FIRST

Do No Harm

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Quality and Patient Safety Division, Massachusetts Board of Registration in Medicine

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Leadership and Pre-Occupation With Failure*

Jim Conway
Adjunct Faculty Harvard School of Public Health
Principal, Pascal Metrics

*Reprinted, with permission, from the *Paediatric International Patient Safety and Quality Community* (PIPSQC) blog at: www.pipsqc.org.

The CMO of a rural community healthcare system was pleased after kicking off a patient safety meeting with more than 100 front-line clinical, administrative and support staff. The organization had shown a dramatic decline in serious adverse events and now the numbers for most months were very small. The chart showing the downward trend was striking. He was therefore stunned with the first comment from staff: "If that's what you think then it is clear you don't have any idea of what goes on in my unit every day."

This story is real. It occurred in an excellent organization, and I was there as it unfolded. The organization's leaders knew that if you try to do everything, you will accomplish nothing, so they set strategic quality and safety targets and the organization was on an active journey forward. However, they became too focused on these few events, forgetting that their targets were a small piece of the universe of harm and failure, maybe just 5% of it. No mention was made at the meeting of the larger context of failure. No mention was made as to how this data linked to all the incident reports that get filed every day. For the front-line staff, what leadership was saying bore no resemblance to the failure they, patients and family members deal with every day.

This story isn't unique. Those privileged to be associated with excellent organizations, such as specialty pediatric organizations, have the opportunity to participate in and experience every day exceptional care and caring, hope, and discovery. Yet, with such organizations come enormous risk due to the arrogance of excellence and the normalization of deviance. [i] By spending every moment of every day in what Karl Weick [ii] calls a pre-occupation for excellence, staff can individually and collectively focus on the good and forget to seek out and confront the failure, suffering, harm, waste, tragedy, and death. Often, the design defects that exist are no longer seen. They are lost in the blur that staff must navigate through as they engage in the processes of care delivery. Do you ever question the normalization of deviance in your organization? Just invite someone with fresh eyes in and discover what they see and how quickly they see it.

Karl E. Weick, Kathleen M. Sutcliffe and David Obstfeld [iii] have taught us that a key element of high-reliability organizations—something we all seek for our patients and staff—is developing a pre-occupation with failure or, in other words, becoming an expert at looking for trouble and doing something about it. Effective organizations do this in at least three ways: by treating any and all failures as windows on the health of the system, by a thorough analysis of near failures, and by focusing on the liabilities of success. In my personal patient safety journey as a leader I've confronted the tensions associated with this pre-occupation with failure by pushing, probing, digging deeper, and more. When you look hard, your organization's harm numbers and rates become higher than most and people around you begin to wonder, often aloud, at times of growing transparency, "What about this is good?" In a 2012 meeting discussion with Daved van Stralen, around the pre-occupation with failure, [iv] an attendee noted that in healthcare failure is seen as a weakness and imperfection. They went on to say that part of the view of professionalism in healthcare is that you don't have failures.

On one occasion during my own career, a physician leader was presenting some strong work from a team on a new clinical information system. At the end of the presentation I congratulated the team and asked "What new categories of error are we implementing with this system?" With a very frustrated and abrupt tone the leader replied, "Aren't you ever satisfied?" I thought and then said "No, I can't be." Years before, I learned from human factors experts at MIT that errors were highest at times of dramatic change—nothing was more dramatic or required more change than a new IT system. From a tragic medical error I had learned what would become a mantra: "Our systems are too complex to expect merely extraordinary people to perform perfectly 100% of the time. We as leaders must put in place systems to support safe practice."[v] Follow up after the presentation of the work of the above noted clinical information system team, using critical risk assessment methodologies, identified many new categories of possible error with this IS install. While we couldn't fix every one instantly, we could certainly mitigate their chances of creating error and causing harm. Every time you change a system, what is your approach to critical risk assessment, to failure detection?

I've also learned this pre-occupation can become personal. As a young leader I loved being a firefighter, coming in on a great big problem, and leading the team that fixed it. Then a

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colleague suggested that maybe those problems shouldn't have risen to that stage if I and we had been doing a better job in the first place. If a strong system had been built, and we were listening to the signals suggesting problems, we could have fixed them earlier. Many clinical colleagues say they've seen a similar scenario, often at morbidity and mortality conferences. The focus is on the save and not on the fact that the harm shouldn't have happened in the first place.

Organizations and their leaders must develop this pre-occupation with failure and then do something with the data. Among the techniques I'm seeing used are:

- The presence of enhanced communication systems. Over and over people say nothing else will matter in patient safety if there isn't good communication in the organization.
- From my colleague Allan Frankel MD of Pascal Metrics:
  1. Daily communication where the value is espoused in a briefing (i.e. "We value your being preoccupied with defects.")
  2. The ability and willingness to identify defects.
  3. Evidence that action leads to improvement.
  4. Leaders who tie 1, 2, 3 to each other - i.e. "you were preoccupied, you identified, this fix occurred" - everyday in every briefing.
- Mechanisms to capture the voice of the patient, family, and front-line staff daily and establish feedback loops. This includes learning to ask the question: "How can we improve?" and then respectfully listening.
- Cultures are established where caregivers are able to speak up if they perceive a failure. The Keystone Initiative has found this the strongest predictor of clinical excellence.[vi] Extensive reviews have been forthcoming on interventions to improve safety culture [vii] [viii] [ix] and a variety of tools exist to check up on culture. [x]
- Organizational courage to begin to utilize the IHI Global Trigger tool [xi] [xii] to understand the full extent of harm, all cause harm, and mitigate it moving forward. Note is made of the exceptional leadership from members of the pediatric community in this area. [xiii] [xiv] [xv]
- The presence of daily huddles, patient safety huddle boards and other vehicles to communicate today's failures today with a goal of eliminating them for tomorrow.
- Systematic study of handoffs and transitions. Every time a team does this they are wowed at all the steps that don't add value and all the failures that occur.
- Patient Safety/Executive Walk Rounds [xvi] should be more than a pass-thru and include specific discussions of what's not working, what are the failure points. In the community hospital where I serve as a trustee, the trustees are an integral and respected part of these rounds.
- The utilization of crisis management and other systematic processes to assure respectful management of serious clinical adverse events. [xvii] With every probe, every "but why," leaders will be stunned by all that is news to them that is familiar to those at the point of care.
- Routine application of approaches and tools such as lean, six sigma, process mapping, critical risk assessments and failure mode & effects analysis to probe for failure points.
- Fresh eyes welcomed to look at the work. They can come from new staff recruited from other organizations, patients and family members, staff from another part of the organization, or staff from another organization.
- Continuing education in high reliability through programs such as High Reliability Organizing.
- Application of tools developed by Karl Weick and colleagues to audit your current practice. [xviii]

Dr. Seuss has taught us "the more that your learn, the more places you will go." John Kelsch of Xerox noted "To do things differently, we must see things differently. When we see things we haven't noticed before, we can ask questions we didn't know to ask before." Each of us has seen and been part of exceptional care and caring. A pre-occupation with failure will help us move closer to that being the experience of EVERY patient, family member, and staff member, EVERY time.

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[xvii] IHI. Leadership Response to a Sentinel Event: Respectful, Effective, Crisis Management.

[xviii] Weick KE, Sutcliffe KM. Managing the Unexpected: Assuring High Performance in an Age of Complexity. This audit tool and other assessment tools for High Reliability Organizing can be found at: http://www.wildfirelessons.net/OrgLearning.aspx.

Improvement Project: Accurate Daily Weights in CHF Patients

North Shore Medical Center
Prashanth Mopala, M.D., Barbara Corning-Davis, Jean Lee-Caccia,R.N., Jesser Mantilla, R.N., Carole Dempsey, CNA., Poongodi Chandrasekaran, M.D., Ashmeet Bhatia, M.D., Rosemary Henchey, R.N., David Roberts, M.D.

Introduction:

In Congestive Heart Failure (CHF) patients', 'daily weight' is one of the key clinical indicators affecting the decision on diuresis. If confounding factors are controlled, fluid balance after diuresis should match the change in body weight; as an example, one liter net negative diuresis would decrease weight by approximately 2 pounds. Clinically though, daily weights are notorious for being inaccurate in the vast majority of inpatients. Inaccuracies in weights lead to inappropriate dosing of diuretics, with subsequent increase in avoidable medical complications and increased length of stay. The improvement team on North Shore Medical Center's (NSMC's) inpatient cardiology unit decided to tackle the problem using the Model for Improvement.[1]

Problem Statement:

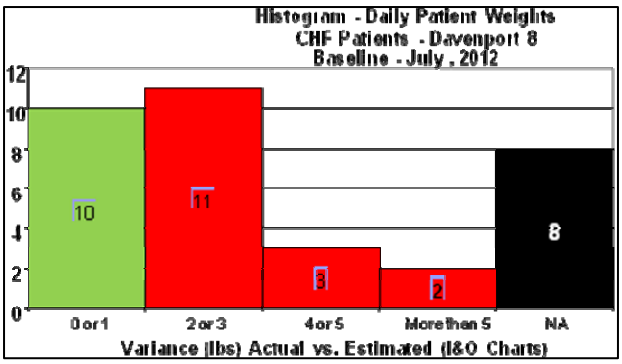
The daily weights of CHF patients on Davenport 8 (NSMC's Cardiac Telemetry floor) are not consistent with the measured inputs and outputs for 47% of patients.

Assessment of Problem and Analysis of Causes:

Baseline data was obtained on all CHF patients being diuresed on the unit. Measures collected included 'daily weight changes' (Wt), corresponding 'net fluid input and output' (I/O) and 'variation between measured vs. expected weight change (V)'. A variation of less than 1 pound was agreed upon to be 'acceptable variation,' to keep the project more feasible.

Baseline Data (N = 34 patients)

1. Variation (V) of < 1Lb (Acceptable Variation) = **29%**
2. V of >1 Lb = **48%** (2-3Lbs =32%, >3Lbs =15%)
3. No I/O (V cannot be calculated) = **23%**



Subsequent brainstorming sessions with team members including Physicians, Nurses and Certified Nurse Assistants (CNA's), led to the identification of multiple barriers. Barriers which were common in the majority of inaccurate weights included: A) using different weighing scales on the same patient during the hospital course; B) if the bed scale was used, 'items on bed,' such as multiple pillows, multiple linen sheets, and personal items were not accounted for; and C) I/O's were not accurately measured.

Aim Statement:

All CHF patients (100%) on Davenport 8 will have weights that match their measured inputs and outputs by November 1, 2012.

Tests of Change:

1) Use of the same weighing device that was used for the admission baseline weight throughout the inpatient stay. For example, if a patient can stand up during the admission process,

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s/he would be weighed using the standing scale throughout the inpatient stay, rather than switching between the standing scale and the bed scale. Also, if the unit has more than one standing scale, each would be named (A, B, C, etc), so as to use the same scale for a given patient.

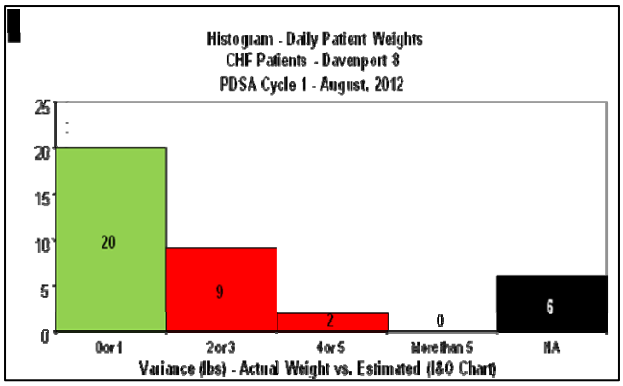
2) A laminated 'Note Card' was attached to all beds, to note the number of pillows, linens, etc., on the bed when patient's baseline weight was measured at admission. With all subsequent measurements the 'Note Card' is referred, to match the items; all extra items will be removed of the bed.

3) The CNA's were identified as the key members of the medical team, to be responsible for the process of daily weight measurements. They were educated about the impact of their work on the physician's decision regarding diuresis and subsequent patient outcomes.

Results:

Post Intervention Data (with N of 37 Pt daily wts)

1. Variation (V) of < 1Lb **Improved by 55%**
2. V of >1 Lbs **Decreased by 60%**
3. No I/O **Improved by 66%**



Lessons Learned:

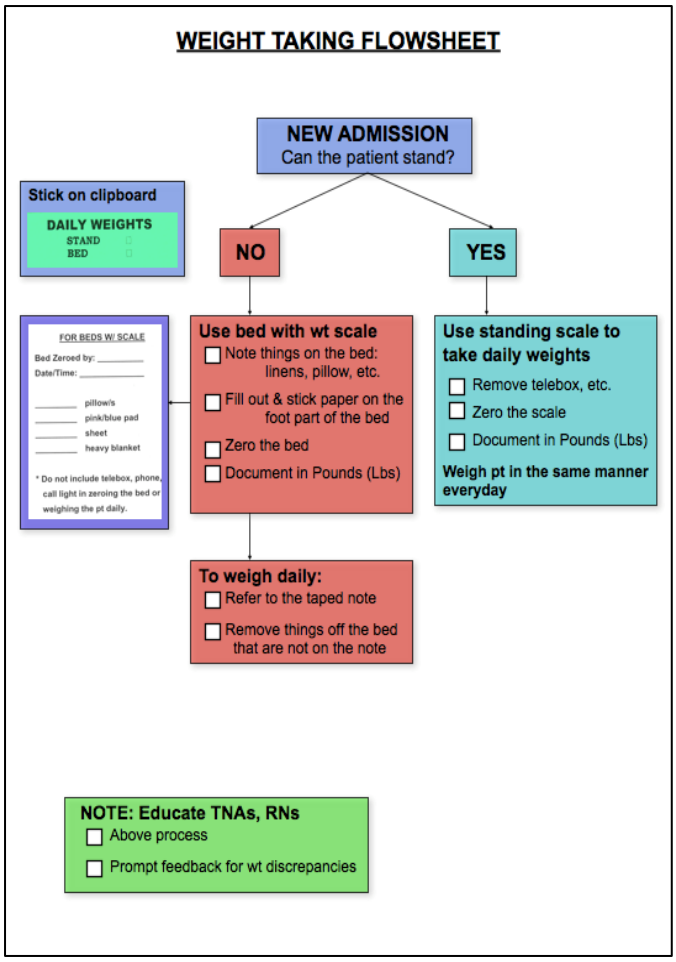
1) The record of **Items on bed** on a bed scale during patient's admit weight measurement and cross checking it during subsequent measurements, decreased weight inaccuracies.

2) Variation in 'daily weights' can result from using different **scales** for the same patient.

3) **CNAs are key members** of the health care team and can have a significant impact on patient outcomes through processes like 'daily weight measurements.'

4) **Improving accuracy of fluid balance** measurements was identified as a future opportunity.

5) The **Model for Improvement** (Plan-Do-Study-Act) is an effective tool for a team to use in identifying and solving problems at the frontline of care. Simple solutions devised by the frontline caregivers engaged in the process can yield powerful results.



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"Hospitals—and those of us who work in them—often fall short of understanding the experiences of hospitalized patients and their families and the perspectives they have that might improve care. Integrating patients and families into a hospital's quality and safety culture needs to become one of the important elements of patient-centered care." Jonathan R. Welch, MD. As She Lay Dying: How I Fought To Stop Medical Errors From Killing My Mom. Health Aff. December 2012; vol. 31, no. 12: 2817-2820.

UMass Memorial Root Cause Analysis Process- *Maximizing the Process for Efficiency and Effectiveness*

University of Massachusetts Memorial Medical Center
Stephen Tosi, MD, FACS, Senior Vice-President/Chief Medical Officer, UMass Memorial Healthcare
Ellen Venditti, MS, RN, CPHRM, FASHRM, Senior Director, Risk Management, UMass Memorial Healthcare

During the summer of 2011, the UMass Memorial Medical Center (UMMMC) Risk Management Department, in collaboration with the Quality and Patient Safety Department, completed an assessment of the UMMMC root cause analysis (RCA) process. We embarked upon the assessment after we had discovered that many of our RCA corrective action plans were vague, focused more on the person instead of the process, and lacked clear ownership.

UMMMC RCAs in 2011

Our assessment revealed that frontline staff rarely attended RCA meetings. This was concerning and caused us to wonder if the number of supervisors and leaders at the meetings had a chilling effect on frontline staff participation.

Additionally, we determined that the time dedicated to corrective action planning was frequently insufficient, coming typically in the last few minutes of the meeting. The assessment results were presented to the Patient Safety Committee, with the recommendation that we needed to improve our entire RCA process.

Creating the Future State of the RCA Process at UMMMC

We discovered that concurrent to the assessment of our process, a number of Massachusetts organizations were planning an educational conference on "Gaining Full Value from RCA Investigations." A representative group of people from across the UMass Memorial Health Care system attended the conference.

Patrice Spath, MA, RHIT, a healthcare quality specialist and educator presented an overview of the RCA process, the steps of a thorough RCA, and the development of effective corrective actions. The UMMMC team came home from the conference with renewed enthusiasm for the RCA process and began immediately to create our "future state" using Lean methodology.

The Process Begins with Report of an Event

Once an event is reported, the Risk Manager conducts a review of the case. If the event seems to have system or process problems involved, whether or not there was actual patient harm, an RCA will be conducted. If the event seems to relate to individual performance or behavior (not rooted in human factors principles), an individual peer review is completed.

Two Meetings Usually Needed

If an RCA is indicated, most often two meetings will be held. The first meeting involves only the people involved in the event, the quality and risk managers who will act as facilitators and the meeting chair (usually the CMO). Managers, supervisors and directors are invited only if they were actually involved in the event.

The first meeting is scheduled to be held as soon as possible after the event. All invitees are prepped by the Risk Manager, so each individual will know what to expect at the meeting. There is emphasis on the peer review protected status of the meeting, as well as the focus on "process versus person" throughout the analysis. The goal is to provide the attendee with a sense of safety and freedom to speak honestly and openly in the meeting.

The RCA Meeting

The meeting typically begins with introductions, explanation of the process, an explanation of the peer review protection and requirements for maintenance of the protection, and the purpose of the meeting. For our revised process, we adopted the Events and Causal Factors (ECF) Model presented by Ms. Spath. The ECF Model is used by the National Transportation Safety Board to investigate accidents. According to Spath, this model makes it easier to understand the event as it occurred, allows for missing information and factual inconsistencies to be more readily identified, and helps the team identify multiple causes of the event, rather than grasping on the most obvious cause.[1]

A short summary of the event with a visual timeline is shared with the meeting attendees (a sample is displayed in Figure 1).

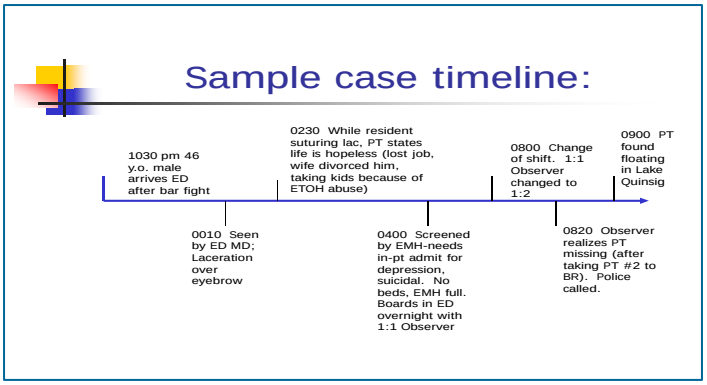

Figure 1

Causal Factors and Latent Causes

The first meeting will then proceed to:

1. Understand what happened;
2. Identify the causal factors; and
3. Identify the root causes.

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The goal of the meeting is to retrace the steps that lead to the root cause by linking the causal factors (what happened that led to event) to each stage of the process. To avoid grabbing onto the first impression, the facilitators will keep asking, "Why", for each of the causal factors. (See Figure 2 for a visual display of a sample ECF Chart).

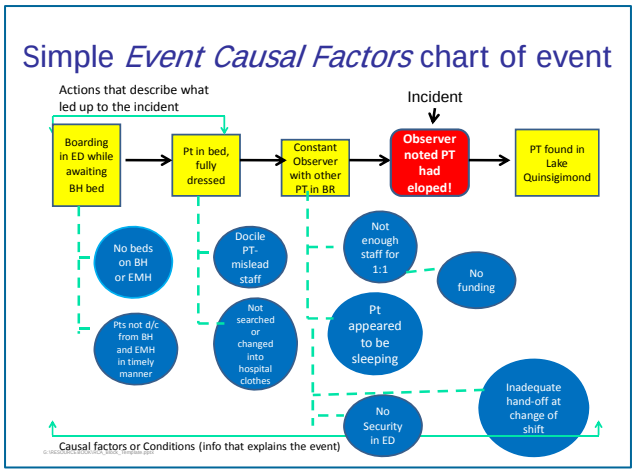

Figure 2

Ultimately, we determine which of the causal factors were actually significant contributing factors. Then, from the pool of significant contributing factors, we can determine which of the significant contributing factors are the true root cause(s). Lastly, we identify latent causes that might have contributed to the event (delayed consequences of organizational decisions and actions; can lie dormant for long periods before defenses fail).[2] We display the process as shown in Figure 3.

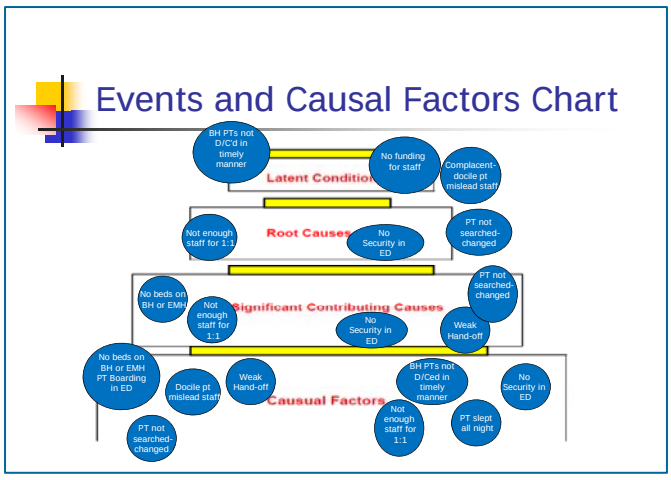

Figure 3

To be certain we have explored all potential contributing factors, we use The Joint Commission's recommended guide to be certain all appropriate questions have been asked and answered. Suggested corrective actions are brought forward to the second meeting where the corrective action planning actually takes place.

The Second Meeting: Corrective Action Planning

The participants at the second meeting are there because they are in a leadership position in the area or service where the event occurred, or because they have special knowledge that might help with corrective measures. The Root Cause(s) and any Latent Cause(s) that were identified at the first meeting are presented and the facilitators help the attendees develop corrective actions to prevent a recurrence of the event.

The key educational component of this second meeting is the introduction of the corrective action scoring tool shared by Spath during her conference. Our Quality staff converted the tool into an easy to use educational tool for the attendees at the corrective action planning meeting. Figure 4 displays our tool.

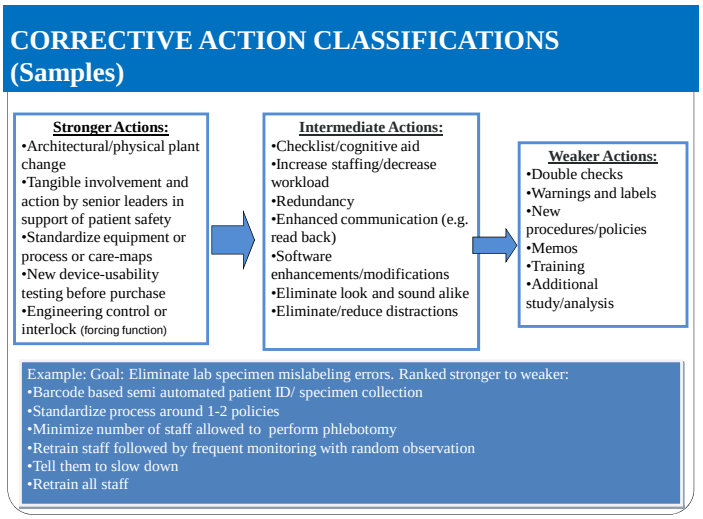

Figure 4

We emphasize the goal of staying in the stronger or intermediate areas when designing our corrective action plans. If we must use a weaker action, we will always attempt to link it with an intermediate action.

Responsible parties from the group are assigned to implement the action items developed. A date (usually three months from the corrective action meeting) is established for the leader with overall responsibility to report to the Patient Safety Committee on the progress of the implementation, the early results of monitoring effectiveness, and the possible need for revisions or additions to the plan.

At the end of the second meeting, we determine if the event meets the criteria of a *Sentinel Event* per The Joint Commission or a *Safety and Quality Review Report* (SQR) per the BoRM Quality and Patient Safety Division. We believe the thoroughness of our revised process has improved the quality of our SQRs.

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Monitoring, Evaluating Reporting

The responsible leader will be expected to come to the Patient Safety Committee on a routine basis to report on the progress of the plan. This reporting continues until the Committee feels the corrective actions have taken hold, the plan has been successful in preventing recurrences and monitoring can cease.

UMMMC RCA Process Today

The process is still being refined, but the feedback from the participants and our leadership team is quite positive. Participants feel they have been heard and have a voice in promoting safety and process improvement at UMMMC, rather than feeling blamed for an event. This supports our desire for an enhanced culture of safety where everyone feels safe to "Speak up."

Our corrective action plans are stronger than in the past, managed by leaders with a commitment to the project and with a more structured method of obtaining support for capital funding when needed for a corrective measure. We are seeing stronger action items, such as a bar-coding system for labeling blood samples to avoid tube mislabeling (or "wrong blood in tube" events) that will also be adapted to our NICU area to avoid wrong breast milk events. Another strong action involved the implementation of metal detectors for scanning of high risk patients in the ED in order to find hidden contraband that could be used for self harm. In addition, we have installed secure, alarmed doors in the ED with a delayed opening which offers the opportunity to intervene in high risk patient elopements.

We have found our revised RCA model has affected patient safety and the quality of care at our organization in a positive manner. Additionally, our new model has elevated collaboration between the Risk Management and Quality and Patient Safety Departments to the highest level we have seen.

Dr. Tosi and Ms. Venditti would like to thank Dr. Robert Klugman, Dr. Lisa Allen, Ms. Ellen Felkel-Brennan and their team of Quality Managers, and Ms. Laurie Reilly and the Risk Management team at UMMMC for their committed work and dedication to this project.

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"Lessons Learned" from Safety and Quality Review Reports

A patient with multiple co-morbidities developed postoperative renal failure. Following review of the incident, the hospital added a new trigger for ASA IV patients to the preoperative checklist. The trigger prompts the surgical team to: "STOP" and check to see that the patient has adequate medical clearance.

In response to several near-miss events involving epinephrine, a change was made to the hospital's Computerized Physician Order Entry (CPOE) to indicate that epinephrine 1:1,000 only be given IM or SC; the option for IV route of administration was removed. Epinephrine 1:10,000 was removed from CPOE as it is only used in code situations and is available on code carts and never ordered through CPOE.

Following review of a case involving a patient who developed thrombophlebitis from a peripheral intravenous line that was inserted by EMS in the field, a hospital implemented the following medical record enhancements: (1) standard documentation for peripheral IV assessment in the computerized record; (2) admission database will include a field to indicate the source of the IV and date of insertion; and (3) an enhancement to the electronic shift to shift report includes a review of IV lines and access.

Despite finding that its Code Team's response to a patient's respiratory arrest was adequate, this rehabilitation hospital determined that more frequent mock codes would help to maintain the skills and comfort levels of providers. The hospital implemented monthly mock codes on alternating shifts. The mock codes provide an opportunity for team members to assess their competence and identify opportunities for improvement.

QPS NOTES

The QPS Division has developed a presentation about the PCA Program that is specifically designed for your health care facility's medical staff. The presentation provides a brief overview of the PCA Program; describes quality and patient safety research relevant to the PCA Program; and explains the physician's role in quality and patient safety. The presentation is one that could be offered through your Grand Rounds or other medical staff educational programs. Please let us know if you would like to schedule a presentation at your facility.

The QPS Division's newsletters and advisories are posted on the Board of Medicine's website: www.massmedboard.org. Click on the Quality and Patient Safety link. We recently sent you an Advisory on Robot-Assisted Surgery. Please let us know if you would like to share your experience in developing your robotic surgery program.

SAVE THE DATES:

Briefing for Hospital Trustees, CEOs & Physician Leaders.
June 3, 2013, 8:00 – 11:15 a.m., MHA Conference Center

Advanced RCA Workshop: Focusing on Sustainable Improvements in Patient Safety
June 13, 2013, 8:00 a.m. - 4:00 p.m.,
Courtyard Marriott, Marlborough, MA

For more information about these programs visit the Board's website: www.massmedboard.org; Click on the "Quality and Patient Safety" link , then on "Announcements."

CONTACT THE QPSD

To be added to the QPS Division Newsletter and advisory mailing list, update hospital contact information, submit an article, request an SQR form, or obtain additional information, contact QPSD: Jennifer.Sadowski@state.ma.us or (781) 876-8296. Send mail to Massachusetts Board of Registration in Medicine, QPS Division, 200 Harvard Mill Square, Suite 330, Wakefield, MA 01880.

Here are examples of the types of patient events reported in Safety and Quality Reviews:

Intra-op flash burn
Sub-therapeutic INR and pulmonary embolism
Fracture while in restraints
Subdural hemorrhage during spinal surgery
Post-op brachial plexus injury
Hemorrhage post-lithotripsy
Unrecognized septic arthritis
Bowel perforation during hysterectomy
Retained piece of drill bit
Post-operative myocardial infarction
Wrong radiation dose to patient
Angioedema with loss of airway
Pulmonary edema following hysteroscopy
PICC thrombophlebitis
Femoral condyle fracture during makoplasty
Delayed diagnosis of epiglottitis
Contrast induced nephropathy
Arterial dissection during cardiac catheterization
Colonoscopy and endoscopy perforations
Spinal hemorrhage after multiple LP attempts
Missed diagnosis of cerebral aneurysm on CTA
Lithium toxicity
Laceration of infant during c-section
Aspiration during suctioning
Trocar injury during lap band procedure
Delayed diagnosis of evolving MI
Pneumothorax during pacer implant
CO2 embolism during laparoscopic sleeve gastrectomy

The QPSD Newsletter, FIRST Do No Harm, is a vehicle for sharing quality and patient safety initiatives of Massachusetts healthcare facilities and the work of the Board's Quality and Patient Safety Division and Committee. Publication of this Newsletter does not constitute an endorsement by the Board of any studies or practices described in the Newsletter and none should be inferred.