



The Patient **Safety** Advocate

Anesthesia & OR Safety

Edition 1: Volume 1

July 2014



Flying Right

Adapting Aviation's 'Sterile Cockpit Rule' to Improve Patient Safety in the OR

Kim Danebrock, RN, JD

The "Sterile Cockpit Rule" is a Federal Aviation Administration (FAA) regulation that was enacted in 1981 after a series of accidents were found to be caused by flight crew distraction from non-essential conversations during the most critical time of the flight takeoff and landing.

Under this regulation, crew members are prohibited from any non-essential duties or activities while the aircraft is below 10,000 feet. The FAA has recently

Continued on Page 2

Patient Safety Q & A

Time-Outs—Worth the Time and the Trouble

Catherine Miller, RN, JD

Q: I'm a circulating nurse and usually lead the Time-Out. Most of the team takes the Time-Out very seriously— we understand that it's really our last opportunity to catch a mistake and prevent a problem like wrong site surgery. Unfortunately, there is one individual in particular who never participates. When I pause to get her attention, she rolls her eyes, sighs, and appears irritated. It bothers everyone. I finally gathered the courage to ask her why she doesn't participate and was shocked by her

Continued on Page 3



How 'Talking Out Loud' and 'Stating the Obvious' Can Prevent Surgical Fires

When a breathing tube caught fire in the mouth of a seven-year-old boy undergoing a tonsillectomy, the surgical team responded with fleet-footed alacrity. The surgeon pulled out the flaming uncuffed 5.5 tracheal tube, burning his own fingers. The anesthesiologist shut off all gases immediately. The boy was transferred to a pediatric intensive care unit and treated for second degree burns to his mouth, lips, and soft palate.

The investigation that followed revealed neither the surgeon nor anesthesiologist communicated to each other in advance (or during the procedure) about the use of cautery or oxygen.

Continued on Page 6



Flying Right *continued from Page 1*

expanded the rule by prohibiting pilots from using their personal tablets, smartphones, and laptops for personal use at any time during the entire flight.

Distractions have caused pilots to forget to set the flaps before takeoff, extend the landing gear in preparation for landing, and to misinterpret the instrument information. Are these omissions any less significant than those found in operating rooms across the country, where distractions result in failing to conduct a proper airway history and assessment, failing to complete the “Time Out” correctly, and failing to correctly count sponges? Distractions threaten performance and jeopardize patient safety.

“Distractions have caused pilots to forget to set the flaps before takeoff, extend the landing gear in preparation for landing and, to misinterpret the instrument information. Are these omissions any less significant than those found in operating rooms across the country?”

According to the American Society of Anesthesiologists Closed Claims Project 2011, the majority (68 percent) of difficult airway claims arise during the induction phase (analogous to takeoff). Retained foreign objects (sponges and instruments) and wrong site surgeries continue to be serious problems in the OR. Patient safety dictates that distractions be limited during specific critical times including the beginning of a case when the patient’s airway is being secured; during the equipment and sponge count; and when the surgical site is being prepped.

Individuals who work in the high risk industries of aviation and medicine have a substantial responsibility for ensuring the safety of the people they serve. Understanding that distractions increase the chance of error, the FAA has taken enormous steps to eliminate activities that could contribute to accidents. Hopefully, medicine will look to other high risk industries with improved safety records and adopt best practices or rigorously enforce its own regulations to eliminate the multiple distractions that plague OR physicians and staff. The safety of our patients demands our full attention. ■



Flying Like the Pros— Proactive Tips for Converting the OR into a Cockpit

Standardize the “Call for Quiet”–

Implement a phrase that all staff will use during the critical times of starting and ending a case. A phrase such as “Safety Silence!” reminds all physicians and staff to cease all non-essential activity and conversation to create an environment that is entirely patient-centered.

De-ice the OR– Create an Atmosphere of Psychological Safety and Teamwork. Highly Reliable Healthcare Organizations (HROs) do not tolerate intimidating behaviors that cause tension and suppress the escalation of safety concerns. HROs value communication, teamwork, and the psychosocial climate that make both possible. Before starting the case, create an atmosphere of teamwork in service of patient safety by asking each team member to introduce themselves and by inviting anyone to escalate a patient safety concern at any time during the case.

Tuning Up the Time Out– Researchers from the Joint Commission cited team inattention during the Time-Out as a predominant risk for wrong site surgery. To improve team attention, consider structuring the Time-Out checklist as a series of questions, so that team members are forced to evaluate information before responding. Additionally, to increase engagement, assign each team member a brief, but specific task. When the entire team is engaged, the chances of catching an error increase greatly. ■



Patient Safety Q & A

continued from Page 1

response. She told me that there has been no significant decrease in the number of wrong site surgeries since the Universal Protocol, so she perceives the Time-Out as a “waste of time.”

I didn’t know how to respond. Is this true? Are we wasting our time? Also, I would appreciate any suggestions on how to deal with this person moving forward.

A: Unfortunately, your colleague is correct about the persistence of wrong site surgery despite extensive efforts to eradicate it. According to Joint Commission estimates, wrong site surgery (WSS) occurs about 40 times per week—that’s nearly 2,000 incidents per year! But the persistence of the problem doesn’t mean that we should abandon the Time-Out—that’s an extreme and an uninformed position. In fact, in light of recent research from the Joint Commission, quite the opposite approach is required. I’ll share some of those research findings and offer a few suggestions for improving teamwork

within your organization.

So, why is WSS resistant to the Universal Protocol? First, there is huge variation across institutions and even within organizations with regard to the quality of the Universal Protocol. For example, performing a Time-Out doesn’t guarantee that it is “robust,” involves full-team engagement, or rises to the level of Joint Commission expectations.

Additionally, **“The take away from this research is that the risks of wrong site surgery can be introduced at every single stage of the entire surgical process—from scheduling to start time.”** the Time-Out is only the end piece to a much larger and very complex process of verification—a process that, according to recent research, begins even earlier than the Joint Commission initially appreciated.

Researchers from the Joint Commission Center for Transforming Healthcare partnered with eight health care facilities to understand why the Universal Protocol hasn’t had a bigger impact on preventing WSS. Their research

involved evaluating the risks for WSS at every step along the entire surgical continuum—from scheduling to start time. The results of this research were truly eye-opening. Researchers determined that in 39 percent of cases, risks for wrong site surgery were introduced at a very early point in the surgical continuum, far outside the reach of the Universal Protocol—in the outpatient

setting during procedure scheduling!

Coleen Smith,
RN High

Reliability Initiatives Director for the Center explains, “We didn’t understand initially that the risks for wrong site surgery start way, way before the patient approaches the operating room. It can start as early as the time the patient is in the surgeon’s office and it’s decided that surgery is necessary. At that point, there could be a simple error where a right or left is written as an R or L and that subsequent letter is misinterpreted

Continued on Page 4

Wrong Site Surgeries: Risks at Every Stage

Findings from research on WSS by The Joint Commission Center for Transforming Healthcare point to risks at every stage in the surgical continuum:

39% of cases risks were introduced during scheduling

52% of cases risks were introduced in pre-op

59% of cases risks were introduced in the OR

Patient Safety Q&A continued from Page 3

as the opposite, so what is supposed to be a right knee surgery could end up on the OR schedule as a left knee surgery—once the error enters the system it could repeat itself and it is very hard to eliminate it⁽¹⁾.” To reduce risk associated with scheduling, Smith recommends improving the legibility of scheduling documentation and eliminating the use of unapproved abbreviations (e.g. “R” and “L” to indicate laterality). Additionally, booking surgical cases telephonically, without written documentation, increases the risk of misinterpretation and is discouraged.

Moving into pre-op, researchers found that in 52 percent of cases, additional risks were introduced. In pre-op, patient information should be verified by meticulously comparing primary documentation (H&P, surgical consent) with the patient’s understanding of the procedure—any discrepancy here signals a potential problem. According to researchers, the most notable deficiencies in this setting involved the absence of primary paperwork, incomplete or ambiguous documentation, and finally, changes to the consent form without appropriate notification of staff. Production pressures in pre-op compound these risks by preventing staff from fully investigating and resolving discrepancies that arise. Finally, Smith states that the risks of WSS increase whenever anesthesia providers decide to “go it alone,” and fail to conduct a proper Time-Out for a regional anesthesia block.

In 59 percent of cases, additional risks were introduced in the OR—the predominant defect being team inattention during the Time Out. According to Mark Chassin, MD, President of The Joint Commission, “there are about 300 ways that time-outs can fail, from not having everyone stop what they’re doing and pay attention...to having a bad safety culture where somebody knows something’s wrong but is too scared to speak up⁽²⁾.” Other common risks in this setting include site markings that were neither visible nor verified by the team—resulting from the use of unauthorized pens whose ink fades after prepping. Additionally, in several cases, x-ray films and other imaging studies used to confirm the correct procedure and surgical site were inaccessible to the team.

Given abundant risk at all points along the surgical continuum, Center authorities urge facilities to evaluate every step in their own process, and where deficiencies are noted, introduce targeted interventions. The Joint Commission Center for Transforming Healthcare has developed “robust,” Targeted Solutions Tools to guide improvement efforts. These tools are available at no cost to accredited organizations.

The take away from this research is that the risks of wrong site surgery can be introduced at every single stage of the entire surgical process—from scheduling to start time. Unless we identify our process vulnerabilities, standardize our processes,



and remain ever-vigilant by continually questioning and reconciling the information in front of us, a simple scheduling error can perpetuate along this continuum and result in a never event. Now, the Time-Out may be only one piece of a much larger process, but a properly conducted

Given abundant risk at all points along the surgical continuum, Center authorities urge facilities to evaluate every step in their own process, and where deficiencies are noted, introduce targeted interventions.

Time-Out with the full attention and active participation of the whole team can prevent the majority of wrong site surgeries. If our duty is to protect and “first, do no harm,” wouldn’t it be egregious to forgo any opportunity, especially the last opportunity we have, to prevent a wrong site surgery, by not

doing a proper Time-Out?

Now, about your colleague. I commend you for speaking up and advocating for patient safety. Those behaviors (eye rolling, sighing) may seem relatively harmless when compared to more

aggressive displays, but they can certainly demoralize the team and

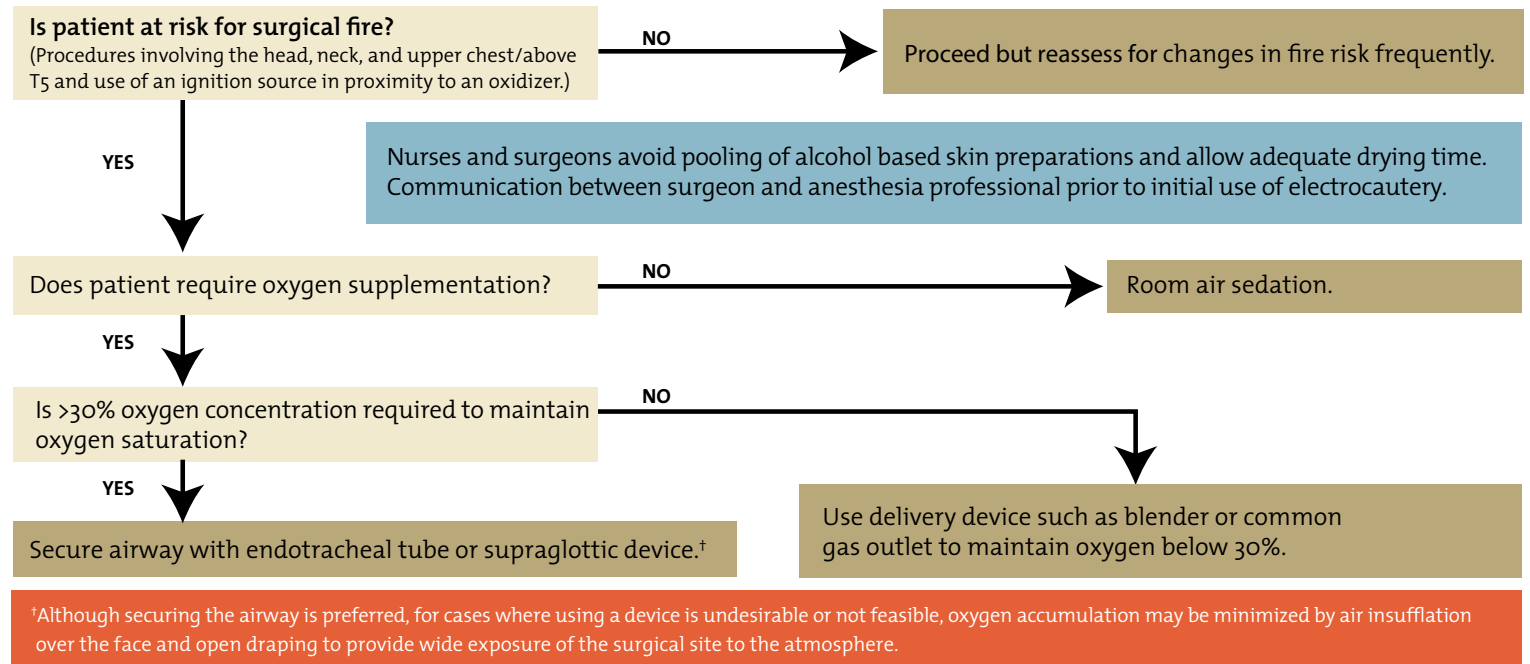
undermine your patient safety objectives. It’s totally appropriate for you to discuss with her—in a collegial and respectful manner—the impact that her behavior has on team morale and performance. She may not realize the harm it does. Further, her appraisal of the Time-Out as a “waste of time”

suggests that she hasn’t had much exposure to what we call the “science of safety.” This education involves understanding error and risk laden processes (like the surgical continuum) as well as the tools we use (e.g. checklists, Time-Outs) to improve patient safety and mitigate risk. Generally, professionals who have received this education aren’t cavalier about the Time-Out and other important patient safety protocols. I suggest you share this information with your OR director, who oversees the education of OR staff. Perhaps she can offer some much needed education to help improve teamwork and collaboration. ■

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Fire Prevention Algorithm



*The following organizations have indicated their support for APSF's efforts to increase awareness of the potential for surgical fires in at-risk patients: American Society of Anesthesiologists, American Association of Nurse Anesthetists, American Academy of Anesthesiologist Assistants, American College of Surgeons, American Society of Anesthesia Technologists and Technicians, American Society of PeriAnesthesia Nurses, Association of periOperative Registered Nurses, ECRI Institute, Food and Drug Administration Safe Use Initiative, National Patient Safety Foundation, The Joint Commission. PROVIDED AS AN EDUCATIONAL RESOURCE BY THE Anesthesia Patient Safety Foundation

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Preventing Surgical Fires

continued from Page 1

Never Assume - Communicate!

A fact well known to patient safety officers and risk managers – communication breakdown is cited as one of the major root causes in the majority of reported sentinel events. Additionally, communication failures remain a leading cause of surgical adverse events, fires included⁽¹⁾.

The surgical field is a dynamic and complex environment where individuals work independently and collaboratively towards a common goal. In this ever-changing milieu, clear, direct, and timely communication is essential to maintaining the teams' "situational awareness," or, collective understanding of an unfolding situation⁽²⁾. In the OR, this collective awareness is critical to anticipating and responding to threats that jeopardize patient safety.

Unfortunately, despite the presence of known combustion hazards in the surgical field (oxygen, ignition, and fuel) surgeons, anesthesiologists, and nurses may not directly share information, often because they assume the other professional will act in a specific way. The anesthesiologist may *assume* the surgeon will announce when cautery will be used, and the surgeon may *assume* that since the anesthesiologist can see the BOVI cautery approaching the face, the oxygen will be turned down.

As Mark Brulee, biomedical engineer and surgical fire expert for ECRI Institute, emphasized in a recent presentation to hospital risk managers, fire risk is omnipresent and prevention is "All about the team!"⁽³⁾. Explicit communication—that is clear, detailed, and leaves no room for doubt, is needed *before* and *throughout* the procedure to maintain team awareness and reduce risk.

The Time-Out: Optimal for Assessing Fire Risk and Clarifying Emergency Procedures

In the high risk industries of aviation and the military, a team briefing at the beginning of a mission is a given. During the briefing, team members evaluate environmental risk and rehearse contingency plans, ensuring maximal situational awareness. This shared mental model of risk and response enables the team to anticipate and respond to threats and changing conditions. In the OR, the Time-Out provides the perfect opportunity to raise team awareness of safety hazards and ensure a coordinated response to a surgical fire.

The FDA and APSF recommend conducting 1) a fire risk assessment and 2) articulating the fire emergency plan. Both can be easily added to the Time Out and completed within seconds. To evaluate fire risk, each member of the



surgical team can identify the particular aspect of the fire triangle (e.g. either oxidizers, fuel, or ignition source) within their control and explain the specific precautions they will take to reduce risk. For example, the OR nurse, generally in control of fuel sources like alcohol based skin preps and surgical drapes, can inform the team that an alcohol based antiseptic was used and was completely dry before draping the

patient. Next, the anesthesiologist can inform the team of the patient's current oxygen requirements, agreeing to forewarn the team of any increase in oxygen. Finally, the surgeon can brief the team on the use of cautery, lasers, and other ignition sources, agreeing to communicate in advance before activating these devices. Although sharing information in this way might feel as if one is "stating the obvious," what is evident to the individual is often not obvious to the team. Clear, direct, and unambiguous communication is critical to raising situational awareness and preventing patient harm.

After assessing fire risk, the team should summarize the emergency plan by having each member of the team briefly describe his or her specific role in responding to a fire (e.g. stopping the flow of airway gases, or extinguishing burning materials). Again, when seconds count, clarifying respective roles ensures a swift and coordinated response to a surgical fire. ■

For video demonstrations of fire risk assessments and emergency procedures incorporated into the Time-Out, visit [www.fda.gov, Resources and Tools for Preventing Surgical Fires](http://www.fda.gov/ResourcesandToolsforPreventingSurgicalFires).



Fire Facts

The Usual Suspects: The three factors needed to start a fire—commonly referred to as ‘the fire triangle’ Oxidizer+ Fuel+ Ignition Source

- 1) Oxidizers-** In about 70 percent of cases, oxygen enrichment is considered the main contributing factor in a surgical fire⁽⁴⁾. Denser than air, oxygen tends to pool around the face, neck, and low-lying areas and absorb into surgical drapes making surgeries of the head neck and upper chest especially risky. In 2009, ECRI Institute in collaboration with the APSF, recommended eliminating the open delivery of oxygen to the face. If patients are unable to maintain safe blood oxygen saturation without supplemental oxygen, then it is recommended to secure the airway with laryngeal mask airway or tracheal tube. To read more about these recommendations (and their exceptions) as well as specific techniques for decreasing oxygen buildup underneath surgical drapes—access the ECRI Institute poster on surgical fire prevention www.ecri.org/surgical_fires.
- 2) Fuels-** Highly flammable alcohol-based skin preps, liberally used in surgery, are notorious for increasing the risk of fire. Prep solutions get trapped under the drapes

and tend to pool in recessed areas of the patient's body. Strict observation of drying times is urged. In fact, Soham Roy, MD, chief of pediatric otolaryngology at University of Texas-Houston and surgical fire expert, believes extending drying time from two to five minutes is wise⁽³⁾. Draping after the complete drying of antiseptic solution is also recommended. Fuels are ever-abundant on the surgical field and include drapes, sponges, endotracheal tubes, patient tissues, and vellus, the fine hair that covers the patient's body that helps fire spread from head to toe, instantly.

- 3) Ignition sources-** Electrosurgical instruments, electrocautery, lasers, and fiberoptic light sources (basically, anything that plugs in!) can generate the spark needed to cause a surgical fire. Announcing use, and deactivating instruments when not in use are among several recommendations provided by the ECRI Institute. Access their free downloadable poster at www.ecri.org/surgical_fires. ■

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Inside this issue:



Flying Right

Adapting Aviation's 'Sterile Cockpit Rule'
to Improve Patient Safety in the OR.



Patient Safety Q & A

Time-Outs—Worth the Time and the Trouble.



How 'Talking Out Loud' and 'Stating the Obvious' Can Prevent Surgical Fires

Communicating to prevent surgical fires.

