Successful Navigation Through an Adverse Risk Environment

By Kevin Klauer, DO, EJD, FACEP

Editor's Note: "Successful Navigation through an Adverse Risk Environment", presented by Dr. Kevin Klauer, is one of our two live Risk Education options for SVMIC policyholders and staff. Using an interactive format, Dr. Klauer engages attendees and explores the multiple high-risk features of common clinical presentations that can quickly deteriorate into urgent medical situations.

Clinical risk management is a top concern among healthcare providers, hospital systems, and other health organizations. The risk environment is continually evolving, requiring an ever-shifting focus and anticipation of new issues. One component of successful navigation tends to remain the same – designing and maintaining effective systems that fit within the practice environment's culture. Everyone who works in a hospital or clinic faces risk and often the trick is to recognize it and be able to respond accordingly to minimize the impact of an unsafe situation or environment. Sounds simple, right? It can be if everyone's goals are aligned. Regardless of the healthcare team's size or resources, with a dedicated team of healthcare professionals trained to survey situations for potential risk and an administration that stands ready to investigate and evaluate appropriate measures, a culture of safety will become the norm.

An example is an EHR that may employ poor clinical decision support or unnecessary alerts. Many clinicians wonder how to address these concerns with administration without being labeled as disruptive. One strategy could be to have a standing agenda item or create a task force to propose reasonable solutions. Both involve members of the healthcare team and administration, while keeping the focus on the issue. The desired result of minimizing existing risk and taking steps to avoid anticipated risks can be realized.

Today's medical practice environment also presents challenges with the increasing number of advanced practice providers. As expected, with the rapid influx of providers, there will be "growing pains" as we define the most effective collaborative workforce models. With the benefit they provide to our healthcare system comes a number of legal and regulatory demands. Many physicians and advanced practice providers are unclear about the roles and responsibilities with respect to supervision or collaboration. Understanding scope of practice, regulatory requirements, and developing a quality improvement plan are crucial to determining best practices when collaborating with or supervising advanced practice providers.

Other risks facing healthcare providers are not generated by or completely within the provider's control. An example is a patient expecting to video or audio record the entire

medical encounter. While there is much debate about such recording of the medical interaction, it is certainly a reality worth addressing. Rather than allowing for unfettered access, or strictly prohibiting recording, practices may consider a policy outlining a mutually agreed upon time to record, such as the discharge discussion.

While clinical risk management is a huge concern, there are strategies and tools for recognizing and handling these situations. I will address these issues and more at Risk Education seminars beginning in June and running through September. Non-clinical risk management principles affecting the practice of medicine and the associated liability exposures involved in each will also be covered. Closed claims analyses, with actual cases; the current evidence supporting best practices; and solid recommendations for risk mitigation will be provided. This seminar takes its cues from the audience, engaging in practical, thought-provoking dialogue on a variety of topics. See a full seminar schedule and register to attend here.

Know Your Medical Devices

By Jamie Wyatt, JD

The United States is the largest medical device market in the world, generating over $180 billion in annual revenue. [1] An area of growing concern for some in the healthcare community, but often unknown to patients, is the role of medical device sales representatives in patient care. Among these concerns are ethical issues surrounding a representative's presence in the operating room, his or her influence in device choice, and a physician's reliance on a medical device sales representative as a resource for treatment decisions during surgery.[2] Proponents of the practice argue that attendance by the sales representatives allows them to provide expertise on the use of a particular product device due to the hands-on training and overall knowledge of the sales representative. They support the development of a loyal relationship between the physician and the representative because they believe it fosters a comfort level among them to freely exchange information while keeping up with technological developments, all said to benefit the practice of medicine. It is important to point out, though, that there needs to be a balance between reliance on a medical device sales representative and independent knowledge when determining the appropriate device and use for your patient. Keep in mind that the ultimate goal of a medical sales representative is to increase awareness of his or her product in order to create sales volume for profit. Relying solely on just your interactions with a representative and knowledge obtained from him or her for a surgical procedure can be a risky proposition for any physician. While there is a joint goal for quality patient care, what happens when reliance on a medical sales representative is misplaced?

This brings us to the case of Dr. Strobl. [3] The patient, a 60-year-old-male, was admitted to the hospital following a motor vehicle accident. An MRI upon arrival revealed moderate stenosis at C3-C4 and severe stenosis at C4-C5 and C6-C7. The patient was advised that he would need decompression surgery at some point. Four months after the accident, the patient consulted with Dr. Strobl for complaints of constant burning pain in both arms and loss of feeling in his hands. Dr. Strobl performed an anterior cervical discectomy C3-C4, C4-C5 and C5-C6 with partial corpectomy at C4, full at C5. The medical device sales representative was in the operating room while Dr. Strobl placed an interbody spacer without plating. After initial assembly of the device, it fell apart and was put back together before being placed during surgery.

On the morning after the surgery, the patient was doing well and walked nearly 100 feet in the ICU. However, there was a dramatic change later that day when the patient was assisted from the bed to a chair by the nurse. When he sat in the chair, he suddenly lost motor function in his left upper extremity. A CT of the cervical spine study revealed that the strut between C4 and C5 had become dislodged causing stenosis on the left side of the spinal canal. Dr. Strobl performed emergency surgery to retrieve and remove the C5 cage interbody spacer and place a C5 titanium cage. He found a retropulsed spacer causing spinal cord impingement and cervical stenosis. He noted separation of the spacer part. Dr. Strobl performed a fusion surgery and later transferred the patient to a rehabilitation facility. At the time of discharge from the rehab facility, the patient could ambulate independently but complained of chronic pain.

Following his recovery, the patient filed suit against Dr. Strobl alleging breach of the standard of care for the use of a prosthetic modular interbody spacer device in the cervical spine without plating. The allegations asserted against the device manufacturer consisted of a claim of negligent design and manufacturing of a device, asserting that defects in the design and construction rendered the product unreasonably dangerous. Damages included, but were not limited to, pain and suffering (both past and future), additional surgery, lost wages, and medical expenses.

The defensibility of the claim was difficult. The medical sales device representative testified in his deposition that his device recommendation was based on the type of surgery Dr. Strobl was to do that day. He gave assurances that off label use was appropriate, but when defending his actions, he and the manufacturer asserted that the product insert for the device clearly stated that it was not intended for the cervical spine and should be used in conjunction with a plate for additional stability. The representative testified in his deposition that Dr. Strobl discussed during the surgery that he would be unable to fit a plate. The representative admitted he acquiesced to Dr. Strobl using the device without plating, testifying that the physician made the decision to go forward after their discussion. Matters got more complicated when conflicting testimony developed wherein Dr. Strobl testified that the manufacturer's representative encouraged him to use the product and assembled the device. However, the representative testified that the product came apart and then Dr. Strobl handed it to the nurses to reassemble. Despite knowing that the literature said that the product was not to be used if this occurred, the

medical device sales representative said nothing. He testified that he believed it was the surgeon's responsibility to know this information, as he was the one putting it in the patient's body. The representative also testified that he didn't think the placement was correct, but did not say anything because he was not the physician. In fact, all of this testimony hurt Dr. Strobl as it was clear that he relied on the representative to put the device together, agreed to move forward without the necessary plating, used the device off label, and had little personal knowledge of the product when it fell apart. In most cases, it is reasonable to look to a representative to provide pertinent information about their device, but it is necessary to have a working knowledge of such a device, risks associated with its use, and contraindications. In this case, Dr. Strobl admitted he did not spend any time familiarizing himself with the device nor reading about it.

The attorney for the manufacturer and representative defended the case with arguments that are typical in these circumstances, such as the device was installed by the physician who should have had a working knowledge of the device, its components, and the possible damages caused by a device since he/she is in the best position to know. In essence, the physician has a duty to know what he or she is installing in the patient's body.

In the end, due to the physician's reliance on the sales representative's assistance regarding the component's use and placement, a settlement was made on behalf of our insured surgeon. The manufacturer also entered into a separate settlement with the patient. The takeaway here should be that a medical device sales representative can be a useful resource in determining the appropriate device for your patient; however, it is necessary to have your own knowledge base when working with a device. While a medical sales manufacturer can certainly face liability on a products claim for a defective product, it will not prevent an action from being filed against you for improper use of such a device, leaving you to defend the adverse outcome.

[1] Zacks Equity Research, *Medical Device Industry Outlook-June 2018*, (June 2018), https://www.nasdaq.com/article/medical-device-industry-outlook-june-2018-cm978557

[2]Relias Media, *Physicians Rely on Device Reps, but have ethical concerns*, (March 1, 2018), https://www.reliasmedia.com/articles/142271-physicians-rely-on-device-reps-but-have-ethical-concerns.

[3] Names and identifying details have been changed for confidentiality

Take a Gemba Walk

By Elizabeth Woodcock, MBA, FACMPE, CPC

Gemba is a Japanese term meaning "the real place." In medical practices across the

country, administrators are taking the walks to the “real places” in their practices – the front office, the exam rooms, the business office, and throughout the halls of their practices. Administrators are performing Gemba walks in order to observe work-in-progress, engage with their team, understand the work process, and identify opportunities for improvement.

A Gemba walk features personal observation of work by dedicating time to observe and interview those who are closest to the work. Instead of reviewing results, deducing opportunities, or promulgating recommendations from the confines of an office, the Gemba walk involves physically walking through the process – and speaking with the team members who are actually doing the work as they are the best candidates to see, understand, and solve problems.

The focus is on the process, many of which were put in place years ago. And, if we do anything well in medical practice operations, it’s doing things like we’ve always done them in the past. This isn’t meant to be a compliment – in fact, it’s time to question ourselves – listen, observe, inquire. Why do we do it this way? How can we do it better?

This procedure can be applied to any work stream: immunizations for well-child checks, scheduling new patient appointments, processing faxed-in referrals, or working an insurance denial. You may discover that immunizations are not always charged; new patients may be abandoning their phone calls because of outdated call routing; fax-in referrals get printed, copied and filed before worked without any acknowledgement; and denials for registration-related errors are written off due to lack of resources. These “aha” moments will not come from reviewing a report, receiving a patient complaint, or reading an email – they come from actually seeing the work being done and improving it on the spot.

One word of caution: Often, the team will not recognize an opportunity because the barrier (or problem) has existed for so long. Be respectful; do not point fingers. Instead, build trust by coaching the person who is showing you the work when you discover a problem, instead of blaming.

Challenge yourself and your team to develop your own solutions with Gemba walks that help you find new ways of working and connecting with patients, while improving the efficiency and effectiveness of your practice operations.

Tips on Getting Started

Establish a standard set of questions for your Gemba walks, focused on each process you’re observing. Ask: Who is involved? What do you do? Why do you do that? Can you show me? What materials are used? How do you know what to do? When does the task take place? What depends on the outcome? How can the task be improved? What road blocks can I remove?

Or, give “trystorming” a chance! We’ve all heard of brainstorming, but what about “trystorming?” Trystorming is a technique that combines brainstorming with action based

on the rapid testing and implementation of an idea. Come up with a potential list of solutions; instead of merely thinking about ideas, take action to test the best solution. If it fails, try the next one. This concept is an exceptional one to review with your team before you start your Gemba walks. It helps to create a culture of action – infused with a spirit of creativity.

Finding - and Resolving - Problems in the Billing Office

By Elizabeth Woodcock, MBA, FACMPE, CPC

As a business, there's a lot of money at stake in a medical practice. When mistakes occur in the billing office, it is easy for you to get frustrated. If you're consistently spending time handling the aftermath of blunders, then it is time to shift your focus from problem resolution to problem prevention. These tips can help your team reduce errors while increasing morale:

Focus first on hiring and training. In the heat of the moment, it is easy to make a hasty hiring decision or to rush new employee training, yet these mistakes can add up to lost time and income as well as employee turnover. Take the time upfront to hire top performers; create a pre-employment test to confirm basic skills, check references and always perform a background check before hiring. Provide high-quality training. Likewise, current employees also need continuous training to enhance their skills; ask them what they need and what questions they have. When you make these early and ongoing investments, it will pay off for years to come in the form of employee loyalty and performance.

Implement a quality improvement culture. Billing and reimbursement guidelines, as well as processes, are always changing; mistakes can and likely will happen. However, employees should not be so terrified of making a blunder that they fail to share concerns and issues with their supervisor. When you implement a quality improvement program, you provide a safeguard for employees, as well as a training tool. Quality checks are also helpful for new employees during the learning process.

Use specific adjustment codes. Whether knowingly or unwittingly, the complexity of billing makes it easy to make mistakes. . Regardless of the intent, these often costly blunders can remain hidden. When you mandate the use of specific *adjustment* codes in your billing system, you can, by effectively monitoring adjustments, uncover mistakes that may have otherwise been concealed. Accounts may be unpaid for a variety of reasons, such as having no authorization, the timely filing deadline passed, the service is not

medically necessary, and so forth. Too often, employees label all adjustments as *contractual*. Yet, distinguishing a legitimate contractual adjustment – the amount you agree to discount your charge to the payer's allowable – from an error that occurred in your practice is vital to revenue optimization. This approach enables you to determine what issues require further time, technology or a change in workflow to fix, particularly those that are costing your practice a significant amount of money.

Conduct ongoing audits. Regular audits are important, as are more unexpected, random checks. On a monthly or quarterly basis, take the time to review 10 accounts that are due, but have been unpaid for several months. Schedule a meeting with your billing office employees to discuss what has been done thus far, what is wrong with each account and how these accounts can be worked more effectively. This shouldn't be an exercise in blame or shame, rather focus on the positive. Make these discussions all about training and moving forward in the right direction. You can integrate these checks into individual employees' performance reviews as well.

Take some time to talk. When was the last time you asked your employees how they were doing? What they were working on? What resources they need to improve the performance of their job? Asking these open-ended questions can lead to process improvements and employee loyalty. Sometimes all your staff needs is a simple tool or answer to improve at their job. Moreover, they will appreciate being asked about their needs, wants and opinions. When you invest time in your employees, the investment typically returns to you tenfold.

Ultimately, investing in good people and practices can prevent unpleasant surprises that can often be costly. Improving your operational processes from the ground floor up will keep wasted money from walking out the door while keeping the best talent inside.
