Defending a "Never Event"

By John R. Shepperd

There are medical mishaps that have been deemed "Never Events" by the Centers for Medicare & Medicaid Services (CMS). This term refers generally to preventable occurrences so egregious that they should never occur. But they do occur. And when they do, litigation often follows. This article focuses on one such Never Event—the operating room fire—with strategies on how to defend it. Information provided in this article was derived from a review of the relevant literature and from the author's personal experience defending lawsuits arising from Never Events, including a jury trial involving a surgeon who was sued for a patient's injuries after a fire erupted in the operating room.

INTRODUCTION: DEALING WITH THE MEDICAL CALAMITY THAT SHOULD NEVER HAPPEN

A hospital can be an intimidating place for patients; it is where a person's vulnerability is heightened. In many instances, the patient enters the hospital in a compromised state seeking treatment and is poked and probed by strangers who give little explanation for their actions or the test results and other findings that their actions generate. Moreover, some treatment occurs while the patient is unconscious and in a nude or seminude state.

Patients submit because they know the treatment is intended to make them better and that the medical system is designed to heal them—even though they are made aware through the consent process that certain untoward events, such as infection, bleeding, or even death, may occur. People accept these risks while recognizing that some complications can occur even when everything is done appropriately.

Still, some complications are deemed unacceptable—complications so beyond the pale that they should never happen. These include operating on the wrong patient, leaving a sponge or some other foreign object inside a patient, and sending a newborn home with the wrong person. These are "Never Events."[1] These are events that can occur only when health care providers fail to take appropriate measures to ensure patient safety. These are calamities that CMS identifies as events that are 100% preventable and, therefore, should never occur.[2]

Published online in Wiley Online Library (wileyonlinelibrary.com) • DOI: 10.1002/jhrm.21277

Yet they do occur. Invariably, they are followed by a health care liability claim that, if not settled, can result in a lawsuit. This article focuses on one such Never Event—the operating room fire—and provides insight on how this Never Event can be defended at trial. Information provided in this article was derived from a review of the relevant literature and from the author's personal experience defending lawsuits arising from Never Events, including a jury trial involving a surgeon who was sued for a patient's injuries when a fire erupted during surgery.

HOW AND WHY OPERATING ROOM FIRES OCCUR

In 2007, a task force assembled by the American Society of Anesthesiologists put together a *Practice Advisory for Prevention and Management of Operating Room Fires*, which was updated in 2013.[3] Both editions noted the three components of any fire: (1) an oxidizer, (2) an ignition source, and (3) fuel.

In the operating room setting, the oxidizer typically is oxygen or nitrous oxide provided to the patient during surgery. The ignition source frequently is the electrocautery device used by the surgeon for cutting and cauterization, but may involve other electrical equipment such as lasers, drills, fiber-optic light cables, and defibrillator paddles. The fuel generally is the surgical drape that covers the patient during surgery, but may involve sponges, flammable skin prepping solutions, gauze, and even the patient's hair.

Depending on the surgery, the oxidizer will be administered in a closed or a semiclosed breathing system. A closed breathing system involves intubation and administration of the oxidizer through the endotracheal tube directly into the patient's airway. An inflatable cuff is used to seal the airway and prevent oxygen leakage. Even if the surgery involves the airway, the risk of fire is extremely low because the cuff prevents oxygen from seeping into the operative site.

In a semiclosed breathing system, the oxygen is administered by mask or by nasal cannula. The risk of an operating room fire is increased with the semiclosed system because of the possibility that the oxidizer will escape. The natural dissipation of the oxidizer as it escapes into the operating room reduces the risk of a fire, but the risk still exists.

The real danger of an operating room fire arises when the patient receives an oxidizer by mask or by nasal cannula while an impermeable drape is covering the patient's face. Any oxidizer that seeps from the mask or cannula will pool under the drape. If the drape enveloping the oxidizer is shifted during the surgery, then a cloud of flammable gas may escape. Should that occur while the ignition source is being used, a spark from the ignition source in the presence of the oxidizer cloud can create a sudden burst of flame that may cause the fuel (eg, the drape) to ignite.

Much has been written on operating room fires and how to prevent them.[3,4] This article does not rehash those publications, but rather focuses on what to do after an operating room fire lawsuit has been filed. Nevertheless, it is important to understand what these "prevention" articles say because they provide a map of how the operating room fire case will be prosecuted.

The American Society of Anesthesiologists' Task Force[3] established 4 basic principles that should be applied to eliminate the risk of an operating room fire:

- All members of the surgical team should collaborate throughout the procedure to minimize the presence of an oxidizer-enriched atmosphere in proximity to an ignition source.
- The surgical drapes should be configured to minimize the pooling of oxidizers under the drapes and to channel the oxidizers away from the ignition source.
- Flammable skin-prepping solutions should be allowed to dry before draping.
- Gauze and sponges should be moistened when used in proximity to an ignition source.

Of these 4 principles, collaboration and communication by the surgical team are perhaps the most important. This includes a team assessment of the fire risk and how to minimize it *before* surgery commences. During the procedure, ongoing communication between the surgeon and the anesthesiologist regarding when the ignition source will be used, and cutting off the oxidizer for that period of time further minimizes the risk that the ignition source and the oxidizer will be present simultaneously.

If these basic principles are followed, operating room fires might be eradicated. But because they continue to occur, several government agencies have addressed this Never Event and created protocols in an effort to eliminate it.

THE POSITIONS OF THE NQF, CMS, AND FDA ON OPERATING ROOM FIRES

The concept of Never Events originated in 2002 with the National Quality Forum (NQF), which referred to these occurrences as "Serious Reportable Events."[5] The NQF's ongoing goal is to facilitate systemic improvement in patient safety nationwide, based on what is learned from the events and how to prevent their recurrence.[5] To qualify for the list of Serious Reportable Events, an event must be, among other things, unambiguous, largely preventable, serious, and indicative of a problem in a health care setting's safety system.[5] The NQF created a list of 28 events that it considered (1) universally preventable and should never occur or (2) largely preventable and may be reduced to zero as knowledge and improved prevention strategies evolve.[5]

DOI: 10.1002/jhrm

In 2006, CMS announced it was investigating ways that Medicare can help to reduce or eliminate the occurrence of these 28 Serious Reportable Events. CMS described them collectively as "serious and costly errors in the provision of health care services that should never happen."[2] It also replaced the phrase "Serious Reportable Events" with the term *Never Events.*

Whatever it is called, the list has always included the following occurrence:

> *Patient death or serious disability associated with a burn incurred from any source while being cared for in a health-care facility.*[2]

This includes an operating room fire. By any standard, an operating room fire is a serious, unambiguous event that reflects a flaw in the health care safety system. But it goes beyond that. An operating room fire challenges the health care facility's public credibility and public accountability. Simply stated, patients who go in for surgery are not supposed to catch fire during the procedure.

The US Food & Drug Administration (FDA) recognized that operating room fires were happening despite the universal belief that they should never occur.[6] Consequently, in 2011, the FDA launched a patient safety initiative program for the prevention of surgical fires that was directed to all health care professionals (surgeons, surgical technicians, anesthesiologists, nurse anesthetists, nurses, etc) involved in surgical procedures.[7] Its purpose was to educate health care professionals on the prevention of operating room fires. The Safety Communication published by the FDA maintains that operating room fires are preventable. The FDA has revisited the importance of preventing surgical fires on several occasions, including as recently as 2015.[8] The objective of these organizations is clear: through universal awareness, operating room fires can and should be eliminated.

But operating room fires persist.

TRENDS AND NOTABLE VERDICTS INVOLVING OPERATING ROOM FIRES

In 2011, an article published in *Anesthesiology*, the journal of the American Society of Anesthesiologists, examined the historical prevalence of operating room fires.[9] The journal's research examined the database of closed claims maintained by the Society. According to the research, between 1985 and 1994, less than 1% of all surgical anesthesia claims involved operating room fires. From 1995 to 1999, the surgical anesthesia claims involving operating room fires increased to 2%. From 2000 to 2008, that number increased to more than 4%. The median amount paid to settle these claims was just over $120 000.[9]

Close to 84% of the operating room fires cited in that paper occurred during sedation for head and neck surgery where supplemental oxygen was administered by face mask or nasal cannula. The ignition source typically was an electrocautery device, and the fuel source typically was the surgical drapes. The remaining cases (16%) involved surgery performed in or around a patient's throat. The patient was sedated through general anesthesia, and a cuff was used as a barrier to prevent oxygen from escaping. In those cases, the cuff either ruptured or leaked during surgery.[9]

Because the database maintained by the American Society of Anesthesiologists captured settlements *and* jury verdicts, an independent Internet search was conducted to get an overview of what was happening in those cases that did not settle and were resolved through trial. This entailed a review of published articles on operating room fires cited through the Google® search engine, using the following key phrases: "operating room fire verdict" and "surgical fire verdict." In addition, a search of articles published in *Outpatient Surgery Magazine* was conducted using the key word "fire."[10]

The verdicts ran the gamut of outcomes, including a few verdicts where no liability was assessed against the defendants at trial. Invariably, the research in those cases revealed that liability was attributed to parties who were not present at trial, such as settling defendants. With respect to those cases where liability was found against the defendant at trial, the smallest verdict was just under $6000[11] and the largest verdict was $18 million against the nonsettling defendants in addition to the $12 million paid by a settling defendant.[12] The median verdict was $450 000.

DEFENDING THE OPERATING ROOM FIRE LAWSUIT: A CASE STUDY

Summary of facts

In this case study, the fact pattern was consistent with the circumstances most commonly associated with operating room fires. The patient was undergoing surgery to remove a tumor on her scalp. The surgeon used an electrocautery device to cauterize the bleeding. Oxygen was administered by mask at a rate of 8 liters per minute. The surgical drape covering the patient's face prevented anyone in the room from observing whether the mask used to administer oxygen was firmly affixed to the patient's face. The surgical drape was not arranged in a manner to minimize the risk of oxygen pooling underneath.

In planning the surgery, there was no consideration given to using something other than concentrated oxygen. Likewise, no consideration was given to using anything other than an electrocautery device to staunch the bleeding. Also, there was no preoperative discussion of fire risk, how to minimize that risk, and what to do should a fire occur. Perioperatively, there was no communication between the surgeon and the nurse anesthetist about coordinating the administration of oxygen and the use of

the electrocautery device so that the oxygen would be cut off for a period of time before the device was used.

In the trial, all experts agreed that the oxygen mask did not create a good seal, and this allowed oxygen to escape from the mask and pool under the drapes. Toward the end of the surgery, as the surgeon was attempting to cauterize bleeding arteries on the patient's scalp, a cloud of oxygen escaped from under the surgical drape at the same moment the surgeon turned on the electrocautery device, which simultaneously emitted a spark.

The spark in an oxygen-rich environment created a sudden burst of flame and ignited the surgical drape covering the patient. The surgeon quickly ripped the drape off the patient and patted out the fire, but not before the patient suffered burns on her left ear and the left side of her face and neck.

When the patient awoke from surgery, her burns were covered with silver sulfadiazine cream, and medications were given to ease the pain. The surgeon requested that the hospital's risk manager approve the patient's admission to the hospital for no other reason than to indicate that the medical personnel were concerned for the patient's well-being. The risk manager opted to send the patient home because the patient's burns were not severe enough to warrant further hospitalization at that time; so the patient was sent home a few hours after recovering from the anesthesia. As the patient rode home, her daughter observed areas where the silver sulfadiazine cream had rubbed off. She noted that pieces of the drape had melted into the patient's raw tissue.

The patient never returned for follow-up care with the surgeon because she blamed him for the incident. Instead, she saw her primary care physician the following day. He sent her to another hospital in a neighboring county, which in turn sent her to a third hospital that had a burn unit. In the burn unit, the patient underwent surgical debridement of her wounds. She also tested positive for bacteria in her wound site, which was treated with an antibiotic. Surgical grafts were not required.

Initially, the patient sued the surgeon and the hospital that employed the nursing staff and the nurse anesthetist. However, the hospital was dropped from the lawsuit after the defendant surgeon, his expert, and the expert for the plaintiff all testified that they were not critical of the hospital's employees.

Venue for the trial

The surgery took place in a small East Texas county with a population of fewer than 40 000 people. The hospital where the surgery took place was the only hospital in the county, and the next closest hospital was 60 miles away. The surgeon had lived in the county for only 2 years before the incident occurred and subsequently moved his practice to another state a year after the surgery. The plaintiff resided in an adjacent county, but one of her daughters lived in the county where the case was filed. Several individuals among the jury panel knew the plaintiff or her family, but no one knew the surgeon. None of the jurors seated for trial knew the surgeon, the plaintiff, or the plaintiff's family.

Plaintiff's underlying theme at trial: Operating room fires do not occur in the absence of negligence

Prosecuting an operating room fire lawsuit is relatively simple, as the theme is straightforward and easy to explain: fires are not supposed to happen during surgery, and they are 100% preventable. Therefore, when an operating room fire occurs, somebody must be at fault. That somebody was the surgeon as head of the surgical team. According to the plaintiff's theory, the surgeon was the "captain of the ship" and ultimately responsible for everything that happened. He also wielded the ignition source.

Defendant's underlying theme at trial: Doctors are not expected to be perfect

The primary theme used in defending this claim came from the definition of negligence found in the Texas Pattern Jury Charge. *Negligence* is defined as the failure to exercise ordinary care, that is, failure to do that which a surgeon of ordinary prudence would do under the same or similar circumstances, or doing that which a surgeon of ordinary prudence would not do under the same or similar circumstances.[13] The standard is not perfect care; the standard is ordinary care.

In essence, the case was defended by steering the jury away from their desire to see doctors as omniscient in dispensing medical care. By repeatedly citing the statutory definition of negligence throughout the trial, defense counsel told the jury again and again that if the defendant acted as a surgeon of ordinary prudence would have acted, then he acted with ordinary care and could not be found negligent.

Defendant's corollary theme: Operating room fires are rare

A Google search on the phrase "operating room fire" will yield more than 850 000 results. Operating room fires are sensational, so they get the reader's attention. Does that mean they are common? No, the opposite is true. In 2010, the Centers for Disease Control and Prevention (CDC) estimated that the total number of surgical procedures at short-stay hospitals per year was approximately 51 430 000.[14] Around that same time, the average number of operating room fires reported was between 550 and 650 per year.[15] Simple math reflects that an operating room fire occurs roughly once in every 100 000 cases. Expert testimony was used to get this information into evidence.

DOI: 10.1002/jhrm

The rarity of operating room fires was further exemplified by the attention that general surgery residency programs devote to teaching about their risk. At trial, both the defendant and the defendant's expert testified that operating room fires were never mentioned in their respective residency programs. Likewise, they knew of no colleagues who had encountered an operating room fire. Even the plaintiff's expert, a surgeon on faculty in a surgical residency program that heeded the FDA Fire Safety Protocol, conceded that he was never trained about operating room fires, that he had never encountered an operating room fire, and that he knew no one who had encountered one. The rarity of operating room fires, coupled with the absence of any training about operating room fires and how to avoid them, played into the defense that a reasonable surgeon exercising ordinary prudence would not have taken measures to eliminate the risk of a fire occurring.

Defendant's expert testified that measures advocated by CMS and the FDA are impractical and unreasonable

Over objections, the trial court allowed the plaintiff's counsel to introduce evidence about the positions taken by CMS and the FDA that operating room fires are 100% preventable and about the initiatives undertaken by these government organizations to stop this Never Event from occurring. The plaintiff's expert testified that the surgeon had a duty to follow measures advocated by the FDA to eliminate the risk of an operating room fire, and that his own practice followed these tenets. This included discussing fire prevention before surgery began and maintaining a constant dialog between the surgeon and the anesthetist so that the electrocautery device would never be used while oxygen was being administered. The plaintiff's expert added that an operating room fire cannot occur in the absence of negligence; in other words, the plaintiff's expert testified that an operating room fire reflects negligence *per se*.

While the plaintiff's expert testified about the importance of adhering to the protocols set forth in the FDA initiative, the defendant's expert took the opposite position and maintained that CMS and FDA protocols did not establish the standard of care. In addition, the defendant's expert testified that the measures promoted by CMS and FDA are impractical and unreasonable. The defendant's expert testified that one particular FDA measure—advising the anesthesiologist to cut off the oxygen for a minute or two before using the electrocautery device—was not practical because the surgeon may use the electrocautery device more than 100 times during a surgery. The defendant's expert also testified that periodic pauses in surgery to allow oxygen that might be present to dissipate would prolong the surgery. The additional exposure to anesthesia resulting from a longer surgery created a greater risk of harm to the patient than the unlikely possibility of an operating room fire. Both the surgeon and the defense expert testified that they did not and would not change the way they operate based on the extremely unlikely risk that an operating room fire might occur.

The "empty chair" defense

The problem with Never Events such as operating room fires is the natural presumption that somebody is at fault. When there are multiple defendants, they face the difficult dilemma of either making a united defense and saying no one is at fault or taking the opposite approach and blaming one another. Both approaches are zero-sum games. It is highly likely that the jury will find at least one defendant at fault and may even find them all liable.

However, the plaintiff occasionally will not sue a potential defendant or may settle with one or more defendants prior to trial. Either decision by the plaintiff creates an opportunity for the defendants who do go to trial because the absence of a potential defendant means there is an empty chair in the courtroom; a chair that otherwise could have been occupied by a "culpable party."

When a potential defendant is not in the courtroom, then the defendants who are present can attack the absent party with impunity. These remaining defendants can blame the empty chair with no fear of rebuttal from the absent party. More importantly, it allows the jury to blame someone who is not present and, therefore, unable to defend against the allegations.

The typical parties in an operating room fire lawsuit are (1) the surgeon, because the surgeon operates the electrocautery; (2) the anesthesiologist, because the anesthesiologist administers the oxygen; and (3) the hospital, because it establishes the operating room protocols. In this case, only the surgeon was left at trial. Consequently, there were empty chairs where the anesthesiologist and the hospital might have been sitting. However, the defense was restricted from blaming these absent defendants outright because it had maintained a unified defense when they were parties to the lawsuit. Both the surgeon and the retained expert offered no criticisms of the hospital or the nurse anesthetist during the discovery phase of the litigation. This meant the credibility of the surgeon and the retained expert would be challenged if the defense were changed to blame the empty chairs directly.

Recognizing from the outset that one or more defendants might be absent by the time of trial, the surgeon neither supported nor attacked the care provided by the nurse anesthetist or the hospital. Rather, the surgeon took the position that he was not qualified to render an opinion as to the care that was provided by them. At trial, with these co-defendants absent, the defense maintained the same position, but emphasized that it was the nurse anesthetist, and not the surgeon, who was responsible for affixing the oxygen mask to the patient, administering the oxygen, and setting the rate of the oxygen flow. Likewise, the defense

emphasized that it was the hospital, and not the surgeon, that was responsible for creating operating room protocols to address any potential risks.

The verdict

After deliberations, a unanimous verdict was reached that the surgeon was not negligent. Afterwards, the jurors stated that they could not find the surgeon liable for an event that was so rare and the potential for which was never addressed during 5 years of the defendant's general surgery residency. The jurors also commented that they believed the absent defendants, and not the surgeon, were at fault.

CONCLUSION

A Never Event such as an operating room fire presents a challenging fact pattern for the risk manager and for the attorneys tasked with defending the case. The obstacles impairing the defense of these lawsuits include the following:

- The inherent belief of the public that Never Events by their very nature should never occur.
- The defendants are saddled with the FDA and CMS publications that maintain Never Events are 100% preventable, and the consequent reasoning by the plaintiff's counsel that their occurrence is *prima facie* evidence of negligence.
- The presence of multiple defendants forces the parties to work together and risk the possibility that all will be found liable or to point fingers at one another, which may result in a similar outcome. In the event the defendants take the position that no one is to blame, then the ability of the nonsettling defendants to argue that the settling defendants are at fault is compromised.

Nevertheless, with thorough planning and a thoughtful strategy, the facts giving rise to the Never Event can be defended successfully at trial.

REFERENCES

1. Never events. Patient Safety Network website. https://psnet.ahrq.gov/primers/primer/3/never-events. Accessed February 23, 2017.
2. Eliminating serious, preventable, and costly medical errors—never events. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2006-Fact-sheets-items/2006-05-18.html. Published May 18, 2006. Accessed December 28, 2016.
3. American Society of Anesthesiologists. Practice advisory for the prevention and management of operating room fires: an updated report by the American Society of Anesthesiologist Task Force on Operating Room Fires. *Anesthesiology*. 2013;118(2):1–20.
4. Thomas BJ. Risk management tips for prevention and management of intra-operative fires. *Anesthesia & the Law—A Risk Management Newsletter*. 2010:26.
5. National Quality Forum (NQF). *Serious Reportable Events in Healthcare—2011 Update: A Consensus Report*. Washington, DC: NQF; 2011.
6. Hart SR, Yajnik A, Ashord J, Springer R, Harvey S. Operating room fire safety. *The Ochsner Journal*. 2011:11(1):37–42.
7. Preventing surgical fires: FDA safety communication. US Food and Drug Administration website. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm275189.htm. Issued October 13, 2011. Accessed December 28, 2016.
8. Preventing surgical fires. US Food and Drug Administration website. http://www.fda.gov/drugs/drugsafety/safeuseinitiative/preventingsurgicalfires/default.htm. Issued August 31, 2015. Accessed December 28, 2016.
9. Mehta SP, Posner KL, Chandanabhumma P, Bhananker SM, Lee LA, Domino KB. Closed claims analysis of cautery fires in the operating room. *Anesthesiology*. 2011:A1722.
10. Search results for: fire. Outpatient Surgery Magazine website. http://www.outpatientsurgery.net/search/?sQ=fire. Accessed December 30, 2016.
11. Mastandrea A. Operating room fire leads to small verdict. *Missouri Lawyers Weekly*. https://ashleymastandrea.files.wordpress.com/2012/08/operating-room-fire.pdf. Accessed February 23, 2017.
12. Fire during surgery on vocal cords results in $30 million for the injured patient. AHC Media website. https://www.ahcmedia.com/articles/110594-fire-during-surgery-on-vocal-cords-results-in-30-million-for-the-injured-patient. Accessed February 23, 2017.
13. State Bar of Texas. *Texas Pattern Jury Charge—Malpractice, Premises & Products*. Chapter 50.1: Physicians degree of care; proximate cause (2014).
14. Number of all-listed procedures for discharges from short-stay hospitals, by procedure category and age: United States, 2010. CDC/NCHS website. https://www.cdc.gov/nchs/data/nhds/4procedures/2010pro4_numberprocedureage.pdf. Published 2010. Accessed January 4, 2017.
15. ECRI Institute. New clinical guide to surgical fire prevention. *Health Devices*. October 2009;38(10):314–332.

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