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Sentinel Event Management Model: A Performance Improvement Project

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Introduction

The purpose of the paper is to describe a performance improvement project that implemented a standard sentinel event management model based on best practices and principles of high reliability organizations. The project utilized define, measure, analyze, improve, and control (DMAIC) performance improvement methodology and Lewin's Theory of Planned Change. The project took place at an acute care hospital that is part of a not-for-profit healthcare system in Louisville, KY.

It is estimated that one in four American families will be affected by preventable harm in healthcare, involving further medical care, disability or even death (Denham, Sullenberger, Quaid, & Nance, 2012). Prevalence studies have estimated that between 3% and 16% of American patients experience preventable harm as a result of healthcare. The Institute of Medicine estimates that over 100,000 preventable deaths occur from healthcare each year (Macrae, 2008). The healthcare industry has improved its ability to identify harm related events; most of these events result in some type of formal investigation and analysis (Agency for Healthcare Quality and Research, 2010). However, safety in healthcare will not improve until organizational learning from adverse events takes place (Macrae, 2008).

Healthcare has examined other industries, such as aviation and chemical processing, for safety strategies. This has led to widespread use of safety event reporting systems. Macrae (2008) explains that when healthcare adopted safety event reporting systems, many of the essential participatory aspects were lost in the transfer. Participation of the people closest to the work challenges deeply held assumptions about who holds relevant knowledge, who is considered an expert and who is both able to participate and responsible for participating in the risk mitigation (Macrae, 2008). The traditional, hierarchical nature of healthcare organizational

structures makes participation in safety improvement more challenging (Roussel & Swansburg, 2009). Event identification and lessons learned should be disseminated throughout healthcare organizations to prevent future occurrences. Learning from failures is a process that requires collaboration, decentralization and the ability to engage front line caregivers to fully understand the causes and successfully implement changes (Macrae, 2008).

Learning from adverse events requires three types of responses. The first response, identification, is the process of identifying adverse events and bringing them to the attention of others in the organization. The second, analysis, refers to the process of analyzing the event with a focus on identifying system level failures and process breakdowns. The third, change, refers to the way organizations implement corrective actions to reduce or eliminate reoccurrence of the adverse event (Ginsburg et al., 2009). The most significant opportunities to improve organizational learning from adverse events may exist around participatory management and change management (Macrae, 2008).

Review of Literature

A search was conducted in the EBSCOhost database using the key words patient safety, medical harm, adverse event and sentinel event. Filters included English language, peer reviewed and published in the last 10 years. Duplicates were removed. Relevant articles were selected based on information related to the current state and evidence-based solutions to close the clinical gap previously identified between best practices and the health system policies and processes. Additional searches were conducted using the Google internet search engine relative to patient safety organizations, resources and regulation. National and international recommendations and guidelines were identified. Regulatory and accreditation standards were also identified for the United States. Seminal literature on patient safety was included, regardless

of publication dates. The literature was appraised using the Johns Hopkins Nursing Evidence – Based Practice model. The evidence ranged from level IV to level V which are the lowest two evidence levels and generally consist of nationally recognized expert opinion and literature reviews. The quality rating were A, high quality or B, good quality (Dearholt & Dang, 2012). Consistent themes for adverse event management fell into the three major categories of identification, analysis and change. Gaps between organizational learning from failure in high reliability organizations, and organizational learning from adverse events in healthcare were identified in the literature.

Current Guidelines and Recommendations for Management of Adverse Events

Several national and international patient safety organizations have published guidelines or recommendations for adverse event management (see Table 1). The guidelines are generally based on reviews of literature and expert opinion. The majority of the guidelines focus on event identification, analysis and change. Some guidelines include prevention and preparation as well as immediate crisis intervention. Additional categories include disclosure of events, patient and family involvement, *Just Culture* principles and measures of the effectiveness of action plans. Organizational learning was identified as a theme in the guidelines (Bagian et al., 2015; Conway, Federico, Stewart & Campbell, 2011; Hoppes, Mitchell, Vendetti, & Bunting, 2012; National Center for Patient Safety, 2011; Taylor-Adams & Vincent, 2001; World Health Organization, 2005).

Identification.

The identification response to adverse events includes recognizing an event has occurred, notifying the appropriate people about the event and launching the investigation to determine more information about what occurred. A formalized team response should be planned for

adverse events. Efforts should be made to increase the engagement of staff and leaders at all levels of the organization in safety improvement (Bagian et al., 2015; Hoppes et al., 2012). Systems should be developed to identify adverse events as early as possible and as often as possible. Organizations have an opportunity to improve patient safety by performing equal investigations for all adverse events and near misses instead of just adverse events (Rivard, Rosen, & Carroll, 2006). The timeliness of investigations should be monitored. Additionally, the organization should consider a consistent role of the patient/family in the investigation process (Conway et al., 2011).

Analysis.

The analysis response to adverse events involves careful review of the event and a systematic process to determine why and how the event occurred. This includes identification of individual and system causal factors. Processes should be developed for performing and reporting the results of aggregate reviews of adverse events and near misses. This is consistent with high reliability organization principles and would provide the opportunity for more learning and prevention of future events (National Center for Patient Safety, 2011). Formalization of analysis teams with training in root cause analysis methodology could make the analysis process more consistent and more effective. Focused efforts to determine relevant contributing factors should occur (Bagian et al., 2015). There are inconsistent recommendations regarding the participation of the caregivers directly involved in the event (Bagian et al., 2015; Conway et al., 2011; National Center for Patient Safety, 2011). The current process of inclusion has contributed to challenges in the analysis process.

Change.

The change response to adverse events involves developing action items that are directly linked to the causal factors found in the analysis in order to prevent recurrence of the adverse event. Action items should be specific, assigned to an owner, include a deadline and be tracked for completion (Bagian et al., 2015; Taylor-Adams & Vincent, 2001). Considerable effort should be used to standardize processes to measure the completion and effectiveness of action items following an adverse event. Metrics can be developed and routinely reported to display progress and demonstrate sustainable efforts to prevent future adverse events (Bagian et al., 2015; Hoppes et al., 2012). The Board of Trustees and senior leaders should be accountable to overseeing the specific monitoring and improvement efforts (Conway et al., 2011).

There are key organizational learning strategies from high reliability organizations that should be considered for adverse event management. High reliability organizations recognize the value of feedback loops and effective communication about safety reporting and safety related activities. These communication channels can be formalized to further engage people at all organizational levels in safety reporting and associated activities. Open communication about adverse event frequency, lessons learned and success stories should be shared within healthcare organizations. Participatory management strategies from high reliability organizations can be utilized during adverse event management. There is an opportunity to shift the hierarchical healthcare culture from deference to authority, to deference to expertise. High reliability organizations consistently generate alerts, reports and stories from safety event reviews which are disseminated to everyone involved in the work (Ginsburg et al., 2009).

Clinical Practice Problem

Response to adverse events at this healthcare system was guided by system policy and procedure which was based on The Joint Commission sentinel event policy for hospitals. The risk management department led investigations and cause analyses that were conducted on adverse events in conjunction with the leaders from the area involved, including the quality department. Each hospital and the physician practice group had directors of risk management assigned. These directors consistently followed the organization's policies and procedures but there was variation in the tools and methodology used during this work. Leaders felt the process was sometimes ineffective and did not always decrease the likelihood of recurrence.

Leaders at the healthcare system expressed this process felt more like a regulatory requirement than a patient safety improvement strategy. The staff and providers who were directly involved in the adverse event were present for the analysis and action plan. This made some people feel it was a punitive process and sometimes resulted in defensiveness which distracted from the objective analysis of the event. Leader engagement in the process was low in some areas and corrective actions were not always tracked for completion and monitored for effectiveness. A clinical gap was identified between the healthcare system's policy and procedure and the guidelines and best practices for patient safety event management found in the literature.

The purpose of this performance improvement project was to implement a standard sentinel event management model in an acute care hospital that is part of a healthcare system, based on best practices and principles of high reliability organizations.

Methods

The project utilized the DMAIC performance improvement model which was the standard improvement model in place at the healthcare system. This model included five phases: *define*, *measure*, *analyze*, *improve* and *control* (Sokovic, Pavletic, & Pipan, 2010). The project scope focused on sentinel events as they are the subcategory of adverse events that tend to be the most serious. The project scope did not include the immediate medical response to the patient, disclosure to the patient or family, or claim or litigation management of the event. Additional performance improvement work for individual sentinel events, such as falls with serious injuries, occurred at the hospital and unit level at the same time as this project. Consideration was given to the overall healthcare system patient safety strategic plan when defining the scope of the project. The current patient safety strategic plan spanned six years. This project was considered to be foundational to future work, and the scope was chosen, based on the state of the culture of the organization at the time of the project.

The DMAIC performance improvement model was team-based. The DNP student, also referred to as the project leader, developed and led the performance improvement team to conduct this project. The team consisted of a performance improvement coach, an executive sponsor, and representatives from key stakeholder groups. These stakeholders included the patient safety reporting system administrator, directors of risk management, and leaders from the acute care hospital that had key roles in managing sentinel events. Input from front line staff and medical staff was gathered during the *define* and *improve* phases. The team leader was responsible for making sure the objectives of each DMAIC phase were met and the team remained within the project timeline. The executive sponsor helped the team overcome barriers and maintained the project status as an organizational priority. The performance improvement

coach assisted the team in selecting and utilizing the appropriate performance improvement tools to meet the project objectives. The stakeholder group representatives ensured the work was accurate and feasible and helped champion the changes to the process among their peers, staff and providers.

One acute care hospital was identified to participate in the DMAIC performance improvement project. The hospital was chosen based on multiple factors. The leadership team was committed to patient safety improvement and had expressed a desire to improve this specific process. They felt this project fit into the other activities that were underway. Additionally, the large size of the hospital and the high level acuity of the patient population increased the likelihood of a patient safety event occurring during the project. This was an important factor to consider because harm related patient safety events are low volume and there was a limited amount of time to pilot test the standard model during the performance improvement project.

Define **Phase**

The project team was established during the *define* phase, including executive level support. The team defined the problem and operational definitions were provided. The project description, scope, goal and timeline were all agreed upon. Performance improvement tools that were used during this phase of the project included the project charter, the Suppliers, Inputs, Process, Outputs, Customers (SIPOC), an affinity diagram of the voice of the customer, a project communication plan and project timeline (see Table 2). The project charter clearly outlined the scope of the project and was used to secure the necessary support and resources as well as obtain key stakeholder support.

The review of literature and evidence appraisal had been conducted by the project team leader but this information was not presented to the team until a later phase. Kurt Lewin's

Theory of Planned Change was used with the performance improvement team. Lewin's theory includes three phases that support change within a system. The first phase is called *unfreezing* and is essentially the preparation for the planned change. The second phase is *moving* and requires both a detailed plan to test the change and engagement of the people involved in the change. Lewin's third phase is called *freezing* and this is where the new state is stabilized and becomes part of the culture to be sustained over time (Lewin, 1997). Like most healthcare organizations, this healthcare system had a centralized and hierarchical organizational structure. This structure was identified as a potential restraining force to the project. The project leader focused on participatory management strategies such as effective communication and engagement during the *unfreezing* and *moving* stages to help the team let go of the old process and make the necessary changes proposed by the project (Shirey, 2013).

The stakeholders for the project included the Board of Trustees, with emphasis on the clinical quality and safety sub-committee, senior leaders, facility leaders, risk and quality directors, department leaders, frontline staff, patients, and patients' families. The project proposal was submitted to the Institutional Review Board and the health system for institutional approval. Data collection and reporting during the project was done in compliance with all organizational, state and federal regulations. The project leader was sensitive to the organizational policies related to external reporting of sentinel event information due to a lack of peer review privilege and tort reform in the state of Kentucky as well as Patient Safety Organization regulations.

The project was funded by the healthcare system and there were essentially no upfront costs associated with it. There were 14 people on the performance improvement team including the team leader. The project leader and team members were salary employees whose

participation in the project was supported by hospital and healthcare system leadership. The project required time from the project leader, the project team members, the patient safety reporting system administrator, and time from in-house legal counsel. The team held eight one hour meetings and one two hour meeting. Occasionally, the team members were asked to do work outside of meeting time. Meeting space was allocated by the hospital for the project. Approximately $200 was spent on the team celebration at the end of the project. The estimated time dedicated to the project can be seen in Figure 1. Development and implementation of the replication plan for the healthcare system was not included in the estimated project hours.

Team Member	**Estimated Project Hours**
Project leader	300
Director of risk management	80
Executive sponsor	25
Average project team member	15
Patient Safety Reporting System administrator time	20
Risk management team education	6
In-house legal counsel	5

Figure 1. Project Time Requirement. The project required time of the project leader, director of risk management, executive sponsor, project team members, patient safety reporting system administrator and in-house legal counsel.

Measure **Phase**

The team developed a deep understanding of the current sentinel event management process during the *measure* phase of the project. This was demonstrated using a process map. The team used an affinity diagram to identify barriers to the ideal sentinel event management process. The project leader continued to use change theory during this phase. Additional barriers to the implementation of a standard sentinel event management model were identified using Lewin's force field analysis tool (see Figure 2). Lewin's theory states that the restraining forces cannot be removed but they can be countered by increasing the driving forces (Shirey,

2013). The team reviewed available data on sentinel events to establish a baseline. The healthcare system had not previously collected data regarding the management of sentinel events so there was limited information available in that area.

Figure 2. Force Field Analysis. The force field analysis describes both the driving forces and the restraining forces of the change related to the project.

Analyze **Phase**

During the *analyze* phase, the team identified opportunities for process improvement using a gap analysis. The current policies and procedures were compared to the review of literature including the national and international guidelines. During this comparison, the team identified the specific clinical gaps in each major category of event management (see Table 3).

Improve **Phase**

The *improve* phase was the most time consuming phase of the project. In this phase, the team designed the new sentinel event management model to be tested. The clinical gaps identified from the literature were used to propose changes in the process for the model. Consideration was given to information learned during the earlier phases of the project. The

team used a process map to establish the future state process for sentinel event management. A toolkit was developed to support the new process to be tested at one acute care hospital. See Table 4 for an outline of the standard sentinel event management model and associated toolkit. All team members provided input to the future state process and toolkit which helped support the change. The team chose a timeframe for the pilot and developed communication and implementation plans for this phase. Data were collected for the project evaluation and later used in the *control* phase.

The standard sentinel event management model developed by the performance improvement team incorporated a planned, team response. The team consisted of an executive sponsor of the event, operational leaders of the area involved and the director of risk management. Standard tools were used by the event management team to assist with the identification, analysis and change responses to the events. The model utilized a series of three meetings. The first meeting was held as soon as possible and within 48-72 hours of identification of the event. The goal of the this meeting was to gather the known facts, ensure the needs of the patient, family, staff and providers were being met, and plan any immediate risk mitigation. The investigation of the event was planned and the people who were directly involved were identified for interviews. The investigation and analysis of the event were conducted to determine what happened and begin to determine why and how it happened. The team developed a flow chart time line and identified the individual and system factors that led to the event.

The purpose of the second meeting was the analysis. At this time, the team validated the findings of the investigation including what happened and why it happened. The causal and contributing factors were identified and tested. This meeting was attended by the core event management team and peer representatives of the clinical staff and providers who were directly

involved in the event. Some attendees were assigned homework to review literature and professional practice standards to help the team develop corrective actions to try to prevent recurrence of a similar event. Approximately two weeks later, the third meeting was held to facilitate change through the development of action items. The actions developed were specific, measurable, included a deadline and were assigned to a specific person. After the three meetings concluded, the director of risk management documented the work and produced an event summary sheet. This sheet was used to provide follow up to the staff and providers who were directly involved in the event. Additionally, the summary sheet was used to share the patient story within the facility and healthcare system for organizational learning. Lastly, metrics were developed to measure the use of the model to manage these events.

The DMAIC tools used in the *improve* phase such as the implementation and communication plan helped the team transition through the change. People affected by the change tend to be less resistant when the communication clearly establishes what is in it for them (Mitchell, 2013). The team members were assigned to parts of the communication plan allowing them to champion the change to their peer leaders as well as the staff and providers at the hospital. The pilot testing period lasted 3 months. The project leader audited the sentinel events that were reported during this time using an audit tool developed by the team (see Table 5). Audit results were presented to the team at the end of the pilot testing period. The team validated the audits and discussed the challenges faced during the pilot. Lastly, the team members made recommendations to mitigate these challenges for greater long term success. These recommendations were also considered in the replication plan.

Pilot evaluation plan.

Process and outcome metrics were used to evaluate the effectiveness of the pilot and can be seen in Table 6. The primary process metric was the percentage of sentinel events managed using the standard event management model. An additional process metric was the percentage of event summary sheets completed for organizational learning. Reports were obtained from the patient safety reporting system to determine the events that met criteria for the audit. All sentinel events reported during the pilot testing period were audited.

The outcome measure was the number of reported sentinel events per 1,000 adjusted patient days for the acute care hospital. This rate was not measured by the facility before this project. Due to the change in the sentinel event definition by The Joint Commission on January 1, 2015, the measurement began with 2015 data as the baseline and will be measured through the control plan. The long term goal was to decrease the rate of sentinel events each year after implementation of the standard event management model. See Table 7 for the project logic model which outlines the key resources, activities, metrics and the impact of the project.

Control Phase

During the *control* phase, the team developed a control plan to monitor the process over the long term. This plan included five metrics, some of which were measured during the project pilot (see Table 8). Additionally, the team handed the process off to the appropriate hospital leaders to oversee the standard process after the project completion. The team developed a replication plan to implement the process at other areas of the healthcare system (see Table 9). The team also held a celebration to recognize the team members and the positive impact the project achieved.

Results

A report from the hospital's patient safety reporting system was used to identify sentinel events for the testing period. Each event was audited retrospectively using the audit tool created by the performance improvement team to measure the project process metrics. The audits were reviewed by the performance improvement team members to ensure the audits were accurate. Any disagreements were discussed until there was full agreement. All sentinel events that were reported within the pilot testing period were managed using the standard event management model which met the project goal. No events were managed using the old process. Some events had all the steps completed during the testing period. Each of these events had a sentinel event summary sheet completed and turned in which also met the project process metric goal. For other events, the process was started but the management process was not able to be completed due to the time limitation of the pilot testing period. One event was not classified as a sentinel event but there was a desire to perform a root cause analysis; therefore, the new model was used for that event as well. This event was not included in the project audits since it was not a sentinel event.

The number of sentinel events, percentage of events managed with the standard model and the percentage of events with completed sentinel event summary sheets were provided to the team for evaluation. Although the toolkit was a helpful guide during the pilot, it was recognized that there were areas that needed further clarification and there were some key parts missing such as talking points for the executive sponsor, interviewing techniques, communication of homework assignments between the second and third meetings and guidance on implementing action items.

Discussion

There was no way to control the volume of events or the type of events during the testing period. However, the team was satisfied with the results and the opportunities to learn during the testing period. Each event that was managed during the testing period was different which provided more learning opportunities for the team. The risk director who facilitated the cause analysis meetings conducted an informal debrief of the executive sponsor and meeting participants at the end of most of the meetings. This included the front line staff and providers in attendance. This information was summarized and shared with the performance improvement team at the last team meeting.

The performance improvement team believed the new model was more successful than the previous approach to adverse events. During the pilot testing period, they felt the cause analysis team had a deeper understanding of what happened and why it happened which allowed them to link the corrective actions when using the new model. The team believed that the new sentinel event management model would help the hospital be more likely to prevent a recurrence of a similar patient safety event. At the beginning of the pilot, the team was concerned about how the frontline staff and providers would react to the people who were directly involved in the event not being included in the cause analysis meeting. However, the informal feedback from those caregivers was overwhelmingly positive during the pilot. For the most part, the interviews and investigations were thoroughly completed prior to the analysis allowing this transition to occur. The team also recognized that the team-based event management approach was more successful.

Challenges

During the pilot, the team faced challenges with meeting scheduling and coordination of the cause analysis meetings, timely access to the people directly involved in the event, and

education about the new process and cause analysis process in general. Adjustments were made to the toolkit during the pilot to make it a more useful tool. Small changes were made during the pilot to mitigate each of these challenges. During the pilot evaluation, the team reviewed the challenges and made formal recommendations to address them in order to sustain the process.

Limitations

There was no way to control the volume of events, the time in between events or the type of events to be tested. The volume of sentinel events was low which was expected by the team, but that did limit the opportunity to test all possible scenarios. Despite the low volume, the team was satisfied with the learning opportunities that the pilot test provided and felt that it was successful enough to make recommendations for long term use.

Recommendations

Based on the results of the pilot test, the performance improvement team recommended this process be sustained at the acute care hospital and replicated to the rest of the healthcare system. The team recommended some revisions to the toolkit. These revisions were not related to the core process steps. They provided additional clarification, instruction or made a tool easier to operationalize. A replication plan was developed for the system risk management and patient safety leaders to deploy within the organization.

Other healthcare systems who wish to implement an event management model should consider the use of standard improvement methodology and change management principles. The structure provided by the DMAIC performance improvement methodology and Lewin's Theory of Planned Change helped the team assess the culture at the hospital and determine what level of change they were ready for and what barriers may be faced during the change. The standard model may not have been implemented successfully if it had been presented to the hospital by

the project leader only and not by the team members. The team approach to the project and the pilot test of change before asking the leaders to commit to permanent change were keys to success that should be considered by other healthcare systems. The pilot test of change provided the opportunity for team members to see the changes and how the model worked before making a long term commitment. The pilot provided a comfort zone where the team members and stakeholders knew they would have the ability to provide input during the project evaluation and help influence the final process to be sustained and replicated. The team members were able to serve as change champions to others within the hospital and help transition to the new sentinel event model.

Conclusion

High rates of medical harm and preventable deaths have been demonstrated around the world (Runciman & Moller, 2000). Despite the international awareness and substantial efforts for improvement, little to no progress has been made in preventing harm to patients (Chassin, 2013). The response to adverse events in healthcare is the opportunity to learn what happened, why it happened and what may prevent a future occurrence of a similar event (Conway et al., 2011). Current adverse event management policies are heavily influenced by regulatory standards and litigation environments which may hinder prevention of future events (Hoppes et al., 2012). Efforts have been made to compare the successful safety records of high reliability organizations to healthcare to demonstrate long term organizational change (Kalisch & Aebersold, 2006).

The healthcare industry is experiencing unprecedented change and can no longer operate under the status quo. Operating expenses are going up and reimbursements are going down. Healthcare organizations cannot afford to simply talk about patient safety improvement. Internal

and external forces continue to add pressure for change that results in measureable improvement (Marshall, 2011). This project demonstrated that the leadership team was ready to make changes to the sentinel event management process to improve patient safety. The team remained engaged throughout the six month project and have committed to sustain the changes by utilizing the control plan.

The performance improvement team recognized that they will need to remain focused in the areas that faced challenges during the pilot testing period such as meeting coordination, access to the people directly involved, and ongoing education regarding cause analysis. The leaders now have a better understanding that the team-based event management model recommended in the literature can be more successful than the historical approach of risk management owning the process. The lessons learned during this project, along with the team's recommendations to mitigate the challenges, will be shared with the other areas of the healthcare system as they replicate the standard sentinel event management model. This foundational work within the healthcare system's patient safety strategic plan will contribute to the overall goal of eliminating preventable patient harm.

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Table 1

National and International Guidelines or Recommendations for Adverse Event Management

Title of Publication/ Guideline	Systems Analysis of Clinical Incidents: The London Protocol	WHO Draft Guidelines for Adverse Event Reporting and Learning Systems	Serious Safety Events: Getting to Zero	Patient Safety Handbook	Respectful Management of Serious Clinical Events	RCA^2: Improving Root Cause Analysis and Actions to Prevent Harm
Author/ Publisher & Year	Sally Taylor-Adams, Charles Vincent (2001)	World Health Alliance (2005)	Michelle Hoppes. Jacque L Mitchell, Ellen Grady Vendetti & Robert F. Bunting; American Society for Healthcare Risk Management (2012)	National Center for Patient Safety: A part of the Veterans Health Administration (2011)	Jim Conway, Frank Federico, Kevin Stewart & Mark J Campbell; Institute for Healthcare Improvement (2011)	National Patient Safety Foundation (2015)
Evidence Level and Quality*	Level IV, B	Level IV, B	Level IV, B	Level IV, A	Level IV, A	Level IV, A
Setting and Audience	Acute care, mental health, ambulances, primary care; use by risk managers or designated teams	All healthcare organizations in the world interested in healthcare improvement	All healthcare settings, risk management and patient safety professionals	Veterans Health Administration and associated caregivers	All healthcare settings; healthcare executives and other leaders internationally	All healthcare, facilities, patient safety professionals
Theory/ Back-ground	James Reason's Model of Organizational Accidents	Review of literature, expert opinion, surveys of countries with national reporting systems	Eliminating preventable harm is a core value of the organization; this should be a competency of risk and patient safety professionals	High Reliability Organizations learning from failures as a model	Drawn from fields of patient and family centered care, patient safety, service recovery, crisis management and disaster planning	Review of literature and expert opinion in patient safety
Operational Definition of Harm Related Event	Non-specific; use of the guidelines determined by the seriousness of the event	Adverse Event: injury related to medical management, preventable or not	Serious safety event: a deviation from generally acceptable practice or process that reaches the patient and causes severe harm or death	Adverse Events: untoward incidents, therapeutic misadventures, iatrogenic injuries or other occurrences directly associated with care or services provided by VHA	Serious clinical adverse event: for the most part preventable and results in permanent psychological or physical harm including death	Adverse event: untoward incident, therapeutic misadventure, iatrogenic injury, or other occurrence of harm or potential harm directly associated with care or services provided
Preparation & Planning	Response team should be established	Not addressed	Advanced planning, credible leadership, formalized planned team responses; crisis intervention	Interprofessional team approach	Plan & prepare: develop transparency, engage leaders, promote safety as a core value; use crisis management team; prioritize needs of patient, family and organization	Risk based prioritization system to determine which events should have cause analysis; planned team response, leadership and board support, define blameworthy events not eligible for RCA

Title of Publication/ Guideline	Systems Analysis of Clinical Incidents: The London Protocol	WHO Draft Guidelines for Adverse Event Reporting and Learning Systems	Serious Safety Events: Getting to Zero	Patient Safety Handbook	Respectful Management of Serious Clinical Events	RCA^2: Improving Root Cause Analysis and Actions to Prevent Harm
Investigation	Gather information, conduct interviews, establish chronology, draft flowcharts	Not addressed	Planned team response; information gathering including interviews, subject expert consultation, equipment involved, environmental factors, medical record review, relevant policy and procedure review, create timeline	Team performs investigation; caregivers directly involved are interviewed and asked for suggestions to prevent similar situations	Include frontline staff to prevent blame and promote learning; interviews, gathering information, internal reporting about what happened; recommendations if external reporting is needed	Begin within 72 hours of notification; fact finding, interviews, review of location, equipment/devices, etc., use triggering questions, involve patient and family when possible, develop timeline, flowchart
Analysis	Systems analysis (strategically not called root cause); identify care delivery problems and contributing factors	Cause analysis, regression analysis, systems analysis all conducted by experts trained to identify causes	Root cause analysis is common but others are acceptable	Root cause, aggregated root cause in focus areas; includes actual and near miss events; caregivers directly involved are intentionally excluded from this stage for objectivity; root cause analysis should begin immediately and be complete within 45 days	Root cause analysis performed by skilled/ trained person; should begin immediately and be completed within 30 days; should include patient, family and caregivers directly involved- extent of involvement should be case by case basis	Use of tools such as cause and effect diagram and five why's recommended, conducted by team; team does not include people directly involved in the event; should not strive to identify one root cause but instead should identify multiple factors, apply five rules of causation
Corrective Action	Prioritize contributing factors, establish responsibility, identify timeframe, identify resources needed, formal sign off for completion, identify date to evaluate effectiveness, action items categorized by local, department and organization and assigned accordingly	Recommendations for preventative strategies should be developed as soon as possible	Action plan should be developed to focus on prevention of reoccurrence; metrics should be developed to measure and report events, effectiveness of actions and sustainability of changes	Use actions to drive change, include human factors engineering	Establish board accountability for long term systems solutions after each root cause to ensure resolution, learning and improvement to the organization safety	Consider use of Veteran Administration's action hierarchy to identify strength of actions; team should not sensor themselves when developing actions; measure implementation and effectiveness with process and outcome measures
Communica-tion/ Feedback/ Dissemina-tion	Not addressed	Recommended actions to be disseminated rapidly through reports, newsletters, normal communication channels	Presentation of findings to leadership and board of directors; lessons learned shared locally, regionally or nationally depending on the organizational culture and whether or not there is pending litigation	Alerts, newsletters, communications, stories of improvement across the system	Multiple tools for internal and external communications	Staff, patient and families should receive feedback
Disclosure	Not addressed	Not addressed	Information from analysis should be shared with patient and family face to face by a designated person/group	Routine response to adverse events; detailed policy outlines procedures for this as VHA	At the time of the event but also consider ongoing needs- use support, empathy, resolution and learning	Not addressed here

Title of Publication/ Guideline	Systems Analysis of Clinical Incidents: The London Protocol	WHO Draft Guidelines for Adverse Event Reporting and Learning Systems	Serious Safety Events: Getting to Zero	Patient Safety Handbook	Respectful Management of Serious Clinical Events	RCA^2: Improving Root Cause Analysis and Actions to Prevent Harm
Just Culture	Separate event management from disciplinary procedures related to persistent performance issues by individuals; work to create open and just culture	Healthcare workers who report events or safety issues should not be punished; reporter identification should not be disclosed to third parties	Not addressed	Non-punitive, systems approach; focus on prevention not punishment	Based on James Reason's work, must eliminate blame for learning and healing	Do not involve people directly involved in the event in the analysis- only in the investigation and action item feedback
Organization -al Learning Strategies	Not addressed specifically	Alerts, safety reports, dissemination of lessons learned, common cause information should all be reported back to community of reporters routinely and rapidly	Dissemination of findings should be shared based on organization culture and philosophy; state laws should be considered; standard metrics for consistent reporting should be used	Involve all levels of staff in analysis, change and communication about events; improvement efforts are recognized locally and nationally; focus leadership on building trust and effective communication	Involvement of front line workers; communication from to top down regarding what happened and what was learned	Leadership oversight and measurement of the overall RCA process should occur; sample metrics provided

Note. *Evidence level and strength were appraised using the Johns Hopkins Nursing Evidence Based Practice model (Dearholt & Dang, 2012).

Table 2

Project Timeline

Phase/ Project Step	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Team meeting 1 Team meeting 2 *Define* Review of literature, evidence appraisal Team established; executive support Charter SIPOC Affinity diagram, voice of customer Project communication plan *Measure* Current State Process Map						
Team Meeting 3 Team Meeting 4 *Measure* Current State Process Map continued Data Collection related to baseline Affinity Diagram, barriers to ideal process *Analyze* Gap Analysis of literature and current state						
Team Meeting 5 Team Meeting 6 *Improve* Solutions Grid Future State Process Map Implementation Plan Communication Plan Pilot Testing Period						

Phase/ Project Step	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Team Meeting 7 Team Meeting 8 *Improve* Pilot Testing Period Results Evaluations *Control* Recommendations Control Plan Replication Plan Celebration!						

Table 3

Health System Adverse Event Management Policies and Procedures Compared to Review of Literature Best Practices

Adverse Event Management Category	Health System Policy and/or Procedure	Best Practice from Literature Review	Changes
Preparation & Planning	• Improvement demonstrated through the AHRQ Culture of Safety Survey • Transparency improving but still have a conservative stance due to litigation exposure in Kentucky • Facility risk director holds primary responsibility versus formal team; other leaders are pulled in on a case by case basis; most events have some involvement of facility administrator, chief nursing officer and medical director where available and applicable • Events identified through Patient Safety Reporting System, Daily Safety Call and internal communication channels; are currently exploring surveillance tools such as trigger tools • Staff and leader engagement is improving but there is still opportunity	• Create culture of safety with real transparency[a] • Form interdisciplinary team for immediate response with crisis intervention and planned response,[a, b, c, d, e] • Identify significant events through more ways than just voluntary reporting systems[e] • Engage all levels of leadership in safety improvement[a, c, e] • Engage all workforce in safety improvement[a, d]	• Planned team response • Improved transparency • Engagement of staff, providers and leaders

Adverse Event Management Category	Health System Policy and/or Procedure	Best Practice from Literature Review	Changes
Investigation	• Equal investigations performed for sentinel events and near misses but near misses of other adverse events may have a lower level investigation • Typically include best practice components including flow charts & timelines • Patient and family may not always be involved in the investigation if they do not request it or assert a complaint or claim • Caregivers involved are included in a respectful, non-punitive way • Investigations are sometimes delayed	• Perform equal investigations for actual and near miss events[c, e] • Consider interviews, medical record reviews, equipment inspection, subject matter expert consultation[a, b, c, d, e] • Interview the patient/family[a, e] • Involve the caregivers directly involved in the event with respect and in a non-punitive way[a, c, d, e] • Begin the investigation immediately[a, b, c, d, e] • Use flow charts when possible[b, e] • Develop a timeline/chronology[b, c, e]	• Job aide to ensure investigation is thorough and credible • Standardized work product

Adverse Event Management Category	Health System Policy and/or Procedure	Best Practice from Literature Review	Changes
Analysis	• Root and apparent cause analysis is typical; there is no standard use of aggregate reviews • Interdisciplinary team performs the analysis facilitated by the risk director; some team members are consistent across all analyses and others are pulled in on a case by case basis • Inconsistent methodologies used with the exception of The Joint Commission framework that is used for all sentinel events • Inconsistent methodologies/findings related to cause and contributing factors • Caregivers involved in the event are at the table during analysis • Patient and family are not included in the analysis but findings are sometimes shared • Timeline for completion varies • Internal communication of findings is inconsistent	• Root cause analysis and aggregate reviews[a, b, c, d, e, f] • Root cause analysis methodologies may include fishbone diagram, 5 whys and or The Joint Commission framework[a, b, c, d, e, f] • Look for probable cause but also identify contributing factors[a, b, c, d, e, f] • Findings should identify preceding causes to any human factors[f] • Deference to expertise versus authority[d, e] • Conflicting recommendations on whether to include the caregivers directly involved with the event[a, b, c, d, e] • Conflicting recommendations on whether to include the patient/family[a, e] • Complete within 30-45 days of becoming aware of event[a, d, e] • Communicate findings specifically to involved caregivers, front line staff/internally and to patient/family[a, c, d, e, f] • Communicate findings of aggregate reviews internally[a, c, d, e, f]	• Provide formal training for meeting facilitators • Standardize tools • Standardize work product including summary sheet • Documentation in the patient safety reporting system

Adverse Event Management Category	Health System Policy and/or Procedure	Best Practice from Literature Review	Changes
Corrective Actions	• Prioritization of causes and contributing factors occurs • Action items focus on prevention • Responsibility and timeframes for completion are assigned/established • Action items tend to remain at the local and facility level; analysis group is not empowered to assign system actions • Many action items are transient and focus on human factors; no standard process for ensuring long term solutions for every adverse event • Written policy requires a determination of how the action items are measured for effectiveness including consideration of quality measures; however, there is inconsistent follow through in practice • No standard process for monitoring organizational change • There are no standard metrics for measuring and reporting adverse events, action items or recurrence of events • Board of Trustees receives internal "Days Since" report that displays the number of days since an event that meet the National Quality Forum Serious Reportable Events criteria for each facility. At times, they receive limited information about why the event happened and what actions were recommended	• Prioritize cause and contributing factors and link corrective actions to each[b, c, d, e] • Focus action items on prevention of future events[a, b, c, d, e] • Assign responsibility[a, b, c, d, e] • Establish timeframes for completion[a, c, c, e] • Consider assignment at the local/unit, facility and system levels for true organizational change[b, d, e] • Consider actions based on feasibility, cost, resources needed, anticipated effectiveness[c, d, e] • Monitor for effectiveness and sustainability over time[a, b, c, d, e] • Develop metrics and standard reporting[c, e] • Board of Trustees should be accountable to long term system solutions for each root cause analysis[a, e]	• Documentation in the patient safety reporting system • Standardize the process for tracking open action items • Involve executive sponsor in tracking • Create system to measure effectiveness of action items

Adverse Event Management Category	Health System Policy and/or Procedure	Best Practice from Literature Review	Changes
Organizational Learning Strategies	• Inconsistent feedback loop to reporters and front line workers regarding reporting and event management • No formal reporting incentives or consequences • Reporting is non-punitive but oversight of this is needed to sustain • Need to develop process for aggregate reviews with communication of findings • Opportunity around participatory management with event management • Opportunity to improve organizational culture and structure to use deference of expertise • Opportunity for standard dissemination of alerts, lessons learned and success stories related to organizational change	• Create a feedback loop for patient safety event reporting for reporters and all front line staff[a, c, d, e, f] • Create incentives to report[c] • Ensure reporting is non-punitive[a, b, d, e, f] • Communicate aggregate trends and related information[a, c, d, e, f] • Use participatory management with analysis of events and corrective actions[c, d, e] • Develop a feedback loop from analyses to those involved in the event, front line staff and all levels of leadership[a, c, d, e, f] • Use a deference to expertise not authority during event management[d, e] • Provide routine dissemination of lessons learned and changes made at the local/unit, facility and system levels[a, c, d, e, f] • Generate alerts, newsletters, internal and external communications to share safety information[a, c, d, e, f]	• Event analysis summary sheet to be shared with people directly involved in the event and facility leaders • Summary sheets will be provided to system patient safety for shared learning • Designate resources for common cause analysis

[a]"Respectful Management of Serious Clinical Events," by J. Conway, F, Federico, K. Stewart, and M. Campbell, 2011. Retrieved from www.ihi.org

[b]"Systems Analysis of Clinical Incidents: The London Protocol," by S. Taylor-Adams and C. Vincent, 2001. Retrieved from www.imperial.ac.uk/

[c]"Serious Safety Events: Getting to Zero," by M. Hoppes, J. L. Mitchell, E. G. Vendetti, and R. F. Bunting, 2012. Retrieved from www.ashrm.org

[d]"Patient Safety Handbook," 2011. Retrieved from www.patientsafety.va.gov

[e]"RCA^2: Improving Root Cause Analysis and Actions to Prevent Harm," by J. P. Bagian, D. Bonacum, J. DeRosier, J. Frost, R. J. Fairbanks, T. Ghandi, H. Haskell, P. McGaffin, and F. Sheppard, 2015. Retrieved from https://www.npsf.org/?page=RCA2

[f]"WHO Draft Guidelines for Adverse Event Reporting and Learning Systems," 2005. Retrieved from www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf

Table 4

Sentinel Event Management Model and Toolkit Outline

Learning Responses from Events*	Sentinel Event Management Model & Toolkit Outline

Identification	Steps in Model:
	• Identification of event or potential event (system policy available)
	• Provide prompt and immediate care to patient and family
	• Contain risk of immediate recurrence
	• Initiate reporting and notification procedures (system policy available)
	• Preserve evidence
	• Conduct Meeting 1
	  ○ Attendees: executive sponsor, operational director and manager, director of risk management, medical leadership and subject matter expert as needed
	  ○ Purpose: ensure immediate mitigation of event is occurring or has occurred; ensure needs of the patient, family, staff and providers are being met; establish the known facts about the event and launch the investigation; and identify key people involved and how to contact them for interviews.
	  ○ Timing: should occur as soon as possible after event identification and no later than 72 hours after notification.
	• Conduct the investigation which includes interviews of the people directly involved, collection of physical evidence, assessment of the environment, equipment and devices, review of medical records, review of policies and procedures, review of literature, and consultation with subject matter experts
	Tools available in Cause Analysis Toolkit:
	• Root Cause Analysis Process Map
	• Sentinel Event Response Checklist
	• Meeting 1 Checklist
	• Who What When (WWW) grid
	• Event Timeline Flow Chart
	• Causal Factor Fishbone

Learning Responses from Events*	Sentinel Event Management Model & Toolkit Outline

Analysis	Steps in Model:
	• Conduct Meeting 2
	  ○ Attendees: the people who attended Meeting 1, peer representatives for the people directly involved in the event, and subject matter experts as needed. The executive sponsor sends the invitation to the meeting using a standard template.
	  ○ Purpose: to analyze the event to validate what happened and determine how and why the event happened. This involves identifying causal and contributing factors.
	  ○ Home work is assigned to some attendees to research literature and professional practices standards related to the causal factors and prevention of recurrence.
	  ○ Timing: should take place when the investigation is complete and no later than 30 days after notification of the event
	Tools available Cause Analysis Toolkit:
	• Root Cause Analysis Meeting 2 Invitation Template
	• Event timeline flowchart
	• Cause Analysis Sign In Sheet
	• Causal Testing Worksheet
	• Root Cause Analysis Meeting 2 Talking Points
	• Causal Factor Fishbone
	• Root Cause Review Homework Assignment Sheet

Learning Responses from Events*	Sentinel Event Management Model & Toolkit Outline

Change	Steps in Model
	• Conduct Meeting 3
	  ○ Attendees: the people who attended Meeting 2, quality improvement and subject matter experts as needed. The executive sponsor sends the invitation to the meeting using a standard template.
	  ○ Purpose: to develop an evidence-based action plan to prevent recurrence of a similar event or decrease the likelihood of patient harm if the event does recur.
	  ○ Timing: should take place within 1-2 weeks of Meeting 2 and no later than 45 days after notification of the event.
	  ○ Action items are specific, assigned to an owner, include a deadline, are tracked to completion and measured for effectiveness. Strength of actions are considered by the team.
	• A Root Cause Analysis summary sheet is completed that includes the event description, causal factors, key lesson learned and action plan. This is shared with the people directly involved as a feedback loop and shared with others in the healthcare system for organizational learning.
	Tools available in Cause Analysis Toolkit:
	• Root Cause Analysis Meeting 3 Invitation Template
	• Root Cause Analysis Meeting 3 Talking Points
	• Cause Analysis Sign In Sheet
	• WWW grid
	• Action Plan
	• Root Cause Analysis Summary Sheet

Note. *"Learning from Patient Safety Incidents: Creating Participative Risk Regulation in Healthcare," by C. Macrae, 2008, *Health, Risk & Society, 10*.

Table 5

Sentinel Event Management Model Audit Sheet

Date of Event: PSRS #:

Auditor: Date of Audit:

Key Element of Model	Completed YES	Completed NO	Comments
Meeting 1: Y = occurred within timeframe and achieved desired outcome including standard tools and documentation			
Investigation completed before Meeting 2 and flow chart prepared			
Meeting 2 invitation template used			
Meeting 2: Y = occurred within timeframe and achieved desired outcome including standard tools and documentation			
Assignments made to research solutions before Meeting 3			
Meeting 3 invitation template used			
Meeting 3: occurred within timeframe and achieved desired outcome including standard tools and documentation			
Event summary sheet completed			

Table 6

Pilot Evaluation Plan

Indicator	Measure/ Operational Definition	Rationale for Measure Selection	Data Collection Approach	Benchmark	Target Goal
Percentage of sentinel events managed using the standard event management model (process)	Numerator = number of sentinel events that were managed using the standard event management model Denominator = number of sentinel events that were reported during pilot testing period	Compliance with standard event management model is strongly desired and evidence-based to improve overall culture of safety	Sentinel event report will be produced from reporting system; events that did not have all of the steps of the standard process completed due to the time limitations of the pilot testing period will be excluded	No baseline or benchmark available; event management was not previously measured by the hospital or health system	100%
Percentage of event summary sheets used for facility or system feedback loop (process)	Numerator = number of sentinel event summary sheets used for facility or system feedback loop Denominator = number of sentinel events included in the audit for the percentage of sentinel events managed using the standard model	This is a high reliability principle that is key to organizational learning to prevent future occurrences of similar events	Sentinel event report will be produced from reporting system; sentinel events included in the audit for use of standard event management will be audited specifically for use of the event summary sheet	No benchmark or baseline available; event summary sheets not used in the past	100%

Indicator	Measure/ Operational Definition	Rationale for Measure Selection	Data Collection Approach	Benchmark	Target Goal
Sentinel Event Rate (outcome)	Number of reported sentinel events per 1,000 patient days	Decrease in sentinel events over time is desired	Sentinel event report will be produced from patient safety reporting system; patient days will be obtained from Finance department reports. Chart will be produced to demonstrate baseline rate, dates of implementation of standard event management model at each acute care facility, and rates during testing periods	Due to the change of definition of sentinel event by The Joint Commission on January 1, 2015, the 2015 data will be used as a baseline. This rate will be monitored long term	20% decrease each year post model implementation; consideration will be given to the fact that typically the rate goes up due to increased education, awareness, and focus before it comes down due to intervention

Table 7

Logic Model

RESOURCES	ACTIVITIES	OUTPUTS	SHORT-AND LONG-TERM OUTCOMES	IMPACT
Project PI team Project leader time Patient safety reporting system administrator time Education and Training time for risk management department In house legal time for applicable P&P revision and consulting related to patient safety work product	Complete literature search and evidence appraisal Conduct current policy and procedure review Perform gap analysis between current policy and procedures and evidence Establish performance improvement (PI) team Perform PI using DMAIC PI model Revise policies and procedures Education and training related to standard sentinel event management model to risk management department	Standard taxonomy related to sentinel events and related policies and procedures Standard policies related to response, communication/notification, investigation, analysis, corrective action and organization learning after sentinel events Educated risk management department	STG: Evidence-based policies and procedures related to sentinel event management Improved organizational learning after sentinel events LTG: Decreased sentinel events Decreased costs related to non-reimbursable care Decreased costs related to claims and litigation associated with sentinel events Improved compliance with accreditation standards associated with sentinel event management	Prevention of sentinel events Improved culture of safety Standard response to sentinel events Increased organization learning after sentinel events to decrease the likelihood of recurrence Improved communication and awareness around sentinel events to senior leaders and board of trustees Decreased costs from non-reimbursable care associated with sentinel events Consistent compliance with accreditation standards associated with sentinel event management

Table 8

Control Plan

Control Element	Metric/ Measure (Op definition)	Owner	Sampling Plan	Measurement Process (How?)	Goal Target	Reaction/ Response
Root cause analyses performed using the standard model	Number of root cause analyses performed with standard model divided by number of root cause analyses performed	Nursing leadership Hospital leadership Risk leadership	PSRS reports and or audits	Run reports in PSRS; audit 100% for first 60 days post implementation of model, then 50%	100%	Meet with cause analysis teams to identify and address barriers to following the desired process
Repeat sentinel events	Number of repeat sentinel events divided by number of sentinel events	Hospital leadership Nursing leadership	PSRS reports	Facility and system, level data; Run PSRS reports and calculate	Need to establish baseline in 2016	Review causes and action plans in aggregate; evaluate effectiveness of action plan

Control Element	Metric/ Measure (Op definition)	Owner	Sampling Plan	Measurement Process (How?)	Goal Target	Reaction/ Response
Action item completion	Number of root cause analysis action items completed or cancelled on or before deadline divided by # of root cause analysis action items	CNO, Hospital Directors	PSRS reports from actions module	System and facility level data; run PSRS reports and calculate	75% first year with gradual improvement to 100%	Ensure open action item reports are being reviewed by nursing leaders on routine schedule; Evaluate barriers and develop action plan
Number and rate of sentinel events	Number of sentinel events per 1,000 patient days or admissions/ visits	Nursing leadership	PSRS report and patient days data from Finance dept.	Pull sentinel events from PSRS and combine with patient days/admissions/ visits to produce a rate at the system and hospital/ division levels	Decreasing trend 1 year post model implementation	Assess causation of sentinel events; re-evaluate effectiveness of sentinel event management model

Control Element	Metric/ Measure (Op definition)	Owner	Sampling Plan	Measurement Process (How?)	Goal Target	Reaction/ Response
Evaluation of root cause analysis	Number of root cause analyses audited and found to be acceptable divided by the number of root cause analyses audited	System Director, Risk Management	Audit 100% of root cause analyses for 60 days post model implementa-tion; and then audit 50% annually	Report of cause analyses will be run in PSRS and events will be selected for audit. Audit will be conducted using modified TJC RCA checklist	85% for 6 months; then 100%	If goal not met, improvement plan will be established and more frequent monitoring may take place

Table 9

Replication Plan

What Action Will Be Taken? Resolution/Tasks (Use a separate line for each task)	**Assign Responsibility: Name of Individual Will Do This Task?**	**Planned Start Date**	**Planned Completion Date**	**How Will You Know This Is Done?**	**Enter date Completed**
Establish system wide timeline					
Communication Plan for stakeholders					
Final revisions to Toolkit and place on intranet					
For Each Facility:					
Establish Guiding Team					
Create shared change vision and strategy					
Develop communication Plan					
Complete gap analysis of current state to new process					
Complete barriers affinity diagram					
Develop implementation plan and timeline					
Develop education plan					
Establish go live date					
Implement system control plan					