Medicolegal Implications of Consensus Statements

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The Journal of the American Medical Association (JAMA) published a new format to be used for consensus statements in the January 4, 1995, issue. Emphasis was placed on a clear definition of the objective of the statement, the basis for the selection of the participants, the manner in which the evidence was reviewed and evaluated, the manner in which "consensus" was developed, and the conclusions of the consensus conference. An explanatory editorial presented the thinking behind this new format in a clear and helpful manner. This section will consider the medicolegal aspects of the consensus conference according to the proposed new JAMA format. Since each of these areas bears importantly on the legal weight of the product of the consensus conference, we will consider the legal implications according to the new JAMA format.

A principle legal function of the consensus conference product is to reflect the "standard of care" in a particular area. This is particularly true when the conference product is intended to codify practice guidelines as is the case in this conference. While this product may reflect the standard of care in normative terms, application of that standard to a specific set of circumstances, as in the court room in the course of malpractice litigation, may be difficult since a number of other determinants enter into the equation, not the least of which being the relative persuasiveness of the opposing expert witnesses. The primary value of practice guidelines, of course, is not their use in litigation but their use in practice: the extent to which they effectively elevate the quality of care is the measure of success. But whether the work product of a consensus conference is used to improve care quality of the practitioner or as a measure of the adequacy of the defendant's care of a particular patient in a particular set of circumstances, the guidelines need to be both credible and usable. The new JAMA format appears to be an excellent model for use in planning a consensus conference since the key elements of credibility are elicited.

"Usability" perhaps is more a function of organization and style: it is impaired if the published guidelines are either overly specific or hopelessly general. In either case, the worth of the guidelines is diminished for both medical practitioners and litigators be they plaintiff or defense attorneys. Ultimately, as Olson points out in JAMA, "Readers themselves must assess the quality and the validity of consensus statements as they do for all literature."

Objective of the Consensus Statement: Immediate and Longer Term

The objective of the consensus statement must be defined clearly. An example of a clear definition of objective was provided by Drs. Dalen and Hirsh in the introduction of the Second American College of Chest Physicians Conference on Antithrombotic Therapy: "We hope that these recommendations will assist clinicians in providing safe and effective antithrombotic therapy to their patients." While clearly expressing the immediate objective, Dalen and Hirsh went on to underscore the important catalytic role of such a conference for the achievement of longer-term objectives: "We are certain that these recommendations will lead to further dialogue and stimulate further studies in this important area of therapeutics." While this function has important implications for the development of Perkins in the scientific data over time that may be expected to improve antithrombotic therapy in the future, the legal implication is also clear: all the answers are not in. Thus, there is likely room for the clinician to exercise his or her judgment with regard to a specific patient with a specific set of clinical characteristics. The guidelines then are intended to be just that: guidelines. If ideally developed and ideally packaged, these guidelines will be of the greatest use to the greatest number of practitioners in providing "safe and effective antithrombotic..." therapy. As such, they will be optimal guides to the standard of care for the protection of the practitioner from committing malpractice, thus performing a legally beneficial role for the benefit of patient and practitioner alike. While guidelines to the standard of care, they are not the standard of care. It is not until the physician makes a judgment as to how a specific patient should be treated (or not treated) with antithrombotic therapy that the theory becomes actuality. It is the action or the inaction in a given set of circumstances that will be judged to fall within the standard of care or below the standard of care. The better the guidelines are, the easier it will be for the physician to act properly in the best interests of his or her patient and this result is clearly the most desirable from both a legal and a medical viewpoint.

There is now good evidence that clinical guidelines tend to improve clinical practice when introduced in the context of rigorous evaluations.

Participants

The credibility of the consensus conference recommendations clearly will depend on the degree to which legitimate differing views are presented and discussed openly, as Olson points out. Not only is this important from the view of comprehensive discussion, it is important from a legal viewpoint in that the law has recognized the opinions of "respected" minorities, which may differ from the majority opinion. Thus, "consensus" must not be forced: it is an anticipated and desirable outcome if it can be achieved. If legitimate respected minority opinion exists, these also should be disclosed as such.

Thus, selection of the participant so that a comprehensive range of scientific and medical opinions will be represented, presented, and discussed is of paramount importance to assure a truly credible and comprehensive set of recommendations. Not only need there be balance on the issue of content, there must also be balance on the issue of personality. A daunting figure on one pole of the argument should not be permitted the opportunity to intimidate a less confident presenter at the other pole.

Finally, the practice of bringing manuscripts to the conference so that publication deadlines can be met should be questioned seriously. Is this not an implicit bias, a somewhat hypocritical indication that "I know the answers already and
don't need to listen to the other participants"?

Efficiency may betray process and defeat the loftier objective of the Consensus Conference. Other ingredients that support credibility include the "stature, expertise and intellectual integrity of the participants" and identification of sponsors and sources of financial support, as Olson points out.

EVIDENCE

When prior consensus conferences have been held and their recommendations published, each of the prior recommendations must be carefully reviewed and critiqued by experts who represent the extent range of opinions on the subject. Criteria for evaluating new scientific and medical data that may bear on the process of modification of prior recommendations and development of new recommendations have now been developed in advance in a number of cases based on suggested models. Opinion, however expert, should clearly be subordinated to credible data published in a respected peer-reviewed journal and preferably validated by independent investigators. Absent a credible scientific database, expert opinion sifted by the process of informed discussion remains the only alternative approach to developing "state-of-the-art" guidelines.

Legal Implications

When contradictory opinions are present in respected medical journals, a condition that is not uncommon, the work of the consensus conference becomes yet more important. A careful discussion of all credible information may lead to an impasse. If so, this must be confronted and reported; the best recommendations based on expert opinion may be the only available alternatives. The level of urgency of any call to expedient development of needed research data should depend on the gravity of the unanswerable therapeutic question.

Consensus Process

It is well recognized that the process by which practice guidelines are developed, as is the case in this consensus conference, clearly influences the working of "consensus" and the final therapeutic recommendations. An array of approaches to development of consensus are identified succinctly by Olson. These range, for example, from the National Institutes of Health process that "combines aspects of the judicial system [in which an impartial jury makes a decision based on the evidence presented], a scientific meeting [in which professional colleagues share their findings], and a town meeting [where any interested person can express an opinion]."

The central purpose in the consensus process, whatever format is chosen, is the following: (1) to assure a comprehensive presentation of all relevant scientific information, including minority opinions by respected experts who are dedicated to the objective(s) of the conference (vs personal agenda, for example); (2) to assure a full and balanced discussion of this information among these experts usually in small groups and in a manner in which the facts are emphasized and personal qualities of persuasion are minimized; (3) presentation of what has been agreed on and what has not been agreed on to the general session; and (4) faithful incorporation of the developed consensus and exceptions to consensus in the article for publication.

Government and Professional Organizations and Practice Guidelines

Practice guidelines for the use of both diagnostic procedures and therapeutic interventions have been developed by the American College of Cardiology and the American Heart Association, often jointly. These apply to a number of specific disease states, eg, myocardial infarction and heart failure, and to a number of procedures ranging from electrocardiography to cardiac catheterization. The purpose of these guidelines is to make clear to the practicing physician/cardiologist what experts in cardiovascular medicine consider to be the minimum acceptable performance standards in each of these areas. Such impartial guidelines should provide a clearer indication to physicians what is expected of them by their peers. This, in turn, will tend to make the somewhat abstract "standard-of-care" quite a bit more concrete for physicians, patients, lawyers, and judges. In terms of balance, this should work in favor of the conscientious practitioner both from a medical and from a legal point of view.

Special Medicolegal Problems in Antithrombotic Therapy

The legal nightmares of antithrombotic therapy are, of course, a plaintiff attorney's dream. In few areas of medicine are the "complications" of the decision to use or the decision to withhold therapy as predictable and as devastating as a crippling stroke, the adverse effect we will concentrate on not because of its frequency but because of its potentially dramatic effects. It is perceived by many as being worse than loss of life. From the viewpoint of legal liability, the patient who has suffered a devastating stroke and has survived brings a much more powerful weapon to the court in a malpractice action, that weapon being the deformed partial person who was like any juror prior to the stroke. Jurors, like most of us, are terrified by the prospect of being the victim of a stroke. Empathy is immediate and powerful. How could this happen? "If it happened to her, it could happen to me." Sensibilities are rubbed raw. It is the physician's job to prevent such a catastrophe in this day and age, is it not? There is a spontaneous reflex toward compensation on the part of the jury that must be overcome by the defense and this may not be possible. The orientation of the jury may be shaped more by emotion than by an inclination to plumb the truth. There is a natural tendency to hold the physician responsible even before the facts are heard. This is a difficult climate, one in which even the blameless physician may be unable to elude a sense of hostility.

Legal Liability Crisis Points

There are a number of medical crisis points in the decision-making process in the antithrombotic area and each of these may become a legal crisis point. As with medical decisions in general, the potential for legal liability in the area of antithrombotic therapy begins when the patient is first considered to be a candidate for antithrombotic therapy or
should have been considered a candidate. However, this field is rather unique in that many such patients are from that moment on at risk for what may be the most feared complication in medicine, ie, a devastating stroke and, worse yet, that such a patient is at risk both with antithrombotic therapy and without it.

Because crippling stroke, while infrequent, is perceived by many to be the worst complication one could suffer, we will continue to concentrate on stroke for the purposes of this discussion. As noted above, the physician may become liable either for the decision to use antithrombotic therapy, eg, should the patient suffer a hemorrhagic stroke, or for the decision to withhold or withdraw should the patient suffer an embolic stroke. Once therapy has been started, the physician may find himself or herself at risk for not reaching therapeutic range in time, for not maintaining the therapeutic range, for failing to detect bleeding at an earlier time. Since a disastrous outcome is to be expected in a predictable percentage of patients with or without treatment and with or without “ideal” treatment, it is clear that there is no “safe” area once the patient is in the “club” as a candidate for antithrombotic therapy. This reality brings with it important forebodings for the physician who is charged with malpractice. The fact that the physician made decisions that would have been viewed to be within the standard of practice does not necessarily mean he or she will be exonerated. While there may be many reasons for such an unreasonable result, one important one is that the jury may not be educated successfully to the fact that these patients are truly living at the edge of disaster, not because of their physician but because of the disease substrate.

The statistical presentations by expert witnesses are often doomed to failure because they require a sophisticated understanding of the unique nature of antithrombotic therapy, an area in which dangerous measures must be mobilized because the patient’s predisposition to form blood clots within his or her circulatory system is a very dangerous condition. A second reason why the physician may fail to prevail despite having provided an acceptable level of care is that even an excellent defense may be insufficient to overcome the emotional impact of the once-healthy plaintiff now before the jury in a wheelchair, drooling, with a flaccid arm on his or her lap. The physician may be painted as a monster by the dramatic power of the outcome even in the absence of clear evidence of deviation from the standard of practice in this area. The wily plaintiff attorney may be successful in pointing out that the physician’s first obligation is to do no harm, and that when there is a risk of great harm, the diligence that the physician must exercise must be proportionate to the severity of that risk. The inference is that the outcome was preventable and the physician failed to prevent that outcome.

We are aware, of course, that some such outcomes, ie, stroke, are not preventable since stroke will occur in a small but predictable percentage of patients in whom antithrombotic therapy is indicated even when the therapeutic decisions are flawless. We are also aware that the frequency of stroke will increase as the therapy falls farther and farther below the “ideal,” whether or not such less-than-ideal therapeutic control is the fault of the physician or due to a number of other uncontrollable factors that are known to influence antithrombotic therapy.

*Can Consensus Statements Help Reduce Legal Liability?*

Maybe. If we could live in an ideal world, we would do well from a medicolegal viewpoint to minimize or better yet eliminate variations in the indications for and methods of initiating, maintaining, monitoring, and suspending antithrombotic therapy. This, of course, is one of the main objectives of a consensus conference. It is also an objective that is virtually never achieved primarily because there is insufficient scientific evidence to force complete unanimity on all important questions. Compromise alone may not be sufficient, however reasonable and well intended. It is often more desirable in the face of differing views to have each view analyzed as to justification. In the absence of credible justification, a view should be rejected. If credible justification exists for differing views, consideration must be given to setting forth these alternative approaches as acceptable options until persuasive data emerge to justify a reappraisal. Practice patterns that have been proved to be effective in a given set of circumstances should not be rejected without solid justification. Alternatively, practice patterns that have been proved to be less effective and that subject the patient to avoidable excess risk must be rejected if the improvements are feasible in all practice settings. The primary purpose of a consensus conference, of course, is to provide optimal guidance to the practitioner in the setting of his or her practice. If the practice guidelines generated by the consensus conference are successful in this regard, they will provide protection to the practitioner against unjustified malpractice actions.

**Strength In Unanimity**

When justified by scientific fact, however, unanimity is most desirable both from a medical practice basis and as a means of minimizing the risk of legal liability. There are a number of areas in antithrombotic therapy that may be amenable to the potential benefits of unanimity, but one should suffice as an example.

Anticoagulant clinics are not employed universally for the follow-up of patients receiving anticoagulant therapy and there are good reasons put forward by both those who use and favor the use of such clinics and by those who use and favor the use of alternative approaches. If there are credible data to support one approach over the other in terms of better control and fewer side effects, there is little doubt that practitioners who use the “less effective” system are at higher risk of legal liability. In the absence of credible evidence to support equivalency of a method in question, a defendant may be seen by a jury as not having exercised a level of diligence demanded by the risk (especially of stroke) to the patient, and should stroke supervene, it will be very difficult to mount a defense sufficient to overcome this charge. While there may be good, important, and practical reasons for the less desirable approach, including the fact that it may not be less desirable but simply has not been adequately evaluated, in the face of the stroke victim staring into the jury, these practical reasons are likely to fall on deaf ears.

If we are about addressing the ways in which the product
of a consensus conference may best produce the desired enhancement of the quality of medical practice and reduce the threat of legal liability, each alternative approach at every step in the continuum of antithrombotic therapy needs to be considered in these terms.

Using Informed Consent as a Defensive Measure

It may be possible to utilize informed consent as both an educational tool with the patient and a defensive measure with regard to legal liability risk. The process of informed consent can be, and perhaps should be, used to convey the fact that the patient being considered for anticoagulant therapy may from that moment never be in an entirely “safe” condition with regard to such serious complications as stroke. While this is conveyed to some extent by the listing of the potential complications of taking and not taking antithrombotic therapy on the informed consent form, the manner in which this information is imparted often fails to characterize the fact that the patient will be, often for the remainder of his or her life, at risk for serious complications, with or without antithrombotic therapy. The purpose of this emphasis is not to protect the physician at the expense of badly frightening the patient, but to provide to the patient what is in fact required by the legal requirements of informed consent, that is, an understanding of all material information about the therapy that the individual may choose to accept and the alternatives to that therapy. Such a process should permit the patient to appreciate that he or she from that moment on is at risk, however small, of a potentially disastrous occurrence as a result of either his or her disease or of the therapy used to protect the patient from that disease.

Such an approach to informed consent is appropriate because anything short of it fails to adequately set forth the patient’s reality, with and without therapy. Further, it forms a solid basis for the patient’s cooperative participation in his or her care.

And finally, it may be the single most important aspect of the physician-patient relationship to be introduced to the jury should a malpractice action be brought.

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