

# Clinical Practice Guidelines: A Malpractice Two Way Street

BY STEPHEN J. SCHEIFELE, M.D.

Clinical practice guidelines are increasingly being used to shape physicians' practice patterns. For the most part, guidelines have been introduced to enhance the quality of care and improve patient outcomes—not just as cost containment measures. For example, adherence to practice guidelines has been demonstrated to reduce adverse obstetrical outcomes. Yet physicians generally prefer to rely on their personal clinical experience rather than comply with guidelines—even when physician adherence to guidelines can reduce the filing of inappropriate suits. When it comes to malpractice litigation, it is clear that practice guidelines are a two way street that can help or hurt the physician's defense.

Attorneys are beginning to pay special attention to practice guidelines as Federal and California state courts allow guidelines to be introduced as evidence. It should be noted that when introduced as evidence, guidelines tend to be more convincing than journal articles or textbooks, especially when they are issued by a professional society (the most frequently cited guidelines in malpractice cases are those from the ACOG).

A basic dilemma is that if clinical guidelines define the standard of care, any deviation can be interpreted as below that standard, yet if clinical guidelines do not define the standard, adhering to them may not offer protection. In most cases, guidelines are introduced as evidence supporting the plaintiff. As the courts appear to be leaning towards using guidelines as a baseline for determining the standard of care, the trend is for departures from accepted authoritative practice guidelines to increase the risk of a law suit.

A number of high profile cases highlight inconsistencies in the interpretation of guidelines in medical malpractice proceedings. A jury found for the plaintiff after a newborn developed neonatal strep when the obstetrician failed to comply with a newly developed screening protocol that had been issued by the ACOG 3 months earlier. A family practice clinic at a teaching hospital was found negligent for failing to perform a PSA test

after an intern followed the established guidelines of providing informed consent as to the risks and benefits of testing and allowed the patient to decide. The court held that the community standard was to order the test without any discussion. Yet in another PSA related case, the court supported the defendant's use of a physical exam with discussion of the pros and cons of PSA testing as adequate screening.

Where does this leave the physician trying to practice quality care and avoid risk?

- Pay attention to clinical practice guidelines—especially those from your professional specialty organization.
- Document informed consent.
- Document and explain any deviation from established practice guidelines.

Efforts at tort reform in several states are attempting to establish guidelines for certain specialists that would be used as the standard of care when reviewed by a mandatory pre-trial screening panel. This would induce more physicians to use guidelines instead of practicing "defensive medicine". Patients would have more effective care at a lower cost and providers would have better protection from malpractice litigation. ■

*Dr. Scheifele is a board member and chair of the Risk Management & Education Committee of PRF.*

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# Availability of the Good Samaritan Defense

BY REBECCA L. CACHIA-RIEDL, ESQ.



## ANNUAL MEETING IS SET FOR APRIL

Every April PRF holds its Annual General Membership Meeting, which is a great opportunity to learn more about PRF and to meet the members of the Board of Directors and the staff. The more you know about PRF, the more PRF can help you to manage your risk. Meeting details will be announced well in advance, so please make it a point to come to the 2005 Annual General Membership Meeting. ■

The purpose of California's "Good Samaritan" statutes is to induce physicians to provide emergency medical care in return for an exemption from legal liability. The defense can include care given inside a hospital and is available to physicians who provide emergency care within their specialties. For example, an obstetrician coming to the aid of another obstetrician for the delivery of an infant is not prohibited from claiming the Good Samaritan defense if there is a poor outcome and the family decides to sue. The Good Samaritan defense can even absolve physicians of liability for negligence, but it has its limits—physicians continue to be liable for gross negligence, recklessness, or willful misconduct.

Generally, a physician claiming Good Samaritan immunity must meet the following requirements:

- The defendant is a licensed physician.
  - The physician rendered emergency medical care.
  - The physician acted in good faith.
  - The physician did not have a preexisting duty to provide medical care to the patient.
- An emergency is simply a medical situation that requires intervention. Death need not be imminent for an emergency to exist—a risk of injury may be sufficient. Factors that are taken into consideration are the "gravity, the certainty and the immediacy" of the medical consequences if no action is taken. For example, if during surgery to remove a malignant ovarian tumor, the tumor unexpectedly ruptures seeding the abdomen with cancer cells, an emergency could be found

to exist because the unanticipated complication required the immediate assistance of another physician during a crucial stage of the operation. The responding physician is protected if he/she had a good faith belief that an emergency situation existed. The responding physician does not lose the protection of the Good Samaritan defense if the treating physician who called for help could have, or should have, anticipated the situation creating the emergency and the need for assistance.

*For the Good Samaritan statutes to apply, the physician must not have a preexisting duty to respond to the call for assistance.* In determining whether a physician had a preexisting duty, the court may consider the following questions:

- Had the physician previously provided any care or treatment to the patient?
- Did the patient have any expectation of being cared for and treated by the physician?
- Did the physician have any expectation of payment for the provision of medical services?
- Was there any kind of employment/referral arrangement that would have led to the physician treating the patient?
- Why was the physician available to treat the patient?
- Did treating the patient during the emergency interfere with the physician's other obligations?

For example, a pediatrician, who was at the hospital rounding on his patients, responded to an obstetrician's "stat" call for assistance upon the delivery of an

infant, who was cyanotic and in respiratory distress. The pediatrician was found to be protected by the Good Samaritan defense. The court determined the pediatrician did not have a duty to respond to the emergency call, because the child was not his patient, he did not have a referral relationship with the obstetrician, he was not employed by the hospital to treat newborns in the event of an emergency, and he cancelled his office appointments to care for the child until the child could be transferred to a neonatal intensive care unit.

However, courts have found a preexisting duty to exist where there was a current patient-physician relationship, an employment obligation to provide emergency care on an on-call basis, or an ownership interest in the medical facilities where the emergency occurred.

Finally, payment for emergency services may result in the loss of a Good Samaritan defense. Payment may indicate that a pre-existing relationship existed obligating the physician to provide care. For example, a physician who provides on-call emergency obstetrical care to the emergency room is prohibited from claiming the Good Samaritan defense if the physician receives "consideration in any form" for serving on-call, unless the physician's call contract with the hospital specifically indicates that the hospital was willing to accept the risk of negligent emergency obstetrical care on the physician's behalf. ■

*Ms. Cachia-Riedl is a partner at Hassard Bonnington LLP and specializes in the defense of physicians and facilities in medical malpractice claims.*

# Preventing Surgical Wound Infections

BY THOMAS K. HUNT, M.D. AND HARRIET HOPF, M.D.

**A**voiding vasoconstriction and ensuring adequate tissue perfusion are the key objectives in the effort to minimize postoperative surgical wound infections. Why? Because phagocytic killing of opportunistic wound-infecting bacteria requires relatively high tissue concentrations of oxygen to be converted to bactericidal oxidants such as hydrogen peroxide to create the so-called “oxidative burst.” Only by maintaining adequate perfusion and thereby adequate tissue oxygenation can we ensure that the patient’s immune system’s ability to resist bacteria is not compromised. Keeping this principle in mind allows for several recommendations for keeping wound infections to a minimum.

## Avoid hypothermia

An important way to avoid local and systemic vasoconstriction during surgery is to avoid intraoperative hypothermia. In patients having high-wound-risk, open abdominal operations, wound infections fell by 60% in patients whose body temperatures were kept in the normal range compared to patients who had cooled even a modest 3 degrees by the end of the procedure. Not only will the infection risk be lowered, but rigorous temperature control also lessens cardiac arrhythmias, coagulation disorders, post-operative coronary infarctions, and deep vein thromboses.

## Avoid hypoxia

Studies have demonstrated that having the patient breathe 80% vs. 30% oxygen produced

similar infection-reducing results as avoiding hypothermia. In subsequent studies, the number of wound infections was inversely proportional to the directly measured wound PO<sub>2</sub>. These observations reinforce the point that wounds are vulnerable because local vascular damage creates hypoxia, and sympathetic vasoconstriction diminishes oxygenation still further.

vous system in the same way as do adrenergic drugs.

## Give prophylactic antibiotics preoperatively

We have known from animal experiments that go back to the 1950’s that prophylactic antibiotics are effective only when tissue levels are already established at the time bacterial contamination occurs.

Having several vasoconstrictive influences may or may not

*Only by maintaining adequate perfusion and thereby adequate tissue oxygenation can we ensure that the patient's immune system's ability to resist bacteria is not compromised.*

## Ensure adequate hydration

Because hypovolemia is vasoconstrictive, studies have demonstrated that increasing intraoperative fluids results in reduced postoperative infections. It is important to recognize that fluid needs are proportional to body mass as well as length of surgery. One size does not fit all! The fluid capacity (and need) of large (especially obese) and warm patients is considerably greater than “average.”

## Manage postoperative pain

Pain causes vasoconstriction and decreases wound oxygenation by triggering the sympathetic ner-

cumulatively increase the risk of wound infection, but correcting any one factor will be ineffective unless all the others are corrected as well. Remember—for the first 24 hours improving oxygenation has a longer lasting effect than that of antibiotics! ■

*Dr. Hunt is Emeritus Professor of Surgery at the University of California San Francisco. He has been a leader in wound research for many years and was the first President of the Wound Healing Society. S. Harriet Hopf, M.D. is Associate Professor of Anesthesiology at UCSF.*

## Preventing Surgical Wound Infections

- Avoid intraoperative hypothermia
- Avoid intraoperative hypoxia
- Ensure adequate hydration
- Manage post-operative pain
- Administer antibiotic prophylaxis before surgery



## PRF NEWS

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Stephen Scheifele, MD,  
Executive Editor  
Robert D. Nachtigall, MD,  
Editor

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Fund, Inc.

1409 Sutter Street  
San Francisco, CA 94109  
(415) 921-0498 - voice  
(415) 921-7862 - fax  
June@PRFrrg.com

**June Riley**  
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# Code Green—Why Is It Important?

**C**ode Green is the name of PRF's risk management program that encourages and facilitates the early resolution of adverse outcomes due to medical treatment or procedures. Not only does Code Green provide a mechanism that lets you demonstrate your genuine concern for your patients and make them "whole again," early application of Code Green has been proven effective in maintaining a good doctor/patient relationship and may result in a patient who is less inclined to file a claim or complaint.

### Code Green is important to you because:

- Any physician can have a patient who experiences an adverse outcome.
- Code Green provides you with an opportunity to resolve the problem without regard to blame or liability.
- As a PRF insured, using Code Green is virtually risk free. With prior approval, PRF will reimburse your payments to the

patient for their out-of-pocket expenses.

- Code Green is good medicine—it puts your patient's health and welfare first.

Whenever you have a patient who experiences any adverse outcome we encourage you to call the PRF office at (415) 921-0498. As a PRF insured, you have a team of medical and legal professionals just a phone call away who are ready to assist you. ■

## Botox Injections

**BY WILLIAM J. WOLFENDEN, JR., M.D.**

**B**otox is the brand name of a formulation of highly purified botulinum toxin refined from the *Clostridium botulinum* type A bacterium. Injected into facial muscles in a very dilute solution that delivers just a few billionths of a gram of toxin, Botox prevents the release of acetylcholine at neuromuscular junctions and brings about temporary local muscular paralysis. The prevention of facial muscular contractions keeps the overlying skin from wrinkling and results in a smoother and more "youthful" appearance that has been widely accepted as an alternative to more invasive plastic surgical procedures. The most popular sites for injection are the frontalis muscle (frown lines), the lateral aspect of

the orbicularis oculi muscle (crow's feet), the corrugator supercilii muscles and pyramidalis nasi muscle, and submental platysma bands. Care must be taken to avoid an immediate supra-brow injection and perioral (levator labii superioris) muscular injection must be done carefully with very small dosages in isolated areas

After dilution with 4 to 5 ml. of preservative free saline, Botox must be used within three days to maintain its effectiveness. Unless the operator is familiar with facial anatomy including muscle location, size and skin depth, ill-placed Botox injections can result in eyelid closure problems, eyebrow ptosis, lip droop, localized paralysis and even dysphagia. Fortunately the effects of the injection will

wear off within nine to twelve weeks following the injection. By the same token, re-injection is required in the same time frame if one desires to maintain the cosmetic effect. Because the popularity of Botox has encouraged inexperienced operators to enter the field, physicians must be aware of their responsibility to oversee its safe use, particularly as disputes arising from complications will be litigated through the supervising physician. ■

*Dr. Wolfenden, a board-certified fellow of the American Academy of Otolaryngology, Head and Neck Surgery, is certified by the American Board of Facial, Plastic, and Reconstructive Surgery and by the American Board of Cosmetic Surgery.*