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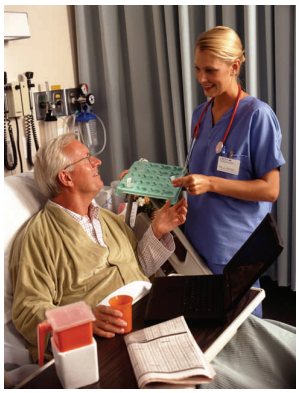

The three "P"'s: A Common Liability Problem

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Failure to follow, lack of, and inadequate Policies, Procedures and Protocols (the three "P"'s) are a common cause for citations and fines in regulatory surveys as well as a frequent liability in hospital and provider negligence claims.

While expert witness statements hold considerable weight in establishing whether or not a standard of care was met, policies, procedures and protocols, are regularly used by plaintiff attorneys as a primary resource in defining the parameters of practice. The reason is that policies and procedures typically reflect industry standards as well as State and Federal law and regulations of accrediting agencies such as the Joint Commission. In effect, policies, procedures and protocols are an institutional barometer of what is considered to be appropriate and safe practice. One example would be the development and implementation of a facility policy requiring a "time out" before a procedure commences in an effort to prevent wrong person, wrong site and wrong procedures. The Joint Commission requires pre-procedure verification and use of a checklist which includes a "time out" immediately prior to starting a procedure in their Universal Protocol. A team pause prior to initiation of a procedure is also a Board of Medicine Standard of Practice (64B8-9.007) in the State of Florida. Another example would be a medication administration policy that requires verification of the 1) right patient, 2) right medication, 3) right dosage, 4) right route and 5) right time prior to giving a medication. These 5 basic rights are a recognized nursing standard of care and failure to administer medications and treatment in a non-negligent manner is also a basis for disciplinary action in the Florida Nurse Practice Act.

Consequently, it is extremely important that a hospital ensure that policies, procedures and protocols reflect the current established practice and that all staff receive adequate training about them upon initial hire and whenever they are updated or revised. Noncompliance should not be an option and any exceptions should be specified.

It is not unusual for a plaintiff attorney to establish that an employee has a duty to follow policies and procedures or that non-compliance should be a consideration in determining negligence or construed as a breach of the standard of care. Depending upon the merits of a claim, losses due to non-compliance can easily extend to include regulatory fines, lack of reimbursement and can affect an organization's accreditation status not to mention one's own professional license.

Cases in Point:

Failure to follow emergency department policies in Barkes v. River Park Hospital Inc. (328 S.W.3d829; 2010 Tenn. LEXIS 1107) in Tennessee went all the way to the state Supreme Court in 2010 which upheld the lower court ruling resulting in a jury award of $7,206,907 for failing to enforce its policies and procedures in patient care. In this case, River Park had a written policy in effect that stated "Any patient arriving at the Emergency Department will be seen by the emergency department nurse, triaged and be seen by the appropriate physician… and "All

patients presenting for treatment in the emergency room are assessed by an emergency physician". The plaintiff, Mr. Barkes, had gone to the River Park Hospital emergency room after his left arm started hurting while working in the garden and clearing brush. Mr. Barkes was triaged by a paramedic but not by one of the ED nurses and his medical screening examination was performed by a nurse practitioner and not a physician, though the NP did discuss Mr. Barke's presentation, symptoms and diagnosis of "left forearm strain due to overuse" with the emergency physician on duty. The emergency physician agreed with the diagnosis and treatment and signed the discharge papers. Two hours after the patient went home, Mr. Barkes collapsed dead in his bathroom from an acute myocardial infarction. Both the nurse practitioner and emergency room physician testified that they were unaware of the hospital's policy that every patient presenting to the ED be seen by a physician.

In May 2010, nine California hospitals received state fines ranging from $50,000 to $75,000 for noncompliance with licensing requirements that either caused or would be likely to cause serious injury or death to patients. All of the citations were due to policy and procedure noncompliance such as: failure to implement established policies and procedures for the safe and effective distribution and administration of medication; not following informed consent and surgical policies and procedures; not following facility policies and procedures for fall prevention and not following surgical policies and procedures for equipment cleaning.

In February, 2011, The Department of Health and Human Services settled with Massachusetts General for $1,000,000 for potential violations of HIPAA. The incident giving rise to the violation was the loss of protected health information of 192 patients (which included patients with HIV and AIDS) that was removed from Mass General's premises by an employee who inadvertently left the information on a subway train which was not able to be recovered. In addition to the monetary settlement, Mass General agreed to develop and implement a comprehensive set of policies and procedure to ensure PHI is protected when removed from premises, educate workforce members on these policies and procedures and designate the Director of Internal Audit Services of Partners HealthCare System Inc. to serve as an internal monitor to conduct assessments of Mass General's compliance and render semi-annual reports to HHS for 3 years.

Compliance with policies, procedures and protocols may not prevent a malpractice lawsuit but it can help prevent mistakes and help eliminate or mitigate employee liability. A few risk management tips for development and implementation of the three "P"'s include:

- Write them in an easily understood manner that leaves little room for misinterpretation yet allows some flexibility to exercise professional judgment in atypical circumstances.
- Effectively communicate them to all staff who are expected to follow them.
- Ensure that they are readily accessible at all times to staff for reference purposes.
- Regularly assess for compliance.
- Incorporate policy and procedure compliance into annual evaluations and/or include in annual competency checklists for those employees who have them.
- Review and update in a timely manner to ensure they reflect current practices.
- Maintain an archive of all previous editions by date. It often takes 3-5 years to litigate a case and it is important to have the policy and

procedure that was in place at the time of an alleged event.

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The power of the partnership: Engage, Enlighten and Empower

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We are constantly reminded of how medicine is changing; new therapies, new communication tools, new roles emerging. It is a complex and intimidating world for many of us to navigate and is incredibly difficult for most patients when they enter into our special enclave. Partnering with patients to help them navigate the shoals of modern medicine is one of our most fundamental obligations as healthcare providers. Our patients and their families should be fully invested in their journey to good health. How can we foster this partnership? I think of the 3 E's: Engage, enlighten, and empower.

Engaging patients to become true partners in their health care requires a small first step, listening to the patient and to *their* concerns. The forces that bring any patient to our environment are a complex brew of concern, urgency, and expectations. Until you have listened to the patient and their concerns it is difficult to discern how they will respond to our expectations for them. Directly asking them to articulate their concerns and then listening to the response is a great way to begin the process of engagement. Addressing their concerns shows your active engagement.

What does an engaged patient look like? Well they keep a list of their current medications, they know who their doctors are, they write down their questions, they ask about medicines being given and therapies being proscribed. We need to let patients know that their engagement is key to their health. We need to enlighten patients about their role as a partner in their healthcare. They should not be a passive vessel that things happen to but an active partner who we do things for. This is a different model for many of our patients. Often times cultural differences or generational expectations influence patients behavior. As healthcare providers we have responsibility to enlighten patients about the importance of their engagement and the power that comes with this. We must enlighten ourselves to the barriers that prevent patients from becoming fully engaged. How do we do this? We can start each conversation by introducing ourselves during each visit, we can provide question prompt sheets, we can explicitly coach them about safety issues they should watch for hand washing, port swabbing, medication verification, we can solicit their input into medical decision making. Letting the patient know that it is appropriate for them to be engaged sets a new level of trust between patient and provider. So enlighten your patients, let them know it is appropriate and helpful to have their partnership.

The power of the partnership. Patients who actively partner with their healthcare providers have fewer medical errors, lower anxiety levels and higher patient satisfaction. We can empower this partnering by actively engaging our patients, enlightening them and ourselves about barriers to engagement and truly empowering them to become our partners.

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Communicating Adverse Events: The Art of Apologizing Without Admitting Liability

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When a serious adverse event occurs, it is distressing to the physician, to the patient and to the patient's family. While physicians know how to handle the clinical aspects of an adverse event, many are less clear about what to say and to whom. Expressing sincere sympathy and concern to the patient and/or family is often the most important response to help diffuse a potentially volatile situation. The patient and/or family are due a prompt explanation. Many lawsuits are filed because patients are angry and confused when physicians do not communicate in a timely and appropriate manner after an adverse event. Repeated requests for an explanation of the event are a common reaction of upset patients and family members. Physicians should remain accessible for questions.

"Apologizing" to Patients

"Apology" does not have to mean an admission of wrongdoing or negligence. Rather, it can be an acknowledgment by the physician of shared regret over the outcome. After an adverse event, organize a family meeting. Empathize with the patient and family without admitting liability. Statements such as "I am sorry that this happened," or "I am sorry that you are in such pain" capture regret in a blame-free manner. Describe the event and medical response in brief, factual terms. If additional follow-up is indicated, discuss those plans with the patient. Show concern for the patient's condition. However, **do not criticize yourself or other caregivers for a poor outcome**. Do not point fingers at other physicians or healthcare providers. Do not engage in "thinking out loud" or speculation about what happened or why. An injured patient who feels that you did your best is not as likely to sue as an injured patient who feels deceived or abandoned by the physician. Such an apology will help you earn esteem with the patient and strengthen the physician-patient relationship.

Informed Consent

Usually an unfavorable outcome is the result of a known risk of the procedure and not the fault of the physician. Key to an apology is the issue of informed consent. A well-received response will arise from a physician-patient relationship where the physician has worked at developing a solid rapport with the patient. In the event that a poor outcome does occur after having previously explained the major risks and complications of the procedure to the patient, there is a pre-established line of communication. This established line of communication allows for a conversation such as "I am sorry to say that your relative has suffered complications from the treatment. These are the problems we are facing and here is our plan." This type of statement expresses regret, places no blame and conveys, "We are in this together."

Preserving Evidence

As soon as possible after the event, factually record the event and medical response in the chart. Document plans for follow-up if indicated. Do not alter any prior documentation or insert backdated information. Record alterations can render otherwise defensible cases almost impossible to defend. An addendum is reasonable, as long as the addendum is designated as such and dated. Accepted rationale for an addendum would be for a correction

of facts (i.e., persons involved, time of event, sequence of events) and for clarifying information. However self-serving, addenda added months after the event may be interpreted as an attempt to alter the medical record and will be used by the plaintiff's attorney to support the plaintiff's claim—so don't do it.

Below are some risk management guidelines to follow after a complication or adverse event.

- Personally let the patient/family know that a problem has occurred
- Offer an immediate explanation with ample time for discussion
- Explain the cause to the patient as accurately as possible. Avoid speculation
- Never use words or expressions such as wrong, error, mishap, accident—all imply negligence
- Never make disparaging comments about persons, products or organizations, or engage in "finger-pointing"
- Avoid characterizing complications or problems as unavoidable, extremely rare or extremely common
- Do not belittle any complication
- Help the patient cope with bad results; discuss the next best treatment options, if applicable
- Keep the lines of communication open

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"The greatest problem in communication is the illusion that it has been accomplished."

George Bernard Shaw

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