

Current Topics

# ***Standards of Care in Perfusion: Should Not Continuous In-line Blood Gas Monitoring Be One?***

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## ***Introduction***

What is a standard of care? Who defines standard of care? And when does new technology, such as continuous in-line blood gas monitoring (CILBGM), become a standard of care? Perhaps the most productive and practical way to view standards of care in perfusion is as, “the best perfusion management we can provide for our patients within reason and affordability.”

Today, CILBGM offers a tangible patient care benefit to perfusion management—real-time, continuous monitoring of the patient’s physiologic responses to cardiopulmonary bypass, allowing the perfusionist to adjust bypass accordingly. At less than \$200 per case, CILBGM is not excessively priced.

Certain basic standards of practice for perfusion, along with the commitment to actively investigate new techniques and equipment, could help assure quality in patient care. If, as in the case of CILBGM, new technology contributes materially to the safety and well-being of a patient, we would be remiss not to endorse it as a standard of quality care.

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Mention “standard of care” among perfusionists and you are likely to elicit as many opinions as there are perfusionists. Some equate “standard of care” with quality assurance, maintaining that at least a minimum standard of care is necessary for any medical professional. Others believe that visibility and vulnerability are inevitably linked, that written

standards of care, even minimum standards, only invite scrutiny by lawyers and consequently a potential risk for even the most conscientious practitioner. To complicate matters further, standard of care is not a static concept. As new knowledge, techniques and technology emerge, the standard of care changes.

What is a standard of care? Who defines standard of care? When does new technology become a standard of care? And what implications do standards of care have for a practicing perfusionist?

## ***The Legal Concept of “Standard of Care”***

Standard of care is a legal concept that relies on a hypothetical “due-care” standard as a benchmark against which the management and outcome of particular cases can be judged. Physicians who meet the “due-care” standard cannot be held liable for every less-than-perfect outcome. Yet a physician may be obligated to indemnify a patient if medical management falls short of the “due-care” standard.

In reality, standards of care are set forth in each court case by expert witnesses for the prosecution and defense. These witnesses may invoke: 1) written standards of care prepared by professional societies, 2) professional literature, 3) prevailing practice, or 4) their own experience. In all likelihood the expert witnesses will contradict one another, one side holding that due-care was delivered, the other that a standard of care was not met. The jury must sift the evidence and choose whom to believe.

Many medical practitioners regard the medical malpractice system as disturbingly unpredictable and perhaps inherently unfair. How can a jury member, uneducated in medicine and unfamiliar with medical practice, be capable of rendering judgment in complex medical cases? In spite of misgivings, physicians generally fare well when a case goes to court; 80% to 85% are exonerated by juries. (1) Statistics on perfusionists

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are not easily accessible, but one would hope perfusionists fare as well when included in litigation. Furthermore, no matter what our opinion of the legal system, it is the only one we have and it is not likely to change soon.

### ***Written Standards of Care***

In 1917, the American College of Surgeons adopted written standards of care for medical records and recommended a method for conducting internal reviews. (2) Thirty-six years later the Joint Commission on Accreditation of Hospitals (JCAH) was formed to promote voluntary compliance with minimum standards of care agreed to by the American College of Surgeons, the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association. Until the 1980s, utilization review (consisting of random review of medical records) served as the primary form of quality assurance for most hospitals. In 1984 the Joint Commission shifted its emphasis away from utilization review and toward a qualitative review process. The Joint Commission now publishes written guidelines designed to monitor quality of care as well as to ensure continuing education for hospital personnel.

Written standards of care for perfusionists have a much shorter history. For many years, standards for perfusionists were simply incorporated into standards for the cardiac surgeons under whose supervision they worked. The American Society of Extra-Corporeal Technology (AmSECT) has, over time, dealt with publishing standards of practice for perfusionists, but historically has focused on scope rather than intent. AmSECT has produced a "Perfusion Scope of Practice." (3)

In 1987, the American Academy of Cardiovascular Perfusion (AACP) released its own "Standards of Practice" (4) that included sections on record keeping, equipment, personnel, prebypass checks, and perfusion management. The Standards are prefaced by these words: "The American Academy of Cardiovascular Perfusion endorses the following standards of practice in the art of Cardiopulmonary Bypass, and acknowledges that the development of standards of practice is an ongoing process due to evolving technology."

### ***Standards of Care vs. Quality of Care***

Although the pressure to articulate a standard of care comes primarily from the legal system, there are compelling professional and ethical reasons for perfusionists to be concerned about standards of care. Though most perfusionists will never be involved in a lawsuit, each time a perfusionist sits behind the pump, there is the potential for a life-threatening event. There is also the happier possibility that diligent, attentive and state-of-the-art perfusion management will safeguard the patient and complement the surgeon's skill to bring about a successful outcome.

Perhaps a more practical and productive way to view standards of care in perfusion is as, "the best perfusion management we can provide for our patients within reason and affordability." This definition replaces the threat of liability with the reward of improved patient outcomes as the motivation for delivering quality care. In addition, it keeps the responsibility for defining and implementing quality care with the perfusionists, not with someone such as lawyers and drafters of legislation, whose training and skills have never been directed toward clinical practice.

Quality of care being the issue, then, where does new technology fit in? Perhaps the best way to illustrate the relationship between quality of care and technology is by using the example of CILBGM.

### ***A Technical Breakthrough in Blood Gas Monitoring***

Blood gas monitoring/analysis is part of a perfusionist's responsibility as described in AmSECT's "Perfusion Scope of Practice," (3) and documentation of blood gas test results is called for in the AACP "Standards of Practice." (4) Before the current technology of CILBGM was introduced approximately seven years ago, blood gas testing for cardiovascular surgery was carried out in the hospital's central laboratory, or in a satellite stat lab. Perfusionists routinely sent a minimum of three to five sets of arterial and venous blood samples for blood gas analysis during the course of bypass. The time between sampling and receipt of results varied from hospital to hospital with turnaround times in excess of 20 minutes quite common. Delays, though sometimes worrisome, were considered unavoidable because no other method for blood gas analysis was available.

The introduction of CILBGM changed all of the ground rules. Suddenly it was possible to monitor real-time arterial and venous blood gas values. Instead of "driving with blinders on," the perfusionist could now see what was happening as it happened and adjust the management of bypass accordingly. The implications for improved patient care were obvious. With moment-by-moment information, the perfusionist could utilize the heart-lung machine as a true respirator, blowing off or maintaining CO<sub>2</sub>, thus using the patient's own natural buffering system to maintain a normal state of acid-base balance. According to investigators, CILBGM also facilitated more consistent management of perfusion parameters within physiological limits. (5)

Is CILBGM destined to eliminate standard laboratory testing? No! Perfusionists still use standard blood gas testing as a cross-check on the accuracy of the results obtained with in-line equipment. For a time it appeared that the Clinical Laboratory Improvement Amendments of 1988, CLIA-88 as they were dubbed, would impact the use of CILBGM in the

operating room by imposing regulatory restraints on decentralized laboratory testing. Fortunately, CLIA-88 as modified is not expected to affect perfusionists' ability to use CILBGM. Today, CILBGM offers a tangible patient care benefit to perfusion management—the opportunity to continuously monitor the patient's physiologic responses to cardiopulmonary bypass providing the perfusionist the opportunity to intervene in a timely and appropriate manner.

### ***The Question of Cost***

More and more today, the cost of new technology poses a real dilemma. Health care reimbursements are more tightly regulated than ever. Yet, it is unconvincing to claim that cost alone should prevent the use of equipment that could enhance patient outcomes, or mitigate disaster. In any event, it has always been easier to calculate the cost of actual occurrences than to quantify the savings associated with prevention. The decision is easier where CILBGM is concerned. At less than \$200 per case, CILBGM is not excessively priced. At most institutions, CILBGM is far less costly than six-to-ten blood gas analyses.

The cost of a particular technology can be balanced against the probable cost of losing, or even successfully defending, a single lawsuit. In *U.S. vs. Carroll Towing* (159 F2d 169), the presiding judge defined negligence in economic terms. (6) Calculate the probability of an accident and multiply it by the cost of the accident. If the result is greater than the cost of preventing the accident, negligence is automatically assumed.

A perfusion survey conducted in 1986 concluded that there was a likelihood of a patient injury or death during cardiopulmonary bypass in the range of 1/4000 cases. (7) In a hospital where 250 open heart procedures are performed annually, the accident rate would be 0.06/year. Multiply that by a hypothetical cost of \$2 million to settle a lawsuit. By this standard, one must spend \$120,000 per year (or \$480/case) on equipment to prevent an accident or be construed as negligent.

### ***Is CILBGM a Standard of Care?***

CILBGM was reportedly employed during 35% to 40% of cardiopulmonary bypass procedures as of 1990. (1) Its popularity attests to the fact that many perfusionists and physicians accept its utility in assuring quality of care. However, to date, no one has challenged the failure to use CILBGM as a standard-of-care issue. But consider the possible line of questioning if failure to use CILBGM were alleged to have caused injury:

- Do you monitor blood gas values while on bypass?
- How often do you send samples to the lab?
- How long must you wait for results?

Isn't it true that continuous in-line blood gas monitoring equipment has been available for more than seven years?

Would real-time blood gas information have allowed identification of the patient's problem sooner?

Why weren't you using it?

The plaintiff's lawyer would likely cite a study entitled "Improved Quality Control Utilizing Continuous Blood Gas Monitoring and Computerized Information Systems" by Justison and Parsons that includes the statement "use of CILM [continuous in-line monitoring] increases the safety margins during cardiopulmonary bypass." (5) And the lawyer would probably conclude by quoting Dr. David Rubsamen: "...continuous blood gas monitoring cannot be regarded as redundant. It must be seen as essential, both from the standpoint of safety and the prevention of devastating malpractice suits." (1)

### ***The Implications for Perfusionists***

Certain basic standards of practice for perfusion could help assure quality in patient care. Among them:

- Quality education and continuing education.
- Strong certification/credentialing process.
- Bypass protocols.
- Prebypass check list.
- Adequate perfusion records.
- Quality, well maintained equipment.
- Quality anticoagulation management mechanism and protocol.
- Use of appropriate safety equipment, i.e., filter/bubble traps, air bubble detectors, low level sensors, oxygen monitors, etc.
- Appropriate physiologic monitoring.
- CILBGM.
- Commitment to actively investigate new techniques, equipment and products that could contribute to better perfusion management and improved patient outcomes.

Standards of care will continue to be the subject of courtroom debate. Our opportunity as perfusionists lies outside the courtroom, in the operating room where quality of care is a daily matter affecting thousands of lives. If we are proactive, our knowledgeable and skillful efforts can have lasting effects on the quality of care provided to patients who undergo cardiopulmonary bypass.

As new techniques and technology evolve, we have a responsibility to critically evaluate them. If, as in the case of CILBGM, they contribute materially to the safety and well-

being of a patient on cardiopulmonary bypass, we would be remiss not to endorse them as a standard of quality care.

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