

RiskResource

A HEALTHCARE PROFESSIONAL LIABILITY RISK MANAGEMENT NEWSLETTER

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Reduce healthcare risks by promoting safe practices through policies and procedures

By Kathleen Shostek, RN, ARM, FASHRM, CPHRM, CPPS Vice President, Healthcare Risk Management

Policies and procedures are necessary in the operation of all healthcare organizations. They serve important purposes, promoting compliance with regulations, statutes and accreditation requirements, and reducing practice variances that could result in unsafe care and patient injury – and ultimately lead to a liability claim. Policies and procedures can be thought of as guidance for safe practices and risk reduction.

Organizational policies and procedures need to be kept current, and providers and staff must be familiar with them in order to carry them out. The task of ensuring that policies and procedures reflect the most up-to-date standards and requirements and that the people expected to comply with them are doing so is challenging, but necessary.

Furthermore, in the event of a claim, policies and procedures may be used by the plaintiff to try to establish a standard of care, particularly if noncompliance can be shown, or if the policies and procedures are outdated. While they are generally admissible as evidence, current trends suggest that non-compliance with policies and procedures does not alone establish a breach of the standard of care. Rather, evidence provided by an expert is needed to establish that non-compliance with the policy and procedure was the proximate cause of the patient's injury.¹

Policy and procedure management

One of the functions of healthcare risk management is to ensure that the organization has robust processes for policy and procedure development, review and revision, and for training providers and staff to follow them. With that, it is important to clearly define the types and scope of policies and

procedures. Policies can be administrative or clinical, facilitywide or unit-specific, and include other documents such as clinical protocols or guidelines to be applied to specific diagnoses or care procedures. For example, a corporatewide policy on the use of "Time-Outs" to verify the correct patient, procedure, side or site may be implemented to ensure consistency across patient care units. Or, the emergency department may follow a sepsis protocol as part of departmental policies for treatment of that suspected condition.

An approved format for policies and procedures is desirable. The following items often make up the policy format:

- Policy type, title and statement Includes the name of the policy and the "owner" e.g., administration, perioperative services, human resources, etc., and states the purpose of the policy (the why) and what activity or operation the policy addresses. e.g., patient identification
- Scope Defines the breadth of application of the policy in terms of organization, facility, service, care unit, or groups of patients or other individuals
- Procedure Includes a description and step-by-step actions to be taken when carrying out the procedure
- Dates Includes the policy and procedure effective date, and review, revision and approval dates; it documents the current version of the policy and indicates whether there are archived versions
- Other Additional items may include exceptions or exemptions to the policy, a list of related policies, applicable clinical protocols or specific additional references such as clinical practice guidelines published by professional associations

As with other department managers, the risk manager is responsible for the policies and procedures pertaining to the risk management department, including those related to patient safety, risk identification, mitigation, control and litigation. Examples include event and near-miss reporting, communication and disclosure of errors and events that occur, and initiation of any needed care for the patient or other person involved in the event.

A formal process for periodic review and revision of all policies and procedures is necessary to ensure that they reflect current regulations, standards and practices. Most organizations now use software systems to index and track policies and procedures, and to prompt reviews for needed revisions. When revised, some systems may notify applicable individuals that policy changes have occurred. However, accountability for communicating changes to policies and procedures, and for providing training and education in carrying them out, should be assigned. This may be a function of the manager closest to the departments and services impacted by the policy and/or done in collaboration with educators or other designees. Documentation of provider and staff education about revised policies and procedures should be included, as well as competency validations for carrying out the policies and procedures consistently.

Example of non-adherence with policies and current practice

A recent case involving non-adherence to infection prevention policies and procedures and current standards of practice illustrates the importance of having up-to-date policies and procedures, and for ensuring that caregivers, including contracted staff, are following them. In October 2015, a nurse contracted by a healthcare agency exposed employees of a New Jersey pharmaceutical company to bloodborne pathogens when current practices for administering influenza vaccine in the clinic were not followed.² According to the Centers for Disease Control and Prevention (CDC), while the nurse changed needles, she reused syringes to administer the vaccine. Reuse of syringes for multiple patients, with or without reuse of needles, is a serious infection control breach that poses risks for transmission of bloodborne pathogens such as Hepatitis B, Hepatitis C and HIV. Testing and post-exposure prophylaxis was recommended for the involved employees. The nurse surrendered her license to the New Jersey State Board of Nursing.³

It is unknown whether any of the employees contracted an infectious disease or if any negligence claims have been initiated against the healthcare agency, the nurse or the pharmaceutical company. Also, it is not clear whether the agency or the pharmaceutical company had current policies and procedures for the flu clinic. However, this case serves as an example of the liability risks and other risks for the involved organizations and the nurse for lack of a process to ensure that current policies and procedures are followed by staff members, especially when they are contractors and not employees or providers with privileges at the healthcare facility.

Furthermore, it would not be difficult to demonstrate through an expert review that the standard of care in this case was not followed. A lack of current policies and procedures and a process to ensure that the contracted nurse was following current practices would support expert testimony. It also opens the door for corporate negligence, and perhaps negligence per se, supporting a finding of liability. In addition, the pharmaceutical company and the contracted health agency could be cast in a negative light – something a jury would consider if a lawsuit ensued and proceeded to that point.

Risk management recommendations

The following are recommended risk management practices for healthcare policies and procedures:

- Assign responsibility for oversight in the organization; identify appropriate individuals and bodies for review, revision and approval of policies and procedures
- Standardize the format across the organization
- Consider implementing system software or another electronic method to index, track and store policies and procedures; ensure they are accessible 24/7; archived copies of outdated documents should be maintained
- Implement an effective process to communicate changes and revisions; validate that providers and staff are trained on how to execute them; document competency validations

- Include a review of applicable policies and procedures in event investigations; assess the content when non-compliance occurs; revisions may be needed for policies that are too narrow or too difficult to comply with
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10 STRATEGIES FOR SUCCESSFULLY RESOLVING A MEDICAL MALPRACTICE CLAIM BY JAYME T. VACCARO, J.D., VICE PRESIDENT, SPECIALTY CLAIMS OPERATIONS

From never being afraid to try a case, any case, to knowing what ultimately motivates the plaintiffs, thinking outside the box and utilizing creativity can be a mantra for successfully resolving medical malpractice claims. In a series of ten articles, Jayme T. Vaccaro shares time-tested strategies for resolving a medical malpractice claim.

Ten strategies:

- 1. Never be afraid to try a case any case
- 2. Always be aware of the plaintiff's attorney vulnerabilities leverage
- 3. Always know where your codefendants lie and wait friend or foe
- 4. Use your tools from high/lows to bifurcation
- The courtroom is sometimes not the place alternative forums
- 6. Know when to hold and know when to fold
- Know what the plaintiff wants out of the case the sweet spot, and it may not be money
- 8. Back to basics know your case inside and out, legal, medical and the like
- 9. Anyone can help you mediate from the judge to the structured settlement representative
- 10. Understand risk appetites client/insured/defendant

In Strategy 1, we discussed lessons learned in never being afraid to try a case, any case. Read this article at: http://

www.sedgwick.com/news/Risk%20Resources/Sedgwick_ PL_Newsletter_final(2016-2ndEd).pdf. In this issue, we will explore Strategy 2.

Strategy 2: Always know the plaintiff's attorney vulnerabilities

While we may assume the plaintiff's attorney is motivated by money or a mission to fight perceived injustice, sometimes there are vulnerabilities or concerns sitting just below the surface of the lawsuit. Take the plaintiff's attorney who recently lost a high-severity case and is gun shy about returning to trial. Perhaps the plaintiff's attorney also put a lot of money into the case he lost and there is a financial pressure. Does the attorney have a vacation paid for and a trial would create havoc on his schedule?

Understanding the case is vital, but understanding the status of the plaintiff's attorney can be the key to gaining leverage in areas often overlooked.

EXAMPLE: WHOOPS, BLEW THE STATUTE

Although Dr. A and B treated the patient and there was a poor outcome, the plaintiff's attorney only sued Dr. A. After two years in litigation, Dr. B was finally named and Dr. A was dismissed. By the time Dr. B was named, the statute had run out on the patient's wife, but not on his two minor children. The problem was that the wife's claim was worth more money because she was entitled to her deceased husband's loss of earnings for some 35 years. The children were only allowed their father's loss of earnings/support claim until the age of 18. The children's claim amounted to a loss of earnings for 10 years and was worth far less. The plaintiffs may have recovered a far greater sum if the statue on the wife had not run out.

If you are the plaintiff's attorney, further litigation that spells out such an error may not be preferred compared to resolving the case and being able to put it behind you. If you are sensitive to the issue as the defense, you have leverage and need to use it.

As a reminder, plaintiff's attorney are also very aware of taking the temperature of the defense:

• Has the defense attorney recently experienced a mega verdict and may be reluctant to try another case?

- Is the carrier for the defense experiencing a change in management that is making them risk-averse and thereby settling more cases and avoiding trials?
- Is the new attitude providing more opportunity for the plaintiff to achieve greater settlement values on severe cases?

It goes both ways on this strategy. While you need to do your homework on the plaintiff and find the issue that could lead to a more equitable resolution, don't forget the defense's vulnerabilities. The goal either way is to better manage your claim outcomes and not miss the elephant in the room.

Next time, strategy 3: Always know where your codefendants lie and wait; understand whether they are friends or foes.

Originally published in The SCAHRM Source, September 2014 - vol. 2.

Preventing infections from flexible endoscopes

BY CHARLOTTE GUGLIELMI, MA, BSN, RN, CNOR, PERIOPERATIVE NURSE CONSULTANT

"Superbug linked to two deaths at UCLA..."¹ "FDA knew of design flaw..."² "Tainted medical scopes have sickened hundreds..."³ Headlines like these have appeared in the media of late, prompting concerns and a call to arms for healthcare providers and raising awareness by the public regarding the management of flexible endoscopes.

The ECRI Institute has listed inadequate reprocessing of endoscopes as the number one concern in its Top 10 Technology Hazards report for 2016. The report cites occurrences of fatal carbapenem-resistant Enterobacteriaceae (CRE) infections in 2014 and 2015. The cause of the infections was inadequate cleaning of endoscopes particularly in the pre-cleaning during reprocessing. Complicating the cleaning of endoscopes is their complex design. Both manufacturers and clinicians need to address these concerns.⁴ Regulators are paying close attention to the manner in which hospitals, clinics and office-based practices are implementing best practices to eliminate these infections.

In 2016, the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) published updated standards for infection prevention in reprocessing flexible gastrointestinal endoscopes. These standards are a valuable resource for assessing practices and identifying vulnerabilities. In addition to outlining steps to follow when managing flexible endoscopes, the guideline places contributing factors that add to the difficultly in reprocessing the scopes into the following categories:

- The complexity of the endoscope design and the variability in the cleaning procedures between manufacturers in relationship to the difficulty of thoroughly cleaning the scopes and the impact of occult damage harboring microorganisms
- Personnel (staff) factors that influence the quality of reprocessing
- Reprocessing factors that are prone to human error such as a high number of steps in the process, delays in reprocessing, and inadequate pre-cleaning and drying, to name a few
- Malfunction of the equipment used for reprocessing endoscopes, use of incorrect connectors and unrecognized problems with the water supply⁵

With an abundance of literature on the topic of endoscope reprocessing offering guidance, sorting through all of the information is a daunting and confusing task. A valuable resource is the work done by The Association of periOperative Registered Nurses, Inc. (AORN). AORN staff reviewed 3,397 published pieces of literature identifying 418 of them containing the strongest evidence to publish its guideline released in February 2016.⁶ The AORN guideline shares six evidence-based recommendations that clinicians should consider:

• Record the times that the endoscopy procedure is completed and the cleaning is initiated

- Mechanically clean and mechanically process flexible endoscopes by exposure to high-level disinfectant or a liquid chemical sterilant or mechanically clean and sterilize
- Use cleaning verification tests
- Use a drying cabinet for storage
- Use a team to determine maximum storage time
- Ensure that cleaning and processing is conducted by individuals who have received training and completed competency verification activities related to endoscope processing^{6,7}

This guideline includes the rated evidence for each of the recommended practices as well as detailed explanations about each of them along with a collection of implementation tools with policy templates and competency validation tools.⁷

There is consensus in the expert community that staff competency is an essential area that needs to be addressed in any work done to reduce infections caused by the improper handling of flexible endoscopes. Education of staff in the operating rooms and procedure areas as well as the central processing department is critical. Educational content needs to be up to date and leadership must make resources readily available at all times. Staff members need to know the steps to do the work as well as how to access key reprocessing procedure information 24/7. This information is to include not only the current standards and guidelines, but also access to the manufacturer's information for use (IFU) for each endoscope instrument.

Staff members must also be familiar with variances between types of endoscopes. Validation of competency for scope reprocessing should occur during the hiring process, prior to placing new instrumentation into service, and whenever changes in processes are introduced. Continuous reinforcement of initial learning is optimal. In addition to traditional in-services, an example of a useful learning tool is the "teach-back." A teach-back is a single page tool that includes the topic, a statement of the focus of the learning, and the steps to take to complete the task in compliance with facility policy. The Perioperative Education team at Beth Israel Deaconess Medical Center in Boston has created a teachback to assist their staff with the difficult task of preparing flexible endoscopes for transfer (as shown below this article.) It includes the six steps outlined by the manufacturer along with photographs of each step that are included in the facility's guideline.

Meticulous compliance with best practices, continued awareness, engagement of staff at all levels and continued partnerships with endoscope suppliers provide the keys to preventing infections caused by contaminated flexible endoscopes.

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- 6. 6 new evidence-based practices for implementing more effective processing of flexible endoscopes. AORN Periop Insider Weekly Newsletter. January 14, 2016
- 7. 2016 Guidelines for Perioperative Practice. Guideline for processing flexible endoscopes. AORN. 657-757. 2016.

Preparing flexible endoscopes for transfer – In response to the large number of publicly reported infections related to flexible endoscopes, this guideline for their care and handling has been revised. Staff must understand the steps they should take to transfer a scope from the cabinet to the procedural area.



Healthcare Risk Management

Preventing workplace assaults in healthcare JOE DALY, DIRECTOR, TECHNICAL PERFORMANCE

Despite several unfortunate and tragic instances in the news recently, workplace violence rates as a whole have been declining. According to the National Council on Compensation Insurance (NCCI) in its 2012 research brief Violence in the Workplace, the rates of workplace violence for both homicides and assaults have dropped. From 1993 to 2009, workplace homicides fell 59% and workplace assaults declined 37%.

However, while the share of workplace injuries caused by assaults compared to overall workplace injuries is small, it is increasing – with the healthcare profession particularly at risk. NCCI reports, from 1999 to 2009, total lost time work injuries fell by 43%, but workplace assaults declined only 7%.

No industry is at bigger risk for workplace assaults than the healthcare industry – four times greater than other professions, according to the Occupational Safety and Health Administration (OSHA). Consider:

- In November 2014, a 68-year-old patient in Minnesota went on a rampage with a metal bar and injured four nurses, two of which were hospitalized, one with a collapsed lung.
- In September 2015, a hospital patient in South Carolina was arrested after assaulting 14 nurses and staff members including striking victims with closed fists, throwing and swinging objects at staff and grabbing one female victim by the hair and throwing her to the ground.

NCCI data indicates nearly two-thirds of all workplace assaults occur in the health services industry. Healthcare support personnel, including nursing and home health aides, are the occupation most at risk for a workplace assault, followed by healthcare practitioners and technicians. And a vast majority of these assaults are to female employees.

According to NCCI, the highest incident rates within the healthcare industry are in psychiatric and substance abuse hospitals with 75 assaults per 10,000 workers in 2009, followed by other residential care facilities (44.2), intellectual disabilities, mental health and substance abuse residential facilities (38.5) and nursing care and community care facilities for the elderly (15.7 and 13.1 respectively).

These reported incident rates are likely lower than the actual totals occurring, as studies have shown many patient assaults on

healthcare workers go unreported. Reasons given for failure to report incidents of assault include managerial attitudes toward incident reporting, concern the incident would upset or anger loved ones of the patient, a feeling that the aggressive behavior was mitigated by the situation, the impact of the assault was relatively mild or inexperience of the healthcare victim.

The healthcare industry itself is growing substantially in some of the areas which present the most significant risk for workplace assaults. For example, as the baby boomer generation ages, the demand for nursing care and community care facilities for the elderly will continue to increase. According to the Administration for Community Living of the U.S. Department of Health and Human Services, The population 65 and over has increased from 35.5 million in 2002 to 43.1 million in 2012 (a 21% increase) and is projected to more than double to 92 million in 2060. By 2040, there will be about 79.7 million older persons, more than twice their number in 2000. A significantly higher population of older patients needing temporary hospitalization or assisted living or nursing home care may lead to more incidents of assault against a growing pool of healthcare workers.

Several states have passed laws making an assault on a healthcare worker a felony. OSHA publishes guidelines for preventing workplace injuries in the healthcare industry, however, there are no federal requirements and most states do not have provisions for incident reporting or violence prevention training. Healthcare facilities can be proactive. As noted by Ann Gaffey, Healthcare Risk Management Consultant for Sedgwick, "Workplace violence in all healthcare settings continues to be a top concern for risk managers. These events, including more recent activity seen around the country with active shooters, require attention at all levels of an organization. The enterprise approach to mitigating these risks has never been more critical, with a need to involve all levels of staff in response planning, training, regular drills and debriefing activities. A free resource we frequently suggest to our clients is the Centers for Disease Control and Prevention (CDC) online course for Workplace Violence Prevention for Nurses."

Healthcare facilities have significant opportunities to develop and implement a workplace violence prevention program. For hospitals accredited by The Joint Commission (TJC), they are surveyed against the standards expected to be met to achieve compliance. One resource offered by TJC is their Sentinel Event Alert, Issue 45: Preventing violence in the health care setting, published in 2010. Additional initiatives to minimize the risk of patient assaults on healthcare workers include (but are certainly not limited to):

- Avoiding a culture of "violence is just part of the job." Although patient care can involve a variety of risk factors that can contribute to patients becoming violent – drug or alcohol intoxication, mental or emotional instability, dementia – violence should not be the expectation in the industry.
- Creating a culture which values reporting of all incidents of assault.
- Having an active health and safety committee to review incidents of assault and make appropriate recommendations. The committee should include members from management and representation from employees working with patients in various departments.
- Establishing a violence prevention program including training for new employees and periodic refresher training for existing employees.
- Developing a comprehensive hazard prevention program. Such a program would need to be specific to the health services provided and the particular facility. The OSHA guidelines provide excellent information for the customization of such a program.
- Adapting and utilizing a workplace violence program checklist. The OSHA guidelines contain sample documents.

Although the risk of patient assaults on healthcare workers may never be eliminated, implementing the above recommendations and other initiatives should help reduce the incidents of workplace violence in the healthcare industry and reduce the share of work-related injuries represented by assaults.

Resources

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UPCOMING EVENTS

Sedgwick's professional liability team will be attending these upcoming conferences:

- OR Manager Conference
 September 21-23 | Las Vegas, NV
 - visit the Sedgwick booth
- American Society for Healthcare Risk Management (ASHRM) Annual Conference and Exhibition
 September 25-28 | Orlando, FL
 - visit Sedgwick at booth #910
 - Annual Business Meeting & Recognition Event, President's Address: Ann Gaffey (September 25)

- Target Markets Program Administrators Association (TMPAA) Annual Conference
 October 17-19 | Scottsdale, AZ
- Professional Liability Underwriting Society (PLUS) Conference November 9-11 | Chicago, IL
- Insurance Managers Association of Cayman (IMAC) Cayman Captive Forum
 - November 29 December 1 | Grand Cayman
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