CHPSO
California Hospital Patient Safety Organization

Patient Safety News
November 2012
Volume 4 Number 10

Socio-Technical Probabilistic Risk Assessment

Part two of a two-part series on prospectively evaluating risks

The need to address human factors and behavioral choices in the proactive risk assessment process is underscored in the complex, hazard-prone field of health care where hand-offs in communication are so often the root causes of patient harm. The socio-technical probabilistic risk assessment (ST-PRA) has emerged as a useful tool in analyzing human factors that are prevalent in error-prone systems. Marx and Slonim(1) proposed that the ST-PRA, a tool used by aviation and nuclear industries to examine low-frequency, high-impact events in complex systems, offers advantages in this respect over Failure Modes and Effects Analyses (FMEAs).

Marx and Slonim believe that the ST-PRA process is more robust than the FMEA in complexity of investigation. The FMEA process is considered a "bottom up" approach, beginning with the process as designed and working outward to identify potential failures within the process. Conversely, ST-PRA is "top down," beginning with a top-level failure and tracing back through the process to identify multiple causal events. In the ST-PRA process, fault trees depict failures or conditions combined by "AND" or "OR" gates to identify higher level failures. Basic events may include human error/behavior or equipment failure.

The resulting shape of the fault tree (see illustration) demonstrates the robustness or vulnerability of the system. The ST-PRA team relies on the expertise of its members to provide probability estimates for each basic event. "AND" gates multiply the probability of basic events, and "OR" gates add them together. Robust systems (those with more "AND" gates) can tolerate one or more failures. Vulnerable systems (those with more "OR" gates) are at risk due to system failure when any one of its components fails. Reliability is built into the system by designing in protective components, such as altering system incentives to reduce the probability of at-risk behaviors, building in redundancies to alter the structure of the fault tree itself, and creating forcing functions that cannot be overlooked or bypassed.

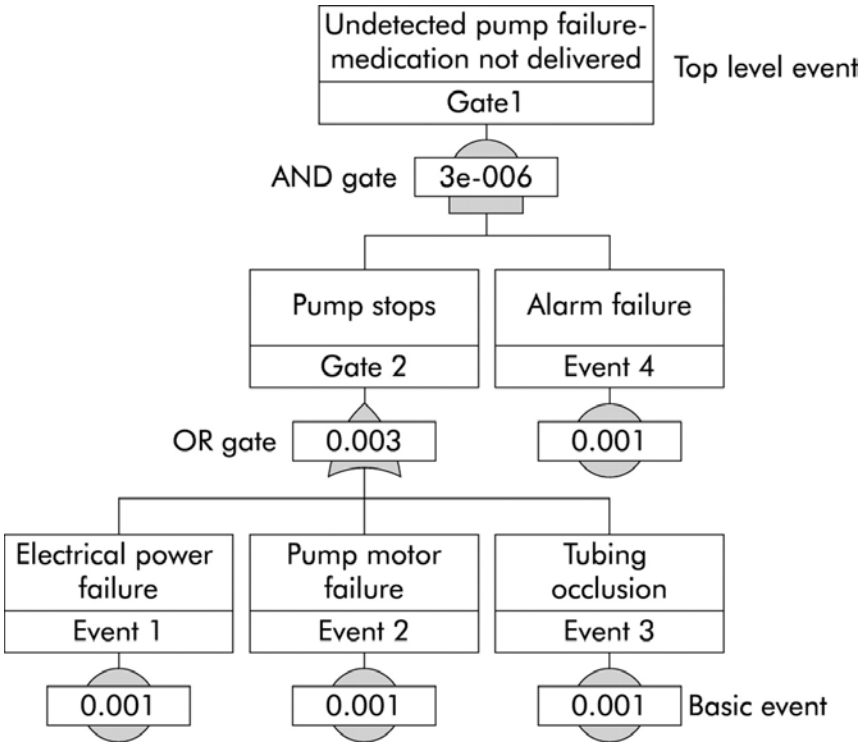

Illustration: ST-PRA Fault Tree

At St. Joseph's Medical Center, Stockton, I facilitated a ST-PRA team of radiologists, emergency physicians, radiology and emergency managers and directors, and quality facilitators to examine failure to communicate incidental radiology findings. The resulting fault tree illustrated the vulnerability of the communication system due to reliance on multiple hand-offs between providers and variations in patient follow-up procedures. The fault tree clearly demonstrated that leaving the patient at the most distant end of the communication chain created multiple vulnerabilities in the patient follow-up process.

By building in direct radiologist-to-patient communication of incidental radiology findings, a more robust system was designed, dramatically reducing the size and shape of the fault tree and significantly reducing the probability of failure. A patient who had been adversely affected by failing to communicate a radiology finding suggestive of lung cancer partnered with the team in the design of

the radiologist-to-patient communication letter. The direct patient communication of incidental radiology findings program, now entering its third year, has significantly reduced the risk of failed patient follow-up from 19.4 percent to 4.3 percent ($p<.01$). The program has been further improved by semi-automating the radiologist-to-patient communication process.

When conducted well and supported by hospital administration, proactive risk assessments are invaluable tools for (re)designing health care systems. Including patients on the team adds an important perspective, with the caution that the patients should be carefully selected for their ability to contribute to the team.(2) Although the Joint Commission only requires a proactive risk assessment every 18 months, health care providers should continually seek opportunities to conduct them. Gaining fluency and expediency in proactive risk assessment performance should yield ample risk-reduction benefits.

— Susan White, director of Clinical Risk Management, Shands at the University of Florida

References

1. Marx DA, Slonim AD. Assessing patient safety risk before the injury occurs: an introduction to sociotechnical probabilistic risk modelling in health care. *Quality & Safety in Health Care*. 2003;12 Suppl 2:ii33–8.

2. Wetterneck TB, Hundt AS, Carayon P. FMEA team performance in health care: A qualitative analysis of team member perceptions. *Journal of Patient Safety*. 2009;5(2):102–8.

Guidance for Outsourcing Sterile Compounding

Compounding pharmacies fill a critical niche in the nation's drug supply, but currently they are regulated primarily at the state level. Licensing standards and inspections may not be as rigorous as for manufacturers. Given the current fungal meningitis outbreak and other recent outbreaks of nosocomial infections due to compounding pharmacy sterility failures, it is advisable to closely scrutinize vendors providing sterile compounding.

The American Society of Health-System Pharmacists (ASHP) Research and Education Foundation distributes an evaluation tool and contracting guidance for sterile compounding. The tool includes 65 questions and a scoring mechanism with criteria for passing scores. Questions address regulatory compliance, quality and patient safety measures, administration safety measures (e.g., labeling), and service excellence.

The contracting guidance is extensive and includes recommendations for RFP (Request for Proposal) requirements, including:

- Assurance that all pharmacists and pharmacy technicians employed at the compounding facility are licensed as required, with verification that they are in good standing on file and available for review.

- Documentation of all accreditation or regulatory survey results conducted of the compounding pharmacy's sites, including copies of any significant regulatory actions brought against the facility.

- Details on the facility's quality management programs, including cleaning and validation, staff training and competency assessment.

- A demonstrated commitment to continually integrating technology and knowledge to improve patient safety.

- A risk-assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities.

- Assurance that the compounded medications are compatible with the client's medication administration devices (e.g., bar-code labeling, smart pumps).

FDA Statement: Drug Shortages Resulting from Ameridose Recall

Yesterday, CHPSO issued an alert that in an expansion of the fungal meningitis outbreak investigation, a related company, Ameridose, had recalled its products. Today, the FDA responded to the resultant drug shortages.

FDA is aware that the voluntary shutdown of Ameridose and the recall of Ameridose products may affect supplies of certain life-saving drugs for some health care systems. FDA has identified six Ameridose products on the FDA critical shortage list, which already were in shortage prior to the recall. The recall has

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

the potential to exacerbate one or more of these shortages:

1. Sodium Bicarbonate Injection
2. Succinylcholine Injection
3. Atropine Sulfate Injection
4. Bupivacaine Hydrochloride Injection
5. Lidocaine Hydrochloride Injection
6. Furosemide Injection

For these six drugs in shortage, these are the actions FDA will continue to take the following actions:

- FDA is working with manufacturers for these six drugs, requesting that they ramp up production if they are willing and able to do so.

- For any manufacturers for these six drugs that may be experiencing manufacturing/quality problems, FDA is offering assistance, where appropriate, to help address these problems to enable those manufacturers to manufacture shortage drug products that are safe and high quality.

- If the manufacturers of critical drugs intended for the U.S. are not able to meet U.S. patient needs, FDA explores companies that are willing and able to import foreign drugs to address the shortage in the U.S. In these instances, FDA evaluates the foreign drug to ensure that it is of adequate quality and that the drug does not pose undue risks for U.S. patients.

- As with shortages of any critical products, FDA will expedite the reviews of any pending applications that could help with addressing the shortages.

- FDA is identifying any additional manufacturers willing to initiate or increase production.

CHA Launches Patient Safety Campaign and Website

The California Hospital Association's Public Advocacy Program recently launched its 2012 "*Caring is our Calling*" campaign to highlight the advances hospitals are making in improving quality and patient safety. At the cornerstone of the campaign is the new www.CaringIsOurCalling.org website.

In September, the *Caring is our Calling* campaign embarked on an educational campaign focused on three clinical topics — reducing hospital-acquired infections like *C. difficile*, promoting medication safety and encouraging surgical safety. The campaign features issue briefs with hospital case studies that measure quality improvement. Patients and the public are also informed about how they can improve their own safe care and help reduce hospital readmissions.

Phase 2 of the patient safety campaign will highlight hospitals' bold support for the CMS Partnership for Patients Pledge. Nearly 400 hospitals in California have signed this national patient safety and quality pledge making it the largest state to achieve this level of shared commitment.

Following the November elections, the *Caring is our Calling* campaign will promote flu vaccinations for everyone, including all health care workers. The program will air 30-second television commercials statewide in English and Spanish to call upon everyone to be vaccinated. For more information, go to www.CaringIsOurCalling.org or contact CHA Vice President of Public Advocacy Tracy Campbell at 916.552.7594.

Save the Date: 2013 Annual Meeting in Sacramento

Mark your calendars for CHPSO's Second Annual Meeting — *Getting to Zero: Innovate, Collaborate, Accelerate* — April 8–9, 2013, at the Hyatt Regency Sacramento. The program is designed for California hospital CEOs, senior leaders, and clinical leaders, including physicians, nurses, quality, risk and patient safety staff, and pharmacists.

The program will give participants innovative strategies and practical tools to take back to their facilities, as well as an understanding of what's on the legal and regulatory horizon in patient safety.

Call for speakers

CHPSO is still looking for hospitals to share their "best ideas in patient safety" at the Annual Meeting. Speakers will represent a variety of hospitals, from small rural facilities to large systems. If you have a successful case study to present, please contact Frances Sutz Brown, CHPSO's director of Operations and Communications, fsutzbrown@chpso.org or 916.552.7598.

Medication Safety Topic of Nov. 19 User Group

Discuss and share ideas to improve patient safety related to medication used in medical office/ambulatory settings during the CHPSO/ECRI user group call, Nov. 19, 11:30 AM–12:30 PM PST. User groups enable CHPSO members to discuss events in a safe, protected environment and learn from one another. Facilitators will review case studies based on events reported by PSO members. No identifying information will be included and the cases will be relevant for any acute care facility. The user group is for CHPSO members only. Members will receive an email a few days before the event with information on how to participate.

CHPSO Calendar Notes

Unless noted, all events are for CHPSO members only. Members will receive an email a few days before each event with information on how to participate. All times are for the Pacific Time Zone.

November

12: *CHPSO*: Members Call. *Responding to near misses and low severity events*. 10–11 AM

19: *CHPSO/ECRI*: User Group Meeting. *Medication Safety in the Ambulatory Setting*. 11:30 AM–12:30 PM

December

10: *CHPSO*: Members Call. *Cancelled due to conflict with the Institute for Healthcare Improvement (IHI) Annual Meeting.*

TBD: *CHPSO/ECRI*: Radiology Patient Safety. Web seminar time *TBD*.

For further information on these events:

info@chpso.org, 916.552.2600

Hospital Council Calendar Notes

November 13 — BEACON Fall Exchange, South San Francisco Conference Center, 9 AM–4 PM

The BEACON Collaborative is hosting its 6th Annual Patient Safety First "Exchange" Nov. 13, 2012 at the South San Francisco Conference Center. Join peers from hospitals throughout Northern and Central California for a day of networking, knowledge exchange and sharing of best practices to improve patient safety. Keynote presenters and topics include Kathleen Bartholomew on Leading a Patient Safety Culture: Beyond the Statistics; J. Bryan Sexton on Caregiver Resilience and Quality Improvement: A Double Edged Sword; and Richard Davies DeBronkart, Jr. on Discovering the e-Patient Movement: How Patient Engagement Can Improve Safety and Quality. For more information go to www.hospitalcouncil.net/post/beacon-fall-exchange.

Hospital Association of Southern California Calendar Notes

November 7 — Patient Safety First (PSF) Collaborative Track I meeting, HAI, Sepsis, Surgical Safety, Pacific Palms Resort Conference Center, 8 AM–3 PM

December 4 — PSF Collaborative Track II meeting — Care Transitions and Readmission Reduction, Pacific Palms Resort Conference Center, 8 AM–3 PM

January 23 — 5th Annual Southern California Patient Safety Colloquium, Orange County Hyatt, 7:30 AM–3:45 PM

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.

Prospective authors may submit articles to Frances Sutz Brown: fsutzbrown@chpso.org, 916.552.7598. Typical articles will be brief — between 200 and 600 words. A completed publication agreement form must be submitted prior to publication.

Contact Information

Rory Jaffe, MD, MBA, executive director, rjaffe@chpso.org, 916.552.7568

Frances Sutz Brown, director of Operations and Communications, fsutzbrown@chpso.org, 916.552.7598

Andee Thorpe, administrative assistant, athorpe@chpso.org, 916.552.7651

CHPSO office, info@chpso.org, 916.552.2600, secure fax 916.554.2299

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