Practice Standards: The Midas Touch or The Emperor's New Clothes?

SPURRED BY AN INTEREST in improving anesthesia care in the operating room and thereby decreasing the incidence of severe anesthesia-related patient injuries, anesthesiology departments in nine Harvard-affiliated hospitals adopted standards for patient monitoring during anesthesia in July, 1985. In effect, these anesthesiologists agreed, whenever possible, to adhere to a set of practice standards in their care of every patient: continuous presence of anesthesia personnel during the anesthetic, measurement of blood pressure and heart rate at least every 5 min, continuous display of electrocardiogram, continuous monitoring (by any means) of ventilation and circulation, use of an inspired oxygen concentration monitor, use of a breathing system disconnection monitor during mechanical ventilation, and availability of a means to measure patient temperature. Fifteen months later, the American Society of Anesthesiologists adopted slightly more specific monitoring standards which "encourage," rather than mention, pulse oximetry and capnography.* In turn, malpractice liability insurers in many areas and at least one state medical licensure board have required that anesthesiologists follow these standards whenever possible. Some insurers have even granted discounts on liability premiums in expectation of fewer claims and reduced payouts. But what has been the impact of this set of standards on the incidence of severe anesthetic-related patient injuries? Has it had the potency of the mythological king who could turn things into gold, or has its influence been illusory?

In an attempt to examine the effect of monitoring standards, Eichhorn presents in this issue of ANESTHESIOLOGY a summary of the experience of the Harvard departments before and after adoption of the monitoring standards. His study is facilitated by a unique database maintained by an aggressive, Harvard-owned risk management company: injuries occurring during the administration of more than 1.3 million anesthetics in the nine hospitals during the period 1976 through mid-1988. The hypothesis (not stated explicitly) is that adherence to a basic level of intraoperative patient monitoring reduces the incidence and severe accidents related solely to anesthesia care, especially those occurring in healthy patients, in whom the incidence of an adverse event should be zero.

From a total of 70 cases reported to the liability insurer, Eichhorn identifies 11 involving "obvious sudden or relatively sudden [intraoperative] accidents," solely related to anesthesia care in stable, ASA Physical Status 1 or 2 patients. These accidents resulted in cardiac arrest with recovery (two cases), severe permanent injury on a scale used in the liability insurance industry (four cases), or death (five cases). Using a case method, he presents his interpretation of the underlying salient problems and issues in the 11 events. Not unexpectedly, given the large and very consistent literature which he cites, unrecognized but preventable ventilatory problems are involved in eight of the 11 cases: hypoventilation in seven cases, and a breathing system disconnection in another. Poor judgment and inadequate supervision of residents and nurse...
anesthetists are also involved in several cases. Whereas ten accidents and five deaths occurred during the 9.5 yr before adoption of the monitoring standards, only one accident and no deaths have occurred during the 3 yr since. Although obviously clinically important, these differences are not statistically significant. Eichhorn is left to regard these results as a "preliminary suggestion of improvement," although he (and probably much of the readership) fully expects that, in time, this type of analysis will establish the value of monitoring standards.

Interestingly, Keenan† recently provided a very similar analysis, almost as an aside, during a refresher course. He reviewed his study³ of 27 anesthesia-related cardiac arrests and 14 deaths in his own institution during the period 1969 through 1983, in which 163,240 anesthetics had been administered, noting also that most of the adverse events were associated with hypoventilation. Like Eichhorn, he selected a subset of sudden intraoperative events that should be detectable early enough with monitoring standards (especially pulse oximetry) to avert catastrophe: there were 11 such events identified in his study, and none in the past 3 yr, during which time another 25,000 anesthetics were given and the monitoring standards were adopted. Yet, the difference is not statistically significant. If the favorable trend continued, he predicted that statistical significance would be reached in another 2 yr.

However, even if the differences in the occurrence rates of adverse events were statistically significant, all that we would know is that the changes probably did not occur by chance. We would still not be able to conclude that the implementation of monitoring standards had any impact, because the design of this analysis of an experiment of nature is fatally flawed. (Journal editors offer provocative reading, but don’t guarantee impeccably designed studies.) This type of study offers no concurrent control population, so one is forced to use the past as an historical control, which necessarily assumes that nothing else in anesthesia practice has changed. However, monitoring standards, including the use of specific devices, constitute only one of many changes in anesthesia technology during the study period. Other changes in our technology include new drugs, new equipment, new knowledge (including awareness of risk management issues), and new ways to organize what we do in new practice patterns. Each of these changes promises improved care, but also has associated hazards. Not to be forgotten, too, are important manpower changes: 12 yr ago, anesthesiology filled only 52.1% of 2450 residency positions with graduates of American medical schools, whereas in July, 1988, our specialty attracted American graduates to 90.9% of 4563 positions.‡ Yet, I cannot argue convincingly that the improved outcomes have resulted from higher quality trainees and practitioners (or any other factor or set of factors) any better than Eichhorn does for monitoring standards.

Even if the study design precludes proving that a set of monitoring standards has decreased the incidence of serious adverse outcomes, are the 11 cases presented suggestive? When considering each case, we must reflect back on several intuitive, thoroughly reasonable assumptions underlying his study hypothesis: earliest warning will maximize the chance of averting patient injury; correct interpretation and response will follow the early warning; monitoring equipment providing early warning will function correctly; and nothing will distract attention from the monitors. As Eichhorn notes, cases 9, 10, and 11 are not preventable by monitoring standards. Adherence to such standards might have resulted in earlier warning of a problem in cases 2, 4, and 5; however, a problem had already been recognized in each, and there were variously improper response, poor judgement, and inadequate medical supervision that precluded effective problem resolution. In case 3, the facts were disputed and, in case 6, very incomplete. Thus, the argument favoring monitoring standards rests on three, or, at most, five, of the 11 cases. However, regardless of whether the reader is convinced, what should not be overlooked is the generally poor quality of care exemplified in many cases; for example, succinylcholine infusion with spontaneous ventilation (case 2), high spinal anesthesia in a patient with a wired jaw (case 7), and failure to secure the airway before inducing general anesthesia in a patient with a large pharyngeal mass (case 8). Can adherence to minimal patient monitoring standards compensate for very poor judgment?

Looking beyond the Harvard hospitals, when we examine trends in adverse anesthesia outcomes, we find additional reason to question the impact of the monitoring standards. Although differences in study design make close comparisons difficult and deaths are, fortunately, rare, anesthesia-related deaths (especially those deemed primarily or solely related to anesthesia care) constitute a convenient comparison measure across studies. The current interest in adverse anesthesia outcomes dates from the Beecher-Todd study, which reported an anesthesia-related death rate of 3.7 per 10,000 anesthetics administered during the period 1948–1952.⁴ Studies undertaken during the following 30 yr reported death rates of 0.7–2.2 per 10,000 anesthetics,⁵ giving rise to the oft-quoted estimate of anesthesia-related mortality as one to two per 10,000 anesthetics, which Eichhorn mentions.

More recent outcome studies document a remarkable


‡ American Board of Anesthesiology data contained in Annual Report, Committee on Manpower, American Society of Anesthesiologists, Park Ridge, IL, September 1988.
reduction in the anesthesia-related death rate. A prospective survey of anesthesia outcomes in France during the period 1978–1982, in which 198,103 anesthetics were administered in study sites, found the death rate solely related to anesthesia to be 0.76 per 10,000 anesthetics. Interestingly, 42% of the events (all of these related to postanesthetic respiratory depression) actually occurred in the immediate postoperative recovery period, reducing the intraoperative rate to 0.44 deaths per 10,000. (This study focused French attention on the need to establish postanesthesia recovery rooms in the many hospitals lacking them.) The most recent large anesthesia outcome study is the British Confidential Enquiry into Perioperative Deaths, to which Eichhorn refers, which surveyed some 485,850 operations undertaken in three National Health Service regions in a 1-yr period beginning November, 1985; the death rate solely related to anesthesia was only 0.054 per 10,000 anesthetics, similar to the rate noted in Eichhorn’s study (0.066 for the premonitoring standards period). In addition to documenting the decreasing contribution of anesthesia mishaps to surgical mortality, the CEPOD study also highlighted the importance of appropriate oversight of trainees (in this case, surgeons). A recent pilot study of a protocol for a national survey in the United States, undertaken to test a methodology and not generate outcome rates, identified only one event due solely to anesthesia among some 8,000 anesthetics, and it occurred in the postanesthesia recovery room. Finally, an ongoing outcome study at the Groote Schuur Hospital in Cape Town has documented a gradual 73% decrease in the anesthesia-contributory death rate over the past 32 yr.

Thus, the death rate related primarily or solely to anesthesia care has decreased markedly during the past 4 decades, and risk management interest is now shifting appropriately to the postanesthetic recovery room. This progress in improved anesthesia outcome was achieved without explicit monitoring standards, not to mention pulse oximetry and capnography. Anesthesia care has become so safe that recent studies using prospectively collected anesthesia outcome data indicate that outcome can be predicted well by knowing only four (and nonanesthesia) preoperative factors: patient age, ASA Physical Status category, intensity of surgery (“major” versus “minor”), and nature of surgery (“elective” versus “emergency”). In fact, once patient- and surgery-related factors are entered into the predictive model, anesthesia-related factors—such as choice of anesthetic agents and even experience of the anesthesiologist (all were board certified with at least 1–2 yr additional training)—do not improve one’s ability to predict outcome. The corollary is that factors under the control of the anesthesiologist have only a minor influence on outcome. Of course, let me anticipate the reader’s response by noting that these studies did not specifically examine whether, for example, the occurrence of myocardial ischemia was monitored with the sophisticated equipment now being promoted, nor whether it was controlled with recently introduced drugs. However, minimal monitoring standards would not address this issue either.

Given the marked improvement in anesthesia outcome and the overriding importance of nonanesthesia factors in determining outcome, one would expect minimal monitoring standards to have a minimal effect. This follows directly from the already very low rate of occurrence of events that such monitoring should detect. We can gain some appreciation for how small the effect is likely to be in the Harvard hospitals, as well as putting it in the perspective of a comparable death rate, by returning to Eichhorn’s data. Recall that there were no anesthetic-related deaths among 244,000 healthy patients anesthetized during the 5 yr following implementation of the standards. Dealing with a “zero numerator” is always problematic; another year or two could go by without a death, or it could occur with the next anesthetic. Barring outright negligent or willful behavior, the rate of occurrence of a rare event can be assumed to be a random event and can be inferred probabilistically. The highest anesthesia-related death rate likely to be encountered at the Harvard hospitals, with a larger sample size and with 95% confidence, is 0.13 per 10,000 anesthetics. Bear in mind that this is the largest likely value, that the value for the premonitoring period was 0.066 in the Harvard hospitals, and that some of the deaths may be due to circumstances not preventable by the standards, as in Harvard series.

Statistics aside, the most obvious reason why minimal monitoring standards are likely to have a minimal effect is that they merely require adherence to what we are already doing. By adopting this set of standards, we are endorsing a current practice pattern. Indeed, this underlies the ease with which the standards were accepted by anesthesiologists at Harvard (and elsewhere). If practice standards are to effect further improvements in care, they must be more specific, directing us to do things we might not do otherwise. However, attempting to improve the quality of care, we may have just the opposite effect. This can occur because all inputs to health care—whether drugs, surgical procedures, equipment, or protocols—have attendant risks and economic costs, as well as the intended benefits (fig. 1, upper panel). Although many find consideration of cost abhorrent in health care decisions, it is increasingly unavoidable because resources are
limited, demand for health services exceeds societal capabilities, and ineffective (not to mention harmful) care displaces useful care merely by consuming resources. Thus, we must focus on the net benefit of any proposed change in care as the difference between the benefit and the sum of the risks and costs involved (fig. 1, lower panel). As additional resources are committed to care, the resultant net benefits ($\Delta B_j$) are smaller, because the improvements in patient outcome become progressively smaller, while costs and risks continue to rise. A point is reached at which the net benefit of additional resources is negligible. Investment beyond this point results in negative net benefit ($\Delta B_j$), which may be manifest as additional complications, deaths, and malpractice liability actions, as well as wasted dollars. Except for situations in which access to care is limited by lack of health insurance, American health care is commonly viewed as being very high on the benefit curve, raising the specter of wasting resources or causing harm as we try to do better. Acute coronary care, for example, has witnessed a vast investment of resources over time without much change in patient outcome.\textsuperscript{16,17} we have learned to practice medicine more expensively. In anesthesiology, these considerations have been raised explicitly only in discussions of manpower decisions\textsuperscript{18} and preoperative laboratory testing.\textsuperscript{19}

At this point, the reader may wonder how minimal monitoring standards, especially the use of pulse oximetry and capnography, could be harmful. Isn’t more information better? Unfortunately, the information, which is very beneficial in specific situations, does not come without costs and risks. The costs for acquisition and maintenance are substantial, especially when one considers that there are about 28,000 operating rooms, plus additional anesthetizing locations and postanesthetic recovery rooms, to equip. The risks are rather subtle and only beginning to be recognized. At the least, these newer monitors engender complacency with regard to direct observation of the patient; less attention is directed to the patient, and we are lulled into believing that all is well if the monitors do not alarm. However, their alarms sound all too often, spuriously; a recent prospective survey in a pediatric hospital noted that alarms (primarily of pulse oximeters) sounded an average of ten times per case, every 4.5 min.\textsuperscript{20} Seventy-five percent of the alarms were false, while only 8% indicated possible patient risk. The multiplicity of devices, each with its own alarm, compunds this growing source of distraction and has given rise to interest in integrated alarm systems.\textsuperscript{21} With monitors "crying wolf" so often, should we be surprised that many anesthesiologists turn off alarms when checking out their equipment? Or should those of us involved in teaching residents be surprised when we are summoned urgently into an operating room to find the trainee's attention devoted to an apparent malfunction of a monitoring device rather than using the five senses to evaluate the patient directly? Additional concerns are the restricted thinking, enhanced malpractice liability, and loss of professionalism which may result from the adoption of standards.\textsuperscript{22} However, my principal concern is that we have yet to learn the true benefits and risks of newer monitoring equipment.

Our ignorance with regard to the value of monitoring devices—and, more broadly, practice standards—is merely a vignette of what is plaguing all of medicine. The driving force behind the development of practice standards in anesthesiology is the interest in improving patient safety. Elsewhere in medicine, there is growing interest in developing practice standards as a way of treating the highly variable rate of use of specific treatments, as a cost-containment initiative. Regardless of the motivation, however, the critical need is to learn more about the re-
relationship between what we do and patient outcome. In this context, practice standards must be regarded as just another form of medical technology: each must be shown to produce a net benefit before it becomes part of clinical practice. The methods are not new. Rather, the challenge is that we expand our horizons from intermediate or process variables—for example, blood pressure or the presence of myocardial ischemia—to include true outcomes. To gain an appreciation of the latter, we need only ask our patients what matters to them; for example, leaving the hospital alive and returning to work, among other socially relevant outcomes. Since outcome studies require very large populations, as we have noted, multi-institutional studies will often be needed. In such studies, we should not lose the opportunity to include institution-specific variables because the institution itself influences outcome. Although newer monitors have already become an integral part of our practice, I am encouraged to learn that the Danes are subjecting the pulse oximeter to a national clinical trial. Until we incorporate the study of patient outcome into our consideration of practice standards, the emperor is naked.

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