

Standard Care, Standards for Care, or Standard of Care?

WHEN does a physician's medical care qualify as "standard?" Is the standard set by scientific evidence, by what physicians typically do, by what physicians regard as minimally acceptable in the same or similar circumstance, or by what panels of experts believe to be best practice? In this issue of the journal, Benzon *et al.*¹ present evidence that calls into question a recommendation contained in the American Society of Regional Anesthesia's (ASRA) Consensus Statement from their 2002 Conference on Neuraxial Anesthesia and Anticoagulation.² Specifically, the new data show that the international normalized ratio has poor correlation with factor VII concentrations during initiation of warfarin anticoagulation. There are patients who, despite an elevated international normalized ratio in the first few days of warfarin therapy, retain more than adequate factor VII levels for coagulation and presumably for safe removal of an epidural catheter. One wonders how many patients have had delayed removal of epidural catheters, unnecessary delay of adequate prophylaxis against deep vein thrombosis, or unnecessary administration of plasma to meet the implied standard contained in the previous consensus document.

These new data underscore the potential problems that can arise when guidelines, advisories, or statements are based on opinions, however expert, in the absence of data. Problems can occur even when the recommendations in a practice parameter or guideline are based on the outcomes of randomized clinical trials, particularly when the results of trials conducted in a relatively small, restricted patient population are extrapolated to a much less-restricted universe of patients. Problems can also occur when using valid results of trials that examine an adverse outcome (*e.g.*, myocardial infarction) that can be superseded by larger trials that examine a more objectionable outcome (*e.g.*, stroke or death). Both these issues arose³ when a variety of well-meaning groups produced practice parameters demanding perioperative β -blocker therapy based on trials showing reduced myocardial infarctions among fewer than 500 total participants.⁴

So, was there a problem with the consensus statement of ASRA on anticoagulation? There was certainly no problem with the intentions of ASRA, which were to provide clinicians with conservative suggestions for safe management of regional anesthesia. ASRA did not seek to define the "outer limits" of safe practice, rather they sought to describe conser-

vative practices with which almost no experienced clinician should find disagreement. ASRA is a relevant, appropriate organization. ASRA vets practice advisories and guidelines using an expert panel that undertakes a detailed and systematic approach to review the existing data. Clinicians were afforded the opportunity to weigh in on the issues at the annual ASRA meetings. Nevertheless, the process used by ASRA is less stringent than the process used by the American Society of Anesthesiologists (ASA). Practice Guidelines and Advisories produced by the ASA are assembled using a consistent approach that spells out the exact level of evidence, ranging from high quality (randomized controlled trials and meta-analyses) to low quality (expert opinion, input from public forums [ASA demands at least 2], and practitioner surveys). The process of ASA is time-consuming and very expensive; some may question whether it is justified when the resulting document is based more on opinions than evidence. In any case, it is inevitable (we hope) that consensus statements based on opinions, however well-intentioned and thoughtfully constructed, will require revision based on scientific advancement and new evidence such as that we are now presented by Benzon *et al.*¹

In the first sentence of this editorial, we posed a question: who defines the standard for medical care? Unfortunately, the answer depends on the context, and there are few rules as to who can opine. In most U.S. jurisdictions, the "standard of care" is defined based on state laws and precedents (except in the District of Columbia or in federal facilities that are governed by federal laws). In most jurisdictions, the standard of care requires that a physician must treat a patient with the watchfulness, attention, caution, and prudence a reasonable physician would use in similar circumstances. Confusion can arise when the average physician in an area does not follow an established clinical practice guideline. For example, assume that the guidelines of the American Heart Association/American College of Cardiology require that all patients receive maintenance dosing of a β blocker and aspirin on discharge from hospital after an uncomplicated myocardial infarction associated with elevated ST segments.⁵ However, none of the 50 physicians in a rural seven-county area follow this guideline, and a patient, so treated, dies of a second myocardial

◆ This Editorial View accompanies the following article: Benzon HT, Avram MJ, Benzon HA, Kirby-Nolan M, Nader A: Factor VII levels and international normalized ratios in the early phase of warfarin therapy. ANESTHESIOLOGY 2010; 112:298-304.

Accepted for publication November 10, 2009. The authors are not supported by, nor maintain any financial interest in, any commercial activity that may be associated with the topic of this article.

infarction 3 months after discharge from hospital. Did this patient's physician meet the standard of care? Despite the fact that the patient received "average" care from the locality, there is a growing legal precedent for regarding a published guideline as both a "clinical standard" and a "standard of care."⁶⁻⁹ This conflict points out the potential problem with having poorly composed consensus statements, guidelines, and parameters, particularly when created by groups without proper standing.

So, what are we to do with the many organizations, foundations, and groups who are providing statements, guidelines, and parameters for anesthetic practice? To a great many of them, we say "Cease and desist." First, it seems obvious that small groups funded either directly or indirectly by pharmaceutical companies (even when the money has been "laundered" through a "medical education" company) lack standing to provide guidelines, practice parameters, or consensus statements, regardless of the credentials of the individuals in the group. We believe that guidelines, practice parameters, or consensus statements ideally would arise only from relevant medical specialty societies. In the case of anesthesiology, such societies would include national and international societies devoted to anesthesiology as a whole (*e.g.*, the ASA, the Canadian Anesthesiologists' Society, the Australian Society of Anaesthetists, or the Association of Anaesthetists of Great Britain and Ireland) or national and international societies devoted to the relevant issue (*e.g.*, ASRA or the European Association of Cardiothoracic Anaesthesiologists), because these organizations would have sufficient numbers of members to adequately fund parameter development, and their meetings would have sufficient numbers of attendees to vet the nascent parameters during open forums.

We thank Benzon *et al.*¹ for scientifically testing a specific consensus recommendation. We should expect that the recommendations in any consensus opinion-based practice parameter may be abruptly overruled by new evidence. We hope that many other investigators will follow the example of Benzon *et al.* and subject other consensus-based practice parameters to scientific scrutiny. We suggest that groups and organizations without proper procedures and standing leave the writing of consensus statements, parameters, and practice guidelines to organizations with sufficient funding and members to properly construct and vet these documents. Finally, we remind all writers of consensus statements, parameters, and practice guidelines of the admonition of the

Austrian-British philosopher, Ludwig Josef Johann Wittgenstein (1889-1951): "Wovon man nicht sprechen kann, darüber muß man schweigen (Whereof one cannot speak, thereof one must be silent)."¹⁰

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