

**CLINICAL GUIDELINES AS A TOOL FOR LEGAL LIABILITY
AN INTERNATIONAL PERSPECTIVE****Jonathan Davies***

Abstract: Clinical guidelines are statements that have been systematically developed and which aim to assist clinicians in making decisions about treatment for specific conditions. They are linked to evidence and are meant to facilitate good medical practice. A key issue that follows is how lawyers and the courts might use such guidelines in medical litigation.

The multiplicity of opinions and scientific professions requiring expertise might influence the expert submitting an opinion to base his opinion on scientific theses which have not been recognized scientifically, are not based on facts and are not supported by professional literature.

Medical evidence has to be methodically based and reliable. In recent years the medical community has developed a new field called "Evidence Based Medicine", meaning, use of medical information based on the best information in the medical literature relevant to the condition being treated. Evidence Based Medicine distinguishes between recognized scientific theories and what is called "Junk Science".

Clinical Guidelines are of value in systematizing medical procedures, mainly those which may have legal implications. In other procedures Guidelines may serve the Court as a source of sound information, provided they are the product of a recognized professional body, and proven to bear no relation to a body which may have interests in the delivery of healthcare.

Clinical guidelines are set as normative standards and used as a tool to indicate the standard of care at the time. They can be used as a tool for assessment of the questionable conduct. Guidelines are consulted by courts because they provide evidence of standards justified in relation to evidence rather than custom, this helps the courts test the expert evidence that radically strengthen the normative dynamic of the law in actions alleging medical negligence

As clinical practice guidelines become more and more prevalent, some authors believe they will define the requisite "standard of care" for medical treatment and impact medical malpractice litigation. They may even replace expert testimony.

Keywords: Clinical guidelines; medical evidence, expert opinion, standard of care, legal liability.

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INTRODUCTION

Clinical guidelines are statements that have been systematically developed thus aiming at assisting clinicians in making decisions about treatment for specific conditions. They are linked to evidence and are meant to facilitate good medical practice. A key issue that follows is how lawyers and courts can use such guidelines in medical litigation.

At the heart of clinical negligence lies the question of whether or not the practice of a defendant doctor has fallen below the required standard of care. Under common law, the minimal acceptable standard of care is measured against responsible medical practice, but not against guidelines in law. Therefore, it is expert medical evidence that primarily assists courts in determining the required standard of care. Clinical guidelines have played a subsidiary role in determining the required standard of care.

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Medical evidence has to be methodically based and reliable. In recent years the medical community has developed a new field called "Evidence Based Medicine", meaning, use of medical information based on the best information in the medical literature relevant to the condition being treated. Evidence Based Medicine distinguishes between recognized scientific theories and is the so-called "Junk Science".

The adversarial system, in which the parties present their evidence, may create a gap between scientific evidence admissible in court and proving it as a respectable scientific theory different from Evidence Based Medicine (EBM).

In an adversarial system it is not the role of the court to choose the kind of evidence that is presented before it and that is recognized by science. The court can accept as evidence a presented scientific theory that has no basis in science whatsoever, and can be considered Junk Science or, at the very least, a theory devoid of scientific foundation that might result in the failure of the judicial proceedings.

THE DEVELOPMENT OF CLINICAL GUIDELINES

The original declared aim of the guidelines was to aid the individual medical practitioner in dealing with the enormous influx of information. However, other interests "joined in" and in some aspects became dominant. These interests were those of the purveyors of medical services, governmental and/or interested corporation such as pharmaceutical companies. The intent of some these agents was to improve the quality of services and eliminate unnecessary procedures. These can cause potential conflict of interests and dialog concerning the quality of the guidelines and thus serve interested parties in a medical claim.

The development of guidelines is a structured process. The first step is to identify and refine the subject area. A multidisciplinary expert group of key stakeholders systematically reviews all the available evidence. The group proceeds to identify and assess relevant evidence around the subject, which then needs to be translated into a practically useable and workable clinical form. Guidelines need to be reviewed and updated regularly.

Clinical guidelines are developed by the techniques of evidence-based medicine. Their potential benefits include provision of management strategy for patients, and maintenance of consistency and quality in healthcare. However, guidelines need to be interpreted and applied in a way that is clinically appropriate for the individual patient, and they represent just one option albeit the desirable one for improving the overall quality of clinical care.

Guidelines are not without their limitations. The primary data, which form the evidence for developing guidelines, are of necessity derived from a sample population. Susceptibility to bias relating to the nature of evidence, misconceptions, and personal recollections dependent upon the beliefs of the developers are some of the factors that may confound the validity of guidelines. A further difficulty arises from the generalization that such evidence is equally applicable to every individual. Clinical judgment may suggest otherwise; guidelines are not 'magic bullets', and enthusiasm for them must be tempered with caution¹²

As expressed in one of the many articles on this subject³:

"Clinical guidelines are only one option for improving the quality of care. Too often, advocates view guidelines as a "magic bullet" for healthcare problems and ignore more effective solutions. Clinical guidelines make sense when practitioners are unclear about appropriate practice and when scientific evidence can provide an answer. They are a poor remedy in other settings. When clinicians already know the information contained in guidelines, those concerned with improving quality should redirect their efforts to identify the specific barriers, beyond knowledge, that stand in the way of behavior change".

THE USE OF CLINICAL GUIDELINES IN LAW

A large number of clinical guidelines exist in different legal systems all over the world. Guidelines for general practitioners published in *The Netherlands* created legal standard of care applied in courts. *French* legislation went even further – practice by the guidelines was made mandatory, and accompanied with sanctions against deviating practitioners.⁴

There are substantial differences between high-standard guidelines on the same well-defined clinical entity. The selection of literature data, and diagnostic and therapeutic recommendations, seemed to be influenced by such cultural aspects as habits, the patient's expectations, and the structure of the healthcare system. All authors agree that clinical guidelines do not substitute the discretion of the doctor in any treatment⁵.

From a litigation perspective, the key question has been whether guidelines can be admitted as evidence of the standard of expected practice, or whether this would be regarded as hearsay. Courts in the USA have been unwilling to adopt broad exceptions to the hearsay rule, which limits the admissibility of out-of-court statements where the author of the statement has not been sworn as a witness and is therefore not available for cross examination. Guidelines may be admissible as evidence in the USA if qualified as authoritative material or a learned treatise, although a US Supreme Court decision⁶ may encourage US judges objectively to scrutinize the motivation and rationale behind guidelines before accepting their evidential value.

In the *UK* the legal standard of care has been enshrined in the *Bolam* test⁷. This test is based on the principle that the standard of care provided by a medical practitioner, in law, depends upon what is done in practice. A doctor can rebut a charge of negligence if he or she has acted in conformity with a similar body of other responsible and skilled professionals. Guidelines, therefore, do not have a 'self-evident' status; they have a subservient role to that of evidence provided by the expert witness⁸. *Loveday*⁹ clearly exemplifies a judicial favor towards this approach. Stuart Smith LJ, speaking about published contraindications to the pertussis vaccine, preferred the evidence of expert witnesses above written material published by learned bodies. The judge said '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).

A shift towards the use of guidelines in determining the standard of care was seen in the case of *Early*¹⁰, a judgment at first instance. The defendants were sued on two grounds. The first was that the attending anesthetist was negligent, and the second was that the procedure adopted to intubate the claimant was faulty. The procedure used for intubation had been based on an orally stated guideline. Both claims failed, and the judge said: '*In relation to this procedure, it was put before the division of anesthesia in the hospital. All the consultants at Newham got together... who then decided that this was a proper procedure to follow and minutes of the discussion were kept*'. The judge clearly showed that he was influenced by the fact that a meeting of the consultants had taken place where relevant guidelines were discussed, and he accepted these guidelines as the standard of reasonable medical practice.

In *Bolitho*¹¹ the court declared that it was not bound to find for a defendant simply because he leads evidence from a body of experts who genuinely believe that the defendant's practice conformed to sound medical practice. The court will require further evidence that the practice proclaimed has a logical basis, and that the defendant practitioner has weighed up the benefits and risks. In other words, after *Bolitho* the defendant would have to justify his stance in addition to having this endorsed by similar

responsible practitioners. Evidence-based medicine and clinical guidelines will begin to have a sharper focus in specifying the required standard of care.

CLINICAL GUIDELINES IN ISRAELI CASE LAW

According to Common Law, submission of an expert opinion is a precondition for proving medical contentions. courts in *Israel* are severe in their admissibility requirements for scientific evidence for the purpose of formulating a legal causal connection. This duty under Israeli law is even stricter than in English or American law.¹²

A scientific theory is proven at trial by means of an opinion by an expert in the field relevant to the case, taking into account the facts of the case. The opinion will be filed by an expert on the issue who has proven experience, and will rely on the case history, the clinical tests and the scientific literature relevant to the issue under dispute. The opinion must distinguish between the basic facts and the results of the work of medical experts.

In *Israel*, there is currently no effective hearsay rule in civil proceedings. The Plaintiff in a Medical Malpractice claim is entitled to present the relevant guidelines to prove that the defendant doctor breached the clinical guidelines and therefore is liable. This was the case in *Hazon V. Kupat Holim Medical services*¹³. The Plaintiff, 34 years old requested her family Doctor to refer her to a mammography test due to family history of breast cancer. The doctor refused claiming that the optimal age for Mammography in her case (family history) is 45. Two years later after detecting a lump in her breast she was referred to a Mammography which detected Breast Cancer followed by Mastectomy.

According to the Family Doctor's Association and the National Cancer Association guidelines, it was recommended that women with family history should do a Mammography at the age of 40. The court found these clinical guidelines as a reflection of the common practice, that could be a directive but certainly do not substitute the doctor's discretion.

One of the drawbacks of the adversarial system is that an expert on behalf of one of the parties owes "loyalty" to whoever commissioned the opinion (as distinguished from professional truth), and therefore the opinions submitted to the court present the scientific theory that suits the parties interest and, in the case of a court appointed expert, the particular school and approach held by the expert which do not of necessity reflect the opinion of all trends in the scientific community in the field contemplated by the opinion.

The presumption of the Courts in *Israel* is that Clinical guidelines reflect customary standards of care; they are an objective tool to measure newly developed recommendations. Guidelines are consulted by courts because they provide evidence of standards justified in relation to evidence rather than custom, this helps the courts test the

expert evidence that radically strengthen the normative dynamic of the law in actions alleging medical negligence.

The decision of the Supreme Court in *Ravid Moshe v. Dr. Dennis Clifford*¹⁴ demonstrates this approach. Ravid, a five year old girl, was given a local anesthetic to her gum, for the completion of a dental filling. Shortly thereafter, neurological symptoms became apparent. On admission to hospital, brain infarction was diagnosed. The neurological damage persisted – permanent neurological impairment, physical as well as cognitive.

The District Court found that the anesthetic was injected into the lumen of the alveolar artery, and thence upstream, to reach the brain. This factual finding has established the question of causation between the injection and the neurological damage. However, since the Court accepted, as argued by the defense, that the defendant acted according to accepted dental practice, in having used a "regular" dental syringe, there was no negligence on the dentist's part. This view was taken by the Court despite evidence as to both the availability of aspirating syringes, and the recommendation for their use. The use of a syringe of the latter type would have indicated the penetration of the artery, thereby preventing the injection into the bloodstream. The Court went further in stating that according to undisputed evidence, minor complications were known to have occurred due to the anesthetic reaching the brain via this route. However, neurological sequels of such gravity were hitherto unknown to medicine. Therefore the defendant dentist could not have anticipated such a complication. The charge of negligence was dismissed.

The Supreme Court established its recognized principle that the standard of medical practice is a matter to the Court, not to be decided or "accepted" by a "respectable body of members of the medical profession". It was emphasized that the standard of practice is established taking into consideration a variety of interests of importance to the public. In view of the severity of the possible consequences, the failure to use equipment which would have enabled the prevention of the calamity was found deficient, namely negligent.

The Supreme Court indicated that according to the guidelines set by the manufacturer of the dental syringe "*To avoid inadvertent intravascular injection an aspiration check should be performed*". This was not done, and therefore the dentist was found negligent. The Supreme Court indicated that Clinical Guidelines set a minimal standard of care and used as an additional tool to measure legal Liability.

CLINICAL GUIDELINES IN ISRAELI LEGISLATION

The criminal law declares all terminations of pregnancy to be illegal; broad defenses are provided in the Penal Code which allows a committee of 3 doctors and a Social Worker

to recommend the women a termination of pregnancy if it finds that the fetus or mother may suffer considerable damages.

Case law in Israel has developed cause of action if the information is not provided. The cause of action is to the handicapped child for Wrongful life and the Parents for

In the case of wrongful birth a mother can claim damages for the costs of raising a handicapped child, on the basis that she would have elected for abortion had she been fully and accurately informed of the facts¹⁵.

This assumes that the doctor was in possession of the information regarding the outcome, and that this was communicated to the expectant mother in a timely fashion. Failure to warn,. Wrongful birth is also applicable to cases where an abnormality is missed on ultrasound scanning. The potential for structural abnormalities to be overlooked during a screening scan is high. The more major structural defects are highly likely to be diagnosed but minor abnormalities which are the first indication of a more global problem are frequently the source of controversy.

The law in Israel does not limit the time for termination of pregnancy. Theoretically the abortion could be done prior to birth. The Jewish Law does not apply. The decision for termination of pregnancy is solely of the parents, the parents are autonomic to decide and the role of the doctors is to supply the information for making an informed decision based on all the

The Israeli Ministry of Health has developed Guidelines¹⁶ for assessing functional disability of the fetus at the viable period (i.e. - later than 24 week) as criteria for recommending termination of pregnancy. To our mind these criteria could not apply as it is impossible for any medical expert to foresee malfunction of 30% prior to birth.

The Guidelines also recommend that doctors who serve as members of medical committee for termination of pregnancy should not have any personal responsibility of their actions. This recommendation is legally wrong and contradicts the law.

It is agreed that clinical guidelines do not actually set legal standards for clinical care but they do provide the courts with a benchmark by which to judge clinical conduct. For this reason it is wrong to use the Clinical Guidelines as a Tool for influencing Legal Liability.

The Ministry of health has used wrongly its force to enact clinical guidelines in order to influence the court and promote special interest groups rather than public interest.

CONCLUSIONS

Clinical Guidelines are of value in systematizing medical procedures, mainly those which may have legal implications. In other procedures Guidelines may serve the Court as a source of sound information, provided they are the product of a recognized professional body, and proven to bear no relation to a body which may have interests in the delivery of healthcare.

Clinical guidelines are set as normative standards and used as a tool to indicate the standard of care at the time. They can be used as a tool for assessment of the questionable conduct. Guidelines are consulted by courts because they provide evidence of standards justified in relation to evidence rather than custom, this helps the courts test the expert evidence that radically strengthen the normative dynamic of the law in actions alleging medical negligence.

As clinical practice guidelines become more and more prevalent, some authors¹⁷ believe they will define the requisite "standard of care" for medical treatment and impact medical malpractice litigation. They may even replace expert testimony. We recommend that in cases of dispute the guidelines should refer to the different schools of thoughts and not state the preferred standard of care.

A different issue is the control of the regulator (i.e. the Ministry of Health) to dictate through the clinical guidelines the standard of care in cases where there is a medical dispute in the specific issue. We believe that it is wrong to enact clinical guidelines in order to influence the court and promote special interest groups rather than public interest.

¹ Cook DJ, Mulrow CD, Haynes RB. Systematic reviews: synthesis of best evidence for clinical practice. *Ann Intern Med* 1997; 126:376-80

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³ S. H. Woolf, R. Grol, A. Hutchinson, M. Eccles, & J. Grimshaw, Potential benefits, limitations, and harms of clinical guidelines, *BMJ* 318:527, 1999.

⁴ H. Maisonneuve, H. Cordier, A. Durocher & Y. Matillon, The French clinical guidelines and medical references programmed: development of 48 guidelines for private practice over a period of 18 months. *J Eval Clin Pract.* 3:3, 1997

⁵ A. Hutchinson, R. Baker, *Making Use of Guidelines I*; Clinical Practice (England, 1999)

⁶ *Daubert v Merrel Dow Pharmaceuticals Inc* 509 US 579 [1993]

⁷ *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582

⁸ *Brian Hurwitz*, How does evidence based guidance influence determinations of medical negligence? *BMJ* 2004;329:1024-1028.

⁹ *Loveday v Renton* [1991] Med LR 117

¹⁰ *Early v Newham Health Authority* [1994] 5 Med LR 214

¹¹ *Bolitho v City and Hackney Health Authority* [1997] 4 All ER 771

¹² In English law, a medical opinion depends upon obtaining the court's permission:

The Civil Procedure Rules, 1998 - 32.4 Court's power to restrict expert evidence

(1) No party may call an expert witness or put in evidence an expert's report without the court's permission.

(2) The court may give permission on or without an application.

(3) The court may direct

American law requires that a scientific theory be proven by means of an expert opinion on the matter at hand:

"If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience,

training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

¹³ CP (Jerusalem) 3532/01 Ruth Hazon v. Kupat Holim Medical Services, Tak-Meh, 2003 (3) 3184

¹⁴ *A/d No. 779/98 Ravid Moshe v. Dr. Dennis Clifford* Tak-El 2003 (2) 1589.

¹⁵ c/a No 4960/04 Eran Sidi et al v. Shrutei Briut Clalit Tak-AI 2005

¹⁶ Ministry of Health Regulation no. 23/07 December 2007

¹⁷ *Tzeel A., Clinical practice guidelines and medical malpractice* *Physicia* Exec. 2002 Mar-Apr; 28(2):36-9