TSG NEWSLETTER

SAVING LIVES - REDUCING RISK

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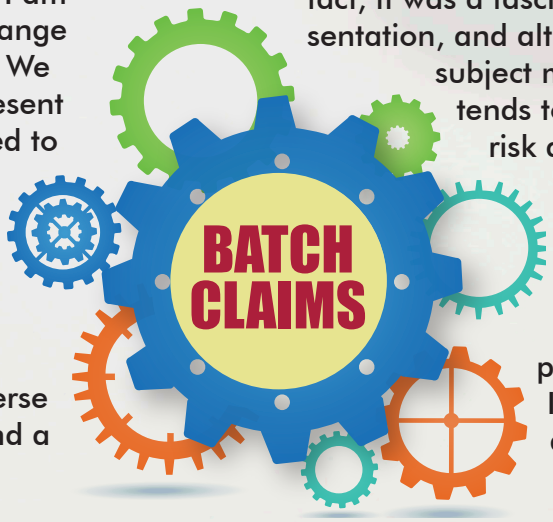
From The Editor

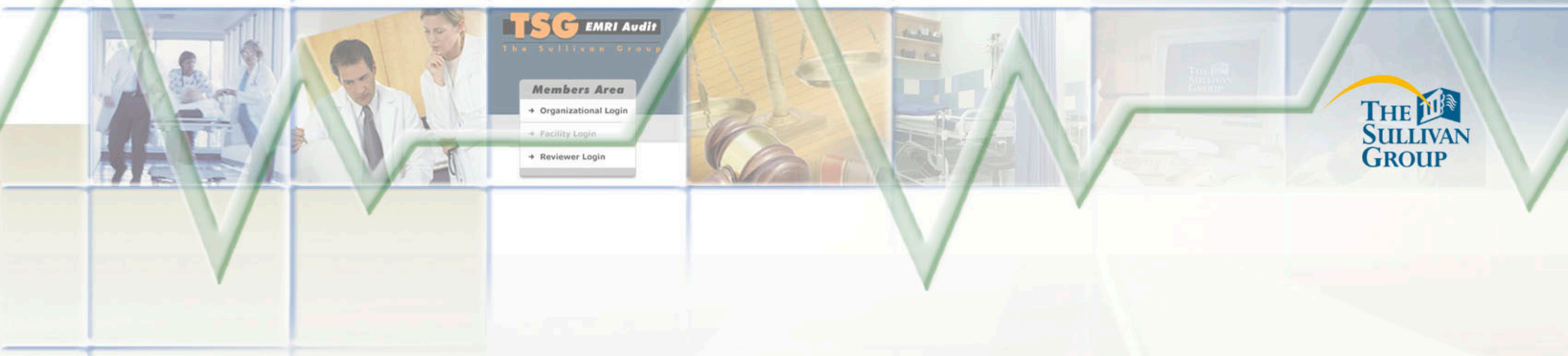
In this issue of the TSG Newsletter, I am going to change gears a bit. We typically present cases related to emergency or acute care medicine with some type of medical error / adverse outcome and a risk and safety discussion. However, I was at a conference recently and attended a session on batch claims or batch events. Prior to that presentation, I had NO idea what a batch claim was, but the course description looked very interesting. In fact, it was a fascinating presentation, and although the subject matter tends to address risk at the hospital or organizational level (i.e., the enterprise), I feel that all practitioners should have a working knowledge of this subject area. As with many TSG offerings, this education has the potential to reduce or avoid potentially catastrophic risk for our patients.



What is a Batch Medical Incident or Claim?

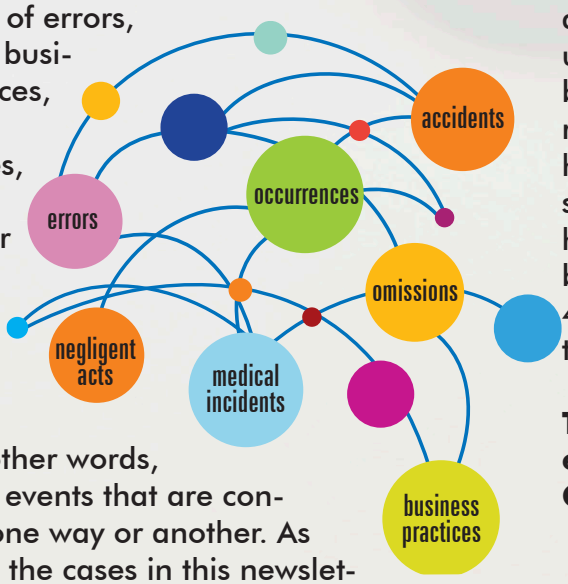
"Batch medical incident" is a term coined by the insurance industry to recognize and manage a certain type of legal claim. But the concept of the batch incident or batch event is incredibly important for practicing physicians and medical system leadership, and it is not often addressed in patient safety and risk reduction education. This is an overwhelmingly important patient safety area.

In This Issue...



Here is one common description: "Batch medical incident" means any related acts, errors or omissions in the rendering or failure to render professional healthcare services that result in bodily injury to more than one patient. The "errors or omissions" language suggests a parallel to the definition of medical malpractice and thus may be a bit narrow. Batch events extend well beyond the medical practitioner-patient relationship.

Thus, others have called batch events "systemic risk." A systemic loss is caused by a series of errors, omissions, business practices, accidents, occurrences, medical incidents or negligent acts arising out of an originating cause; in other words, a group of events that are connected in one way or another. As you review the cases in this newsletter, it will become apparent that this is a very fitting description.



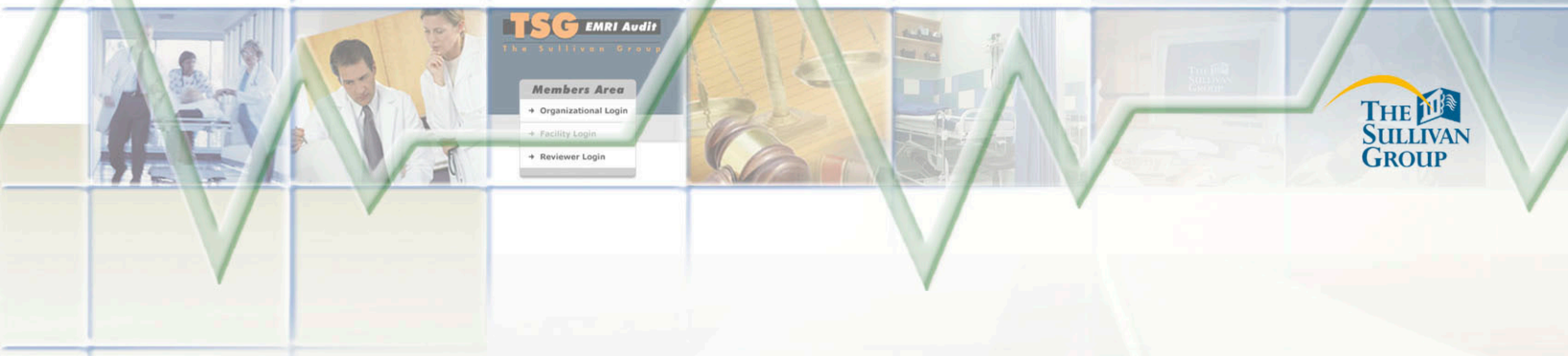
Many of you will recall the **Angel of Death** case. This quote is from a media report:

"No one will ever know how many patients Charles Cullen murdered over the course of his 16-year career as a night nurse."

From 1987 until 2003, the man who may be the most prolific serial killer in American history was the subject of dozens of complaints and disciplinary citations, a handful of police investigations, up to 20 suicide attempts, and several lockdowns in a psychiatric ward. Many of his supervisors and colleagues were aware of his dangerous and unethical practices, but his professional resume remained untainted as hospitals sent him with glowing references to become someone else's problem. He worked at nine hospitals in total, murdering an unknown but large number of people—as many as 400 patients—with toxic intravenous injections.

That is a batch event; it is a group of events that are connected by Charles Cullen's homicidal intentions.

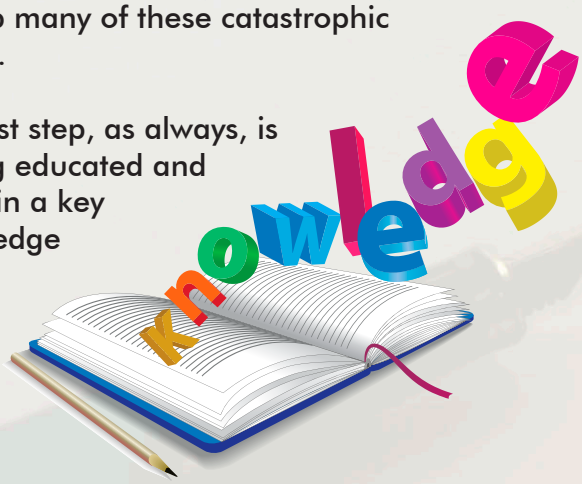
Key Point: *Somewhere along that chain of events, a careful credentialing process, intervention or a well-managed reporting process may have stopped Cullen and saved many lives.*



- Although this is a striking example of a batch event, it serves to underscore a series of key elements that are typical of this phenomenon.
- They usually involve patient injury, often death.
- Before the conduct or problem is recognized, many patient lives may be affected.
- In retrospect, there are usually recognizable patterns of events.
- Often colleagues, supervisors or hospital leadership have some level of awareness of the problem.
- With appropriate systems, surveillance, credentialing, communication and open lines of reporting, these events can often be prevented or minimized.

There are batch events that are so unique and unusual as to be unpredictable. It is impossible to eradicate batch or systemic events completely. However, there is much that can be done to significantly limit or stop many of these catastrophic events.

The first step, as always, is getting educated and filling in a key knowledge gap!



In this issue, we will briefly provide some examples of batch claims and suggest methods by which the disastrous consequences can be mitigated or avoided altogether.

Much of the information related to these claims is not made public, as hospitals and organization act quickly to settle and avoid highly damaging publicity. Thus, most of the information comes through the printed media and not actual court documents.

Also, there is a full treatment of the subject of batch claims in the TSG RSQ® Education online library. If you find yourself interested in the subject, take a look at the course. The fact patterns are simply incredible! Also note that this is our first analysis into this important subject area and does not represent a complete treatment of batch claims or events. The following sections provide a profile or overview of various types of batch events.

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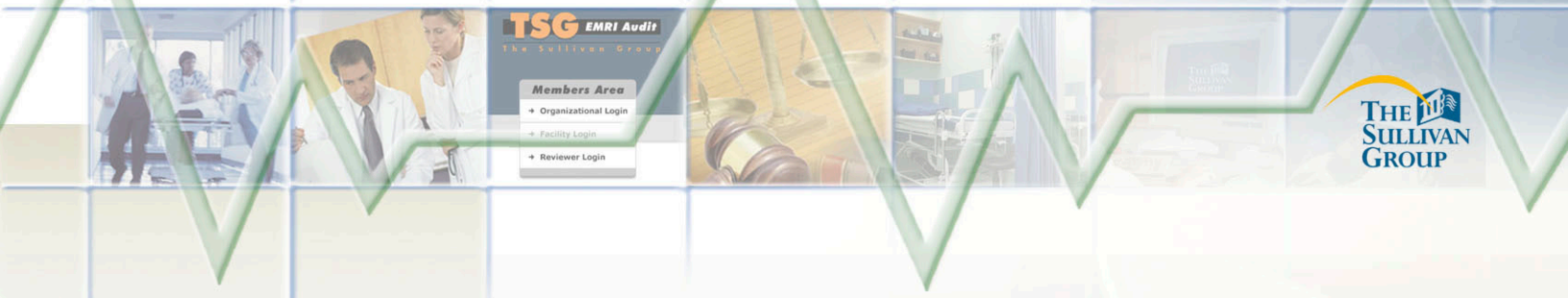

In our quest to be the leader in clinical risk management and patient safety, TSG continues to broaden its offering into other high-risk areas of healthcare. Historical malpractice claims data and a current review of the literature continues to direct our focus to adverse events related to **Surgery** and **Electronic Fetal Heart Rate Monitoring** in Obstetrics. TSG is pleased to offer robust e-Learning solutions for both of these high-risk areas to our clients.

Please contact Brant Roth:
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to learn more.

Surgery e-Learning Curriculum

- Standard of Care Risk Management Issues
- Surgery: Risk & Safety Overview
- Surgery: Risks in Decision-Making
- Surgery: Risks with Informed Consent
- Surgery: Risks in the Preoperative Phase
- Surgery: Risks in the Intraoperative Phase
- Surgery: Risks in the Postoperative Phase

Click on the course name to see the course description.

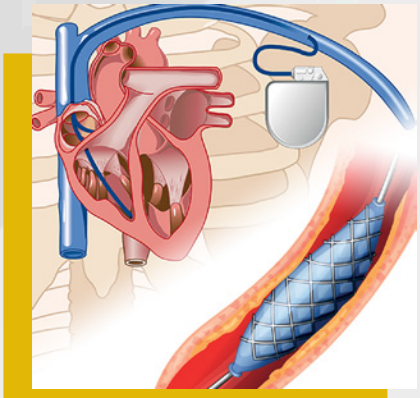
Electronic Fetal Heart Rate Monitoring e-Learning Curriculum

- Electronic Fetal Heart Rate Monitoring: Definitions, Interpretation and Management
- Electronic Fetal Heart Rate Monitoring: Definitions, Interpretation and Management - Part 2
- FHM Vignette #01: A 32-Year-Old G2P1 at 40½ Weeks
- FHM Vignette #02: An 18-Year-Old Primigravida in Labor at 37 Weeks
- FHM Vignette #03: A 39-Year-Old Obese Diabetic
- FHM Vignette #04: A 42-Year-Old G1P0 with IVF Pregnancy
- FHM Vignette #05: A 29-Year-Old with Mild Gestational Hypertension
- FHM Vignette #06: 36-Week Twins/ Anaphylaxis of Pregnancy
- FHM Vignette #07: A 27-Year-Old G1P0 at 39 Weeks
- FHM Vignette #08: Healthy 24-Year-Old Primigravida
- FHM Vignette #09: A Term Pregnancy with Vaginal Bleeding and Abdominal Pain
- FHM Vignette #10: A 37-Year-Old, G3 P2002, Late-Term Induction
- FHM Vignette #11: A 23-Year Old with IUGR at 37 Weeks
- FHM Vignette #12: Clinical Management Problem
- FHM Vignette #14: Clinical Management Problem II

Click on the course name to see the course description.

Inappropriate and Needless Procedures

Inappropriate and unnecessary procedures lead the list. The most common claims overwhelmingly involve cardiac procedures. Looking through lists of batch type events, the inappropriate placement of cardiac stents and pacemakers is the most frequently identified claim. In most cases there is an allegation that a cardiologist or a group of cardiologists have inappropriately placed coronary artery stents without an appropriate medical indication. These claims sometimes include hundreds of patients at the hands of a single physician or physician group.



Other "inappropriate" surgeries with claims include open heart surgery, spine and breast surgery, and the misuse of embryos and eggs in the fertilization clinic setting.

Inadequate Credentialing

Inadequate credentialing will overlap with a few other categories. These claims generally involve inadequate credentialing of a licensed practitioner, who then goes on to commit some wrong. These cases range from inadequate credentialing of the Angel of Death mentioned previously to allowing an individual with no training in orthopedics to perform spine surgery.

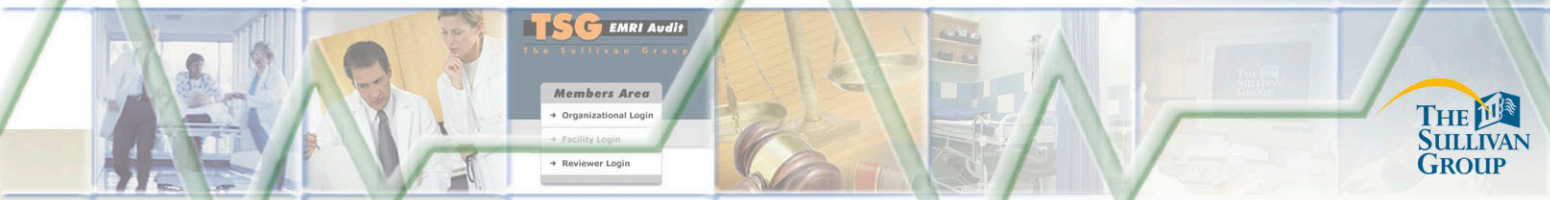
In retrospect, the credentialing problem is often apparent, and the impact on patients' lives, communities, hospitals and staff can be absolutely devastating. In general, these cases don't go well for the credentialing organization. It is often impossible to litigate, as the public storm of controversy is simply too overwhelming. It is not unusual for settlements related to negligent hiring, supervision or retention to be in the tens to the hundreds of millions of dollars.

Problems Related to Sterilizing Equipment

There are all manner of claims and fact patterns involving the inappropriate sterilization of equipment. They range from the use of equipment that simply has not been sterilized to the use of hydraulic fluid instead of typical sterilizing solutions.

Sexual / Physical Abuse

These cases typically involve a practitioner or member of the support staff sexually or physically abusing the elderly, pediatric patients, or adults who are too ill to defend



themselves. Sometimes the root cause of sexual or physical abuse batch events is inadequate credentialing; other times credentialing is completely appropriate, and the key point is creating an early and aggressive reporting system and a climate where staff has a high comfort level reporting up the chain of command. In retrospect, these cases unfortunately often demonstrate decades of aberrant behavior that has been overlooked or ignored.

Infectious Exposure

These cases are particularly tragic; a drug-seeking practitioner will gain access to parenteral narcotics as a result of inadequate credentialing. Parenteral drug seekers often have pre-existing infection such as HIV or Hepatitis C. The practitioner gains access to the drug, self-injects it, and then replaces the narcotic with saline or sterile water in the contaminated syringe. These batch events can involve dissemination of infectious disease to large numbers of patients before the circumstances point to the offending practitioner.

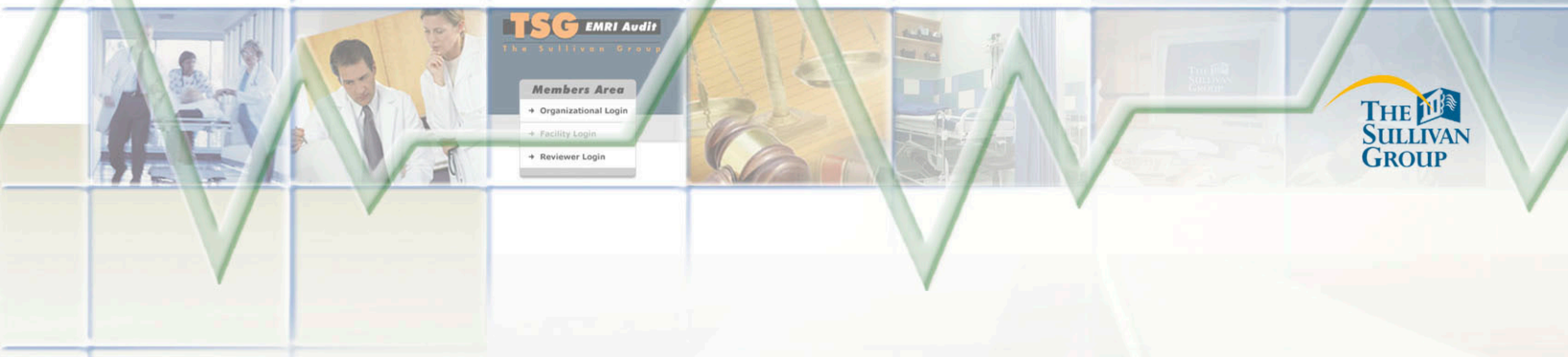
Medical Product and Equipment-Related Events

In these events, medical products don't always work the way they are intended, or they may be mismarked or mislabeled by the manufacturer. The label may simply have a misplaced decimal point for the strength of a narcotic medication resulting in dosing that is ten times what is intended. Resolution depends on early recognition, reporting and early response.

This is one area of batch events where it may be difficult to exercise an ounce of prevention. It may simply be impossible to detect or be aware of a malfunction or inappropriate label before a number of patients are injured. But an aggressive and proactive reporting system may minimize the impact of the problem.

Damaged medical products provide a greater opportunity for discovery because systems such as checklists can be set up to review, for example, the high-risk elements of a cardiac catheterization suite.

Now take a look at a couple of interesting batch event fact patterns. The full profile of batch type events, fact patterns and recommendations for avoiding or mitigating these events is presented in the TSG RSQ® Education online course.



You can find the course at > https://www.thesullivangroup.com/unifiedgateway/un_product_description.asp?gateway=61&hospId=1779&courseid=558&versionid=1&from=add

Hydraulic Fluid Used as Sterilizing Agent

Employees of the Automatic Elevator Company drained hydraulic fluid from two elevators they were servicing at Duke Health Raleigh Medical Center and stored it in plastic buckets provided by Duke. The empty buckets had come to Duke from a sterilization products vendor and were marked as containing sterilization products.

Workers at Duke Health Raleigh spotted the buckets in a storage area; thinking they'd been delivered to the hospital by the sterilization product vendor by mistake, called the vendor to have them picked up. The sterilization company picked them up but eventually sold the buckets, still marked as containing sterilization products, and their hydraulic fluid contents back to Duke.

According to the media, about 3,800 surgical patients at Durham Regional Hospital and Duke Health Raleigh Hospital were exposed to instruments that had been washed with the used hydraulic fluid in late 2004. Dozens of patients said they suffered health problems ranging from infections to immune system reactions after the exposure. Duke Health officials maintained the instruments were safe because they were sterilized after being washed in the hydraulic fluid, but they settled in May 2008 with 127 patients for $26 million.

A federal investigation ensued. While hospital staff rewashed some instruments that were reportedly "slick," the federal investigation includes comments from surgical room staff performing medical procedures with instruments that were slippery and difficult to hold on to.

Discussion

The allegations against Duke provide some focus on avoiding or mitigating the patient safety issues, the damage to reputation, the financial losses, and the laundry list of negative outcomes associated with such an event.

The allegations:

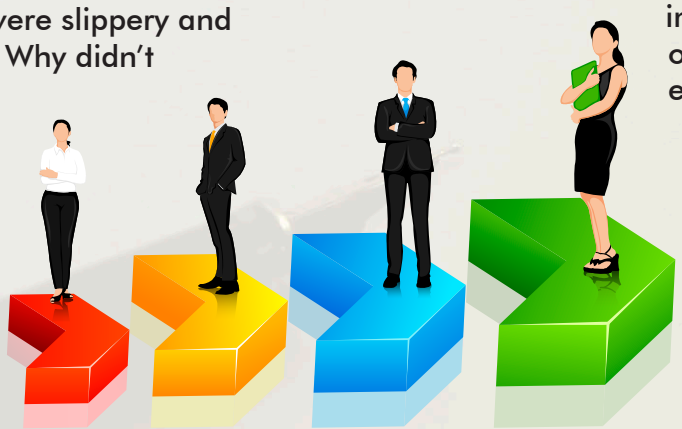
1. Duke was negligent in allowing empty sterilization detergent barrels to be used as waste containers.

2. Duke was negligent in accepting unsealed barrels as detergent.

3. Duke was negligent in failing to identify the problem quickly when hospital employees complained of unusually slick and greasy instruments.

Allegations 2 and 3 have some merit. If the containers were not sealed, as alleged, they should not have been used. Staff should be aware that materials of this type could only be opened by breaking some kind of seal. Opening unsealed containers of sterilization material would be inappropriate, probably negligent. Education of relevant staff around this issue would be key to preventing future occurrences.

Medical instruments were slippery and difficult to hold on to! Why didn't that get reported and go up a chain of command? It would seem that reaching out and holding on to a slippery surgical instrument, supposedly sterilized, would be a highly unusual event. Certainly this would be a reportable event.



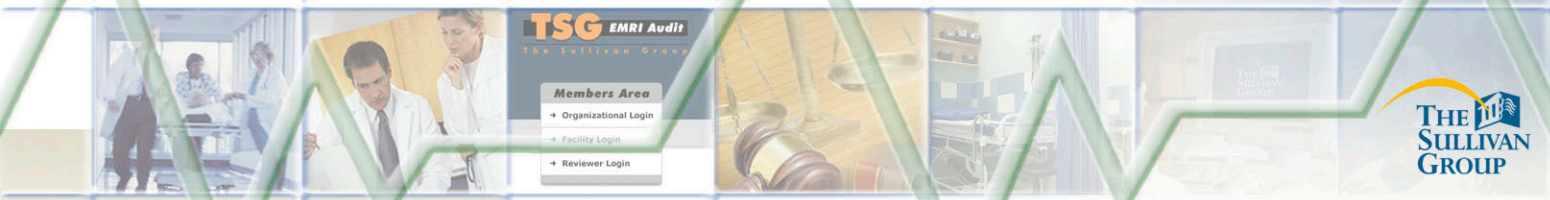
What were the steps to reporting in the Duke environment? If there is any complexity to reporting, most things don't get reported. If the organization had created an environment with rapid, easy access reporting, this process may have been stopped very early on.

Operating Surgeon Not Actually a Surgeon – False Credentials

This batch event included both inappropriate credentialing and inappropriate procedure issues, but the credentialing issues seem to be at the heart of the matter.

Dr. Christian Schlicht, an anesthesiologist and pain management specialist, is accused of using fraudulent credentials to operate on patients at Gerald Champion Regional Medical Center in Alamogordo, New Mexico, even though he wasn't a surgeon. He injected Plexiglas-like cement into patients' spines in a procedure that turned out to be neither safe nor effective.

When an operating room nurse at the hospital reported to a supervisor that Schlicht's back surgeries had gone too far,



another doctor said that the nurse told him that she was told "to leave things the way they are." And after a health insurance company balked at paying for his procedures and questioned his qualifications, records show officials at the hospital took Schlicht's side and threatened to sue the insurer.

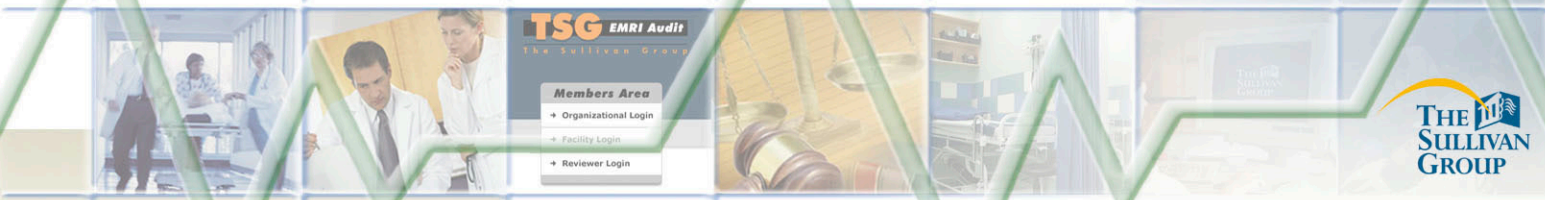
Two years later, former patients began to file lawsuits, contending the spinal procedures left them with debilitating injury and pain. Court records allege that some have partial paralysis and others have lost bladder and bowel functions.

Former patients alleged in lawsuits that they were injured when Plexiglas-like cement that was used in spinal procedures and supposed to act as a cushion in the disk space and relieve spinal pain had seeped into other areas of the spine before it hardened, or it hardened and later cracked into pieces. The patient claims, which grew to about 80 over the year, forced the hospital to seek bankruptcy court protection. A partial settlement in the litigation totaling more than $33 million has been reached.

Discussion

There is the obvious problem with credentialing here which, if done properly, may have avoided the entire catastrophe. Dr. Schlicht was an anesthesiologist, but apparently presented some neurosurgical credentials and was allowed to operate. The exact mechanism by which Dr. Schlicht falsified his credentials is not apparent based on available reports. Obviously a high level of scrutiny is critical, particularly when credentialing high-risk specialties.

There is also the key "code of silence" issue. A nurse actually reported up the chain of authority and was told not to rock the boat. It is alleged that the hospital leadership was aware of the issues but allowed the procedures to continue because they created a significant revenue flow for the hospital.



Once again, a reporting system with someone listening and a hospital commitment to respond would have gone a long way to mitigate patient injury and other damages.

Conclusion

The online RSQ® Education course provides recommendations regarding how to manage batch type events and how organizations can get proactive and try to avoid them altogether. A more general awareness of batch type events may help mitigate or avoid the catastrophic consequences associated with such events at your hospital or organization. In many of these cases, there was an "awareness" or a "feeling" that something was amiss, but intervention did not occur. All practitioners should feel free to report and to act in these circumstances in the healthcare environment.

There seems to be a gap in medical education related to

batch event fact patterns. We invite you to learn more about it with our online RSQ® Education Program and would greatly appreciate any communication regarding batch type situations for us to grow that important part of our library.

As always, all thoughtful comments and questions are more than welcome!

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