

FMEA: Not Just for Compliance Anymore

Most patient safety, quality and risk management professionals in hospitals today have at least some experience with failure modes and effects analysis (FMEA). Many were introduced to FMEA via the Joint Commission's requirement — first implemented in 2002 — that hospitals perform a proactive risk assessment on a high risk process at least once each year. While some organizations might still treat FMEA essentially as a line item on their survey readiness checklist, effective FMEA programs can deliver real, measurable benefits to the healthcare organization, its staff and its patients.

Prevent it today or investigate it tomorrow

Root cause analysis (RCA) is a powerful and necessary tool that helps us learn from things that went wrong. The good news is that hospitals have developed deep skills in conducting RCA and are learning from investigations into adverse events that occur within their institutions. Unfortunately, hospitals get more RCA practice than they'd probably prefer; there are plenty of adverse events to investigate. For the patient whose case initiates it, an RCA is too late. FMEA's intent is to identify and address weak spots in a high risk process before errors can occur — those tiring of RCA might consider taking a more serious look at FMEA. They can apply many of the systems improvement skills they use in RCA investigations to improve clinical processes proactively with FMEA. One way of looking at it: the better you are at FMEA, the fewer RCAs you'll have to do.

Cure diseased processes while changing culture

A systems view of hospital errors suggests that most errors — many of them devastating on a human scale and extremely costly on an organizational scale — are symptoms of diseased processes. Whereas RCA is like removing a tumor, FMEA takes a more holistic view of a clinical process, addressing its overall health to reduce the risk that a tumor will appear. FMEA begins with the fact that each process, no matter how it is defined, has a desired outcome. It acknowledges the complexities and interactions that occur as the process unfolds and then asks of those who know the process best, in the real world: "what might go wrong here?" Because FMEA is prospective (and not investigative) it allows subject matter experts (those who really know what happens inside the process) to name the weaknesses in the system without fear of recrimination. For front-line clinicians, FMEA can provide a view of their work processes (a "systems view") they might not have ever considered before — and the "ah-hah" moments can have lasting impact that spreads to others in their organization.

Benefits beyond compliance

At its core, FMEA employs simple, common-sense concepts to produce results. It provides a structure and methodology that allows professionals to step back and look objectively at their work processes, identify areas where failures are likely to occur and prioritize actions to eliminate defects and/or their effects. While no one will say FMEA is "easy", neither are the required actions (such as RCA investigations) that result from a failure

to mitigate risk proactively. FMEA can produce success stories for every health-care stakeholder:

For patients, FMEA helps create safer care and more trust in their provider;

For healthcare professionals, FMEA can provide confidence in the working environment and a sense of ownership in its design;

For the organization, FMEA can reduce financial risk, drive operational efficiency and create competitive advantage; and

For payers and insurers, FMEA can lower overall healthcare costs, drive out waste and help form more positive perceptions of the industry.

— Tom Leifer, QI Path, tom.leifer@qipath.com

Silence

Just this week, concurrent with the 2011 AORN Congress, AORN released an article that was really quite interesting. The article, entitled "The Silent Treatment," discusses the shortcomings of checklists, bundles and Safety Tools. They're hardly the first to address this concern. While many have been insisting on culture change as an essential element to implementing these very effective Tools, the most recent authoritative voice may be that of Peter Pronovost, MD, PhD.

Most of you probably know of Pronovost's work that resulted in the Central Line Checklist, which virtually eliminates CLABSI. A simple Tool, the key to its success according to Dr.

Pronovost is culture. Dr. Pronovost insists that the checklist, protocol, or safety Tool is only going to be effective if you have a culture wherein ANY member of the healthcare team, including environmental services, housekeepers, transporters, techs, administrators, nurses, mid-levels, etc. can, **and will**, speak up and challenge non-compliance or safety concerns.

The AORN article is noteworthy because it presents research indicating that many times clinicians won't speak up. In fact, they found that 58% of nurses reported a failure to speak up when they witnessed a violation of protocol or a safety concern. Moreover, 17% of the nurses polled said that this happens "a few times a month."

My colleagues and I have been down this road and there's an even more difficult situation than the one investigated in this study. The query in the article asks about known problems that were made evident by a Safety Tool. The more subtle and much more difficult situation is when a member of the healthcare team merely "thinks" there may be a problem. People don't want to look silly, don't want to make a fuss over something trivial, etc. So they don't speak up!

While it's a good idea for nursing executives, administrators, department chairs and others to say, "We want you to speak up if you see something wrong," the simple truth is that this encouragement is insufficient. The best way to ensure that the staff in this OR, on this shift, on this ward, etc. will speak up is for the most empowered (licensed) person on the team to articulate this expectation in real time. It's good to know that my hospital wants me to speak up, but if the ED physician says something like, "If anyone has any concerns about the welfare of any of our patients tonight, I expect you to speak up," this is a very strong statement of expectation **here and now**, when it

matters. This is the kind of action that changes culture, one shift at a time.

Safety Tools, checklists and protocols are effective ways to standardize best practices, but if they're not embedded in a culture of mutual support they're unlikely to yield significant improvements.

— Steven Montague, Vice President,
[LifeWings, lifewings@verizon.net](mailto:lifewings@verizon.net).

CHPSO Addition

To better serve our members, we have hired an additional clinician with great experience in patient safety. Bobbie Dietz, CHPSO's Director of Quality and Patient Safety, has been instrumental in the implementation of quality and patient safety programs at a number of organizations, including several HMOs, Vanderbilt University Medical Center, and a division of HCA. She also produced implementation guides used by University HealthSystem Consortium for improving patient safety.

Bobbie is a graduate of the nationally-renowned AHA-NPSF Patient Safety Leadership Fellowship. The Fellowship is co-sponsored by the American Hospital Association (AHA) and the National Patient Safety Foundation (NPSF) in partnership with the Health Research & Educational Trust (HRET), Health Forum, the American Society for Healthcare Risk Management (ASHRM), the American Organization of Nurse Executives (AONE) and the Society of Hospital Medicine (SHM).

Additionally, and most importantly, she is a delightful person skilled in working collaboratively to help develop optimal solutions to shared challenges. Bobbie will be starting mid-May, and we encourage you to meet her, in person, by email or by phone. We will be circulating her contact information as soon as she starts.

Avoidable Blood Use Bleeding Hospitals Dry

In an era of bloodless medicine and bloodless surgery, hospitals are using increasing amounts of blood, or certainly not using less blood. The Society of Thoracic Surgeons (STS) tracks an ever growing list of clinical metrics from open heart surgery patients. The STS data set reveals that patients who undergo relatively bloodless open heart procedures have better outcomes and lower mortality rates. ICU patients maintained at hemoglobin levels of 7 gm/dL have similar outcomes to those maintained at 10 gm/dL, yet have length of stays one day less. However, virtually all hospitals have been unable to promote anemic blood use.

Bloodless centers, numbering less than 5 percent of American hospitals, treat many patients such as Jehovah's Witness patients with practically no blood. Patients with pre-existing anemia and coagulopathy are often treated without blood transfusion prior to or during surgery, when only a few years ago none of these patients would have been considered surgical candidates without transfusion. Yet even some bloodless programs admit that blood use by non-bloodless

Subscription service (additions and removals): La Shon Tate ltate@calhospital.org

Questions or comments: Rory Jaffe, MD MBA rjaffe@calhospital.org

Copyright © 2011 [California Hospital Patient Safety Organization](http://CaliforniaHospitalPatientSafetyOrganization.org)

This newsletter may be freely distributed in its original form.

Opinions expressed by the authors are their own and not necessarily CHPSO's.

physicians in their own facilities is unnecessary.

Why is blood use so pervasive in American health care when evidence points to so many harmful effects? Increased myocardial injury, congestive heart failure, immune suppression, respiratory failure and a host of other conditions alongside traditional infectious risks have all been reported. Perhaps our cultural perception that “Blood Saves Lives” is responsible. “The doctors are doing everything for Mom. They are even giving her blood,” is frequently heard.

No simple cause or solution may be found. In an era when 30 to 50 percent of blood transfusions are likely unnecessary, physicians have little awareness of modern transfusion principles. They practice from rote memory or fear of the unknown, using archaic rules. Such rules are frequently passed along through misguided mentorship devoid of objective data pointing to rational practice.

A major problem has been that double-blind randomized prospective controlled studies demonstrating best transfusion medicine practices are very difficult to construct. Evidence that blood transfusions are not good for patients is mounting and it would be easy to speculate that if blood were a new drug, it would not be approved by the FDA.

Fortunately advancements in blood component substitutes continue, so that one day many cases treated by transfusion may be managed by pharmacologic means. Recombinant Factor VII (Novo-7), costing several thousand dollars per dose, is just one such example of pharmacotherapy. While the cost of such agents appears superficially extreme, the ability to heal patients more rapidly makes such costs rational when the total cost of patient care is considered.

Currently 60 to 80 percent of patients receiving blood transfusion receive at least one unit of medically unnecessary blood; many receive multiple units of non-beneficial blood. When total costs are factored in, including therapy for untoward events and extended length of stay, a unit of blood costs \$1500 per unit, not just the \$250 or more to purchase the unit, while unnecessary blood use may lead to thousands of dollars in avoidable patient care costs per patient.

Unnecessary and even inappropriate blood use likely stems from multiple other factors, including failure of adequate peer review by the transfusion committee. Most hospitals report that transfusion review processes rarely find instances of inappropriate blood use even though a major portion of blood use is non-beneficial. There are multiple causes for the failure to recognize or report unnecessary blood use and each hospital should search out solutions to this problem. One answer is to perform objective external chart review on redacted chart documents in a standardized manner so that each hospital chart, each physician and each hospital is comprehensively evaluated in a standardized process applied universally across the nation. The capacity to review all hospital records exists and the prospect of reviewing health care records redacted of identifying information holds the promise of eliminating internal reviewer bias and other shortcomings of internal utilization and medical peer review.

— David F. Jadwin, DO, FCAP, [Columbia Analytics](http://ColumbiaAnalytics.com), djadwin@columbia-analytics.com

Objective Impact of Clinical Peer Review on Hospital Quality and Safety

Owing to the generosity of Thomson Reuters and Premier Inc., electronic reprints of the latest findings on clinical peer review effectiveness will be available at no cost until the end of May. The article appears in the April issue of the *American Journal of Medical Quality*. The publisher usually charges a fee of \$20 for each download to non-subscribers.

While you may redistribute the hyperlink below without restriction to colleagues in your organization and elsewhere, you are advised to abide by copyright restrictions and make photocopies only for your personal use. There is no restriction on reproduction of the article abstract.

Edwards MT. The objective impact of clinical peer review on hospital quality and safety. *Am J Med Qual.* 2011;26(2):110-119. goo.gl/fa4jJ.

Abstract: Despite its importance, the objective impact of clinical peer review on the quality and safety of care has not been studied. Data from 296 acute care hospitals show that peer review program and related organizational factors can explain up to 18% of the variation in standardized measures of quality and patient safety. The majority of programs rely on an outmoded and dysfunctional process model. Adoption of best practices informed by continuing study of peer review program effectiveness has potential to significantly improve patient outcomes

You'll find additional support for program improvement, including a free,

evidence-based online Peer Review Program Self-Evaluation Tool at QAtoQL.com. For CHPSO members, there is no cost to report data to the non-commercial Normative Peer Review Database Project (QAtoQL.com/proj_normative_database.htm) as Patient Safety Work Product. It is designed to support studies in health care operations improvement, publication of findings and feedback for improvement of quality and safety. Participants complete an annual program information report and contribute specified peer review program data semi-annually. In return, they receive normative performance reports. Data is now being received for the period October 1, 2010 through March 31, 2011.

— Marc Edwards, MD MBA [QA to QL Consulting, marc@QAtoQL.com](mailto:QAtoQL@Consulting.com)

Managing Sponges in Labor and Delivery

Retained vaginal sponges after a spontaneous vaginal birth or vaginal packing left after an operation are reportable Retained Surgical Item events. For the purposes of this report, a sponge is considered retained if it was discovered after the immediate recovery period (one to two hours after delivery). Vaginal packing is considered retained if a patient still has a pack in her vagina 24 hours after delivery or after discharge from the hospital. Minnesota has been proactive in addressing this problem and this definition is consistent with their guidelines and those used in general obstetrical practice. (1) Retained vaginal sponges may not be frequently reported because they are removed in physician's offices but when reported the vagina is the most common site for a retained sponge after the chest and abdomen. (2,3,4)

Poor communication between birth attendants (physicians, nurse midwives)

and other labor and delivery staff and problems with obstetrical practices of sponge management can result in the failure to remove surgical sponges after a vaginal birth. Although the practice of surgical counts has long been standard in operating rooms, a lack of familiarity with the practice for vaginal births is one reason why vaginal sponge retention is a problem. Another reason is underappreciation of patient harm that can result from retention.

Sponges left in the vagina are usually the 4x4 cotton gauze X-ray-detectable sponges ("Ray-Tec®"). These are small in comparison to a post-gravid vagina and contrary to obstetrician's perceptions that they will be able to see or "find" them, indeed, they are missed. Women usually present days to weeks after delivery with a vaginal discharge. Sometimes they have a fever and abdominal pain and signs of endometritis. They go to doctor's offices and to the emergency room. Sometimes they remove or report the finding of a soiled, fetid piece of "tissue" or gauze that falls out in the toilet or they perceive something is inside of them. They are often put on antibiotics. There have been reported cases of toxic shock syndrome associated with a missed retained vaginal sponge. (5) Hospitals have to report these cases per California statute if they are discovered or patients can report them.

Birthing and L&D (labor and delivery) areas in addition to obstetrical ORs should have in place a standardized practice for the management of surgical sponges. (6) Which practice is chosen is dependent on the local environment and facility resources. It is probably a good idea that the practice which is in place in the OR is also employed in the L&D areas. L&D personnel often do not have familiarity with sponge management practices like OR nurses do so help from their OR colleagues can make their

learning curve shorter. Some additional safety actions are to use 4"x18" gauze sponges instead of the 4x4s because they are longer, have a blue marker which can hang outside of the perineum during a repair and some think they are easier to find so will be easier to keep track of.

Vaginal packing should not be in the delivery packs. If vaginal packing is needed a pack with a radiopaque marker should be opened. Vaginal packing is considered a dressing so a process has to be in place outside of the OR or birthing room which will ensure that the dressing pack is removed before the patient goes home. This three-step practice is recommended (7) —

1. During the nurse handoff to post-delivery personnel there is formal notation made that there is a pack in the patient
2. The obstetrician writes an order that there is a pack placed and the timing and plan for pack removal
3. The patient is informed there is a pack in her and it must come out before she goes home.

When surgical sponges are used they should be accounted for at the end of the procedure. Obstetricians and perinatal personnel should adopt safe practices to ensure that patients and new mothers leave the OR or procedure area with "NoThing Left Behind".

— Verna C. Gibbs, MD, [NoThing Left Behind®, drvgibbs@nothingleftbehind.org](mailto:drvgibbs@nothingleftbehind.org) and Brenda Chagolla, RN, Catholic Healthcare West, Brenda.chagolla@chw.edu

References

1. Institute for Clinical Systems Improvement. (2007). [Prevention of Unintentionally Retained Foreign Objects During Vaginal Deliveries](#).
2. Wan, W., Le, T., Riskin, L., & Macario, A. (2009). Improving safety in the operating room: a systematic literature review of retained surgical sponges. *Current Opinion in Anaesthesiology*, 22, 207-14.
3. California Department of Public Health. (2010). [Fiscal Year 2010-2011 Adverse Events Addendum](#).
4. Institute for Clinical Systems Improvement. (2009). [Prevention of Unintentionally Retained Foreign Objects During Vaginal Deliveries](#).
5. McGregor, J.A., Soper, D.E., Lovell, G., & Todd J.K. (1989). Maternal deaths associated with *Clostridium sordelli* infection. *American Journal of Obstetrics and Gynecology*, 4, 987-95.
6. Chagolla B. A., Gibbs V.C., Keats J.P., & Pelletreau B. (2011). A Systemwide Initiative to Prevent Retained Vaginal Sponges. Accepted for publication, *The American Journal of Maternal Child Nursing*.
7. Gibbs V.C. — [NoThing Left Behind](#)®: A National Surgical Patient Safety Project to Prevent Retained Surgical Items.

CHPSO Just Culture Support Call Schedule

We asked via survey for suggestions to make the Just Culture Support Calls be of most value to CHPSO members. In response to that input we have assembled a panel of experts and redesigned the call agenda. We are cancelling April's call to allow time to fully implement these

changes. The May call (May 9 at 10 AM) will proceed as scheduled. Enrollment for the May call will open May 1.

WHO Hand Hygiene Survey

Worldwide, 327 facilities made 76,803 observations of hand hygiene. The rates of compliance, by region, were:

| | |
|-------|-----------------------------|
| AMRO | 26% (the Americas) |
| EURO | 64% (Europe) |
| EMRO | 44% (Eastern Mediterranean) |
| WPRO | 61% (Western Pacific) |
| SEARO | 54% (South-East Asia) |
| AFRO | 48% (Africa) |

Calendar

The following upcoming events are still open for enrollment. For more information or to enroll, use the contacts listed below.

April

- 7: SCPC (Southern California Patient Safety Collaborative): Track III — Perinatal Care. Industry Hills.
- 10: CHPSO: Just Culture Support Call is cancelled for this month only and will resume in May.
- 14: BEACON: Compass Series 4 of 4. Oakland.
- 19: PSCSD&IC (Patient Safety Council of San Diego & Imperial Counties): HAI Elimination. San Diego.
- 25: BEACON: Annual Exchange Pre-Conference. Burlingame.
- 26: BEACON: Annual Exchange. Burlingame.

29: PSCSD&IC: Standardizing Dosing Limits. San Diego.

May

- 9: CHPSO: Just Culture Support Call. 10–11 AM.
- 10: PSCSD&IC: Reduce Preventable Readmissions through Networking (PRN). San Diego.
- 19: PSCSD&IC: Ending Elective Deliveries Before 39 Weeks Gestation. San Diego.
- 24: SCPC: Perinatal Monthly Webinar. 12:15 PM.
- 24: SCPC: Track I — Hospital Acquired Infections in the ICU Setting, Sepsis and Surgical Care Improvement Project. Industry Hills.

June

- 13: CHPSO: Just Culture Support Call. 10–11 AM.
- 17: CAPSAC: California Patient Safety Action Coalition. Pasadena.
- 21: PSCSD&IC: HAI Elimination. San Diego.
- 21: SCPC: Track II — Pressure Ulcers, Readmissions and Transitions of Care. Industry Hills.
- 28: PSCSD&IC: Standardizing Dosing Limits. San Diego.
- 28: SCPC: Perinatal Monthly Webinar. 12:15 PM.

July

- 11: CHPSO: Just Culture Support Call. 10–11 AM.

CHPSO Patient Safety News

April 2011 ≈ Page 6

13: *PSCSD&IC*: Reduce Preventable Readmissions through Networking (PRN). San Diego.

13: *SCPSC*: Track III — Perinatal Care. Industry Hills.

August

8: *CHPSO*: Just Culture Support Call. 10–11 AM.

9: *SCPSC*: Track I — Hospital Acquired Infections in the ICU Setting, Sepsis and Surgical Care Improvement Project. Industry Hills.

16: *PSCSD&IC*: HAI Elimination. San Diego.

23: *SCPSC*: Perinatal Monthly Webinar. 12:15 PM.

24: *PSCSD&IC*: Ending Elective Deliveries Before 39 Weeks Gestation. San Diego.

30: *PSCSD&IC*: Standardizing Dosing Limits. San Diego.

September

9: *CAPSAC*: California Patient Safety Action Coalition. Sacramento.

12: *CHPSO*: Just Culture Support Call. 10–11 AM.

13: *SCPSC*: Track II — Pressure Ulcers, Readmissions and Transitions of Care. Industry Hills.

14: *PSCSD&IC*: Reduce Preventable Readmissions through Networking (PRN). San Diego.

27: *SCPSC*: Perinatal Monthly Webinar. 12:15 PM.

October

10: *CHPSO*: Just Culture Support Call. 10–11 AM.

18: *PSCSD&IC*: HAI Elimination. San Diego.

20: *PSCSD&IC*: Standardizing Dosing Limits. San Diego.

25: *SCPSC*: Perinatal Monthly Webinar. 12:15 PM.

November

8: *SCPSC*: Track I — Hospital Acquired Infections in the ICU Setting, Sepsis and Surgical Care Improvement Project. Industry Hills.

9: *PSCSD&IC*: Reduce Preventable Readmissions through Networking (PRN). San Diego.

14: *CHPSO*: Just Culture Support Call. 10–11 AM.

15: *SCPSC*: Track III — Perinatal Care. Industry Hills.

15: *PSCSD&IC*: Ending Elective Deliveries Before 39 Weeks Gestation. San Diego.

December

2: *CAPSAC*: California Patient Safety Action Coalition. Torrance.

12: *CHPSO*: Just Culture Support Call. 10–11 AM.

13: *SCPSC*: Track II — Pressure Ulcers, Readmissions and Transitions of Care. Industry Hills.

13: *PSCSD&IC*: HAI Elimination. San Diego.

15: *PSCSD&IC*: Standardizing Dosing Limits. San Diego.

For further information on these events:

BEACON: Petrina Aiello paiello@hospitalcouncil.net or www.beaconcollaborative.org

CAPSAC: John Keats John.Keats@CHW.edu or www.capsac.org

CHPSO: Rory Jaffe rjaffe@calhospital.org

PSCSD&IC: Lindsey Wade lwade@hasdic.org

SCPSC: Julia Slininger jslininger@hasc.org

Instructions to Authors

Prospective authors may submit articles to Rory Jaffe, MD, MBA (rjaffe@calhospital.org, 916.552.7568). Typical articles will be brief — between 400 and 650 words. Additional information may be provided as web links. If accepted, the additional information may be hosted on the CHPSO website. A completed [publication agreement form](#) must be submitted prior to publication.

About This Newsletter

CHPSO Patient Safety News provides lessons learned from reviews of patient safety events and news of patient-safety activities in this state. We hope you will find it useful in your efforts to improve patient outcomes. This newsletter may be freely distributed in its original form. Copies of each newsletter are archived on the CHPSO website (www.chpso.org).

— Rory Jaffe, MD MBA rjaffe@calhospital.org