Clinical practice guidelines as legal norms

Daniel Jutras, LLB, LLM

What would the impact be of clinical practice guidelines on malpractice litigation? Would the organizations developing and implementing such guidelines run any risk of being held liable? These are the two most obvious legal questions raised by the development and implementation of clinical practice guidelines, but there are many other potential areas of interaction. One could examine, for instance, the impact such guidelines would have on the criminal liability of physicians or on legal actions arising from a violation of the codes of professional ethics that have the force of law. One could also consider whether practice guidelines would constitute an illegal form of restraint of trade, as has been argued in the United States.[1]

These issues cannot be covered in a short, introductory paper, but examination of the relation between practice guidelines and civil liability should suffice to illustrate the basic conclusion: the medical profession can strongly influence the content of the legal standard of care, but that standard is ultimately set by the courts or the legislator. Thus, the medical profession alone cannot determine the content of legal norms.

Malpractice and clinical practice guidelines

In the civil law of Quebec and the common law of other provinces professional liability can arise whenever it is found that someone suffered damage because of the wrongful behaviour of another. In the medical context, wrongful behaviour of the physician can occur at different stages of the relationship with the patient; for example, at diagnosis, selection of treatments, securing of informed consent, performance of the treatment or procedure, follow-up and record keeping. There could also be liability for unnecessary procedures or tests if it were found that no reasonable physician would have offered these procedures to the patient in the same circumstances and that the procedures caused harm to the patient that would have otherwise been avoided.

Clinical practice guidelines could address all aspects of medical practice in an effort to improve the quality of care and reduce unjustified variations in medical practice. Generally speaking the guidelines would be developed from a medical point of view and would not likely be adopted in an effort to establish the legal standard of care with respect to such matters as informed consent and choice of therapy. Nevertheless, they would provide formal, written and therefore easily accessible normative statements. The possibility that clinical practice guidelines could be used to determine what is wrongful conduct in the legal sense is obvious.

The key, then, is to determine the extent to which clinical practice guidelines can be viewed as the expression of the legal norm — that is, the extent to which those guidelines, adopted for separate purposes, nevertheless state the relevant legal standard of care. If the guidelines became legal norms, then parties, lawyers, judges and payers (e.g., self-insurance organizations) would evaluate the behaviour of health care providers from the point of view of the guidelines and make legal decisions accordingly. Did the physician's behaviour conform to the written standard? Clinical practice guidelines could discourage frivolous claims, lead payers into refusing to compensate or convince a judge to relieve a physician of any blame. Conversely, they could provide evidence that a claim is likely to succeed, convince payers to settle and not litigate or simplify the judge's task by indicating clearly what amounts to negligent care.

Clinical practice guidelines could also affect how the causal relation is viewed between certain im-

Reprint requests to: Professor Daniel Jutras, Faculty of Law, McGill University, Chancellor Day Hall, 3644 Peel St., Montreal, PQ H3A 1W9

proper practices and the damage suffered by a patient.[2] Problems of causation are often the most vexing in malpractice litigation, and practice guidelines could play an important role in that respect if they contained statements about the potential adverse consequences of a failure to comply with the recommended procedures.

Of course, all this can happen only if the practice guidelines acquire a decisive or crucial role in the determination of the legal norm. This can occur in several ways. The most obvious is a statute or regulation providing that a given practice guideline states the legal standard of care for the purposes of professional liability. Another way would be if a guideline were the object of a binding undertaking by a physician, as would be the case if a physician were to promise a patient that he or she would comply with the terms of a certain guideline in treating that patient.

Beyond these simple but rather unlikely cases, clinical practice guidelines would determine the issue of the legal standard of care only if they were viewed by the key legal players (parties, lawyers, judges and payers) as the expression of the legal norm.[2-4] Various factors make this more or less likely: the extent to which guidelines are accepted by the medical profession and the degree of care that they require. In addition, the language in which the guidelines are couched would determine whether they could play a decisive role in malpractice litigation.

Acceptance by the medical profession

From the point of view of civil liability an important factor is that clinical practice guidelines could be perceived by the medical community as a convincing statement of the proper standard of care. At a human level judges are inclined to trust authoritative statements of norms once their authority has been established. This should be true of practice guidelines, particularly if they are defined outside the context of litigation by respected and disinterested parties. For example, a 1975 report on oral contraceptive drugs published by the Health Protection Branch, Department of National Health and Welfare, carried great weight in a recent Quebec case: the plaintiff raised the issue of the contraindication of oral contraceptives when phlebitis or a history of phlebitis is present.[5]

In that sense, the identity of the drafters and the process through which the guidelines are drafted could be crucial considerations in establishing their authority in both the medical and the legal community. At a more technical level, experts testifying for the parties are allowed to invoke only standard or authoritative texts to buttress their opinion. Thus, at the very least, clinical practice guidelines must achieve the same level of recognition as standard textbooks and learned treatises to be introduced and discussed in court.[4,6]

Most important, acceptance by the medical community matters because the legal standard of care is largely determined by reference to the views and practices of that community. In general, a physician will not be found liable if it is established that his or her behaviour was in accordance with what could be expected of a reasonable physician in the same circumstances. In setting that standard, judges give great weight to commonly accepted practices, unless those practices are demonstrably unreasonable. Thus, to the extent that the medical community recognizes a given set of clinical practice guidelines as a proper expression of an acceptable, reasonable medical standard those guidelines would likely be perceived in the same way by the legal community. In that sense, guidelines could affect the determination of the legal standard of care only if there were evidence that they were known, relatively noncontroversial and reflected in the common practices of the medical community.

If guidelines were not well known and widely distributed they could be perceived as the expression of one opinion among many about the proper standard of care, and experts would have to debate their accuracy and authority before the court. Even if the guidelines were well known and well distributed the same debate could take place, because they could be viewed sceptically by physicians. Indeed, guidelines are unlikely to influence the legal standard of care unless they first settle debates within the medical community about what range of conduct does or does not constitute reasonable medical care. For the same reason, guidelines cannot play a decisive role in litigation as long as there is a significant discrepancy between widespread practices and what the guidelines require. Yet this is likely to occur quite often, to the extent that practice guidelines are meant to change practices rather than to codify them. In that sense, guidelines could expand the range of conduct viewed as reasonable (e.g., by giving legitimacy to new procedures), but they would not necessarily restrict that range. There is room for argument about the legal standard of care as long as there is some distance between the written norm and what is still viewed as reasonable practice by many.

Short of a statutory recognition of the guidelines as the legal standard nothing could stop anyone from making an argument for or against the legitimacy and reasonableness of a given practice, regardless of whether it is addressed in the guidelines. But these arguments would lose some of their force if the medical authority of practice guidelines came to be widely recognized by physicians. At the very least,

guidelines could be used by a judge to confirm a conclusion about what amounts to reasonable behaviour. For example, in a recent Quebec case a judge found a physician liable for failure to diagnose an inflammation of the epiglottis that had caused the death of a child. Although that conclusion was reached mostly on the basis of the expert evidence presented to the court, the judge noted in passing that the physician had failed to comply with the internal protocol and the *fichier thérapeutique pédiatrique* of the hospital in not requesting radiography.[7]

Thus, if the guidelines came to be viewed as the expression of what is reasonable care by a substantial proportion of the medical community, physicians who complied with them would most likely be exonerated even if other (better) practices were also accepted. Conversely, physicians who failed to comply with them would make their own exoneration more difficult, exceptional circumstances aside. I emphasize reasonable care here because that is the degree of care required by law. For clinical practice guidelines to have an important role in malpractice litigation the degree of care they require must be as close as possible to the degree of care required by the law.

Degree of care

Research activities aside, the law requires the same level of care that a reasonable physician would have provided under similar circumstances — no more, no less. Clinical practice guidelines, however, could set the standard of care at any level, depending on their purposes.

Guidelines are likely to be developed to improve the quality of care currently given and thus set up an ideal to be attained. Practice guidelines might make recommendations on the basis of optimum or ideal resources and, therefore, be more demanding than the legal standard of care, which takes account of the particular circumstances in which the medical decision or act had to be made. Similarly, given that guidelines would be constantly updated to integrate the latest developments in medical science they might go beyond what is expected of a reasonable physician at that time. The law does not require that all physicians always be at the forefront of their profession. It asks them just to take reasonable steps to be up to date and to act reasonably in light of the knowledge that is currently available. Furthermore, the law tolerates a margin of error (particularly with respect to diagnosis) that might be wider than that expressed in the guidelines. Errors that a reasonably careful physician could make in the same circumstances are not negligent errors and, hence, do not give rise to liability. In short, one must distinguish ideal medical care from reasonable medical care. Only the latter is relevant for jurists.

On the other hand, one could also envisage practice guidelines that would demand less care than the legal standard. This could happen, for example, if the practice guidelines described an absolute minimum quality of care with a view to cost control and reduction of unnecessary care.[8] It could also happen if guidelines were not updated regularly and lagged behind what might be expected of a reasonable physician. In either case, complying with them would certainly not shield a physician from civil liability. From a medical or legal point of view a physician cannot abdicate his or her responsibility for the exercise of professional judgement, despite the existence of guidelines.

So far, I have suggested that practice guidelines will not be viewed as the expression of the legal standard of care unless they describe what is perceived as reasonable medical care by health care providers (acceptance by the medical community) and by jurists (identity of the medical and the legal norm). Assuming that practice guidelines satisfied these two conditions they would become a crucial element in malpractice litigation. But even then they would rarely be decisive, given the differences between the discourse of law and the discourse of medicine to which I now turn.

Formulation of clinical practice guidelines

Moving from the medical, scientific discourse to the legal discourse is always a problem in malpractice litigation. Qualified (scientific) answers must be transformed into unqualified (legal) conclusions; this explains largely why there is room for debate about good faith between reasonable experts.

One can expect that standards expressed in clinical practice guidelines would be formulated in qualified terms, in recognition of the need to take account of particular or even unspecified circumstances affecting the choice of one procedure over another. They would most likely recognize the possibility of exceptional cases and stress the importance of treating each patient as a distinct individual, with particular needs and a particular history. This would be even more important if the guidelines addressed the issue of the patient's informed consent, in which the scope of duty is crucially affected by the special circumstances of each patient and each procedure.

It is because of such desirable qualifications that practice guidelines would rarely be decisive in malpractice litigation. The formulation of a rather general and open-ended standard, allowance for exceptions and emergency situations, and recognition of a range of acceptable practices — all leave ample room

for legal argument. Thus, even on the assumption that practice guidelines are taken as the expression of the legal standard of care, that standard will likely be flexible enough to allow both sides to debate whether it was breached.

It should be clear by now that clinical practice guidelines would not relieve jurists from the difficult task of determining the legal standard of care for the purposes of professional liability. Medical standards of care and legal standards of care are different, even though the content of one set strongly influences the content of the other. The norms in the two sets generally take a different form and have distinct purposes. The very fact that a transition from one set to the other must take place in the judge's mind means that the relationship between the two is always debatable until the debate is settled by some act of authority within the legal sphere.

Liability resulting from the drafting and implementation of guidelines

So far I have assumed that the guidelines would state accurately what is sound medical behaviour. The question was whether this medical definition of appropriate care would influence the legal definition of appropriate care. However, another question must be addressed briefly: What if the guidelines were drafted in such a way that they led to unjustifiable harm to a patient?

There is a remote risk of liability for the drafters and implementers of clinical practice guidelines,[2,4] but although theoretically possible it is not very likely that such a liability would arise, for a number of reasons. First, the guidelines would have to either recommend an unreasonable course of action or eliminate from consideration a reasonable course of action that ought to have been considered. Indeed, unless the harm suffered by the patient is the result of an unreasonable practice the patient does not generally have a claim in liability. It seems unlikely that such unreasonable practices or omissions would ever be endorsed by a serious group of physicians. But if they were, the drafters (as well as those who relied on the guidelines) could be held liable if it were found that there had been negligence in the drafting, updating or implementation of the guidelines — that is, if the care that could be reasonably expected in drafting, implementing and relying on the guidelines had not been taken. Second, the "wrongful" guideline would have to be a necessary cause of the harm, in the sense that the harm would not have occurred without it. That physicians are expected to exercise their own professional judgement, even in the presence of guidelines, provides a strong argument for the protection against liability of drafters and implementers, particularly if the guidelines allow for the possibility of exceptions and stress the importance of individual judgement. Conversely, anything that constrains the exercise of that judgement (e.g., financial coercion of any sort and inflexibility of guidelines) increases the likelihood that a claim will be brought against the drafters or the institutions implementing the guidelines, without the physician necessarily being relieved of his or her personal liability.

In short, if the guidelines were drafted and updated regularly with reasonable care and if they emphasized the importance of professional judgement without trying to constrain that judgement unduly, then it is not very likely that drafting or implementation would lead to liability.

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