Risk Rx

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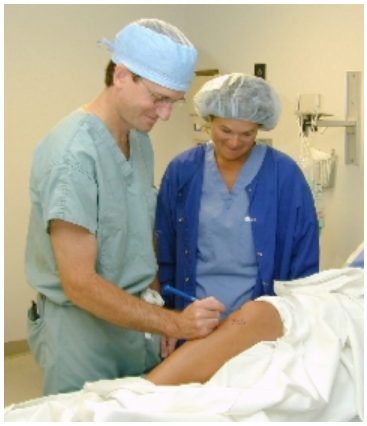

Preventing Wrong Site Surgery

J.J.Tepas III MD, FACS, FAAP
Professor of Surgery and Pediatrics
College of Medicine - *Jacksonville*

In its December, 2008 report, the Florida Board of Medicine addressed four cases of wrong site surgery that had just been reviewed and adjudicated. The Board was concerned by the persistence of this "preventable type of error that we see too often." The good news was that the incidence of "wrong lens" ophthalmologic cases had diminished. Since these represented 17% of the previous wrong site surgery experience, this was considered an indicator of patient safety program success. Apparently, this is but one piece in what is actually a distressing mosaic of provider performance. Data from the Joint Commission on Accreditation of Health Care Organizations indicates that the incidence of wrong site surgeries is increasing! These were treated as sentinel events and underwent root cause analysis. This is indicative of one of the key characteristics of what should be the quintessential example of preventable error. The relative infrequency of these "never events" makes it difficult to determine efficacy of prevention programs.[1, 2]

Further analysis of the Joint Commission's assessment indicates that the major problem with wrong site surgery involves orthopedic, urologic, and neurosurgical procedures.[3] Four specific risk factors have been defined and include:

1. Multiple surgeons included in the case.
2. Multiple procedures conducted on the same patient, often by different surgeons or different services
3. Unusual time pressures that result in significant validation steps being rushed or excluded, and
4. Unusual patient characteristics that may undermine or mask definitive assessment of the correct side for surgical intervention.

It is obvious that the glue that ties all four of these factors together is communication. While it seems that something that is as simple as operating on the correct side or site should be a "no brainer," in reality the enormous press of time and patient volume in modern health care clearly sets lots of traps that can practically guarantee that the system will fail. Review of these traps as defined above demonstrate that the major component in preventing wrong site surgery is effective communication between the responsible surgeon and the patient. It also clearly places the onus of assuring this communication on the surgeon, and nobody else! While the patient may be completely lucid and able to define specific characteristics of a problem during office assessment, that same patient, when partially sedated in the recovery room, may be less alert and even confused. In addition to this obvious core issue of communication there are other specific processes related to each of the four categories above that should minimize or even eliminate potential for wrong site surgery. Michaels et al describe an excellent system for assessment of the existence of an appropriate process for wrong site surgery prevention, as well as recommendations for assessment of staff knowledge of protocols and determination whether the protocols are actually effective.[2] What follows below are suggestions for consideration by the individual who bears ultimate responsibility for care – the surgeon. Each of these ideas is intended to enhance understanding of the basic problem from the perspective of a simple

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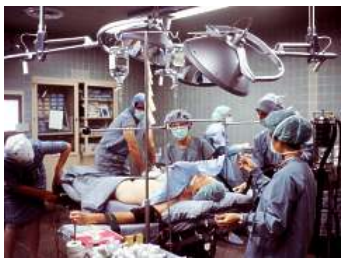
commitment of time and refocusing of effort can avoid personal and professional disaster.



Problems 1 and 2 : ***Multiple surgeons and multiple procedures conducted on the patient during the same anesthetic period***: These cases are not that uncommon and usually end up as a sequence of events in which a surgeon "comes and goes" while completing his or her own busy schedule.

Recommendation: Require that any physician who will touch the patient in any way be known to the patient and discuss with the patient operative plans, risks and complications. Multiple procedures and the sequence of physicians performing them should be listed on the front of the patient's chart and approved by the patient or appropriate surrogate before initiation of anesthesia.

Problem 3: ***Unusual time pressures that result in significant validation steps being rushed or excluded***. Process can be defined as procedures performed according to policy. Policy is intended to optimize process by assuring that procedures are safe, efficacious and efficient. The critical element of this issue has been initiation of the "time out". As this becomes more inculcated into our surgical culture, the likelihood of this issue remaining a problem will diminish.

Recommendation: Insist that everyone in the room pay attention during the "time out"!

Problem 4: ***Unusual patient characteristics may undermine or mask definitive assessment of the correct side for surgical intervention.*** Risk factors can be categorized in three groups. Those that exist at the time of patient encounter (obesity, diabetes, asthma, etc) are functional comorbidities that must be cataloged on initial evaluation and considered both during patient counseling and for operative risk stratification. In addition to these pre-existing factors are care related factors associated with processes and devices used in daily patient care. These include everything from aspiration during placement of a nasogastric tube to urinary tract infection related to bladder catheters. Procedures planned and patient characteristics should predict much of what may be required during the course of care and must be reviewed with the patient before the procedures. The third category of risk factor is often the effect of the first two and relates to physiologic derangement. Sepsis from an infected central line or bladder catheter may be associated with hypotension or hypoxia, thereby producing serious risk to patient survival that is the result of synergistic interaction of pre-existing and procedural factors defined above.

Recommendation: All of the above points to the obvious fact that the best strategy for avoidance of problem four is detailed documentation of all relevant patient characteristics. In other words, no unusual "site masking patient characteristics" should ever be a surprise first uncovered in the pre-operative holding area.

All of the above underscore just how critical is the requirement that the physician who is ultimately responsible for the surgical intervention be able to meet with the patient "one last time" before induc-

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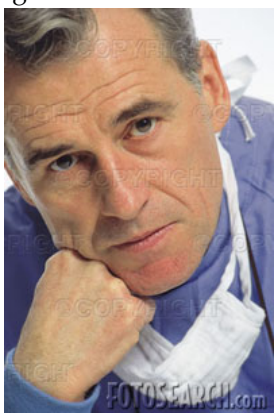
tion of sedation and/or anesthesia. He or she must confirm with the patient and, if possible, the patient's kin what is to be done, where the incision will be, and expected immediate outcome. Unfortunately this translates to an additional time burden on the surgeon. It would be nice to think that the system could be modified in such a manner to guarantee that there would be reliable surrogates for this, but, in reality, the buck does indeed stop with the person holding the knife. If wrong site surgery is to be eliminated, then the physician responsible for initiation of the surgery must make this time investment to confirm the identity of the patient on whom the surgery is being initiated as well as the site of the procedure before the process begins. Anything less is an invitation for disaster and, in the eyes of the Florida Board of Medicine a prescription for avoidable catastrophe. It is indeed a catastrophe for the patient who bears the brunt of incorrect surgery, for the physician who bears the guilt of negligence, and for society, which must endure yet another preventable adverse outcome from the professionals in whom it places its highest hopes and trust.



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Frequent Board of Medicine Disciplinary Actions

Gregory A. Chaires, Esq.
JoAnn M. Guerrero, Esq., LHRM
Chaires, Brooderson & Guerrero, P.L.

For many physicians, the experience of opening a letter from the Department of Health inspires pangs of anxiety and concern, generating the oft asked questions:

Did someone file a complaint? Why am I being investigated? Will I be disciplined? Could I lose my medical license?

This article will focus upon some of the most frequent Department of Health (the "Department") investigations and resultant disciplinary action, which may be taken in a variety of circumstances.

Applicable Law & Most Common Violations

Investigations by the Department are governed by Chapter 456, Florida Statutes and typically involve potential violations of Sections 456.072, Section 458.331 and 459.015, Florida Statutes. Chapter 456 sets forth the general provisions for Health Professionals and Occupations, while Chapters 458 and 459 are the acts specifically governing allopathic and osteopathic physicians, respectively.

Among the most frequent violations that give rise to investigations is the very broad-based description that the physician failed to meet the accepted standard of care or committed medical malpractice. These investigations can be generated by patient complaints, complaints from other practitioners, medical malpractice litigation or closed claims reports that are generated when a settlement has been paid on behalf of a physician.

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As you may be aware, practitioners are required to report adverse incidents that occur in their offices and hospitals, and ambulatory surgical centers must as well. Given the obligation to report certain incidents and events under Florida law, wrong-site procedures, wrong-patient procedures and wrong procedures are also frequently investigated and often result in disciplinary action, particularly as they relate to failure to comply with the pause rule. These are known as Code 15 Reports.

Additionally, as noted above, Florida law requires that any claim or action for damages for personal injuries claimed to have been caused by error, omission, or negligence in the performance of such insured's professional services or based on a claimed performance of professional services without consent of the patient be reported to the Florida Office of Insurance Regulation. See Fla. Stat. 627.912. Thus, many investigations ensue from medical malpractice closed claims reports of underlying civil litigation. Other often-seen violations relate to poor documentation and record-keeping, as well as improper prescribing.

Disciplinary Actions

According to the Florida MQA Annual Report for July 1, 2007 through June 30, 2008, 5,055 statutory reports and 5,452 complaints were received by the Department involving allopathic physicians and 777 statutory reports and 649 complaints were received against osteopathic physicians. While the number of reports and complaints are significant, it is important to also note that probable cause was found against allopathic physicians in 246 cases and in 40 cases against osteopathic physicians.

What kinds of discipline can be imposed?

For the period of July 1, 2007 through June 30, 2008, the Department reported the following outcomes of its investigations:

Allopathic Physicians:

> 20 revocations, 44 voluntary surrenders, 28 suspensions, 29 probations, 164 limitations/obligations, 200 fines, 51 reprimands, 305 citations and 100 dismissals.

Osteopathic Physicians:

> 3 revocations, 6 voluntary surrenders, 12 suspensions,
> 5 probations, 36 limitation obligations, 43 fines,
> 13 reprimands, 22 citations and 6 dismissals.

When a Board enters a final order against a physician resulting in a discipline, the order typically incorporates terms and penalties from a negotiated Settlement Agreement entered into between the practitioner and the Department of Health. Penalties issued by the Boards, depending on the allegations in the complaint, typically require payment of an administrative fine, payment of administrative costs, completion of community service, presentation of a lecture or seminar relevant to the violation at issue, evaluation by Florida Cares, quality assurance review of the physician's practice by a licensed risk manager, and/or completion of continuing medical education courses. Depending on the seriousness of the alleged violations, or whether it is second or third time offense, a Board may impose a period of probation, which can include indirect or direct supervision, license suspension or license revocation. In cases where practitioners are believed to suffer from chemical or other dependency, psychiatric illness or impairment or where boundary violations exist, a Board may require that a physician be evaluated by the Physician Recovery Network ("PRN") and comply with any and all of PRN's recommendations.

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Finally, as record-keeping and documentation violations are also prevalent, physicians are responsible to ensure that their documentation is thorough, legible and accurate. The Board of Allopathic Medicine has a very good list of frequently answered questions on its website for practitioners dealing with record keeping issues that we encourage all physicians and providers to review. http://www.doh.state.fl.us/mqa/osteopath/

As healthcare attorneys, we frequently are asked by investigated physicians about the "maximum penalties" relative to their alleged violation(s). This is dependent upon several factors, including whether the violation is a single isolated violation, if there are multiple counts, if the violation stems from a recurrent offense, if the physician has violated an existing final order and so forth. Under Rules 64B8-8.001 and 64B15-19.002, Florida Administrative Code, the Boards of Medicine and Osteopathic Medicine provide disciplinary guidelines "which will be routinely be imposed unless the Board finds it necessary to deviate from the guidelines." See 64B8-8.001, F.A.C. In the interest of brevity, we recommend that each practitioner review the rules to understand the nature of the offenses, as well as the concomitant recommended penalty range. See 64B8-8.001, F.A.C. and 64B15-19.002.

While many patient complaints may ensue after even the best of care from physicians, and the law requires the reporting of closed malpractice claims and certain incidents, we urge physicians to be ever vigilant in employing risk reduction strategies. Considering that the most reported violations involve standard of care issues, wrong-site procedures and wrong procedures; physicians must review their practices on a regular and continuing basis to ensure that satisfactory procedures and protocols are in place to reduce risk. For example, the frequency of such incidents and resultant investigations could be drastically reduced through effective use of the "Pause Rule" (otherwise referred to as "Time Out"), not only by physicians, but by the entire medical team. It is important to remember that the "Pause Rule" is a requirement that must be followed and documented in a patient record in any surgery setting, whether in the office or an institutional facility. See 64B-9.007 F.A.C.

It is quite unfortunate that in many cases, disciplinary action has resulted where the Pause Rule was implemented and initiated, but was incorrectly or incompletely performed. More frustrating is the recognition that such investigation and discipline could possibly have been avoided had the involved practitioner(s) taken a few moments to review the file, meet with the patient or discuss the planned procedure with the assisting medical team, prior to initiating the procedure.

We encourage practitioners to always consult with their health care legal counsel with any questions regarding investigations, disciplinary actions and related matters. Additionally, we strongly advise that physicians read the appropriate rules governing physicians and the medical practice, as well as review profession updates by the respective Boards at their websites. There is helpful information on the website for the Florida Board of Medicine (http://www.doh.state.fl.us/MQA/medical/me_home.html), http://floridashealth.com/mqa/osteopath/os_home.html, the Florida Administrative Code (http://www.flrules.org) and the Florida Statutes (http://myflorida.gov).

In closing, it is imperative that physicians and practitioners alike focus upon the reality of Department investigations and continue to be more proactive in risk prevention. One very effective manner to facilitate such strategy is to focus upon the nature of different kinds of risk exposure and poten-

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tial outcomes. Understanding the nature and frequency of the circumstances, however, can only benefit a physician in focusing upon particular areas of his or her

practice which could perhaps use more attention.

Credentialing for New Procedures

Cristina Palacio, Esq.
Associate General Counsel
Shands Healthcare, Inc.

Carol Shaw, CPMSM, ,Director,
ShandsHealthCareCredentialingVerification
services and Shands at UF Medical Staff Services

New technology creates challenges for many in the healthcare field. Prior to granting privileges to perform a new procedure or use new technology, The Joint Commission requires hospitals to have a process to determine whether sufficient space, equipment, staffing, and financial resources are in place to support each requested privilege. In the field of credentialing, many questions must be answered when new technology is introduced, including whether or not credentialing criteria should be developed for the new technology. Generally, if the new technology or procedure is one in which special training and/or experience would be required, the challenge of developing criteria to demonstrate competency to use the new technology or perform a newly developed procedure that can then be applied consistently to any individual requesting these new privileges must be addressed. Patients on whom new procedures are being performed should feel confident that the physician performing the new procedures is appropriately trained and competent. When new technologies are introduced, hospitals may not be able to rely on residency training completion as one validation of competence. Eventually, as residency training programs begin training all residents for the new technology, hospitals may be able to rely on the training received in residency training as a measure of competence. Introduction of procedures and/or technologies such as carotid stenting, Da Vinci robotically-assisted procedures, or even laparoscopic procedures in the 1980s, requires establishment of criteria against which applicants for the privileges may be measured to assure their competency and ultimately to assure the safety of patients.

As an academic medical center, Shands at UF has had numerous opportunities to address new technology through the credentialing process, since those cutting edge procedures are often introduced in the academic medical center setting. The credentialing process must be responsive to new procedures and be able to identify appropriate credentialing criteria to apply to these new procedures.

There are several resources that are used to develop credentialing criteria for new procedures and technologies. The Credentialing Resource Center, a national consulting firm on medical staff matters, develops credentialing white papers that are compilations of recommendations from professional societies and other organizations, along with suggested credentialing criteria. These provide an excellent starting point when a hospital receives a request for privileges for new procedures.

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Oftentimes, however, academic medical centers are introducing new procedures for which clinical white papers have not yet been developed. In addition, many of the professional societies publish literature in which training requirements for particular procedures are analyzed and recommendations are outlined for application to the credentialing process. In some cases, professional societies have joined together to develop consensus recommendations. Such consensus documents were used, for example, in developing credentialing criteria for carotid stenting procedures. Finally, benchmarking with other hospitals may result in identifying credentialing criteria that can be adopted or used by the Medical Staff as a starting point for developing appropriate criteria.

In each case in which a new procedure or technology is introduced, which may require development of credentialing criteria, Medical Staff representatives of the specialties involved in the procedure are consulted for input into the development of the credentialing criteria. When literature is available, and/or when clinical white papers have been developed, those documents are provided as a basis for the development of the criteria. The Medical Staff Office coordinates the review of the information and the development of criteria that, ideally, is agreeable to all involved specialties. However, in the absence of agreement of all specialties, the Medical Executive Committee, with input from the Credentials Committee agrees upon a final recommendation for submission to the Shands HealthCare Board of Directors for final action. Once those credentialing criteria are approved, individuals may then apply for those privileges and must meet those criteria to be granted the privilege. In recent years, the development of credentialing criteria also includes criteria for the renewal of those privileges that often includes a requirement for continuing medical education related to the new procedure or technology. Some examples of credentialing criteria that have been developed to address new technologies over the past several years have included robotically-assisted procedures and carotid stenting procedures. Sometimes, credentialing criteria are developed for technologies that cross specialty lines and a number of such criteria have been developed over the past several years, including: cardiac imaging with computed tomography and magnetic resonance (performed by both cardiologists and radiologists); obstetrics (performed by both OB/GYN and Family Medicine physicians); peripheral vascular procedures (performed by vascular surgeons, interventional radiologists, and interventional cardiologists), all of which have led to the development of specific credentialing criteria.

With ever-changing and evolving new technology in health care, today's new technology becomes tomorrow's norm and the need for specially developed criteria is reduced as training eventually becomes routinely accomplished through the residency training programs. Until such procedures become the norm, however, the need for development of credentialing criteria for new technology will continue to require the attention of hospitals and their medical staffs.

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Log on To SIP!

Are you a Shands employee or University of Florida employee or student performing clinical or patient care functions at the Health Science Center? Have you heard the terms Self-Insurance Program, professional liability insurance, or reportable occurrences and wanted to know more? If the answers are yes, take a little time to explore the Self-Insurance Program's website at www.sip.ufl.edu and participate in our on-line learning module dubbed ***SIP 101*** (http://www.sip.ufl.edu/tests/sip101/overview.php). This brief PowerPoint presentation provides an overview of the history of the program, the limited waiver of sovereign immunity, protections provided by the program, and the responsibilities of the participants. If you have any questions or would like more information, please contact our Risk Management/Loss Prevention staff at 352-273-7006.

Send comments or article suggestions to:
rmeduc@shands.ufl.edu

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