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LEGAL IMPLICATIONS OF GUIDELINES*

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All too often I have come across situations where doctors, particularly inexperienced doctors, have made inappropriate clinical decisions in situations where if guidelines or protocols had been available, the mishap would not have occurred. I remember one instance where a junior doctor gave intrathecal penicillin in the wrong dose to a child where she suspected meningitis as a consequence of which the child died. There was in fact a protocol in the hospital which stated 'Intrathecal antibiotics are rarely indicated and should not be given without the consultant's authorisation'. Tragically the existence of the protocol had not been brought to the attention of the junior doctor. The relevant consultant was available in the hospital but the junior doctor did not consult him. Had it been otherwise the consultant would certainly not have prescribed intrathecal penicillin in this case and the child might not have died. Even more tragically, the autopsy revealed that the child did not have meningitis.

For doctors the critical issue is whether guidelines may rob individual clinicians of their freedom to practice according to their own clinical experience and individual patient needs, and whether failure of doctors to comply with consensus guidelines may give rise to litigation based on the fact that the doctor has deviated from accepted opinion and therefore can be considered to have acted negligently.

So the critical issue is—could the recommendation of a clinical guideline ever be held to carry the force of law?

POTENTIAL ROLE OF CLINICAL GUIDELINES IN LITIGATION

Under United Kingdom law the standard of medical treatment that a doctor owes to a patient was established in Scotland by the *Hunter-v-Hanley* test.[1] Its equivalent in England is known as the Bolam test[2] and the test is the standard of the ordinarily skilled man exercising and professing to have that special skill. To put it simply, the Lord President (Lord Clyde) stated that to establish liability by a doctor where deviation from normal practice is alleged, three facts require to be established. First of all it must be proved that there is a normal and usual practice; secondly it must be proved that the defender has not adopted that practice; and thirdly (and this is of crucial importance) it must be established that the course the doctor adopted is one which no professional man of ordinary skill would have taken if he had been acting with ordinary care...

Protocols or guidelines may be introduced to a UK court by an expert witness as evidence of accepted and customary standards of care. However, they cannot be introduced as a substitute for expert evidence; the courts are traditionally wary of evidence which is not subject to cross-examination.

Expert testimony helps the court to ascertain what is the accepted and proper

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practice in specific cases. Although questions of breach of the doctor's duty are decided primarily on the basis of such expert evidence, in the English case of *Sidaway*[3] Lord Bridge did not accept that the 'test' required handing over to the medical profession the entire question of the scope of this duty including the question of whether there had been a breach of that duty. 'Of course, if there is a conflict of evidence whether a responsible body of medical opinion approves ... in a particular case, the judge will have to resolve that conflict. Expert medical evidence is therefore not conclusive'.

The mere fact that a protocol exists for dealing with a specific condition or situation cannot itself establish that compliance with it would be reasonable in a particular circumstance or that non-compliance would be negligent. As was stated in *Hunter-v-Hanley*[1] in 1955, 'in the realm of diagnosis and treatment there is ample scope for genuine difference of opinion and one man is not negligent merely because his conclusion differs from that of other professional men.

In the case of *Early-v-Newham Health Authority*[4]—notwithstanding the testimony of a professor of anaesthesia who said of the particular protocol used by the defendant doctor that 'no reasonable competent medical authority would have condoned this drill', the judge found in favour of the defendant—not because the doctor had adhered to a protocol but because the protocol concerned was deemed by the judge to meet the standard of care required by law. The case is important irrespective of the conclusions arrived at, because it shows how a court goes about examining the status and authority of clinical recommendations. It supports the view that Civil Courts have not generally accorded to guidelines special legal status in actions alleging medical negligence.

The patient was a 13-year old girl who was taken to an operating theatre to have an appendectomy. The anaesthetist was unable to intubate her and he followed a protocol laid down by the 'defendant Health Authority which was: '... where the intubation fails, cricoid pressure should be maintained, ventilate with oxygen, do not give a second dose of suxamethonium, do not persist with repeated attempts at intubation, turn patient on side, call for help. If the procedure is not for a life-threatening condition, continue oxygenation and allow the patient to wake up'. Adopting that procedure, the plaintiff came to when her body was still partly paralysed, producing panic and distress. The judge held that it was not established that the procedure was such that no reasonably competent Health Authority would have adopted it.

The judge did not find the evidence of Professor Robinson, who criticised the Health Authority's protocol, at all convincing. He rejected his evidence as being unreliable and therefore came to the contrary view that, unless a medical procedure is patently unsafe or goes against common practice or usage, a court should not attempt to substitute its views for those of the profession. He preferred the evidence that all the consultants (about 10) had got together and decided that this was the proper procedure to follow. The judge thought it was unfortunate that Professor Robinson should suggest that those consultants and the drill that they adopted was nevertheless such that no reasonably competent Medical Authority could have adopted it. He therefore concluded that he was dealing with a competent Medical Authority who had applied its mind to the problem and came up with a reasonable solution.

Expert medical evidence is therefore not conclusive. To be credible in court expert witnesses must have first hand experience of the appropriate health care

practice. The fact that the plaintiff's main expert witness in *Early* was a retired anaesthetist may have been a factor in the judges's decision not to accord his evidence much weight.

There is concern in the medical profession that unless they comply with a clinical guideline or protocol there may be a threat of liability and negligence. The fear is that this will make doctors modify their clinical practice and so erode clinical judgment. Courts in the UK however, acknowledge the importance of reasonable discretion in coming to a clinical decision. The key issue which a court would need to consider, if a guideline is to be taken as evidence of the standard of medical care required in a particular case, is whether the guideline did in fact embody a consensus standard as represented by customary practice. The mere fact that clinical guidelines exist for the care of a particular condition cannot itself establish that compliance with them would be reasonable in the circumstances or that non-compliance would be negligent. In the case of *Loveday-v-Renton and Wellcome Foundation Limited 1990,*[5] where brain damage from whooping cough vaccination was alleged, this point was illustrated. The court there held that failure to observe contra-indication guidelines when administering whooping cough vaccination, '... would not in itself constitute negligence because there was a respectable and responsible body of medical opinion that some contra-indications should not be observed because the risk of disease outweighed any action or possible risk from the vaccine'.

Mere deviation from a guideline is therefore unlikely to be accepted as evidence of negligence unless the particular deviation was of a type which no doctor acting with ordinary skill and care would make. The case of *Cranley-v-Medical Board of Western Australia in 1990,*[6] in which misconduct by an Australian general practitioner was alleged, further illustrates the point. In prescribing injectable diazepam to heroin addicts, Dr Cranley deviated from guidance contained in the 'Australian National Methadone Guidelines' and, as a consequence, was found guilty of 'infamous and improper conduct'. After hearing of a minority medical opinion in Australia which supported treatment of opiate addicts within a harm-reduction framework as pursued by Dr Cranley, the Supreme Court of Western Australia upheld his appeal. They were of the view that the minority medical opinion was both respectable and reputable in support of treating opiate addicts within this harm-reduction framework, and moreover found that the national methadone guidelines could be understood as reflecting general harm-reduction policies.

In the absence therefore of professional consensus that medical practice should only conform to a single approach in a particular clinical situation, the view that clinical guidelines could lead to undesirable uniformity or fossilisation of medical care lacks a legal basis.

Mere deviation from a guideline would be unlikely therefore to be accepted as evidence of negligence by a UK court unless the deviation itself was of such a type that no doctor acting with ordinary skill and care would make it. However, there remains a danger that where professional consensus about the validity of an approach to a clinical situation is lacking, courts may be influenced by a dominant view, which in the context of existing guidelines could lead to undesirable uniformity of medical care.

In *Dally-v-GMC*[7] Dr Dally stood accused of serious professional misconduct in prescribing methadone and in failing to follow guidelines laid down for good

clinical practice—guidelines which she had herself helped to formulate. Although Dr Dally was not found guilty of misconduct on account of breaching the guidelines, she believed that the hearing against her occurred essentially because she had deviated from a prevailing establishment view on how drug addicts should be treated. She later commented, 'In medicine, guidelines drawn up by the establishment are all too easily converted into regulations and a means of punishing dissenters'.

Dr Dally's harm-reduction approach to the treatment of morphine addicts had not accorded with the policy recommended by Dangerous Drug Units nor with the 1986 Department of Health Guidelines. The legal scholar, Russel Smith, agreed with her assessment. In *Dally-v-GMC* he argues, 'One was left with the unhappy situation of a doctor having her conduct adjudicated and its undesirability declared, presumably for the benefit of the whole medical community in knowing what was acceptable conduct in the eyes of the GMC, when she had merely been following one school of thought which had its own substantial body of advocates'.

With respect to withdrawal of treatment, the ruling by the House of Lords in the case of *Tony Bland*[8] offers a clear instance in which a court found that written guidelines drawn up by a responsible body of opinion can protect clinicians from liability in the eyes of the law. Lord Goff's judgment stated that, 'if a doctor treating a PVS patient acts in accordance with the medical practice now being evolved by the Medical Ethics Committee of the BMA, he will be acting with the benefit of guidance from a responsible and competent body of professional opinion as required by the Bolam test'. It is important to notice that the judgment contains an appreciation that the guidance was 'being evolved' to imply that the content of the required standard of care was likely to change over time.

Courts have occasionally found professionally accepted standards of practice deficient particularly in the matter of how much information patients need to receive before they can validly express and form consent or dissent to a procedure. In Australia this has led to the creation of guidelines on providing information to patients, and to calls for legislation to ensure that such guidelines are admissible in court actions relating to failure to disclose adequate information.

There is clearly an onus on doctors to be aware of guideline statements which, in their field of practice, may embody the minimum standard of law that may be required. However, it is not clear how doctors are to recognise which of the many clinical guidelines in existence possess this particular status. The question was addressed by Lord Denning in the case of *Crawford-v-Board of Governors of Charing Cross Hospital*[9] in which he said, 'It would be quite wrong to suggest that the medical man is negligent because he does not at once put into operation the suggestion that some contributor or other might make in a medical journal... The time may come in a particular case when a new recommendation may be so well proved and so well known, and so well accepted that it should be adopted, but that was not so in this case'.

The key elements in Lord Denning's test are proof, dissemination, acceptance and adoption, each in combination with the notion of wide professional approval over time. Having read the SIGN (Scottish Intercollegiate Guidelines Network) publication on the criteria for appraisal of guidelines for national use, I am sure that this publication will lead to the implementation of valid guidelines and

protocols which would pass Lord Denning's test. Such guidelines should protect doctors from liability.

Atypical or bizarre guidelines and consensus guidelines which fail to achieve professional acceptance would be expected to fail this test and similarly fall foul of the *Hunter-v-Hanley* test. A similar fate may await guidelines designed to hasten the incorporation of research findings into routine clinical care, because such guidelines despite their possible scientific validity would be unlikely to represent customary care until some time after their publication and distribution.

Guidelines and protocols do vary in their validity. Of the many guidelines published until now, few have been shown unequivocally to be effective. Many remain pure opinion or musings of expert committees. Others are rooted in solid scientific data, usually not detailed enough to shape prescriptive rules—not so with SIGN.

Even if the guideline is well thought out, rigid adherence to it may be inappropriate leading to the erosion of clinical judgment and the deduction of medical practice to little more than a mechanistic rule of thumb following activity.

The case of *McFarlane-v-Secretary of State for Scotland*[10] shows how a court can reverse a guideline which has been applied too mechanistically. The Royal College of Ophthalmologists advises the Secretary of State for Transport on the minimum field of vision considered safe for driving. Mr McFarlane appealed to the Sheriff Court in Scotland against the decision made by the Secretary of State to revoke his driving licence after uncontested findings that his field of vision did not amount to the minimum recommended by the Royal College of Ophthalmologists—at least 20° above and below the horizontal. The Sheriff noted that the Secretary of State's advisers had 'simply followed the recommendations in the guidelines laid down'. Further expert testimony focused upon the congenital nature of the appellant's defect, which was neither degenerative nor progressive, and to which he had fully adapted. McFarlane suffered from a left upper homonymous quadrant hemianopia which, it was deemed, would have little significance to a driver looking straight ahead, or from side to side in the rear mirror. He was not thought to be a danger to the public and his driving licence was duly reinstated.

This case highlights the importance of appreciating that advisory statements entitled 'guidance', 'guidelines' or 'recommendations' are usually not hard and fast rules but need to be interpreted by a proper exercise of discretion.

In legal cases which have featured guidelines, the courts generally recognise that translating rules into action requires discretion just as the exercise of discretion may involve using rules sensibly. Some guidelines such as those issued by the World Health Organisation for the treatment of hypertension are explicit in recommending the exercise of interpretation and choice in their use.

If I leave you with no other message today it is that a doctor should quite happily follow a clinical guideline which accords with his own clinical judgment but cannot claim as a defence to negligence that his own clinical judgment had been corrupted by clinical guidelines simply because he complied with the guideline without protest. As the court said in the United States' case of *Wickline-v-California 1986,*[11] 'A physician who complies without protest when his medical judgment dictates otherwise cannot avoid responsibility for his patient care'.

A case where the early discharge of a patient according to treatment

guidelines which featured criteria for length of stay approved for payment purposes, resulted in the premature discharge of the patient who later had to undergo an amputation, the court ruled that 'if a doctor does deviate from a guideline or protocol' particularly where it is a significant departure, he may well want to consult others. He should also ensure the decision is documented in the patient's case notes at the time it is taken as this will confirm that the doctor took account of the protocol of guideline and decided to depart from it by applying his medical judgment for the reasons he should record.

If a doctor breaches a duty of care towards his patient and an injury occurs as a result then with or without guidelines the court's common law jurisdictions will continue to hold him accountable.

REFERENCES

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[3] Sidaway v Board of Governors of the Bethlehem Royal Hospital and The Maudsley Hospital (1985). AC 871; (1985) 1 All ER 643.
[4] Early v Newham Health Authority (1994) 5 Medical Law Reports 215–217.
[5] Loveday v Renton and Wellcome Foundation Ltd. (1990) QBD 1 Med LR 117–204.
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[7] Dally v GMC, Privy Council, No 7 of 1987 (Transcripts, 14 Sep 1987).
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[11] Wickline v Blue Cross of Southern California (1986) 192 Cal App 3d 1630 (Cal CA).