

# Correspondence

Dear Editor:

It was with great interest that I read Mr. Ferries' article "Standards of Care in Perfusion: Should Not Continuous In-Line Blood Gas Monitoring Be One?" (*J Extra-Corpor Technol.* 1993; 24(2): 45-48.), and after several readings and several lengthy discussions with colleagues and physicians I have several questions I would like to pose to the perfusion community.

Both questions Mr. Ferries asks and attempts to answer, "What is a standard of care?" and "Is continuous in-line blood gas monitoring (CILBGM) a standard of care?" I do not believe the answers he provides are adequate and only seem to provide strength for the practice that standards seem to be set by the legal community and not the perfusion and medical communities.

I do not disagree that reliable and accurate CILBGM is an excellent concept; however, to my knowledge that is all it is at this time — a concept. The only device currently available is the CDI device that requires constant adjustment and readjustment to analyzed lab results. The device appears to be no more than a trending device and not a true monitoring device. What will happen to the perfusionist who incorporates CILBGM, has a false reading, and causes injury to the patient? Again, what it boils down to is which expert witness is most convincing.

It is impossible to argue with the concept of continuous or, at least, rapid blood gas analysis, particularly in the venous blood for the CPB apparatus. The pulse oximeter has already alerted us to the fact that observing the color of the blood is a poor substitute for some quantification of the oxygenation of the blood. However, pulse oximetry is not a new concept. The basis for the technique has been available for more than 30 years. The reason the technology was not adopted sooner is simple. Until the past 10 years, they were neither accurate nor reliable. Consequently, the instruments available 25 years ago gave too many false-positives and too many false-negatives to be clinically useful. Only with the demonstration in repeated publications that the current generation of pulse oximeters were reasonably reliable and accurate did the pulse oximeter become a "standard of care" for the anesthesiologist (and, indeed, for the critical care physician.) (1)

Again, I do not argue against CILBGM; my concern is that someone with the excellent reputation and experience of Mr. Ferries would reach the conclusion that CILBGM, as we have available today, should be a standard of care for the perfusion community. He states in his closing paragraph, "As new techniques and technology evolve, we have a responsibility to critically evaluate them." Yet, no where does he indicate that this evaluation has occurred. The literature, as of yet, does not clearly support the use of CILBGM without the continued use of clinical

laboratory analysis and therefore one must ask if it is of true benefit.

Mr. Ferries also briefly addresses the cost equation. He mentions an approximate cost of \$200 per case, but what he fails to mention is that this is solely for the costs of the disposables and does not take into account the cost of the capital equipment as well as the continued need to send blood to the lab for analysis to verify the CILBGM device's results.

The standard of care question is certainly one whose time is long overdue. In establishing standards, we must be careful that we do not fall into the trap of trying to find an easy fix to this monumental challenge. We must continue with the process started by AmSECT's Perfusion Quality Committee and take a systematic approach to answering the questions that establishing standards will entail.

Sincerely,  
Craig R. Vocelka, CCP  
Lynnwood, Washington

1. Merin, RG. Con: Continuous blood gas monitoring should not be a standard during cardiopulmonary bypass. *J Cardiothorac and Vasc Anesth.* 1992; 6(1): 109-110.

Dear Editor:

I welcome the addition of the most recently added feature of the *Journal of Extra-Corporeal Technology*, "Current Topics." Such a forum for prominent issues within our profession is a welcome addition to the journal. I am, however, compelled to comment on the content of the article "Standards of Care in Perfusion: Should Not Continuous In-Line Blood Gas Monitoring Be One?" submitted by LeRoy H. Ferries. I would submit the following text to the editors of the journal, and all practitioners within our profession, as being vital to a valid understanding of the issues to which Mr. Ferries refers. In fairness to Mr. Ferries, he has received this text in personal communication, and the following text is an excerpt from that communication:

I would support any positive effort to define "standard of care" in more meaningful terms. Such a move would benefit all of medical practice. However, it is not likely that the term or its definition is likely to change as it relates to perfusion, let alone all of the other medical specialties which operate under its "spell." Your own definition, "...the best perfusion management we can provide for our patients within reason and affordability..." is certainly adequate. However, this definition in no way replaces

the threat of liability with the reward of improved patient outcomes. Words such as “within reason” ultimately place the burden of determination exactly where it now exists, and probably will exist for some time: in the hands of a jury. I agree that our efforts as professionals can certainly affect “what is reasonable.” Most importantly in this area, a well-organized, well-informed, cohesive professional camaraderie will advance our efforts most effectively; regrettably, we do not have such a profession. Your desire to keep the responsibility for defining such standards out of the hands of lawyers and drafters of legislation is, to an extent, impossible. It is, however, rare that specific standard of care issues appear in legislation. It is not so rare to see those matters more specifically addressed in insurance policies.

It is worth remembering, at this point, that the standard of care is often defined in local terms — the standard of care is that standard which prevails generally within the locale under scrutiny. Perfusionists who organize on the local level have a great advantage over those who do not, in this particular area.

As to your reference to *United States et. al. v. Carroll Towing Co., Inc. et. al.*, 159 F.2d 169 (2d Cir. 1947), such reliance is entirely invalid. This case deals with an admiralty issue of negligence. Admiralty law is rarely used as authority for non-admiralty cases. The formula to which you refer as a means of finding negligence in fact does not render a finding of negligence “automatically assumed,” for such a concept is entirely foreign to negligence theory. No such burden can be “automatically assumed” in legal theory, and especially in civil law. If that were the case, we wouldn’t have law suits, only settlements. Furthermore, the calculation is clearly restricted to the facts within the case, and include: (1) the probability that she (barge) will break away; (2) the gravity of the resulting injury, if she (barge) does; (3) the burden of adequate precautions. In fact, the opinion itself not only restricts itself to these facts, but leaves the question open to interpretation as to other facts present within the case, such as weather, time of day and any other significant variable. Most importantly, a search of the history of this case, and its sister cases, reveals that this concept of liability determination is NOT adopted either in the 2d Circuit or in other circuits and has only been cited sparingly within its own circuit — the only place where it MIGHT be given the distinction of primary legal authority. Nor has it ever been cited as a basis for recovery in any medical case at any time within the 2d of any other circuit. Its most current reference within the 2d Circuit was in a case involving enterprise liability, and in that case the formula to which you refer was NOT used, nor could it have been. It is an entirely irrelevant source of authority for the purposes of discussion the standard of care in perfusion.

Your reference to studies that may be advanced by a plaintiff’s lawyer is likewise inappropriate. No evidence is introduced by a lawyer for either plaintiff or defendant. Evidence is introduced through mechanisms set out by the rules of civil procedures and the rules of evidence, and nearly always involves testimony by persons, either live or through deposition. A plain-

tiff may introduce the evidence to which you refer, but he must in most jurisdictions (and under the Federal Rules of Civil Procedure) reveal to the opposing side the basis of his testimony. My experience tells me that RARELY does an expert place his reliance upon any single article, treatise, book or other publication, because it is fair game for the opposing side to prepare for, and rebut, any such reliance. Additionally, Dr. David Rubsamen’s article to which you refer is NOT a scientific presentation, but merely editorial comment (though placed in a reputable publication), and as such, if not pure heresy, would be non-authoritative. This is not to say I fully support the manner of introducing evidence that we are forced to operate under, but it is nonetheless reality in our approach to liability abatement.

Mr. Ferries, please do not misconstrue my intentions. As I stated, I support your work in general. I do believe, however, that our profession can benefit from informed, properly stated argument. It is to this end that I make a good faith contribution. Thank you for your consideration, and I look forward to continued communications.

Sincerely,  
James J. Ramsey, BA, CCP  
Franklin, Tennessee

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Dear Editor:

I appreciate the opportunity to respond to Messrs. Ramsey’s and Vocolka’s responses to my article “Standards of Care in Perfusion: Should Not Continuous In-Line Blood Gas Monitoring Be One?” published as the first of an added *Journal of Extra-Corporeal Technology* feature called “Current Topics.” Your goal to stimulate interest and possible debate with this new feature seems to have had some initial success.

As most people probably know, I have been and continue to be a strong proponent of “minimum standards of care in perfusion.” If my article has stimulated just 10 percent of the members of the perfusion community to seriously look at themselves and their practice, then it has accomplished something. So often we continue to do “our thing” in life, both personal and professional, without taking time to do a self-assessment: “How am I doing compared to my plan and in the case of standards, the rest of the world out there?” I believe minimum “generic standards” for perfusion can and must be identified and endorsed by the perfusion community. AmSECT is certainly working toward that end with the “Perfusion Essentials and Guidelines.”

I do not wish to get into a legal debate whether or not one judge’s opinion/interpretation of negligence has been adopted by the United States Supreme Court, or whose interpretation of “standards of care” is used. Suffice it to say, if anything has been written and/or spoken and debated in any area, such as this publication for instance, there is a probability it will be used in a litigation if felt to be of value, relevant or not. Relevance is left for the courts to decide.

I used Judge Learned Hands' definition of negligence and the hypothetical case illustrated how ridiculous and unbelievable litigation cases can become. The intent was to shock perfusionists out of any false sense of security they may have in thinking: "It has never happened to me in all these years and our patients do pretty well." Reality, like it or not, can be a cruel world out there should you ever need to justify your actions in a malpractice suit. Having protocols, check lists, game plans, physiologic monitoring etc. will be of value in such a litigation, but more importantly, they will be of greater value in your everyday practice.

Mr. Vocelka's statement that "...standards seem to be set by the legal community and not the perfusion and medical communities" is pretty much true to this point in time. Historically, the medical community has never supported written standards due primarily to the fear of them being used against them in case of a malpractice suit. Resulting effect, lawyers have referenced any and all written materials and utilized expert witnesses they feel will best represent their position. Without acknowledged standards, such information, along with good intentions, is about all the courts have to go on.

As to the value of CILBGM, I cannot imagine any perfusionist not seeing the value in some type of in-line monitoring that provides real-time information. Would you drive a car without a speedometer, or fly an airplane without an altimeter? Probably not. Is the CDI system, as referenced by Mr. Vocelka, a panacea? Of course not, but gas calibrated per manufacturer's recommendation and then adjusted if needed to bench method blood gas analysis 15 to 20 minutes into the pump run when everything is relatively stable, it has proven to have minimum drift and is very reliable. We choose to do a second bench method comparison early in our rewarming/before partial bypass, which in most cases requires very little if any adjustment. Earlier models were very sensitive to moisture in the sensor and care needed to be taken in setup, but not so with the current model. As with any lab value, if it doesn't fit the clinical picture, question it and repeat/confirm if possible. Even if you feel you can only trust such devices as a trend monitor, they can provide valuable clinical data and, from a legal aspect, that certainly is better than nothing at all.

Evaluating new techniques and technology as to cost/benefit should be a continuum of every institution to assure quality patient care that is cost justifiable. Our practice used to be a set of arterial and venous blood gases (A-V BGs) pre and post cardiopulmonary bypass (CPB), plus every half hour on CPB. Today, we do pre and post CPB A-V BGs with one set at 15-20 minutes and another prior to partial CPB as stated earlier. On shorter cases, the pre partial CPB could be waived unless there were questions. On a two-hour pump run, that saves us at least three sets of A-V BGs. Providing real-time clinical data is the greatest value of CILBGM, especially during the latter stages of a case when there may be a need to maneuver the heart to make repairs on the under side for an extended period of time. A pump run that may have been "textbook" is now part of a major physiologic insult. Without real-time in-line monitoring, treatment of the resulting effects would be done after the fact. With

real-time in-line monitoring, timely adjustments in CPB management can generally be made to prevent any major swing in the patient's physiology.

In closing, CILBGM was used as one example of an in-line real-time technology I feel should be used by every perfusionist. As professionals, we must continue to seek ways to enhance the quality of patient care and patient outcomes. Perfusion professional organizations must continue to identify and endorse minimum standards for perfusion practice.

Once again, thanks for the opportunity to expound on something I feel very strongly about — standards of care in perfusion.

Sincerely,  
LeRoy H. Ferries, BS, CCP  
Marshfield, Wisconsin