colleges	16.7	63.9	19.4
National Societies (e.g. British Society of Rheumatology, British Society of Dermatology, British Society of Haematology)	1.9	43.9	54.2
SIGN	0	6.5	93.5
NICE	13.6	60.9	25.5

[†]Percentage of completed responses. Percentages may not be rounded off to 100.

3. Use of Guidelines in Litigation

3.1 Observed use of guidelines in negligence actions

Eighty-nine per cent of respondents reported that they or someone in their team had used guidelines in clinical negligence cases that they had handled in the past three years (17 per cent often or very often and 72 per cent sometimes) (Table 3). A similar proportion had seen guidelines used in a case by the opposing side during the past three years. Lawyers were somewhat more likely to report having seen guidelines used for inculpatory purposes (87 per cent) than for exculpatory purposes (79 per cent).

The most prevalent specific use of guidelines was citation in medical expert reports (25 per cent very often/often and 69 per cent sometimes). About half of the respondents reported having seen guidelines used in each of the following ways: by a witness during his or her testimony, by a lawyer in direct examination of a witness and by a lawyer during cross-examination. Significantly more barristers than solicitors reported having observed the use of guidelines during examination-in-chief ($p = 0.02$), during cross-examination ($p = 0.01$), in deciding the case in favour of claimants ($p = 0.01$) and in deciding the case in favour of defendants ($p = 0.01$).

Just over 40 per cent of respondents believed that the use of guidelines had been influential in the court's decision in clinical negligence cases. Forty-four per cent perceived that the guidelines had influenced the court to decide in favour of the claimant (5 per cent often and 39 per cent sometimes) and 48 per cent felt they had influenced the court in favour of the defendant (4 per cent very often/often and 44 per cent sometimes). Of those who reported seeing guidelines used for

Table 3. Lawyers' Observed Uses of Guidelines in Clinical Negligence Litigation ($n = 110$)[†]

In clinical negligence cases you have handled as a lawyer during the last 3 years, how often have guidelines ...	%			
	Very often	Often	Sometimes	Never
<i>Parties using</i>				
Been used in a case by you or your team?	0.9	16.5	71.6	11.0
Been used in a case by the opposing side?	0.9	7.5	71.0	20.6
<i>Purpose of use</i>				
Been used (by anyone in the case) to help prove that a doctor did <i>not</i> meet the standard of care?	0.9	10.9	75.5	12.7
Been used (by anyone in the case) to help prove that a doctor <i>did</i> meet the standard of care?	0.9	10.3	67.3	21.5
<i>Method of use</i>				
Been cited in a medical expert's report?	2.7	21.8	69.1	6.4
Been cited by a witness during his/her testimony in court?	0.9	4.7	43.0	51.4
Been cited by a lawyer in the direct examination of a witness?	1.0	1.9	46.7	50.5
Been cited by a lawyer during cross-examination of a witness?	0.9	2.8	48.6	47.7
<i>Effect of use</i>				
Influenced the court to decide in favour of the claimant?	0.9	5.0	39.0	56.0
Influenced the court to decide in favour of the defendant?	1.0	3.0	44.0	52.0

Percentages may not be rounded off to 100.

inculpatory purposes, 48 per cent believed that the guidelines had swayed the court toward the claimant at least sometimes. Of those who had seen guidelines introduced for exculpatory purposes, 55 per cent believed that they had influenced the court to decide in favour of the defendant at least sometimes. Barristers were more likely than solicitors to report that guidelines had been influential in court decisions for both claimants ($p = 0.01$) and defendants ($p = 0.001$).

Table 4. Lawyers' Observed Uses of Particular Guidelines in Litigation ($n = 110$)[†]

In clinical negligence cases you have handled as a lawyer during the last 3 years, how often have each of the following guidelines been used by someone in the case?	%			
	Very often	Often	Sometimes	Never
The Royal Colleges	1.9	13.1	68.2	16.8
National Societies (e.g. British Society of Rheumatology, British Society of Dermatology, British Society of Haematology)	0.9	0.9	38.3	59.8
SIGN	0	0	2.8	97.2
NICE	0.9	6.5	43.5	49.1

[†]Percentage of completed responses. Percentages may not be rounded off to 100.

Table 5. Lawyers' Perceptions of Factors Influencing the Future Use of Guidelines in Litigation ($n = 110$)[†]

Do you think any of the following will affect the future use of guidelines in litigation?	%		
	Yes, will increase use of guidelines	Yes, will decrease use of guidelines	No effect
The remit of NICE	85.2	0	14.9
Clinical governance agendas	74.7	1.1	24.2
Patient awareness	70.0	0	30.0
Patient-centred organisations	67.0	0	33.0
The judgment in the case of <i>Bolitho</i>	48.0	0	55.0

[†]Percentage of completed responses. Percentages may not be rounded off to 100.

3.2 Observed use of specific guidelines

The Royal Colleges' guidelines were reported to be used most often in clinical negligence litigation. Eighty-three per cent of respondents had seen them used at least sometimes during the past three years (Table 4). Reported use of other guidelines was substantially lower. Solicitors reported greater observed use of NICE guidelines than barristers ($p < 0.01$).

3.3 Perceived future use of guidelines

The majority of respondents felt that several developments would lead to increased use of guidelines in litigation in the future (Table 5). The

key drivers were thought to be the remit of NICE (85 per cent), clinical governance agendas (75 per cent), public awareness of guidelines (70 per cent) and efforts by patient-centred organisations (67 per cent). Many (48 per cent) also felt that *Bolitho*⁴⁹ would be influential in promoting the use of guidelines in litigation.

IV. DISCUSSION

Our results indicate that a high proportion of practising lawyers in England and Wales have used guidelines and have observed their use in medical litigation. This supports the hypothesis that guidelines may act as legal standards governing liability.⁵⁰ The potential utility of guidelines in litigation is underscored by doctrinal developments, most prominently the shift away from *Bolam*⁵¹ and toward more extrinsic evidence of what constitutes reasonable care. This shift is potentially useful in combating the problem of cognitive bias in expert testimony, and the development of clinical guidelines holds particular promise in this regard.⁵² Other forms of empirical evidence, such as physician survey responses concerning hypothetical vignettes of issues that are litigated,⁵³ could also be employed to establish the legal standard, although there is little evidence that they are currently being used. Our results indicate that a high proportion of practising lawyers in England and Wales have used guidelines as part of the litigation process.

A. Current Use of Guidelines in Medical Litigation

1. English Jurisdiction

1.1 Appellate courts

As yet the higher courts have never been asked to make a definitive pronouncement on the role of guidelines as standards for liability in clinical negligence. However, the courts have indicated that guidelines may be relevant in determining the appropriateness of a doctor's conduct in

⁴⁹ *Supra*, n. 3.

⁵⁰ C.C. Havighurst, 'Practice Guidelines as Legal Standards Governing Physician Liability' (1991) 54 *Law and Contemporary Problems* 87.

⁵¹ Whereas expert testimony may be based primarily on personal or anecdotal experience, it is assumed that this experience is a conglomeration of factors of which objective medical evidence must be one. The more recent call for objectivity in determining the legal standard of care is based on trying to develop models whereby objective empirical evidence takes precedence over personal experience.

⁵² See W. Meadow and J. Lantos, 'A Proactive Database Determination of the Standard of Medical Care in Pediatrics' (1998) 101 *Pediatrics* 6. This paper cites several psychological studies quantifying the phenomena of recall bias.

⁵³ A. Hartz *et al.*, 'Physician Surveys to Assess Customary Care in Medical Malpractice Cases' (2002) 17 *Journal of General Internal Medicine* 546.

relation to withholding or withdrawing life-supporting treatment at the end of life.

The House of Lords, in *Bland*, considered guidelines produced by the Medical Ethics Committee of the British Medical Association regarding the discontinuation of artificial nutrition and hydration (ANH). Lord Goff noted that 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 relevant professional opinion, *as required by the Bolam test*’⁵⁴ (emphasis added). Although their Lordships made an independent study of the document, and did not automatically accept it on the basis of its authority as a publication from an eminent professional organisation, they did find that it represented a responsible body of medical opinion.

A similar conclusion was reached by the Court of Appeal in *Burke*⁵⁵ regarding GMC guidance on decision-making in respect of life-prolonging treatment.⁵⁶ The claimant, who suffers from a progressive degenerative neurological condition, expressed his wish to be given ANH during the final stages of life and that he did not want this either withdrawn or withheld on the basis of a decision taken by doctors that his life was no longer worth living. Such a decision by doctors would be supported by, and in accordance with, GMC guidance, which he contended was incompatible with his human rights. At first instance, Munby J. held on the basis of a powerful rights-based discourse that the GMC guidance was incompatible with the rights under the Convention.⁵⁷ The Court of Appeal⁵⁸ reversed the decision thereby implying (and in congruence with the *Bland* principle) that in the context of withholding or withdrawing life-supporting treatment in the incompetent patient, a doctor’s practice in acting in conformity with guidance from a responsible professional body would be in keeping with reasonable practice.⁵⁹

⁵⁴ *Airedale NHS Trust v. Bland* [1993] 1 All ER 821.

⁵⁵ *Burke v. General Medical Council (defendant) and Disability Rights Commission (interested party) and the Official Solicitor (intervenor)* [2005] E.W.C.A 103.

⁵⁶ General Medical Council, *Withholding and Withdrawing Life-prolonging Treatments: Good Practice in Decision-Making* (GMC 2002).

⁵⁷ The first instance judgment in *Burke* ([2004] E.W.H.C. 1879) has raised a number of issues, including the determination of best interests in the incompetent patient, the engagement of Article 3 of the Convention in end-of-life decision-making and the status of an advance directive requiring ANH being able to override clinical judgment thereby compelling the physician to provide treatment.

⁵⁸ *Supra* n. 55.

⁵⁹ The Court of Appeal did not address some of the wider issues raised by the first instance judgment on the basis that these did not pertain to this particular claimant.

The references to guidelines in *Bland* and *Burke* were in relation to the withholding or withdrawal of life-prolonging treatment. It is arguable that in the context of such decisions, the courts would be more willing to give greater weight to guidance endorsed by relevant clinical opinion on the basis that the principle determinative in such cases is the medical prognosis of the patient. This may not necessarily reflect the view taken in relation to guidelines representing a purported standard of care in litigation.

1.2 *First-instance decisions*

There is limited evidence of the use of guidelines in determining the standard of care in courts at first instance. The High Court in *Re C*⁶⁰ commented on guidance from the Royal College of Paediatrics and Child Health.⁶¹ In approving the guidance, the court stated that what had been proposed by the attending doctors with regard to the withdrawal of treatment had the support of reliable opinion from the College and was therefore justified. In *Early*,⁶² the claimant alleged that a particular procedure used by the defendant anaesthetist was faulty. The procedure for intubation was based on guidelines that had initially been stated orally but which were later put in writing. Bennett J. noted that '[i]n relation to this procedure, it was put before the Division of Anaesthesia in the hospital. All the consultants at Newham got together ... then decided that this was a proper procedure to follow and minutes of the discussion were kept'. In this pre-*Bolitho* judgment, the judge accepted the guidelines as being indicative of the standard of reasonable medical practice and found in favour of the defendant because it was persuasive in that the guidelines had been reviewed at a meeting of the consultants. In a more recent case,⁶³ an obstetrics senior registrar employed by an NHS Trust performed an instrumental delivery at a time when guidance from the Royal College of Gynaecologists and Obstetricians stipulated that it was not acceptable medical practice to do. The child sustained injuries at birth. In finding for the claimant, Gray J. held that these guidelines, which would have been circulated to medical staff prior to the date of the incident, gave clear and authoritative indication that to attempt instrumental delivery at that time of the claimant's birth (prior to full dilatation of the cervix) was not acceptable practice. These cases indicate that guidelines have been used in litigation for both claimants and defendants.

⁶⁰ *Re C (a minor) (medical treatment)* [1998] Lloyd's Rep. Med. 1.

⁶¹ Entitled 'Withholding or withdrawing life saving treatment in children, a framework for practice'.

⁶² *Early v. Newham Health Authority* (1994) 5 Med. L.R. 214.

⁶³ *DF (by her litigation friend and mother CF) v. St George's Healthcare NHS Trust* [2005] E.W.H.C. 1327.

In *Thomson*,⁶⁴ a general practitioner failed to observe published guidance when advising the parents of a child about the vaccine for measles, mumps and rubella. On medical advice, the child was not vaccinated and subsequently contracted measles. Meningitis developed as a complication with the tragic result of permanent brain damage. The first-instance finding was in favour of the claimant; the doctor was found to have breached the standard of care by not following relevant guidelines. On appeal, the case failed on causation and the Court of Appeal consequently avoided grappling with the issue of the relationship between the standards embodied in the guidelines and the legal standard of care.⁶⁵ More recently in *Penney*,⁶⁶ Peppitt J. tested the evidence of experts using the *Bolitho* approach (that expert evidence should be able to withstand logical analysis) and stated: 'I do not consider that the evidence of Drs Hudson and Boon (defendant experts) stands up to logical analysis as that phrase was used by Lord Brown-Wilkinson in *Bolitho*. ... This is not to disparage the evidence of either. It is rather that in my judgment, their opinions cannot stand'. The Court of Appeal upheld the analysis (and decision) of the judge at first instance, approving of a more interventionist stance in determining the legal standard of care. It follows that questioning the use (or lack) of national guidelines by the court would form part of this interrogative approach.

1.3 Use of guidelines by lawyers

To date, there has been no published empirical research in the UK on the use of guidelines by lawyers. Respondents in our survey were most familiar with, and had most often seen used, guidelines from the Royal Colleges, followed by guidelines from NICE and other national learned societies. The findings concerning the Royal College guidelines are unsurprising in light of the Colleges' longstanding recognition as authoritative medical bodies. Lawyers' familiarity with, and the use of, guidelines from NICE is more interesting. NICE guidelines appear to have taken root in the legal community to an even greater extent than those of other learned national societies which have been in existence for a longer time. This level of heightened awareness is congruent with the current political, social and legal climate in the UK and is reflected in the stated higher prevalence of the use of NICE guidelines in litigation by lawyers. These factors may be mutually reinforcing: the greater the lawyers' familiarity with the NICE guidelines, the

⁶⁴ *Thomson v. James and others* (1996) 31 B.M.L.R. 1.

⁶⁵ V. Harpwood, *Modern Tort Law* (Cavendish 2003).

⁶⁶ *Penney, Palmer and Cannon v. East Kent Health Authority* [2000] Lloyd's Rep. Med. 41.

more likely they may be used; the more often they are used, the more they may become known and accepted by judges.

Solicitors reported a significantly higher awareness of NICE guidelines compared to barristers. It is possible that the level of awareness among solicitors might be related to their perception of their potential benefit. Another explanation might be that solicitors tend to use such guidelines at an early stage of dispute resolution. This would concur with the objective of the CPR to facilitate early resolution of cases and promote alternative dispute resolution (ADR).

In terms of actual use of guidelines, we found that nine out of ten respondents stated that they had used guidelines in litigation proceedings during the past three years, and a similar proportion reported seeing guidelines used by the opposing side. These findings are consonant with lawyers' high reported knowledge about guidelines from authoritative sources. Our study also shows that guidelines have been used by both claimants and defendants, although there was no statistically significant difference between these groups to suggest either a greater inculpatory or exculpatory use.

The reported prevalence of the use of guidelines in our study is considerably higher than that reported by a similar, but not equivalent, study from the USA.⁶⁷ Our study cannot be directly compared to the American study due to differences in methodology, recall periods (one versus three years), samples (two insurers and a random survey of attorneys in 50 states versus all solicitors and barristers handling clinical negligence litigation in the UK) and response rates (approximately 60 per cent versus approximately 30 per cent). Despite these differences, our study provides suggestive evidence that the current use of guidelines in England may be higher than their use in the USA a decade earlier. There is, however, no up to date evidence from the USA to make a contemporaneous comparison. Furthermore, data from the National Audit Office indicates a steep rise in both clinical negligence claims and settlements which might be an additional factor for the higher use of guidelines observed in this study. There has been considerable concern about the possible escalation of future costs, the unpredictability of claim outcomes and the length of litigation, all of which could be potentially ameliorated through the application of guidelines.⁶⁸ Just over 40 per cent of respondents believed that their use had actually influenced the outcome of cases. One reason for this relatively low figure might be

⁶⁷ A. Hyams, J. Brandenburg, S. Lipsitz, D. Shapiro and T. Brennan, 'Practice Guidelines in Malpractice Litigation: A Two Way Street' (1995) 122 *Annals of Internal Medicine* 450.

⁶⁸ National Audit Office, 'Handling Clinical Negligence Claims in England: Report by the Comptroller and Auditor General' (NAO 2001).

that guidelines are used mainly to inform the standard of care rather than being determinative and are taken as one piece of relevant evidence.⁶⁹

2. USA Jurisdiction

2.1 Case law

Reported cases from the USA reveal that guidelines have been used both as a 'shield' (for exculpatory purposes by the defendants) and as a 'sword' (for inculpatory purposes by the claimant).⁷⁰ They are not treated as dispositive, but are considered as one piece of evidence among others that bear on liability determination.

Non-adherence to established guidelines does not necessarily bode an adverse outcome for the defendant. The claimants in *Lowry*⁷¹ argued that the defendant, the treating physician, had deviated in an arbitrary manner from established guidelines of the American Heart Association for advanced cardiac life support, in that the defendant had administered atropine rather than epinephrine.⁷² The defendant argued that guidelines were not mandatory and could be overridden by the requirements of an individual case based upon clinical judgment. The appeal court affirmed the judgment in favour of the defendant; it did not see the guidelines as being more persuasive than the facts of the case itself or the evidence that was given by expert witnesses.

Equally, adherence to guidelines may not exonerate the defendant. A standard of care proffered as adequate and supported by customary practice that is based on guidelines (as opposed to being based solely on responsible opinion) was rejected in *Helling*.⁷³ The Washington Supreme Court, in allowing the claimant's appeal, refused to be bound by widely endorsed guidelines that formed the basis of the standard asserted by the defendant. This case is viewed as something of an aberration, however, and has not often been followed. Other courts have taken into account further sources of information in determining the standard of care, including factors such as the hospital's own procedures and policies and any other 'voluntary' standards.⁷⁴

⁶⁹ It was unfortunately beyond the scope of the present study to undertake an analysis of reported cases in order to assess whether legal practitioners' perceptions about the relevance of guidelines in determining the outcome of the case are borne out.

⁷⁰ This paper does not propose to go into a detailed litigation analysis of the use of guidelines in the USA, as there is already a corpus of literature on this subject (see various footnotes and references).

⁷¹ *Lowry v. Hendry Mayo Newhall Memorial Hospital* 229 Cal 620 (1986).

⁷² Epinephrine and atropine increase the heart rate by different physiological pathways and mechanisms.

⁷³ *Helling v. Carey* 519 2D 981 (Wash 1974).

⁷⁴ *Denton Regional Medical Centre v. Lacroix* 947 SW 2D 941 (Tex appeal 1997).

Overall, the US courts have been permissive towards the use of guidelines in the determination of the standard of care in medical malpractice litigation, moving away from sole reliance upon opinion-based customary practice. Guidelines have been advanced by both parties in litigation, and compliance or non-compliance does not invariably inculpate or exculpate the physician nor are guidelines *per se* binding in any way. The role of guidelines as a standard for legal liability is not straightforward. However, one principle that emerges with relative clarity from the US experience is that guidelines function as a facet of evidence that is informative, rather than determinative, of the legal standard of care.

2.2 *Sword or shield?*

2.2.1 *An affirmative defence.* Although the common-law approach in the USA is not to treat guidelines as dispositive, there has been statutory experimentation with making guidelines definitive of the expected standard of care for purposes of creating an affirmative defence. Maine initiated a statutory demonstration project which provided an affirmative defence for physicians who voluntarily agreed to follow established clinical practice guidelines in four speciality areas.⁷⁵ The purpose was to provide physicians with greater certainty as to what was expected from them, and to reduce the need for practising defensive medicine. Anaesthesia, emergency medicine, radiology and obstetrics and gynaecology were chosen as it was believed that they were those most highly affected by costly negligence claims, leading to a high degree of defensive medical practice in these areas. Specialist advisory committees were formed and funded to commission guidelines based on good evidence and methodologically sound processes. The outcome of this large, well-resourced project has been frustratingly unclear due to several possible factors. These include lack of reliable data available from managed care and other healthcare plans, lack of appropriate tools to measure whether a reduction (if any) in defensive practices was influenced by legislation and the use of clinical judgment in instigating investigations over and above those prescribed by the guidelines in order to avoid missing diagnoses that could have a critical effect on the patient.⁷⁶ It is known that only a handful of physicians availed themselves of the safe harbour erected by the demonstration project.⁷⁷ The reasons for

⁷⁵ See R.P. Solomon, 'Guidelines in the United States: Perspectives on Law and Litigation' in *Guidelines: Law, Policy and Practice*, *supra*, n.12 at 137–59; see also M. Bagle, 'Maine Physician Practice Guidelines: Implications for Medical Malpractice Litigation' (1995) 47 *Med. L.R.* 69; G.W. Kuc, 'Practice Parameters as a Shield Against Physician Liability' (1994) 10 *Journal of Contemporary Health Law Policy* 439.

⁷⁶ *Supra*, n. 75.

⁷⁷ G.H. Smith, 'A Case Study in Progress: Practice Guidelines and the Affirmation Defence in Maine' (1993) 19 *Journal of Quality Improvement* 355.

the low uptake were not clear; two possibilities are that either the group of physicians covered by the statute was too narrow or the guidelines were not relevant to any of the malpractice cases that arose during the period of the demonstration project.

Florida also established a project to evaluate the effect on the costs of defensive medicine and professional liability of allowing compliance with practice guidelines to constitute an affirmative defence.⁷⁸ An evaluation of the project concluded that the availability of the defence was an insufficient incentive to reduce defensive medical practice. Furthermore, it could not be determined what effect the use of the guidelines had on insurance premiums or on the frequency of malpractice claims in Florida.

The main point of legal interest that emerges from these projects is that they create an asymmetry: a physician is deemed not negligent if the conduct in question falls within approved guidelines, but failure to comply with guidelines does not constitute *prima facie* evidence of negligence. Such a rule can be problematic and runs the risk of precluding potentially meritorious claims. For example, where a physician's practice has been conducted on the basis of a minimalist approach but in compliance with a relevant guideline, lawyers or courts may turn away patients who have been injured by negligence that takes the form of not departing from or adding to a guideline when particular circumstances call for such conduct. Guidelines cannot account for every contingency that might occur in the clinical decision-making process and are at best summaries of the most common clinical management pathways. They cannot be used to supplant clinical judgment where special action is merited.⁷⁹ It is debatable whether there is a greater need in terms of societal policy to protect physicians from negligence liability compared with other groups of defendants, as the cost for litigation is high in other areas as well as in medicine.

A further question about the Maine approach is whether the use of guidelines in this manner would violate the constitutional requirements of the USA Constitution concerning 'due process' and 'equal protection of the law'. These issues have not yet been tested and may constitute barriers to permitting the use of guidelines only as an affirmative defence.⁸⁰ In any event, the current approach in the USA is to permit guidelines to be used as both inculpatory and exculpatory evidence—what some commentators have referred to as 'a two-way street'.⁸¹

⁷⁸ Florida Statute's Title (1992), Chapter 408.02(9); See also R.P. Solomon, *supra*, n. 75.

⁷⁹ M. Mello, 'Of Swords and Shields: the Use of Clinical Practice Guidelines in Medical Malpractice Litigation' (2000) 149 *University of Pennsylvania Law Review* 645.

⁸⁰ *Ibid.*

⁸¹ *Supra*, n. 67.

2.2.2 *A two-way street.* There is a paucity of empirical evidence on 'real-time' prevalence of the use of guidelines in medical litigation in the USA. The study by Hyams and colleagues⁸² provides some helpful data. Five hundred and seventy-eight personal injury lawyers were surveyed to determine the frequency and manner of the use of guidelines in litigation. In this study, 48 per cent of lawyers reported having had at least one case per year in which guidelines played a role and 36 per cent had one case per year in which they played an 'important' role. The researchers also reviewed records of two professional liability insurance companies. Overall, the use of guidelines occurred in 7 per cent of the claims reviewed ($n = 17$). Of the 17, 12 had been used by the claimant (as a sword), four by the defendant (as a shield) and in one the use was indeterminate. They concluded that although the use of guidelines was relatively infrequent, it might be increasing.⁸³ Guidelines were used in litigation by both defendants and claimants, but the use by claimants was three times higher than the use by defendants. Claimants successfully used guidelines as a 'sword' in both the pre-trial and trial stages of litigation.⁸⁴ The survey also indicated that despite a low prevalence of usage, guidelines still had a definite impact on the outcome of litigation.⁸⁵ The guidelines most frequently used were those of the American College of Obstetricians and Gynaecologists, followed by the American Society of Anaesthesia. Specific characteristics defining or predicting the use of practice guidelines were difficult to identify and it appears that guidelines might be more frequently used in claims involving smaller hospitals or non-teaching hospitals, although the reasons for this remain unclear. Possible uncorroborated reasons might be due to the more limited budgets of smaller hospitals and their lesser potential to defend malpractice claims.

Although useful, the Hyams study has limitations. Only two insurance companies were surveyed, claims were relatively old (late 1980s) and there was no information available as to the proportion of cases in which a guideline may have been applicable but not used. It is therefore not possible to extrapolate the results to form an estimate of the current use of guidelines. The most significant finding was that guidelines were used for both inculpatory and exculpatory purposes. Proponents of systems for healthcare reform, clinicians and guideline developers should all be aware that guidelines

⁸² *Ibid.*

⁸³ *Ibid.* In the Hyams study, 178 out of the 578 lawyers surveyed believed that the use of guidelines was increasing, whilst only seven thought that it was decreasing.

⁸⁴ See R.P. Solomon *supra*, n.75 at 154.

⁸⁵ Twenty-two per cent reported that a clinical guideline had influenced a judge or jury in at least one case in the previous year.

are a double-edged sword. The potential for a two-way use in litigation might induce higher rates of compliance with guidelines in clinical practice.⁸⁶

3. Lessons from the English and USA Experience

It is clear that in the UK and USA both claimants and defendants deploy clinical guidelines in medical litigation. Experience from the USA shows that authoritative guidelines are not automatically conferred the status of being definitive of the legal standard of care. The outcome of cases in which guidelines have been raised either as a shield by the defendant or as a sword by the claimant has depended upon the particulars of the case. It is as yet unclear to what extent guidelines will *simplify* the system of medical litigation. However, there are at least three relevant lessons to be gleaned. These relate to (a) scrutiny of guidelines by the court before admissibility, (b) the continued need for expert testimony and (c) whether guidelines will be deployed in a one-way or two-way fashion.

The US experience underscores the importance of ensuring that guidelines pass muster under applicable rules of evidence, particularly those concerning out-of-court statements. American courts apply a presumption against allowing out-of-court statements, or hearsay, into evidence because the speaker has not been sworn as a witness and is not available for cross-examination. American courts have made an exception to the hearsay rule on the basis that a clinical guideline is a 'learned treatise'. Although there is no rule that guidelines need to be so qualified before they are admitted as evidence in court, a 1993 US Supreme Court decision known as *Daubert* created strict standards for the judicial evaluation of scientific data that are offered as evidence.⁸⁷ Before scientific evidence is admitted, it must be shown to be both reliable and relevant to the matter under consideration.⁸⁸ Judges have a gate-keeping role in terms of evaluating and selectively admitting such evidence.⁸⁹ The Federal Judicial Center has been active in educating judges in the methodology of statistics and epidemiology in order to prepare them for this challenge.⁹⁰ The decision in *Daubert* encourages judges to take a more objective stance in evaluating the processes that underpin the development of guidelines before according such material evidential status in court. There is no effective hearsay rule in civil proceedings in the UK, although it has been questioned as to whether the

⁸⁶ R. Grilli and J. Lomas, 'Evaluating the Message: the Relationship Between Compliance Rate and the Subject of a Practice Guideline' (1994) 32 *Medical Care* 202.

⁸⁷ *Daubert v. Merrill Dow Pharmaceuticals Inc.* 509 US 579 (1993).

⁸⁸ The principle of *Daubert* validity is considered later in section C of the discussion.

⁸⁹ *Supra*, n. 87.

⁹⁰ See, for example, the Federal Judicial Centre reference manual on scientific evidence (Second Edition, 2000).

court should not be asked in every case to determine whether a proffered guideline is reasonable and rational before relying on it as a standard of acceptable medical practice.⁹¹

Guidelines are issued by a variety of organisations, with possibly significant differences in approach. This could result in competing or conflicting guidelines and theoretically a defence to a 'guideline sword' would be to raise another as a 'guideline shield'. A claimant or defendant could challenge the credibility or authority of a guideline by showing that the developmental process was ineffective, thereby precluding its use in court. The credibility of guidelines used by the court would therefore need to be assured on the basis of pre-determined standards.⁹² *Levine*, in which conflicting guidelines on mammography were considered, illustrates the point. The claimant's experts raised the recommendations of the American Cancer Society, whereas the defendant's experts raised those of the American College of Obstetricians and Gynaecologists.⁹³ The court acknowledged that there were two competent bodies of medical authority that may differ and permitted the use of guidelines raised by the defendant on the basis that the defendant's conduct was strongly supported by respected professionals. Expert opinion will always be required in such cases and possibly also in assisting the court in evaluating *Daubert* validity for the admissibility of guidelines. A claimant might still argue that even if a defendant provider has complied with clinical guidelines, the care provided constitutes the minimal necessary standard and is not a sufficient determinant of reasonable care under the circumstances. In a case of obstetric malpractice, where it was alleged that failure to monitor during labour resulted in a child's death, it was argued on appeal that although the standard of care provided complied with that of the American College of Obstetricians and Gynaecologists, nonetheless there was actionable negligence because those standards were the minimum expected standards and that more should have been done by the defendant.⁹⁴ Expert testimony will be required as to what more should have been done. It therefore seems improbable that the need for expert testimony will be supplanted by the use of guidelines.

⁹¹ See S.M. White 'Letters to the Editor' (2003) 96 *Journal of the Royal Society of Medicine* 254 and S.M. White, 'Not NICE Advice' (2003) 15 *Anaesthesia* 295. These comments were raised in relation to NICE guidance on the use of ultrasound scans for the placing of central venous catheters which was the subject of some criticism.

⁹² This is developed later in section B of the discussion at 2.3.1.

⁹³ *Levine v. Rosen* 616 A 2d 623 (Pa 1992).

⁹⁴ *Jewett v. Our Lady of Mercy Hospital*, 82 Ohio App 3D 428; 612 NE 2d 724 (Ohio 1992).

It is unlikely that guidelines will take root as a one-way process (used just by claimants or just by defendants). The principal example of one-way use of guidelines as an affirmative defence in the Maine model has been indeterminate. Other potential models in USA tort reform where guidelines may be regarded as carrying greater determinative one-way weight are the contract and judicial notice models. Problems with the contract model include lack of information, understanding and training that patients might have in terms of being able to choose from a range of guidelines, because of their comparative lack of clinical acumen. Decisions may be focused on short-term rather than long-term outcomes, and a differential of choice might exist depending upon the source of funding for healthcare for that particular patient. The model of 'judicial notice' is one whereby the court takes note of guidelines as the standard of care with departures conclusively establishing negligence. This model proposes that with the help of an impartial court-retained medical expert, a set of guidelines would be identified as authoritative and applicable to the conduct in issue and would be adopted as the standard of care. Breach of the standard would be substantiated by proof that the physician diverged from the practice guidelines. Problematic issues have been raised with regard to this model. Guidelines may not represent the perfect standard of care and may only represent the basic or minimal standard of care. The application of guidelines to a particular case is a matter of clinical judgment and expertise and this decision cannot be 'second guessed' by a judge. Furthermore, such a model would only be practicable where a single set of guidelines is recognised as authoritative by medical practitioners. These models are theoretical and untested, but undoubtedly would have inherent difficulties if applied in practice.⁹⁵ The conclusion to be drawn is that the use of guidelines probably cannot be confined only to exculpatory use.

B. Future Use of Guidelines

1. Factors that Might Promote Greater Use

Over four-fifths of respondents felt that the use of guidelines in medical litigation would increase in the future. The principal reasons for this were governance and associated agendas and patient-centred initiatives.

1.1 Governance

Clinical governance is the framework by which NHS organisations are accountable for safeguarding high standards of clinical care.⁹⁶ This includes establishing clear lines of accountability and implementing

⁹⁵ *Supra*, n. 75.

⁹⁶ *Supra*, n. 17.

comprehensive programmes that use evidence-based guidelines in clinical practice. The remit of clinical governance is wide and encompasses several key processes. Clinical effectiveness relies on data from primary research and systematic reviews and involves the development of standards of best practice through guidelines based on evidence. The underlying rationale of clinical effectiveness is to apply the best available knowledge to specific clinical interventions in order to achieve optimum processes and outcomes for the care of patients. Potential benefits⁹⁷ of adherence to guidelines are inextricably linked to clinical audit and risk management. Audit represents a key component of good clinical practice and guidelines provide an external standard against which audit may be conducted. Guidelines also engage as part of the risk management standards and strategies. The Clinical Negligence Scheme for Trusts is a collective scheme with the remit of assisting Trusts to meet the costs of defending clinical negligence actions and promotes the use of guidelines as a means of reducing medical error.⁹⁸ Integrated governance is the overarching framework that includes all contemporary NHS governance approaches.⁹⁹ In theory, the lines of responsibility and accountability underlying integrated governance could advance and monitor the use of evidence-based guidelines in routine practice.

In the current tort system, liability for clinical negligence remains fault-based, despite several attempts at reform.¹⁰⁰ A radical change would be a transition to an administrative or no-fault system for compensating medical injuries. A central tenet of such a proposal is that the system should make compensation decisions, and clinical guidelines that might bear on issues of causation or avoidability would be likely to play a pivotal role. A no-fault system in specific defined circumstances was proposed by the consultation document *Making Amends*,¹⁰¹ but subsequently rejected by the Chief Medical Officer¹⁰² because of the

⁹⁷ For a more detailed analysis, see DJ. Tuffnell, 'Why Guidelines? A Medical Perspective' in *Guidelines: Law, Policy and Practice*, *Supra*, n.12 at 19–35.

⁹⁸ National Health Service Litigation Authority, 'General Clinical Negligence Scheme for Trusts. Clinical Risk Management Standards' (HMSO 2005).

⁹⁹ Department of Health, *Integrated Governance Handbook* (HMSO 2006) at <http://www.dh.gov.uk/PpolicyAndGuidance/OrganisationPolicy/Governance/fs/en>, accessed on 11 April 2006.

¹⁰⁰ This paper does not propose to go into detail regarding fault-based and non fault-based liability. For a more general discussion, see S. Maclean, 'No Fault Liability in Medical Responsibility' in M. Freeman (ed.), *Medicine, Ethics & the Law* (Williams S Heinne & Co. 1988); R. Stephens and R. Mann, (eds). *No Fault Compensation in Medicine* (Royal Society of Medicine 1989).

¹⁰¹ See *Making Amends supra*, n. 16.

¹⁰² *Ibid.*

potential rise in claims that would be far higher than under the present system. To be affordable, compensation would need to be set at substantially lower levels.

In the context of legislative reform, the House of Lords is currently considering the NHS Redress Bill 2005,¹⁰³ which proposes to provide a mechanism to redress relatively small claims without recourse to civil proceedings. It would apply to personal injury or loss arising out of or in connection with a breach of duty of care owed to a person in relation to the diagnosis or treatment of any patient or occurring as a consequence of any act or omission by a healthcare professional provided that such an act or omission would merit compensation under existing tort principles.¹⁰⁴ Although it was proposed by the Chief Medical Officer in *Making Amends*¹⁰⁵ that a 'fairer test' than that accorded by *Bolam* should be used, this proposal ultimately failed to be included in the Bill. It now seems likely that the current test of eligibility for redress is likely to remain the *Bolam* standard.¹⁰⁶ The Bill in its original form has received short shrift from several consumer interest groups.¹⁰⁷ The main thrust of such criticism is that claimants would not have the benefit of being represented by independent advisors, but by persons who are on the payroll of the defendant organisation. An alternative to *Bolam* is an 'avoidability test', whereby an adverse event will be compensatable except where it is the result of an unavoidable complication regardless of treatment or non-treatment.¹⁰⁸ These proposals for reform which are likely to resurface in the future in one guise or another indicate the emergence of a model moving away from the *Bolam* standard and might evolve into one that has a greater dependence on guidelines.

Additional possibilities to no-fault liability could be achieved by channelling claims through ADR or mediation. In March 2001, the Lord Chancellor made a pledge to employ ADR in suitable cases.

¹⁰³ The House of Lords Bill 141 (previously 137) received its first reading in the House of Lords on 1st March 2006. In July, it was returned from the House of Commons with amendments (HL Bill 141 2005–6).

¹⁰⁴ An earlier version of the Bill was the subject of a study by the Constitutional Affairs Committee which provided a detailed statement on the Bill and its defects. See 'Compensation culture: NHS Redress Bill' 5th Report of Session 2005–6.

¹⁰⁵ See *Making Amends*, *supra* n. 16.

¹⁰⁶ The charity Action Against Medical Accidents has suggested an alternative 'avoidability test' which would mean that an adverse event could attract compensation unless it was the result of an unavoidable complication. See *Briefing on the NHS Redress Bill* at http://www.avma.co.uk/index_main.asp, accessed on 11 April 2006.

¹⁰⁷ Such as Action Against Medical Accidents, the Patients' Association and Patient Advice and Liaison Service.

¹⁰⁸ *Supra*, n. 106.

This approach was seen to be more advantageous than a fault-based tort system, with considerable savings in legal costs as well as avoiding the acrimony of the adversarial process.¹⁰⁹ Mediation is an approach that might also offer satisfactory resolution to some claims of clinical negligence, whereby a neutral third party intervenes to facilitate negotiation. In both these processes, the use of guidelines, or lack thereof, could possibly be a significant factor in the settlement of claims.

1.2 Patient-centred initiatives

Government-led quality initiatives have sought to focus on a culture that is more patient-orientated rather than medically dominated.¹¹⁰ Patients' participation is statutorily defined and places a duty on NHS and primary care trusts to 'make arrangements to involve and consult patients and the public in service planning, operation and in the development of proposals for changes'.¹¹¹ Furthermore, patient organisations have played a crucial role in the development of the Expert Patients Programme,¹¹² thereby creating a model for professionals and patients to work together to facilitate patient empowerment. The effect of this may be to encourage the implementation of guidelines at a local level.

The National Patient Safety Agency (NPSA), an independent organisation networking with reporting systems to receive and act on information about adverse events, and the Patients' Advocacy and Liaison Services that provide patients with information about their treatment might further contribute to a demand for the use of evidence-based practice and guidelines. The NPSA is now a special health authority, and it is also responsible for ensuring that research is carried out safely through its responsibility for a central office for research ethics committees (COREC) and for addressing concerns about performance of individual doctors through its responsibility for the National Clinical Assessment Service (NCAS).¹¹³ The NPSA is expected to collect and analyse information to learn lessons, produce solutions and disseminate these in relation to adverse events. In the pursuit of learning, the NPSA must undertake root cause analyses, which involves scrutiny of the circumstances surrounding an adverse event for systems failure, human error and failure to follow operational processes or evidence-based guidelines and protocols. There is an expectation that this work will be in partnership with all

¹⁰⁹ Department for Constitutional Affairs, 'Monitoring the Effectiveness of the Government's Commitment to Using Alternative Dispute Resolution' (DCA 2004).

¹¹⁰ J.C. Bridgeman, 'Learning from Bristol: Healthcare in the 21st Century' (2002) 65 Med. L.R. 241.

¹¹¹ S.11 Health & Social Care Act 2001.

¹¹² [Http://www.expertpatient.nhs.uk/](http://www.expertpatient.nhs.uk/), accessed on 5 March 2006.

¹¹³ As of 1 April 2005.

stakeholders involved in patient safety. At Trust level, these are the Trust board, the Patient Advice and Liaison Services, the risk management department, clinical governance committee and the Chief Executive. At local level, stakeholders include the Independent Complaints Advisory Service and the Strategic Health Authority, the coroner and the police; at national level, the NHS Litigation Authority (NHSLA) and professional organisations such as the Royal Colleges, NICE, the Department of Health and the Healthcare Commission. The NPSA's wide remit strengthens the likelihood that clinical guidelines that relate to the prevention of medical injuries will be seriously taken into account in the performance of its function of learning from adverse events and disseminating solutions.

Patient safety is an important challenge for modern health services and NPSA enforces this through the Patient Safety Observatory and the National Reporting and Learning System.¹¹⁴ This will identify trends and patterns in patient safety problems and will assist working at local levels by developing an understanding of patient safety incidents and root causes. Evidence suggests that such initiatives have already had some effect, for example, by using guidelines for the assessment and prevention of falls in older people.¹¹⁵ The adversarial nature of the clinical negligence system is at odds with the free-reporting ethos needed to make patient safety initiatives work. This mismatch may be addressed by using guidelines as a tool for patient safety as well as for NHSLA claims management.

2. Factors that Might Deter Greater Use

A minority of respondents felt that the use of guidelines in the litigation process was unlikely to change in the future. Although the study was not designed to explore the basis of such an assertion, we suggest some possible reasons for this belief.

2.1 Limitations of guidelines

Guidelines have a number of inherent limitations. There is a danger in applying the generalised prescription of guidelines in a rigid fashion to every patient. This possible interference with clinical freedom gives rise to the accusation that guidelines can result in 'cookbook medicine'. There is always a need for flexibility in patient care, and although guidelines are designed to promote best practice, in any given clinical episode, the slavish adherence to guidelines may not be the best practice for that particular patient. In medical practice, many situations

¹¹⁴ National Patient Safety Agency, *Building a Memory: Preventing Harm, Reducing Risks and Improving Patient Safety* (HMSO 2005).

¹¹⁵ *Ibid.*

arise where the art of identifying patient problems and the application of clinical acumen to individual patient's needs remain removed from the science and technological advances of the discipline. Evidence-based medicine cannot fully capture the art of medical practice, and there remains a need for clinical judgment and discretion.¹¹⁶ Additionally, guidelines are only as good as the underlying empirical evidence and the appropriateness of the conclusions reached on the basis of synthesis of evidence. The validity of guidelines may be undermined by weak research data as well as confounding factors and biases emanating from misconceptions, personal experiences and beliefs of the developers.¹¹⁷

The potential for using guidelines or evidence-based approaches to medicine as a mechanism for rationing healthcare has been flagged as a matter of concern.¹¹⁸ Decisions reflected in some guidance might be motivated predominantly by economic considerations. NICE, for instance, has a specific remit to ensure the cost-effectiveness of treatment or interventional modalities, and its guidance is frequently against clinical interventions on the basis of cost. A review of guidance by NICE in its first five years from 1999 up to April 2005 showed that 86 guidelines were published on 117 topics. Recommendations were distributed over four categories: recommended in 23 per cent; recommended with minor restrictions in 26 per cent, recommended with major restrictions in 32 per cent and not recommended in 19 per cent. Just over one-fifth of guidance produced by NICE gave a clearly affirmative recommendation. Of the negative recommendations, two-thirds were on grounds of insufficient evidence and one-third because of unacceptable cost-effectiveness. Overall, about one-quarter of interventions failed to be recommended due to cost implications. Furthermore, it has been argued that as the work of NICE is critically important to the rational

¹¹⁶ See, for example, J.R. Hampton, 'Guidelines—for the Obedience of Fools and the Guidance of Wise Men?' (2003) 3 *Clinical Medicine* 279; S.H. Woolf, R. Groll, A. Hutchinson, M. Eccles and J. Grimshaw, 'Guidelines: Potential Benefits, Limitations and Harms of Guidelines' (1999) 318 *B.M.J.* 527; D. Black, 'The Limitations of Evidence' (1998) 32 *Journal of the Royal College of Physicians of London* 23.

¹¹⁷ See, for example, R.L. Kane, 'Creating Practice Guidelines: the Dangers of Over Reliance on Expert Judgement' (1995) 23 *Journal of Law, Medicine and Ethics* 62.

¹¹⁸ For a general discussion, see O.F. Norheim, 'Healthcare Rationing: Are Additional Criteria Needed for Assessing Evidence-based Clinical Practice Guidelines?' (1999) 319 *B.M.J.* 1426; see also B. New, 'The Rationing Agenda in the NHS- Rationing Agenda Group' (1996) 312 *B.M.J.* 1593. More specifically and in relation to guidance from NICE, see K. Syrett, 'NICE Work? Rationing, Review and the 'Legitimacy Problem' in the New NHS' (2002) 10 *Med. L.R.* 1. For some issues regarding the practical implications for Trusts, see A. Samanta and J. Samanta, 'Evidence-based Medicine. A Tool for Rationalising or Rationing Healthcare?' (2005) 10 *Clinical Governance: An International Journal.* 308.

distribution of NHS funds, its appraisal of treatments should be insulated from external pressures which includes pharmaceutical companies and patient lobby groups.¹¹⁹ If guidelines are perceived as a tool for rationing healthcare, it is less likely that they will be used by the court as a determinant of the legal standard.

Another inherent problem with guidelines is that they may be proven wrong over time. For example, doubt has been cast over certain guidelines that have emanated from NICE.¹²⁰ Moreover, where guidelines do not reflect current clinical practice,¹²¹ their potential to impact on legal proceedings may be small. Guidelines may not even reflect prevailing practice at the time of their adoption. The lack of concordance between guidance and prevailing practice has been one of the fundamental criticisms of using guidelines as the gold standard to set the legal standard of care.¹²² Because physician compliance with most guidelines is low,¹²³ many guidelines cannot be said to be representative of prevailing medical practice. Despite the perceived authoritative status of NICE, even the uptake of these guidelines has been variable.¹²⁴ Guidance is more likely to be adopted when there is strong professional support and when a stable and convincing evidence base exists.¹²⁵ Where there is a gulf between guidelines and custom, using guidelines as the legal standard of care could increase, rather than decrease, clinicians' uncertainty about what the law requires of them.

2.2 *Judicial reticence*

A particularly interesting finding of our study is that the majority of respondents stated that in their experience guidelines had not played a role in determining liability. Fifty-six per cent stated that guidelines had never played a role in determining liability in favour of the claimant

¹¹⁹ See, for example, J. Raftery, 'Review of NICE's Recommendations, 1999–2005' (2006) 332 B.M.J. 1266; see also, R.E. Furner and S.E. Mc Dowell, 'How NICE may be Outflanked' (2006) 332 B.M.J. 1268.

¹²⁰ For example, recent literature shows the 'open mesh technique' rather than laparoscopic surgery to be the preferred technique for the repair of inguinal hernias.

¹²¹ See R. Choudhury and A.M.F. Hassan, 'Guidelines are Less Clinical Excellence than Hindrance' (2003) 326 B.M.J. 114; see also K. Bloor, N. Fremantle, Z. Khadjesari and A. Meynard, 'The Impact of NICE Guidance on Laparoscopic Surgery for Inguinal Hernias. Analysis of Interrupted Time Series' (2003) 326 B.M.J. 578.

¹²² *Supra*, n. 79.

¹²³ See H. Teff, *supra*, n. 2. See also P. Day, R. Klein and F. Miller, 'Hurdles and Levers: A Comparative US–UK Study of Guidelines' (London: Nuffield Trust, 1998).

¹²⁴ See G. Gill, 'Going Dutch? How to Make Guidelines Work—An Innovative Report from Holland' (2001) *Clinical Medicine* 307. See also J.R. Hampton, *supra*, n. 116.

¹²⁵ See T.A. Sheldon, N. Cullen, D. Dawson, A. Lanksher, K. Lowson and I. Watt, 'What is the Evidence that NICE Guidance has been Implemented? Results from a National Evaluation Using Time Series Analysis, Audit of Patients' Notes and Interviews' (2004) 329 B.M.J. 999.

and 52 per cent stated the same in respect of the defendant. Although lawyers may not be able to accurately predict the factors that persuade judges' decisions, observation suggests a degree of judicial scepticism about the weight of guidelines in determining the legal standard. Judges may feel that guidelines are for guidance rather than prescription in this determination.

Guidelines may not be decisive in determining the outcome of negligence cases because of a mismatch between the statistical concept of significance that forms the scientific evidence base of medical interventions and the legal standard of proof. Clinicians, statisticians and jurists have different ways of thinking about whether a piece of information is 'significant' in proving or disproving a proposition, and there are inherent difficulties in trying to bridge this gap.¹²⁶ Statistical thinking represents a relationship between the outcome and a number of underlying variables. Clinical thinking is an *approximation* derived from this relationship as opposed to being a certainty. What might appear to be statistically meaningful may not be clinically meaningful. Not all statistically significant differences lead to appreciably different clinical outcomes. If this is the case, it is questionable as to why *legal significance* ought to be attached to this information. Statistical and legal significances represent different constructs. Conventionally, statisticians require significance at the 95 per cent level or higher ($p < 0.05$).¹²⁷ In civil litigation, proof is required on a balance of probabilities at the 51 per cent level. In practice, these two kinds of 'significance' have been conflated. Courts have spoken of the 51 per cent standard as though all it requires is a p -value of 0.51, but this is not correct and remains greatly problematic when equated with clinical significance.¹²⁸

A further problem of mismatch between clinical and legal thinking relates to the determination of causation.¹²⁹ Causation in medicine is determined through consideration of a 'mosaic' comprised of a number of pieces of evidence, whereas causation in legal thinking is dependent upon a causal connection established by an unbroken chain of events.¹³⁰ Clinical causation is dependent on the probability of

¹²⁶ For a more detailed discussion, see M. Mello, 'Using Statistical Evidence to Prove the Malpractice Standard of Care: Bridging Legal, Clinical and Statistical Thinking' (2002) 37 *Wake Forest Law Review* 821.

¹²⁷ *Supra*, n. 48.

¹²⁸ *Supra*, n. 126.

¹²⁹ J.R. Matthews, 'Practice Guidelines in Tort Reform: the Legal System Confronts the Technocratic Wish' (1999) 24 (2) *Journal of Health Politics, Policy and Law* 275.

¹³⁰ For a more detailed discussion, see B.J. Charlton, 'Attribution of Causation in Epidemiology: Chain or Mosaic?' (1996) 49 *Journal of Clinical Epidemiology* 105; on causation in legal theory, see in particular Chapter 4 of H.L.A. Hart and T. Honore, *Causation in the Law* (Clarendon Press 1985). See also K.G. Sweeney,

injury occurring in the future based upon action that is taken currently, whereas legal causation is determined by a retrospective analysis of a chain of events leading to the injury sustained by a particular individual. The principal basis of medical causation is research evidence that is derived from comparisons of groups (for example, in randomized clinical trials), rather than an examination of what happens to a specific individual within a group. The law is more concerned with what happens to the individual as opposed to medical outcomes in relation to groups because the objective of the tort system is to put an injured person to the position that he or she would have been in had the tort not occurred. Medical research, and consequently guidelines, can never definitively predict what might happen to an individual. Clinical outcomes including those based on guidelines are viewed probabilistically as to what might happen; in contrast, juristic thinking is in terms of a binary model of either liability or no liability. The inherent differences that underlie thinking within medical and legal cultures may affect judges' inclination to embed guidelines in making liability determinations.

It may also be necessary for the courts to distinguish between what are regarded as 'appropriateness' guidelines and 'standard-of-care' guidelines.¹³¹ Appropriateness guidelines are developed for the purpose of reducing the rates of various procedures between individual clinicians in order to reduce variations in care and may also be motivated by financial concerns. Standard-of-care guidelines are aimed to reduce medical injury and maximize clinical effectiveness and are driven by standards of care consistent with patient safety and quality rather than merely financial considerations. The courts may (and indeed should) be cautious about applying appropriateness guidelines as the standard of care than they are about applying standard-of-care guidelines, and telling the difference between the two may not be straightforward. Furthermore, guidelines might be promulgated by insurance companies with a view to reduce insurance premiums, although it is unlikely that insurance companies will insist on the mandatory use of such guidelines, possibly because of the potential conflicts that could arise in the event of a suit being based on the content of the guidelines.¹³² In a case where

D. MacAuley and D.P. Gray, 'Personal Significance: the Third Dimension' (1998) 351 *Lancet* 134.

¹³¹ T.A. Brennan, 'Methods for Setting Priorities for Guideline Development: Medical Malpractice' in M.J. Field (ed.), *Setting Priorities for Clinical Practice Guidelines* (National Academy Press 1995).

¹³² This is mainly a concern with the use of guidelines in the USA as seen in the development of the American Society of Anaesthesiologists' guidelines to prevent hypoxic accidents by the use of certain equipment and effective equipment maintenance. Although this particular project was highly successful in terms of reducing adverse

failure to diagnose breast cancer was alleged,¹³³ a possible reason for the court's refusal to admit guidelines relied upon by the defendant might have been that they were promulgated by a private insurance company as part of an insurance contract and may not have represented standard medical practice.¹³⁴

Judges may be reluctant to lean too heavily on guidelines because the authors of guidelines will not usually be called as witnesses. In the absence of the ability to cross-examine the authors, there may be a judicial reluctance to accept their pronouncements as dispositive of the case.¹³⁵ Indeed, guidelines may be overshadowed by live testimony provided by expert witnesses. This is exemplified in *Loveday v. Renton* which involved consideration of contraindications to the pertussis vaccine.¹³⁶ In explaining his preference for the evidence of expert witnesses over written material published by learned societies, the judge opined: 'The evidence contained in the contraindications against pertussis vaccination published from time to time in this country by the DHSS and similar bodies in other countries *cannot be relied upon as though it was evidence of qualified experts not called in witness*' (emphasis added).

Guidelines may not always represent or even influence contemporaneous medical practice. In a recent study, the evidence was tenuous that NICE guidelines were implemented in a manner that they actually had an impact on clinical practice.¹³⁷ Uptake of NICE guidelines had been variable and to some degree inconsistent.¹³⁸ It is likely that implementation of such guidance would have been improved if the evidence base was strong and relatively stable and if adequate funding was available to support, disseminate and implement such guidance.¹³⁹ In the absence of clear evidence that guidelines are actually implemented and followed, even when they are provided by an authoritative body such as NICE, the courts may be reluctant to actively adopt them in determining the standard in clinical negligence.

events and also bringing down insurance premiums, it is unlikely that guidelines will be mandated by insurance companies. See R.P. Solomon *supra*, n. 75.

¹³³ *Quigley v. Jobe* 851 P 2D 236 (Colo. CT App 1992).

¹³⁴ This is of particular interest as it re-emphasises the importance of Troy Brennan's distinction of 'appropriateness guidelines' versus 'standard-of-care' guidelines in the use of medical malpractice litigation, *supra*, n. 131, section A3 of the discussion regarding some of the difficulties with the contract model of tort reform.

¹³⁵ *Loveday v. Renton* [1990] 1 Med. L.R. 117.

¹³⁶ *Ibid.*

¹³⁷ *Supra*, n. 125.

¹³⁸ *Ibid.*

¹³⁹ Further correspondence and discussion of this paper can be found in the B.M.J (2005) 330 at 1084-6.

2.3 Challenging guidelines

In the context of tort litigation in the UK, the authority of guidelines has not yet been challenged directly. The likely issues in such challenges are outlined below.

2.3.1 Standards. A number of key attributes bolster the authority of guidelines. A guideline should command credibility as a statement of good practice. Guidelines created by professional bodies of esteem and standing are likely to carry greater authority.¹⁴⁰ The process through which guidelines are developed should be robust, exacting and evidence-based. Ideally, guidelines should reflect actual clinical practice among respected specialists in the field.

Many approaches to guideline development have been taken, but credibility can be enhanced by using a hierarchy of development strategies.¹⁴¹ Having ascertained an area of need, relevant stakeholders are invited to form a guideline development group. Evidence needs to be searched for and obtained and graded according to its hierarchy. The meticulous appraisal of scientific evidence and its strength are crucial to the status of authority that guidelines would carry.¹⁴² Guidelines are then developed, piloted and refined. Dissemination and implementation strategies promote use and credibility. Design and presentation are keys to successful implementation. Several diverse methods need to be used in order to disseminate guidelines successfully. Extensive dissemination strategies underpin the contention that the guideline is meant for widespread use and that medical practitioners should be on notice regarding its content and application.¹⁴³

The proliferation of guidelines has generated a system for guideline appraisal.¹⁴⁴ Several questions covering specific areas such as the guideline development process, content, presentation and applicability have been developed, and by answering these questions, an estimate of the guideline's overall worth is made. In 1998, the USA government launched an internet website intended to make evidence-based clinical practice guidelines widely available to healthcare professionals. The National Guidelines Clearinghouse (NGC) has adopted minimum

¹⁴⁰ J. Grimshaw and I.R. Russell, 'Achieving Health Gains Through Clinical Guidelines: Developing Scientifically Valid Guidelines' (1994) 2 *Quality in Healthcare* 204.

¹⁴¹ S.H. Woolf, 'Practice Guidelines: A New Reality in Medicine. Methods of Developing Guidelines' (1992) 152 *Archives of Internal Medicine* 946.

¹⁴² D.J. Tuffnell and J. Wright, 'Designing Clinical Guidelines: Steps and Procedures' in *Clinical Guidelines: Law, Policy and Practice*, *supra*, n. 12 at 37–52.

¹⁴³ NICE, for example, has a dissemination strategy that widely circulates its guidelines.

¹⁴⁴ F. Cluzeau, P. Littlejohns, J. Grimshaw *et al.*, 'Draft Appraisal Instrument for Clinical Guidelines' in *The Development and Implementation of Clinical Guidelines* (Royal College of General Practitioners 1995).

criteria of inclusion on the website. Guidelines should contain systematically developed statements that have recommendation strategies or information that assist healthcare professionals and patients in making informed decisions about appropriate healthcare. Guidelines should be produced by relevant professional organisations, and those that are developed by individuals who are not officially sponsored or supported would not meet the inclusion criteria for NGC. There is a requirement that corroborating documentation can be produced and verified in order to confirm that a systematic literature search and review of existing scientific evidence in peer-reviewed journals has been performed. Any gaps in this process need to be identified and clearly stated. Finally, the most recent version of the guidelines should be produced with documented evidence that this was developed, reviewed or revised within the last five years.¹⁴⁵ As yet there exists no equivalent quality assurance body in the UK, although the new performance framework for the NHS driven by 'Standards for Better Health'¹⁴⁶ might represent a first tentative step in this direction.

2.3.2 Institutional legitimacy. Managers and healthcare professionals have limited budgets and competing claims for services. It falls upon them to prioritise these claims, and evidence-based medicine may be used to address the problem of limited healthcare resources.¹⁴⁷ On the basis of distributive justice, to ensure a more effective service for all, best scientific evidence could be used to inform the way resources are prioritised in order to avoid input into what may be deemed 'ineffective' treatment.¹⁴⁸

A practical approach to priority setting was recently defined and used for programme budgeting and marginal analysis followed by pragmatic considerations in determining how resources are allocated at local and institutional levels.¹⁴⁹ Programme budgeting and marginal analysis include determining locally relevant needs, identifying where services could grow and where resources could be released through improved efficiency, evaluating investments and reallocating resources. A number of practical and ethical considerations need to be taken into account,

¹⁴⁵ The National Guidelines Clearinghouse can be accessed on <http://www.guideline.gov>, accessed on 11 April 2006.

¹⁴⁶ Department for Health 'Standards for Better Health' on <http://www.dh.gov.uk/assessRoot/>, accessed on 11 April 2006.

¹⁴⁷ R. Klein, 'The NHS and the New Scientism: Solution or Delusion?' (1996) 89 *Quarterly Journal of Medicine* 85.

¹⁴⁸ O.F. Norheim, 'Clinical Guidelines: Healthcare Rationing and Accountability for Reasonableness' in *Clinical Guidelines: Law, Policy and Practice*, *supra*, n. 12 at 161–180.

¹⁴⁹ S. Peacock, D. Ruta, C. Mitton *et al.*, 'Using Economics to set Pragmatic and Ethical Priorities' (2006) 332 *B.M.J.* 482.

which include establishing the objective of the institution, establishing appropriate advisory panels with key stakeholders, ensuring implementation of results and reviewing, re-evaluating and reallocating resources.

As part of prioritising its resources, an institution or Trust may decide not to accept or implement guidelines in a certain clinical area.¹⁵⁰ However, in order to be seen as legitimate, an institution must be based upon an order that is worthy to be recognised and respected,¹⁵¹ and its decision-making process should be patently transparent through the application of the framework for the 'accountability for reasonableness'.¹⁵² There are three main conditions: publicity, relevance and appeal. A fourth condition, enforcement, has an oversight function; its purpose is to ensure that the first three conditions are met in a satisfactory manner. It has been suggested that this framework has important implications for clinical governance at all levels¹⁵³ and would apply to institutional decisions not to endorse or use nationally accepted guidelines. The publicity condition requires that the rationale underlying decisions is made explicit and publicly accessible. The relevance condition requires that the decision makers take into account the factors relevant to all key stakeholders and that they are sure that the exercise of their discretionary powers has been unfettered, particularly with respect to the interests of groups which might be made more vulnerable in the future as a consequence of a negative determination not to use guidelines.¹⁵⁴

There is no explicit mention in this model for public participation in decision-making.¹⁵⁵ The central theme of the new NHS is to empower patients, and there should be more active involvement of patients and the public within the framework of due process in order to enhance legitimacy. It is only recently that social value judgments have been considered as a principle that underpins the development of guidelines.¹⁵⁶ Setting limits on treatment options through guidelines should involve patients and the public.¹⁵⁷ The Freedom of Information Act 2000

¹⁵⁰ In *R v. North Derbyshire HA, ex p Fisher* (1997) 8 Med. L.R. 327, the health authority refused to provide beta-interferon treatment for multiple sclerosis in contravention of national guidelines. Some aspects of this are discussed in the next section at 2.3.3.

¹⁵¹ See K. Syrett, *supra*, n. 118.

¹⁵² N. Daniels, J. Sabin, 'Limits to Healthcare: Fair Procedures, Democratic Deliberation and the Legitimacy Problem for Insurers' (1997) 4 *Philosophy in Public Affairs* 303.

¹⁵³ See A. Samanta and J. Samanta, *supra*, n. 118.

¹⁵⁴ *Ibid* and *supra*, n. 19.

¹⁵⁵ *Supra*, n. 151.

¹⁵⁶ See the post-consultation draft: National Institute for Health and Clinical Excellence, 'Social Value Judgments: Principles for the development of NICE's guidance' (21 September 2005) at <http://www.nice.org.uk/download.aspx?o=271977>, accessed on 11 April 2006.

¹⁵⁷ *Supra*, n. 153.

allows for information regarding decision-making in institutions to be made freely available to the public.¹⁵⁸ A potential claimant who might wish to challenge the process would be entitled to such information through the provisions of the Act. The appeals condition allows for an internal review of the decision-making process.

2.3.3 Judicial review. The courts can provide a mechanism for external scrutiny and enforcement of guidelines affecting the distribution of healthcare resources when other processes have been exhausted or unsuccessful. The case of *R v. North Derbyshire Health Authority, ex parte Fisher*¹⁵⁹ concerned a failure to follow national guidance regarding beta-interferon treatment for multiple sclerosis. The health authority adopted a policy under which funding for the treatment would be considered only for patients participating in a randomised controlled trial. This was contrary to the guidance in a government circular, which stated that the patient should be referred from primary care to secondary care specialist neurological services for assessment. The court held that as there was no such randomised controlled trial ongoing, the health authority's failure to adopt the policy effectively amounted to a ban on treatment with beta-interferon, and although it was not mandatory to follow the national guidance, the failure to do so should be justified. In *R v. Secretary of State for Health, ex parte Pfizer*,¹⁶⁰ the guidance itself was at issue. The pharmaceutical company, Pfizer, challenged the lawfulness of a Department of Health circular containing guidance on the prescription of one of Pfizer's products, sildenafil (Viagra). The guidance stated that 'doctors should not prescribe sildenafil. Health authorities are also advised not to support the provision of sildenafil at NHS expense ... other than in exceptional circumstances'.¹⁶¹ The court held that the circular was unlawful because in stating that the drug should not be prescribed, it was in effect a mandatory prohibition and therefore put primary-care physicians in breach of their terms of service by overriding their clinical judgment.

These two cases show that courts may require justification when guidance excludes or restricts treatment modalities. This, in a sense, is an enforcement of the reasonableness condition, whereby reasons that are relevant and fair need to be advanced by the decision maker in support of the decision that has been taken. However, the vigour with which the judiciary is willing to oversee the process of limit-setting decisions in the economics of healthcare has been questioned. Following the decision at first instance in the Viagra litigation, the Secretary of State, utilising powers under the National Health Service Act 1997,

¹⁵⁸ S. 1(1).

¹⁵⁹ *R v. North Derbyshire Health Authority, ex parte Fisher* (1997) 8 Med. L.R. 327.

¹⁶⁰ In *R v. Secretary of State for Health, ex parte Pfizer* [1999] Lloyd's Rep. Med. 289.

¹⁶¹ *Supra*, n. 151.

added Viagra to the schedule of drugs whose availability on the NHS was limited to specific medical conditions or classes of patients. The effect was that Viagra was partially 'blacklisted' except to those who were already receiving treatment and to those with specific medical conditions. This was challenged under the 'Transparency Directive' 89/105/EEC on the basis that some form of explanation, with regard to the relative priority of the treatment of erectile dysfunction against other non-life-threatening conditions, should be provided. The Court of Appeal¹⁶² held that there had been no breach of the Directive.¹⁶³ This result has been seen as disappointing, an indication of the judiciary's unwillingness to engage more fully with rationing in the NHS. It has also prompted questioning of judicial review as an effectual mechanism for facilitating legitimacy in resource allocation decision-making.¹⁶⁴

Finally, it must be acknowledged that a number of hospitals within the NHS are under-funded and this may sometimes need to be taken into account when determining the standard of care owed to patients. Although this suggestion might appear controversial, it has been argued that its adoption would harmonise negligence cases with judicial review decisions.¹⁶⁵ Whether the courts will take a similar approach to guidelines that are challenged as being reflective of the standard of care in litigation remains to be seen.

C. A Proposed Conceptual Model for the Use of Guidelines

The use (or non-use) of guidelines in informing the standard of care may be raised by the claimant questioning why they were not used or complied with or by the defendant who might argue that the use and compliance with guidelines supports the requisite standard of care. A four-stage conceptual model is proposed for the analysis of using guidelines in medical litigation: (a) is it *Bolam*-defensible, (b) is it *Bolitho*-justifiable, (c) is it *Daubert*-valid, and (d) how does it apply to the particular circumstances of the matter in question (case-specific application)?

The *locus classicus* of the *Bolam* test was that a doctor does not breach the standard of care if he is acting in conformity with customary practice endorsed by a responsible body of medical opinion. The

¹⁶² *R (on the application of Pfizer Ltd) v. Secretary of State for Health* [2002] E.W.C.A. Civ. 1556.

¹⁶³ For a detailed analysis of the issues argued and of this case generally, see K. Syrett, 'Impotence or Importance? Judicial Review in an Era of Explicit NHS Rationing' (2004) 67 M.L.R. 289.

¹⁶⁴ *Ibid.*

¹⁶⁵ C. Witting, 'National Health Service Rationing: Implications for the Standard of Care in Negligence' (2001) 21(3) *Oxford Journal of Legal Studies* 443.

principal criticism of *Bolam* emerged shortly after the judgment, from Professor Montrose, in an erudite article arguing that normative values should be applied to the standard of care and that the question of negligence is what *ought to be done* rather than *what is done* in similar circumstances by most people.¹⁶⁶ Since then, a corpus of legal literature has challenged the philosophical basis of a test that has become embedded and frequently cited in medical and legal circles. Among the reasons that *Bolam* might not be sustainable, we have argued, is that recent changes imposed by the government and restructuring of the NHS have established a new climate supporting a shift towards a normative test based on professional consensus guidelines.¹⁶⁷

The results of our survey indicate that lawyers have a high familiarity with guidelines, that they have used guidelines for claimants and defendants in cases of clinical negligence and that they expect that there will be a greater use in the future. Even if a shift away from the *Bolam* test were to occur, the prospect of English courts suddenly revising an age-old tradition and actively arrogating themselves to making decisions in the absence of expert witness testimony is remote.¹⁶⁸ It is likely that equilibrium will be reached halfway between the current traditional status and a complete rejection of *Bolam*. We suggest that guidelines may serve to inform the standard of care, thereby providing an added dimension to the evaluation of the legal standard of care and promoting a move away from a hard-line *Bolam* approach.

The first stage of the proposed conceptual model would be for the court to decide whether or not the defendant's conduct in relation to the use of guidelines is *Bolam*-defensible. If the conduct is not *Bolam*-defensible, this will lead the court to conclude that the conduct is such as no reasonable doctor could have held, and *prima facie* the defendant has failed to meet the standard of care.

The second stage would be for the court to determine whether the non-compliance or otherwise with guidelines was *Bolitho*-justifiable. The key to understanding how *Bolitho*-justifiability might work in relation to clinical guidelines informing the standard of care lies in the speech of Lord Browne-Wilkinson: 'The court has to be satisfied that the exponents of the body of opinion relied upon can demonstrate that such opinion has a *logical basis*. In particular, in cases involving, as they often do, the weighing of risks against benefits, the judge

¹⁶⁶ A. Montrose, 'Is Negligence an Ethical or Sociological Concept?' (1958) 21 M.L.R. 259.

¹⁶⁷ V. Harpwood, 'NHS Reform Audit Protocols and Standard of Care' (1994) 1 *Medical Law International* 241.

¹⁶⁸ This is supported by the contention held by M. Brazier and J. Miola, 'Bye Bye *Bolam*: a Medical Litigation Revolution?' (2000) 8 *Med. L.R.* 85.

before accepting a body of opinion as being responsible, reasonable or respectable, will need to be satisfied that, in forming their views, the experts have directed their minds to the question of *comparative risks and benefits* and have reached a defensible conclusion on the matter' (emphasis added).¹⁶⁹

In essence, Lord Browne-Wilkinson's speech contains two key *obiter* components: logical analysis and risk analysis. In considering a logical basis for the use of guidelines, a number of factors might be taken into account, such as whether guidelines relating to that condition were published, available and clinically accepted at the time the treatment was provided. Additionally, there is a concern that the process of logical analysis might get metamorphosed to a *Bolam* standard in another guise, as it has been questioned as to whether a judge might try to second guess the technical merits or arguments of such a stage.¹⁷⁰ However, a judge may be well positioned to undertake such a critical evaluation, particularly when combined with the component of risk analysis. What would have been the risk in using the guidelines compared with the magnitude of the injury that might occur by not using them? This is where *Bolitho* might really take effect by assessing the validity of accepting the lack of use of guidelines and, more importantly, the validity of rejecting the competing position in terms of using guidelines. A number of factors need to be taken into account, including the magnitude of risk, the comparative risk of using guidelines, the seriousness of the consequences and the ease by which such risk might be avoided, as well as the implications of such avoidance in terms of finances and resources of healthcare.¹⁷¹

The courts are familiar with performing such a risk assessment. *Hucks v. Cole*¹⁷² concerned whether the general practitioner in question should have continued to prescribe tetracycline for puerperal fever when penicillin was the better antibiotic. Tetracycline was slightly cheaper. Despite expert evidence that a respectable body of opinion supported the prescription for tetracycline, Sachs L.J. said that when 'risks of grave danger are knowingly taken, however small the risk, the court must anxiously examine the lacuna—particularly if the risk can be easily and inexpensively avoided'.¹⁷³ There was no convincing evidence provided by the defendant experts as to any obvious means of eliminating that risk and protecting the patient. *Hucks v. Cole*¹⁷⁴ was cited with

¹⁶⁹ *Supra*, n. 3.

¹⁷⁰ *Supra*, n. 168.

¹⁷¹ See A. Samanta and J. Samanta, *supra*, n. 34.

¹⁷² *Hucks v. Cole* (1968) [1993] 4 Med. L.R. 393 (CA)

¹⁷³ *Ibid* at 397.

¹⁷⁴ *Ibid*.

approval in *Bolitho*. In a post-*Bolitho* case, *Marriott v. West Midlands Health Authority*,¹⁷⁵ a similar approach was used. The issue in question was whether a general practitioner should have referred the plaintiff to hospital earlier in a case where a plaintiff fell, injured himself, suffered a skull fracture and developed a large extradural haematoma that was evacuated but which subsequently left him paralysed. Although a wealth of expert opinion supported the notion that a referral to a hospital for neurological assessment was not indicated at an earlier point, in the light of the plaintiff's symptoms and clinical course, a weighing of the risks suggested otherwise. The risk of making such a referral for assessment, balanced against the risk of a serious adverse outcome, pointed toward an earlier referral. The seriousness of something going wrong could not really support the defendant witnesses' testimony on a logical basis. There is no reason, therefore, as to why the failure to use clinical guidelines cannot be critically evaluated by a court in terms of risk assessment.¹⁷⁶

The application of *Bolam*-justifiability to a situation where there has been compliance with guidelines might be as follows. First is where there might be two sets of competing guidelines. Before considering whether or not to admit a proffered set of guidelines into evidence, the judge may wish to consider whether it was *Bolitho*-justifiable not to have used the competing set of guidelines and whether the defendant had considered that question and had a reasoned basis for rejecting them. Secondly, it could be that the defendant was unaware of the existence of the competing set of guidelines. The lack of knowledge of a procedure or interventional modality was addressed in *Crawford*.¹⁷⁷ In that case, the Court of Appeal reversed a finding of negligence against a surgeon whose patient experienced an arm injury during

¹⁷⁵ *Marriott v. West Midlands Health Authority* [1999] Lloyd's Rep. Med. 23.

¹⁷⁶ The US case of *Helling v. Carey*, *supra* n. 73 related to a suit brought against ophthalmologists when the plaintiff suffered severe visual impairment due to glaucoma. She had been under the care of the ophthalmologists for nine years and had complained of deteriorating vision, but had never had an intraocular pressure test. Evidence was presented to show that professional custom was not to perform glaucoma tests in patients such as the plaintiff because of glaucoma being very rare in that age group. The Washington Supreme Court held that customary practice in this case did not constitute reasonable care because a test for glaucoma was inexpensive, easy to administer and could reduce a fairly serious risk of loss of vision. Although this particular case was one of the few where the judgement went against what was regarded as customary practice, it nonetheless demonstrates that the courts are not unwilling to take a risk assessment approach and balance what has been done against what should have been done in terms of the avoidance of the risk and the relative ease by which this might have been achieved.

¹⁷⁷ *Crawford v. Board of Governors of Charing Cross Hospital* (1953) *The Times* 8 December.

surgery as a result of being positioned in a way that an article published six months earlier in the *Lancet* had warned could cause injury. Lord Denning, giving judgment, said that it would be too high a burden to expect a medical professional to read every article in the current medical press and it would be wrong to suggest negligence because suggestions in a medical journal are not put into practice immediately.

Given the very rapid progress in medicine and the prodigious number of medical publications, it would indeed be unreasonable to expect every doctor to read every article. At the same time, it would not be unreasonable for a doctor to take steps to become aware of important developments within the field of his or her practice in a timely fashion. It is, as yet, open as to what constitutes a reasonable awareness of developments within a doctor's field of expertise. *Crawford* was a pre-*Bolam* decision and it is arguable whether the *Bolam* standard would engage as the test for such an issue. It seems likely that the standard would be more objectively determined, for example, by standards set by medical professional bodies. The GMC has stressed that a doctor must be fit to practise and that a key component is continuing professional development by keeping abreast with advances in medicine.¹⁷⁸

Judicial authority for this proposition of 'keeping up-to-date' is found in *Gascoine*,¹⁷⁹ where it was held to be the responsibility of a practitioner to generally keep informed of such developments, although it could not be expected that the practitioner had read every article on the subject. The courts have indicated that when the significance of new information is still being established it is not expected that doctors will necessarily be aware of that. However, with widespread dissemination methods such as the intranet and internet, knowledge about medical advances as well as alerts are relatively accessible, and expectations are rising that doctors should be cognisant of these.¹⁸⁰ With regard to awareness of clinical guidelines, an important issue would be how well disseminated they had been and their relevance to that particular clinical practice. Lack of knowledge of guidelines may not be *Bolitho*-justifiable.

The third stage would be to determine whether or not guidelines should be admissible as evidence. The ruling in *Daubert*¹⁸¹ in the USA has indicated that the court should take a more proactive view and scrutinise the guidelines carefully before allowing their

¹⁷⁸ *Supra*, n. 26.

¹⁷⁹ *Gascoine v. Ian Sheridan & Co, and Latham* [1994] Med. L.R. 437.

¹⁸⁰ J.K. Mason and G.T. Laurie, *Mason and McCall Smith's Law and Medical Ethics* (Seventh edition) (Oxford University Press 2006).

¹⁸¹ *Supra*, n. 87.

admissibility. A preliminary assessment would include questions relating to the theory and technique by which the guidelines have been developed, whether they have been subjected to peer review, any known or potential error rate and whether they have widespread acceptance within the relevant medical community. This inquiry focuses principally on the principles and methodology of the scientific work rather than on its conclusions. The touchstones on the admissibility of guidelines are *reliability* and *relevance*. Relevant evidence is that which would make a determination of fact more or less probable than it would be without the evidence. The crux of relevance is whether the guidelines would assist the judge in understanding the evidence to be adduced or in determining a fact in issue. Reliability must be supported by appropriate validation, proper reasoning and methodology and would depend upon the developmental process of the guidelines as well as the standards inherent in the guidelines.¹⁸² Guidelines that are developed using rigorous methodology and are evidence-based are unlikely to be regarded unreliable, and the principal matter that the court may have to decide is whether the admission of the guidelines would be relevant to that particular case. Judges should apply an analytical framework to evaluate scientific evidence based on a range of factors and act as gatekeepers before accepting guidelines as admissible evidence.

The fourth stage would be the application of guidelines to the specific facts of the case in question. It is envisaged that at this stage there would be narrow issues to address. The first would be whether the specific recommendations of the guidelines have or have not been applied. This is mainly a matter of fact. The second issue would be a value judgment as to whether the conduct of the practitioner fell below what would be expected of a reasonable doctor. This would still require expert testimony, but guidelines might serve to inform the standard of care and lend greater credibility to the opinion offered.

The model proposed is a halfway house between the traditional *Bolam* test and the one in which guidelines define the standard of care. There is a serious fear that the use of guidelines (particularly in the legal context) might lead to the ossification of medical practice by stifling the art of medicine in preference to using scientific evidence by rote.¹⁸³ This model would avoid such a consequence and would serve to fulfil two key functions: first, using guidelines to inform the legal standard would import evidence-based medicine into the judicial decision

¹⁸² *Ibid.*

¹⁸³ D. Black, 'Guidelines or Gumption? The Role of Medical Responsibility: A View from the Profession' in S.R. Hirsch and J. Harris (eds), *Consent and the Incompetent Patient: Ethics, Law and Medicine* (Royal College of Psychiatrists 1998).

making process; second, at the same time, the door remains open for using expert evidence in court—a necessary requirement for assessing the permissible limits of clinical judgment. This model blends a scientific evidence-based approach with clinical autonomy that is an inherent component of medical practice and provides a framework for structured judicial decision-making.

V. CONCLUSION

There are clear advantages of using well-constructed and authoritative clinical guidelines to establish the standard of care in medical litigation. Their judicious use could elevate the quality of healthcare and provide doctors with greater certainty as to what is expected of them by law. This is in concordance with the government agenda for quality in healthcare and professional reform in the context of contemporary societal expectations. Guidelines, however, have limitations and represent a generalisation of empirical evidence which may not always be applicable to individual patients due to the need for the exercise of clinical judgment. Their use in litigation therefore necessarily requires caution and a careful and structured framework to ensure appropriate application. Ideally, this should tread a middle path between the traditional *Bolam* approach and the alternative notion that guidelines are determinative if the standard of care.

Our study shows that a high percentage of lawyers are familiar with clinical guidelines and have observed these being used by both claimants and defendants in cases of medical negligence. Furthermore, the majority perceived that guidelines would be used to a greater degree in the future. A limitation of our study was the relatively low response rate, a problem commonly encountered in surveys of busy professionals, particularly when no honorarium is paid for participation.¹⁸⁴ A low response rate raises the possibility of non-response bias, thereby limiting the ability to generalise our findings. This study represents a starting point for future research. Further studies could seek to determine the prevalence of the use of guidelines through an analysis of litigation cases, use of focus-group methods to explore how solicitors, barristers and judges believe guidelines should be used and an assessment of the extent to which guidelines influence trial outcomes and pre-trial settlements.

We suggest that the use of guidelines in legal practice is more than minimal and can be expected to increase in the future. The proposed

¹⁸⁴ D.A. Asch, M.K. Jedrzewski and N.A. Christakis, 'Response Rates to Mail Surveys Published in Medical Journals' (1997) 50 *Journal of Clinical Epidemiology* 1129.

conceptual model for the use of guidelines in clinical negligence litigation serves as a halfway house between the current *Bolam* test and the diametrically opposed view that guidelines should be definitive of the legal standard. Such a model has the attraction of introducing evidence-based science into judicial decision-making whilst at the same time permitting expert testimony to assess the exercise of clinical judgment. In this way, the courts can achieve a pragmatic balance between predictability and flexibility in determining liability for clinical negligence.