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Root Cause Analysis to Improve Incident Reporting in an Ambulatory Care Setting

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Table of Contents

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Abstract

Problem: The subject organization (SO) is a Federally Qualified Health Center (FQHC) with an internally developed incident reporting system. The SO wanted to improve patient and employee safety using data from incident reports, but the incident reporting system did not give enough information to recognize patterns and develop countermeasures.

Context: Supervisors welcomed the opportunity to learn more about incident report follow-up and conducting root cause analysis (RCA). Members of the Safety Committee were eager for data to use to develop countermeasures to improve patient and employee safety. Decreases in employee injuries can save the SO from increases in the cost of worker's compensation coverage, so the SO leadership supported the project. The organization is covered by the Federal Tort Claims Act (FTCA) for malpractice insurance, but there is always a cost to preparing a defense against claims, so the Chief Financial Officer was supportive of a project that could reduce the chance of claims.

Interventions: The project was conducted in three stages. The first stage was to design a data collection tool for supervisors to use to guide incident report follow-up and document RCA. The second stage was to conduct training sessions for supervisors to teach them about organizational fairness, using a human-factors approach to evaluate incidents, how to conduct an investigation, and how to perform RCA. The third step was to send the data collection tool to supervisors to collect additional information about incidents. The data were extracted from the completed tools and presented to the Safety Committee.

Measures: The project measured effectiveness of the class in increasing confidence with doing RCA and conducting IR follow-up. The project also measured the effectiveness of the class in training supervisors to use the data collection tool correctly. A third measure was whether the

training and use of the tool improved the rate of RCA documentation in IRs when it was assigned to supervisors.

Results: The emphasis of the class training shifted due to the need to do remedial incident report training with the supervisors, therefore completion of the data collection tool was de-emphasized. Of the returned responses, most (95.7% for general incident and 98.4% for employee incident) respondents completed the section requesting an analysis of accident causes. Just over half of the respondents (54.3% and 51.6%) completed the analysis of workflow variance, and few (17.4% and 20.3%) provided a root cause. The comfort level with collecting additional information after an incident increased 24.9% and the agreement with understanding how to conduct RCA increased 46.5%. The completion rate of RCA documented in the IRs themselves increased slightly from 61.5% in the 24-week period before the intervention to 67.9% in 24-week intervention period.

Conclusions: While the project has not yet provided a direct benefit to the SO by producing countermeasures for incidents, the work done by the project lead and the Senior Vice President and General Counsel (SVPGC) will enable the SO to improve the incident reporting system. The project implies that more training is needed for supervisors to conduct follow-up investigations and to do RCA after an incident. The findings also imply that the organization needs to spread a culture of safety to all departments and to all levels. In addition to improving patient care by decreasing errors, establishing a culture of organizational fairness and safety may support other quality improvement efforts and help with employee retention.

Key words: incident report, root cause analysis, training, Federally Qualified Health Center, human factors, data collection tool, follow-up investigation

Section II. Introduction

Problem Description

The SO is a large community clinic organization dedicated to serving the medically underserved population with approximately 1700 employees at 30 locations in Southern California. The organization is an FQHC providing primary care and specialty care including cardiology, podiatry, behavioral health, dental care, optometry and ophthalmology, and adult and pediatric physical therapy. The SO is accredited by the Joint Commission in both Ambulatory Care and Laboratory Services. Accreditation by the Joint Commission is voluntary for community clinics and shows the organization's commitment to quality and safety. The organization is a teaching health center with a family practice medical residency program. Various incidents are reported via an online incident reporting system. In California, FQHCs are allowed to hire physicians, nurse practitioners, and physician assistants, collectively titled licensed independent practitioners (LIPs), as employees. Except for a few specialists, all LIPs at the SO are employees.

The Joint Commission's Ambulatory Care Standards (2017) and the Bureau of Primary Health Care (BPHC) Health Resources and Service Administration (HRSA) expect that the organization will collect and use data to improve the quality and safety of patient care. HRSA (2017) released a Program Assistance Letter outlining requirements for FQHCs to have risk management programs in place, including the use of IR data, to apply for FTCA coverage for malpractice claims.

The organization has an internally developed incident reporting system that allows employees to enter information about incidents occurring throughout the organization. Types of incidents reported include general or patient-related incidents, staff-related incidents, and

potential HIPAA breaches. Employees, including LIPs, are also encouraged to report near-miss events. General or patient-related incidents include events such as patients or visitors tripping in the clinic, patients expressing suicidal ideation, loss of vaccine due to temperature excursions, medication errors, delays in care, etc. Employee-related incidents include sharps injuries, repetitive motion injuries, employee falls, etc. Some, but not all, IRs require extensive follow-up and RCA by supervisors. While IRs of mandated abuse reports, patients who report suicidal ideation, and pediatric patients who fall or run into furniture are examples of incidents that do not usually require RCA, reports involving an error or delay in care will require an RCA. When an incident is reported, the department supervisor is assigned the responsibility of providing follow-up information, including results of RCA, if needed. Incidents involving LIP practice or quality of care issues are handled through a peer review process by medical leadership. RCA is not consistently done or reported, and the quality of additional information provided with the IR varies and is not aggregated or reported. Data are reported to the Safety Committee regarding location and type of incidents, but insufficient information was collected to plan strategies to reduce incidents.

Available Knowledge

In September 2017, a search of databases was conducted to find relevant articles for review. The PICOT question guiding the search was "in primary care settings (P), does use of root cause analysis (I) versus the use of current follow-up investigation methods (C) improve the quality of data for developing safety improvement suggestions (O) in a three-month period (T)?"

The database searches were all limited to publications in English from 2012 to the present. Searching CINAHL Complete using the terms *root cause analysis* and *safety* yielded 12 articles. Searching PubMed, using the search terms *root cause analysis* and *safety* yielded two

additional articles. Using the Cochran Library using the search terms *root cause analysis in healthcare* yielded one additional article. An additional search of the Joanna Briggs Institute Evidence-Based Practice Database using various related terms did not reveal any relevant articles.

Articles were considered for review if they contained a discussion of the effectiveness of (RCA) to provide ideas for process or systems improvement to increase patient or healthcare worker safety. After a critical review of the articles presented, eight were chosen for more detailed study. The articles were critically appraised using the Johns Hopkins *Research Evidence Appraisal Tool* (Dearholt & Dang, 2012). Individual critical appraisal ratings can be found in Appendix A, along with a summary of the articles. Articles were chosen which reviewed the effectiveness of RCA and solutions developed from RCA, which described an implementation of RCA or a similar process into a healthcare system or showed the systematic use of RCA in a clinical setting.

Hettinger et al. (2013) reviewed 334 RCA cases and 782 proposed solutions from IRs in a multi-institutional dataset and developed guidelines for RCA teams to develop more sustainable and effective solutions. Percarpio and Watts (2013) analyzed RCA data for 139 Veterans Administration Medical Centers (VAMC) and concluded that large centers conduct more RCA per year than small centers and that centers with less than four RCA per year have higher rates of postoperative complications. Kellogg et al. (2017) looked at incidents which were reportable to the state and required RCA follow-up. They reviewed 302 cases and 499 solutions and concluded that the most commonly proposed solutions were weak and that more work needed to be done to make RCA an effective tool.

Bowie et al. (2016) created a conceptual framework with tools for doing enhanced significant event analysis (SEA), which is similar to the RCA but starts the focus on the system to avoid the blaming and judgment that often occurs with RCA. They trained participants in a primary care setting and conducted pre-post surveys to determine the usefulness of the tool and self-rated effectiveness of doing enhanced SEA. Paul et al. (2014) looked at online incident reporting in an anesthesia pain service before and after training and implementation of RCA and reported decreases in rates of overall events (2.35 to 1.47), respiratory depression events (0.71 to 0.41), and severe hypotension (1.34 to 0.78).

Yadav, England, Vanderkolk, and Tam (2017) engaged a multidisciplinary team to undertake RCA to identify issues and implement solutions to improve water quality in a dialysis unit. The medical center achieved 100% compliance with regulatory standards. Sauer and Hepler (2013) used a multi-level RCA to determine common root causes for four types of medication errors in a large healthcare coalition. The coalition members determined that a number of common system failures at multiple levels of the health care system resulted in the errors but did not propose specific corrective actions. Dolansky, Druschel, Helba, and Courtney (2013) reported the use of RCA to enhance Quality and Safety Education for Nurses (QSEN) concepts in a case-study write-up of an incident of a BSN student making a medication error. The Dolansky et al. (2013) article detailed the use of RCA tools and spelled out recommendations to enhance communication and change the curriculum to reduce the chance for further errors.

Rationale

Two conceptual frameworks supported this project. The first was the model for improvement as described by Langley, Nolan, Nolan, Norman, and Provost (2009). The model

for improvement outlines three key questions to answer and uses a Plan Do Study Act (PDSA) cycle for project implementation, as illustrated by Appendix B. The first question asks what the organization is trying to accomplish, which guides the aim statement and the PICOT question. The second question, asking how the organization will know a change is an improvement, leads the organization to develop the measurement tools and plan the data analysis. The third question, asking what change will result in an improvement, leads the organization to plan the details of the project, including the development of a timeline and work breakdown structure. The PDSA cycle provides a guide for managing the project with small tests of change leading to fuller implementation of the project.

The second framework, developed by Kotter (2014), describes a network-like structure that can operate in conjunction with a traditional organization hierarchy to produce rapid change in an organization. The eight steps of acceleration are shown in Appendix C. The work of this project was done across departmental lines, so developing an informal network to drive the project was critical. Since the need for change was pressing, it was important to shorten the implementation timeline with early cultural buy-in to drive the change. The project manager does not provide direct supervision over the stakeholders needed to do the work of the project, so needed to lead by influence and generate support and enthusiasm for the work.

Specific Aims

The aim of this project was to have a 20% increase in compliance with documentation of incidents and root cause analysis by using a structured method to do follow-up after training and implementation of the follow-up tool over a three-month period. An additional aim was to improve supervisor IR investigation self-confidence rating scores by 20% after completing a training session.

Section III. Methods

Context

Supervisors who are assigned follow-up for incidents occurring in their departments were a key stakeholder group. The supervisors at the SO welcomed additional guidance and training to do follow-up investigations for incidents. Members of the Safety Committee who receive data about incidents were another stakeholder group. The Safety Committee members are asked to prioritize areas for improvement and had been asking for better data and richer information about trends and underlying reasons for incidents. The Executive Management Committee (EMC) was looking forward to a more evidence-based approach to process improvement and fewer risks to patient and employee safety. A long-term downstream effect of decreased incidents may be reduced fees for worker's compensation coverage, so the Chief Financial Officer was supportive of efforts to improve employee safety. Malpractice coverage is through the FTCA, so there will be no effect on malpractice insurance costs, but a reduction in errors decreases the likelihood that claims will need to be settled, representing a potential long-term cost savings as well. Support for the project was demonstrated by the letter of support shown in Appendix D.

Intervention

The project involved three phases, described more in depth in the discussion of the work breakdown structure and Gantt chart. The first phase included designing a data collection tool to enhance information gathered about incidents that could be affected by system improvements. After designing tools for both general and employee incidents, the project lead determined that the relevant information was already being collected for employee incidents, so only information from general incidents was collected in the third phase of the project. The tool is included as Appendix E.

The second phase of the project involved teaching groups of supervisors how to complete IRs, how to use a non-blaming algorithm to determine appropriate corrective action, and how to do root cause analysis. The presentation slides are included as Appendix F. The class curriculum included completion of a Qualtrics survey before and after the class and completion of data collection tools as they worked on two incident scenarios. The feedback from supervisors as they used the tools in class scenarios was used to improve the tools as a series of PDCA cycles. The feedback about what supervisors liked and didn't like about the class was used to improve the presentation throughout the training period. The focus of the information presented in the class shifted based on responses from participants as the project lead realized that many supervisors lacked experience in incident reporting, follow-up, and safety culture. The learning needs of the supervisors and the SO outweighed the need of the project, so the curriculum was modified. The pre- and post-class questionnaires are shown in Appendix G.

The third phase of the project involved sending the data collection tools to supervisors to provide structure to follow-up investigations and to lead them to do RCA of the incidents. The types of incidents the tool was used for included wrong paperwork given to patients, medication or vaccine errors, and minor patient injuries. The complex nature of LIP peer-reviewed incident reports required separate administrative procedures outside the job duties of supervisors and were therefore not included in this project. In future, the tool could be used for such investigations.

Gap Analysis

The SO's incident reporting system did not provide enough data to guide clinical teams to make improvements in workflow, documentation systems, space design, etc. to reduce errors. Supervisors in the organization were asked to provide follow-up information, including details

about the incident that had not been included in the initial report and results of RCA, but did not provide a consistent level of quality of feedback, and rarely provided results of RCA. Not all supervisors had been trained to conduct and document results of IR follow-up, including RCA. The Gap Analysis is shown in Appendix H.

Timeline and Work Breakdown Structure

The project was done in three phases, as described below and outlined in the attached Gantt Chart (Appendix I) and Work Breakdown Structure (Appendix J). The first phase of the project was to design and pilot a data collection tool to enhance the information collected through the incident reporting system. The project lead and other participants reviewed current literature and resources, including ECRI Institute and the Institute for Healthcare Improvement, to develop a taxonomy and to find common data elements collected with incident reporting systems. The project lead reviewed historical IRs and determined what additional data would have been useful to collect. The SO's worker's compensation carrier and other members of the Safety Committee were asked to provide input. IRs were also reviewed to develop a risk log, including likelihood, magnitude, overall rating, and controls for categories of risks. A framework for the risk log created is shown in Appendix K. The team chose to develop separate tools for employee incidents and general incidents. Preliminary data collection tools, including a place to document results of RCA, were developed and then revised using PDCA cycles during the supervisor training sessions. The types of incidents for the use of the tool were defined as patient injuries from vaccination or medication errors and delays in care, potential HIPAA breaches, and employee injuries. During the project implementation, the project lead decided to limit use of the tool to medication/vaccine errors, paperwork and filing mix-ups, and minor patient injuries.

The second phase of the project was to conduct classes for small groups of supervisors to teach them how to collect the information needed to fill out the data collection tool and how to conduct and document an RCA. Six classes were held to accommodate all supervisors who signed up for training. The class participants were split into groups with a mixture of clinical and non-clinical supervisors in each group. The first class contained several members of the medical leadership team and they were grouped together to facilitate a more meaningful discussion for the clinicians. After learning about RCA, organizational fairness, human factors, and safety culture, the groups were given two scenarios and role-play assignments. One scenario described an error in vaccine administration and the other described an employee injury. Each scenario had general background information and defined roles with background information for each role. The person chosen for the "supervisor" role was asked to interview other group members to learn more about the incident. Groups of participants used the scenarios to work through RCA and incident investigations and were to document the findings on the IR documentation tools. To determine the effectiveness of the class, the responses on the practice tools were scored to determine whether the participants were able to complete the tools successfully with the expected responses, including the correct documentation of RCA. The participants were also asked to complete a questionnaire regarding confidence with completing IR follow-up, including RCA, using a Likert scale at the beginning and the end of the class to measure whether the class increased participant confidence.

The third phase of the project included implementation of the data collection tool to develop recommendations for quality and process improvements. The project lead assigned responsibility for IR follow-up, including RCA, by sending supervisors the data collection tool to complete and return. While tools were developed for both employee incidents and general

incidents, only the tool for general incidents was used for the project, as many of the questions on the employee incident tool were already collected by the incident reporting system. Responses from the completed tools were aggregated and analyzed, and the results were shared with stakeholders. Key stakeholders included members of the Safety Committee, which was chaired by the project lead, and the SVPGC, the project lead's supervisor. During Safety Committee meetings, after reviewing incident data, the risk log was evaluated to determine whether the categories and ratings still apply, to evaluate the effectiveness of the controls (countermeasures), and to determine whether additional countermeasures were needed. The Safety Committee reviewed the reports from the data collection tools to determine whether countermeasures could be developed for root causes whose scores were high.

Responsibility/Communication Plan

The project lead prepares a monthly report for the SVPGC. During the implementation of the project, the project lead included a status report of the project's progress using the project overview format shown as Appendix L. The project lead also sent the project overview to the student's academic advisor at the end of each semester. The project overview showed milestone dates, a graph of progress toward milestones, and an overall percentage of total project completion. Any late tasks were highlighted on the form, along with the identity of the person(s) responsible for the late tasks. During the implementation and review stages of the project, the project lead also sent the SVPGC updates including learning derived from the project. The updates included results of a small literature search with a proposal for modifying IRs, an analysis of the responses from the classroom work, and an overview of the results of the data collection tool with a recommendation for next steps.

SWOT Analysis of Current State

The SWOT analysis is shown as Appendix M. Strengths included the fact that the SO had been using an incident reporting system that was developed in-house over ten years ago. The employees were familiar with the system and knew how to report incidents. The incident reporting system produced reports detailing types of incidents, location, and employee involved in the incident. The Safety Committee, which reviewed incidents and recommended focus areas for group improvement work, had several members with many years of experience with the SO and were very familiar with processes and systems.

A weakness was that the incident reporting system did not collect data on underlying reasons for incidents such as staffing conditions, the presence of a supervisor at the time of the incident, number of patients seen during the day of the incident, etc. Another weakness was that the organization had grown in recent years in the number of clinical sites and the number of employees, and had clinics and departments of varying sizes, so comparison of numbers of incidents across sites or over time was not helpful. Many of the SO's supervisors were promoted from within and did not have any post-secondary education. Their writing and analytical skills had not been developed, and IR completion was a challenge for them.

There has been increased focus and research done on healthcare safety in the past ten years, and there was evidence to support the use of enhanced incident reporting, including root cause, could lead to safety improvements, which was seen an opportunity. Another opportunity was that there were incident reporting systems available for use from companies with extensive healthcare incident reporting experience.

Incidents could lead to expensive worker's compensation claims or a rise in the SO's insurance premiums, which was a threat. Another threat was that errors could lead to legal

action and increased regulatory scrutiny. The difficulty in finding a taxonomy that meets the needs of an ambulatory care healthcare organization was another threat.

Budget and Cost Avoidance Analysis

The budget, shown in Appendix N, was calculated using hours of work and hourly wages of all participants to finish each step of the project. In addition, a contingency factor of ten percent was added for future work. The first year of implementation cost the organization $47,490, including the time to analyze and present the results. The second year it is projected to cost $30,687 and increase 4% annually in subsequent years. If the project continues, it is expected to save the SO $420,334 over four years with an aggregated 228% return on investment (ROI). The ROI was based on the cost of investigating and correcting HIPAA and vaccine/medication errors. The areas were chosen because both are under the supervision of department leaders that are committed to change and systems improvement. The Director of Nursing, the Director of Care Coordination, and the Manager of Health Information Management Services have shown interest in decreasing errors in their respective areas. It was assumed that the number of errors would decrease to 55 in quarter two of the improvement period and continue decreasing through subsequent quarters. It was also assumed that the ratio of HIPAA errors (12%) and vaccine/medication errors (88%) would remain constant and that training efforts would continue in the coming years. The cost avoidance/benefit analysis is presented as Appendix O and the ROI calculations are shown as Appendix P.

Study of the Intervention

In an evolving organization, it is difficult to discern whether change happens as a result of one intervention or whether other forces were at work during an intervention period. In the SO, partially due to the focus of the project lead on improving incident reporting, several things

occurred during the intervention period which may have impacted the project's outcome measures. The SVPGC did presentations for the LIPs, which encouraged them to complete IRs any time they suspected quality of care might be jeopardized. An issue arose with a contracted organization which caused several questions of care quality which were reported during the intervention period. The SVPGC also worked with the Information Technology team to change the classification of incidents to break out specific types of incidents. The discussion to follow and appendices point out when confounding factors may have caused change.

Measures

Measures used to evaluate the effectiveness included: responses from questionnaires completed by supervisors who attended training sessions, assessment of completion of sections of the IR follow-up tool during the training sessions, counts of IR RCA completion, and data collection tool completion. The number of countermeasures proposed resulting from the information collected from the IR follow-up tools was intended to be an additional measure, but the Safety Committee members did not generate any countermeasures, as discussed in the results section.

The original plan was to design very specific data collection tools for a few types of incidents. The project lead did not find good examples of incident reporting forms to suit a community clinic environment, so modified a data collection tool suggested by a representative of the worker's compensation insurance carrier. The tool proposed by the worker's compensation representative did contain elements the project lead felt were important, such as looking for unsafe acts, elements of human behavior, and unsafe conditions. The team members tasked with assisting to create the tools did not have anything else to offer, so the tool was modified to create two versions for the project. One version contained questions for general

incidents, and one version was for employee incidents. Both versions were used and modified during the classes, but only the data collection tool for general incidents was sent to supervisors to gain additional information after incidents occurred. The final data collection tool is shown as Appendix E.

Questionnaires administered to supervisors who attended the training were developed through Qualtrics templates and were adapted from a questionnaire used by Bowie et al. (2016), which had undergone pilot testing by the researchers. The questionnaires are shown as Appendix G. Quantitative comparisons were made to results from two of the questions asked before and after the training. Responses to the outcome measure questions were felt to be truthful because respondents were very frank in their comments about their impressions of the class. Additional open-ended questions were added to both questionnaires to guide the project lead to cover the topics the class participants were most interested in, and to improve the class for future sessions. The responses to the additional questions were analyzed real-time and were used to generate PDCA cycles to improve the class.

Supervisors who attended training sessions were asked to participate in a group exercise and use the knowledge gained in the class to complete data collection tools about scenarios used for the exercise. The returned data collection tools were assessed for completion of each section. A tally sheet was used to count completed sections from each returned tool, and the scores from each section were written on the top of the tool so the count could be verified quickly to validate correct results. Copies of the data collection tools were also distributed to participants to harvest suggestions for improving the tools, resulting in PDCA cycles of improvement for the data collection tools.

During the third phase of the project, the revised data collection tool was sent to supervisors after incident or HIPAA breach reports were filed. The types of incidents for which the tool was used included misfiled documents, paperwork being handed to the wrong patient, suspicious or missing lab tests, patient injuries, and vaccine or medication errors. The data collection tool included a specific place to document root cause and countermeasures. Responses from the data collection tools received from employees were coded and extrapolated to provide data for quantitative and qualitative analysis. Using information provided by the supervisors in free text, some of the responses were re-coded to provide a more accurate representation of the incidents. The free text answers to the data collection tool questions "what are the reason for variance from correct process" and "what was the root cause" were coded by the project lead, who has prior experience with coding free text answers as a market research analyst. No secondary coding was done to validate the interpretation due to time and budget constraints.

Analysis

The data were collected by various means and analyzed. Quantitative data were reviewed for patterns and trends, particularly with comparison of pre- and post- intervention scores. The response rates from surveys and data collection tools along with a discussion of responses are presented here.

Pre- and Post-class Questionnaires

Participants were asked to complete questionnaires before and after the training sessions. Participants rated their comfort level with their ability to collect additional information after an incident using a seven-point scale ranging from extremely comfortable to extremely uncomfortable. Class participants were also asked to use a seven-point scale to rate their

agreement with the statement “I fully understand how to undertake and lead a Root Cause Analysis”, with response choices ranging from strongly agree to strongly disagree. The pre-class survey was completed by 97% of participants present at the beginning of the class and the post-class survey was completed by 95% of those present for the entire class as shown in Appendix Q. Three practitioners were unable to complete the class due to scheduling conflicts.

Response Tool Completion During Class

Data collection tools were distributed to class participants who were asked to complete them based on the results of the role-play scenarios. Completed tools were returned by 61.3% of class participants for the general incident scenario and 85.3% for the employee incident scenario. Since the general incident was related to a vaccine error, it is possible that some of the non-clinical participants did not feel comfortable completing the form. The participants were also given a second copy of each data collection tool and were asked to provide feedback to make the tools more clear or useful. Suggestions to improve the tool were received from 32% of class participants for the general incident tool and 40% of participants for the employee incident tool. The suggestions were used to generate small PDCA cycles of improvement. Response rates from class participants are shown in Appendix Q.

The data collection tools given to class participants had two sections of questions. One section looked at causes of incidents, including sections for unsafe acts, human factors, unsafe conditions, and causes of unsafe conditions. The next section asked the respondents to describe the correct workflow, the variance from the correct workflow, and the reason for the variance. The class participants were verbally asked to document the root cause and proposed countermeasures to prevent future incidents. The data collection tools were assessed for completion of each section. Since completion rates were low, the responses were not assessed

for correctness. However, the verbal report-outs were analyzed for content and a summary was presented to the SVPGC. The completion rate for each section is shown in Appendix Q. The scores should give an indication of whether the class was successful in training supervisors to use the data collection tool. During the class sessions, however, it became clear that the discussion and knowledge-sharing parts of the exercise were of more value to the supervisors than completing the tool, so the project lead decided not to emphasize tool completion at the expense of robust discussion.

To conclude the exercise each group reported out their process and findings. After the all the classes were conducted, a summary report was given to the SVPGC noting none of the groups suggested a corrective action for an employee who was wearing unsafe shoes that were in violation of the dress code, and who was on her phone when she slipped in water on the floor. In contrast, several of the groups suggested that an employee who was working without support under undesirable circumstances should be disciplined. In the scenario, the employee missed a step in the vaccine administration process, allowing the employee to administer the wrong vaccine. The report to the SVPGC suggested that more work needs to be done to change the culture of the organization to look at systems issues as well as employee behavior.

Responses from Incident Reports

It is the practice of the SVPGC to assign RCA to supervisors when further information is needed to get a complete picture of the incident and to generate countermeasures. A review of incident reports was completed to tally the number of incidents to which RCA was assigned and the completion rate by supervisors. A review was completed for reports submitted during the measurement period and for a similar timeframe prior to the intervention for comparison. The response rates for RCA increased by 6.4% during the measurement period (Appendix S).

The newly developed data collection tool was sent out by the project lead to generate additional information about the incidents and to guide the respondents to think about systems and process issues and human factors influencing employee behavior. The data collection tool also prompted respondents to examine the variance from expected work processes that may have contributed to incidents and to document root cause analysis and countermeasures adopted to prevent future incidents. The tools were sent out for 120 unique incidents and returned for 44 incidents, a 37% response rate, as shown in Appendix T. Response rates for HIPAA-related incidents were higher (55%) than for general incidents (22%). The project lead is responsible for closing out HIPAA reports. and sent reminder emails asking supervisors to provide additional information and complete the data collection tools. The SVPGC determined that enough information was uploaded into incident reports and closed out general incidents without requiring the information to be documented on the data collection tools. Due to staffing changes at the SO, at the conclusion of the measurement period, a change was made to track and report close-out rates of HIPAA-related incidents. Had the change been made earlier, the data collection form return rate from HIPAA-related incidents may have been higher

It should be noted that 44 responses were received from 37 unique individuals, but only 13 of the 37 had attended the training sessions. Attendance at the training sessions was voluntary, so only some members of the target audience received training. In addition, in a few cases, the supervisors asked the front-line employees involved in the incidents to complete the tool rather than interviewing all involved parties and completing the tools themselves. The incorrect responses being chosen by the supervisor or front-line employee and changed by the project lead to reflect a more accurate picture of the incident is a weak point in the data analysis.

The data collection period extended longer than originally planned. The Safety Committee only meets once a quarter and the project lead wanted to collect as many responses as possible to provide robust results for the committee to evaluate. The corrected responses were entered into a spreadsheet to generate reports presented to the Safety Committee for review. The responses were broken out by general incidents and HIPAA breaches to see if there were differences, as shown in Appendix T and described in the results section.

The number and type of incidents reported the SO's incident reporting system in the 24 weeks prior to the intervention were compared to the number and type of incidents reported during the 24-week data collection period, as shown in Appendix U for general incidents and HIPAA breach reports. The categories do not meet the needs of the reporters, as demonstrated by a 37% rate of "other" chosen across the two time periods. "Other" is the highest category chosen for incidents. There is no mechanism for changing the category once the IR is filed for reports filed in the current reporting system. The incidents were reviewed by the project lead and the categories chosen by the employees are not consistent for various types of incidents. For example, employees completing incident reports selected various categories to report filing of mandated reports of domestic violence, elder abuse, and child abuse. During the measurement period, a category was added called "mandated reporting". Another category was added for 911 calls, which had previously been captured under various other areas, including emergent condition and "other". The number of reports filed increased from one period to the other, but because of the two new categories, the numbers within some categories are not comparable.

Ethical Considerations

As identified by Nicolini, Waring and Mengis (2011) and Iedema et al. (2005) changing a culture of an organization to view IRs and subsequent RCA investigations as the means to find

areas of improvement is a difficult task that requires sensitivity. Wu and Steckelberg (2012) wrote that the healthcare worker involved in an incident might also suffer the same symptoms as patients with acute stress disorder and needs caring support. It is important to conduct RCA investigations carefully, thoroughly, and with sensitivity. Iedema et al. (2005) noted that involving clinicians in the process of root cause analyses can lead to anxiety, shame, and expressions of defiance.

During the training sessions, all identifying information for patients and employees were removed so that the training did not violate confidentiality. The project was implemented within the Code of Ethics for Nurses (American Nurses Association, 2015), particularly provision one, which includes practicing with compassion and respect. The project itself promoted provisions four and five by enhancing supervisors' ability to take actions to provide optimal, safe care. The training for supervisors was designed to promote the Jesuit values of the University of San Francisco, particularly emphasizing the respect and promotion of dignity for everyone. The project was not research, and did not require approval of an internal review board, as seen in Appendix V. There have been no conflicts of interest identified among any of the project participants.

Section IV. Results

Pre- and Post-Class Questionnaires

One of the goals of the project was to have an increase of 20% in top two scores for confidence in conducting follow-up investigations and doing RCA from class participants. As seen in Appendix R, the self-confidence rating scores increased 24.9% for conducting follow-up investigation and the agreement with understanding how to conduct RCA increased 46.5%. The project was successful in achieving this goal.

Response Tool Completion During Class

Response rates from class participants are shown in Appendix Q. The tools themselves had response rates of 61% from the general incident scenario and 85.3% from the employee incident scenario. As discussed, the employee incident was more familiar to all supervisors, which may have encouraged them to complete the tool. Of the returned responses, most (95.7% for general incident and 98.4% for employee incident) respondents completed the section requesting an analysis of accident causes. Just over half of the respondents (54.3% and 51.6%) completed the analysis of workflow variance, and few (17.4% and 20.3%) provided a root cause. The goal for correct completion of the data collection tool after the class was 90%. Since not all sections were completed by at least 90% of class participants, the goal was not met.

Responses from Incident Reports

Another goal was to have a 20% increase in use of a structured method to do follow-up, including RCA after the training period. The project lead did a manual count of incidents for which RCA was requested by the SVPGC and the number of those for which RCA was completed. The number of data collection tools sent versus the number returned was also compared to the completion rate for RCA performed as shown in Appendix S. The percent of completed RCA increased 6.4%, from 61.5% to 67.9%, which was below the target increase. The completion rate from the data collection tools was 37%.

The data collection tool responses from incidents showed that just over half (52.3%) took place in the middle hours of the 4-hour shift, which is defined as mornings or afternoons. Over half of the incidents (61.4%) occurred when the supervisor was present, and 84.1% of the incidents occurred when there was optimal staffing. None of the respondents reported that the employee had not received training to perform the task. Many respondents indicated the

employee or patient involved was not paying attention to hazards (40.9%) or were trying to gain or save time (20.5%). When describing the reasons for variance from the expected workflow, lack of attention (29.5%) and working too quickly (18.2%) were the most common reasons given.

It is notable that, as shown in Appendix T, 17.2% of responses for HIPAA breaches had "shared PHI" written in as the unsafe act that contributed to the incident. In those instances, inadvertent sharing of PHI was the actual incident being reported and should not have been selected as a contributing factor. In response to the high incidence of incorrect responses on the data collection tools, the project lead used any free text information to re-code the responses. In addition, since responses to the variation from correct process and explanation of the root cause were free-text answers, responses were coded to report common themes. The responses were not validated due to time and budget constraints

Many of the responses for RCA were not true root causes. Lack of attention was listed as the root cause for 55.2%, and high volume of work was listed for 17.2% of HIPAA errors. The completion rate of RCA documented in the IRs themselves increased slightly from 61.5% in the 24-week period before the intervention to 67.9% in 24-week intervention period, as shown in Appendix S. The 6.4% change fell short of the 20% goal.

The final goal was to have at least a 10% increase in countermeasures proposed because of data reported to the Safety Committee. When the data tables were presented, and volunteers requested for follow-up, the group members did not feel empowered to propose a solution to leadership. The most notable result was that in 40.9% of incidents the employee was not paying attention to hazards, and in 20.5% the employee was trying to gain or save time. The responses on the tools show a lack of awareness of RCA, safety culture, human factors approach, and other

topics covered in the training. The members of the Safety Committee suggested the underlying issue is the organization's lack of a culture of safety, but none of the group members volunteered to take on the challenge of changing the culture of the organization.

Section V. Discussion

Summary

Overall, the project did improve incident reporting at the SO. The specific aim of the project was to have a 20% increase in compliance with documentation of incidents and root cause analysis by using a structured method to do follow-up after training and implementation of the follow-up tool over a three-month period. The compliance with RCA completion was only partially met, at 6.4% increase. An additional aim was to improve supervisor IR investigation self-confidence rating scores by 20% after completing a training session. The goal was met, as described.

Some unexpected things also helped to improve incident reporting at the SO. The first class included several members of medical leadership. They were inspired by the class to invite the SVPGC to do a presentation to all LIPs in their team meetings to discuss the importance of incident reporting and how to decrease liability for the organization. The SVPGC also presented the material to members of the Director Council and to the Governing Board of Directors. Due, in part, to the classes and the SVPGC presentation, the number of IRs increased over the measurement period versus the same amount of time prior to the intervention.

Next Steps

The literature searches done by the project lead to research the PICOT question and to prepare for the class were shared with the SVPGC, who requested a proposal from the project lead to change the IR system. At the request of the SVPGC, the IT team has agreed to modify

the online IR format. The articles found to describe an IR taxonomy (Chang, Schyve, Croteau, O'Leary, & Loeb, 2005) and IR coding (Mansfield, Caplan, Campos, Dreis, & Furman, 2015) will guide the IR system revisions. The results of the DNP project will inform leadership as the organization revises the IR process. Specifically, key members of the leadership team need access to change responses to more accurately reflect the categories of incidents, so raw data and subsequent reports are more accurate. Another proposed change to the IR format will be a specific set of questions sent to supervisors for certain incidents, such as whether human factors played a part in the incident, whether the employee has a history of careless or reckless behavior, and whether systems issues played a part in the incident. A third proposed change is to allow the SVPGC or the project lead to score the incident using the Joint Commission's SAFER matrix format (The Joint Commission, 2018) and to code the incident using a coding system such as the one proposed in the risk register by Mansfield, Caplan, Campos, Dreis, and Furman (2015). Data from the incident reporting system are presented quarterly to senior leaders. The Safety Committee members also receive reports and use them to evaluate whether the risk management plan ratings need to be adjusted and whether additional countermeasures need to be developed for areas whose risk scores have increased.

Lessons Learned

One of the key findings was that using a process for self-selection will not always result in the appropriate people being trained to do specific job duties. The data collection tools sent to supervisors after incidents were returned by 37 unique individuals, but only 13 of the 37 had attended the training sessions. Other findings were that supervisors are not always trained to complete IRs when they were oriented, and that licensed independent practitioners did not have an understanding of the importance of reporting quality of care issues.

Interpretation

The findings from this project were consistent with Kellogg et al. (2017), in that more work needs to be done to make RCA an effective tool at the SO. Unlike Bowie et al. (2017), the training did not demonstrate an increase in systems thinking on the part of respondents, perhaps because the tool was sent out to supervisors who not had received training in how to view incidents and do an RCA. The project lead did provide hard copies of reference materials, including tools to conduct RCA (CMS, 2014), the Organizational Fairness Algorithm (Frankel, Leonard, and Shapiro, 2018), and the Human Factors Approach (Mahajan, 2010) to class participants, and made the materials available online to all supervisors. Unlike Paul et al. (2014) and Yadav et al. (2017), the SO did not experience a decrease in incidents resulting from the RCA process being emphasized for incident report follow-up. It is possible that institutionalizing training and the use of RCA may result in safety improvements.

The project did influence the SVPGC to initiate a request for change in the incident reporting system, which was a positive outcome. The anticipated outcomes were not met because fewer than expected supervisors received the training and those that did come to the class reported a need for more elementary knowledge of incident reporting and follow-up than the project lead had anticipated. It also became clear during the class sessions and the measurement period that the organization should establish the culture of safety needed to make the project successful.

The cost to the organization was significant in supervisor time to attend the training and to complete the investigation and return tools after incidents. If the project is expanded so the training reaches the target audience and succeeds in changing culture, then the result will be a long-term decrease in time spent following up on employee errors. The supervisors stated the

group work was the most valuable part of the class, suggesting that an online presentation of didactic material would be less valuable. The ROI calculation included plans for continued training sessions for supervisors, and the financial analysis assume the project will eventually result in decreased errors. It could be argued that the time spent by the project lead researching the PICOT question, preparing for and leading the classes, reviewing incidents, and analyzing responses could have been spent working directly with supervisors to do RCA at the sites, however the overall incident reporting system will be stronger for the work done, and time spent with individual supervisors is only valuable for as long as the supervisor remains employed by the SO.

The findings of this project will guide the SO leadership to improve the incident reporting system based on a review of evidence. Furthermore, the SO leadership should examine the culture of safety of the organization and ensure that it extends to each department and team. The SO may wish to explore mechanisms to achieve a safety culture, such as TeamSTEPPS (King et al., 2008). One of the assumptions is that the tool and RCA approach can be used for more sensitive incidents that would have greater implications for patient safety. Any gains achieved by improving care transitions or follow-up will have a greater impact on ROI with increased cost-avoidance.

The conceptual frameworks used were valuable for project design and for giving the project the impetus it needed to succeed. The model for improvement (Langley et al. 2009) gave the project planning the structure needed to create a successful and meaningful project. The eight steps of acceleration from Kotter (2014) showed the project lead how to gain energy and support for moving the project through to completion. The project lead shared the vision of the

project with the SVPGC and other leaders as well as potential supporters from other departments to form a guiding coalition and create a sense of urgency about the project.

The project has increased organizational awareness of the need for IR training for LIPs and supervisors. It has also provided structure for suggested improvements to the incident reporting system. While the project did not directly provide improvements to patient safety by producing countermeasures, it set the stage for further change needed in the SO. The project lead has spread knowledge about incident reporting. risk management, and how to conduct evidence-based improvement projects through several committees in the organization. The project lead is hopeful that additional work will be done to move the organization toward a culture of safety.

The project was improved from the original plan due to use of the PDSA method. The data collection tool was enhanced from feedback from the class instead of being pilot-tested in the planning phase. The class curriculum was modified to reflect the learning needs of the participants to provide more basic information about incident reporting and less focus on conducting root cause analysis. The information collected from the data collection tools needed to be reclassified for accuracy. The class curriculum was revised to meet the needs of the class participants, and the data collection period extended longer than planned. The variation log is shown as Appendix W.

Limitations

A limitation of this project included competing attention for other projects, both ongoing and urgent. To keep attention on the project, the project lead used opportunities to bring the evidence pointing to the value of the project to leadership's attention. Not all supervisors were able to attend the training sessions, and some follow-up tools were assigned to supervisors who

did not receive the training. The project would have been strengthened by making the training mandatory for all supervisors who respond to incident reports. The project lead found opportunities to talk with some of the supervisors who had not signed up for a training session to introduce the use of the tool and the importance of RCA, using the concepts found in Kotter's (2014) framework. The class materials were made available to all supervisors. To please the project lead, supervisors may have responded to survey questions in the way they thought would help the project instead of responding honestly. The project lead reinforced the need for honesty in survey responses in the written and verbal survey instructions. Using professional software like Qualtrics made the project seem more official and should have encouraged a professional evaluation and response from participants.

Unfortunately, the training did not have the desired impact on the ability of supervisors to do root cause analysis and look beyond blaming individual behaviors for errors. Among supervisors who did and did not attend the training, human error was explicitly or implicitly called out as the reason for many of the incidents.

Conclusions

While the project did not provide an immediate benefit to the SO by producing countermeasures for incidents, the work done by the project lead and SVPGC will enable the SO to improve the incident reporting system. The literature supports a more structured approach to gathering information for incident report follow-up and coding the responses to provide more meaningful reports (Chang, Schyve, Croteau, O'Leary, & Loeb, 2005; Mansfield, Caplan, Campos, Dreis, & Furman, 2015). The project findings imply that more training is needed for supervisors to conduct follow-up investigations and to do RCA after an incident. The findings also imply that the organization needs to spread a culture of safety to all departments and to all

levels. In addition to improving patient care by decreasing errors, establishing a culture of organizational fairness and safety may support other efforts and help with employee retention.

Findings from the project suggest that more work needs to be done to provide evidence-based incident reporting guidelines for ambulatory care. HRSA and partners are providing more resources for FQHCs to enhance their risk management systems and access to Patient Safety Organizations so organizations can learn from others about safety improvements. FQHCs should take advantage of the resources provided whenever feasible. Health professionals should be encouraged to learn more about risk management and evidence-based improvement projects, regardless of their length of service in healthcare.

Section VI. Funding

All costs were absorbed by the SO. The University of San Francisco provided the use of Qualtrics and the Gleason Library. There were no sources of outside funding for this project

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Section VIII. Appendices

Appendix A

Evaluation Table

Citation	Conceptual Framework	Design/ Method	Sample/ Setting	Variables Studied and their Definitions	Measurement	Data Analysis	Findings	Appraisal: Worth to Practice
(Hettinger et al., 2013)	None mentioned	Non-experimental	334 RCA cases, 702 solutions, 44 participants from various departments in multiple institutions	Solution categories - Compliance Check, Contact Third Party, Counseling, Disciplinary Action, Forms & Paperwork, Institutional, Information Technology (IT) Structure, Physical Environ-ment, Policy, Process, Review, Risk Manage-ment, Training	Internal rating of effectiveness of solutions identified from RCA	Means and Standard Deviations of scores	Developed guidelines for RCA teams to produce systems-level sustainable and effective solutions	**Strengths:** Large dataset **Limitations:** Retrospective review, used interviews not observations **Critical Appraisal Tool & Rating:** John Hopkins III B*

(Percarpio & Watts, 2013)	None mentioned	Non-experimental	RCA data for 139 VA medical centers	PSI rate – Mean Patient Safety Indicator Rate	PSI scores for low, medium, and high RCA groups	ANOVA for patient safety indicators	Large centers do more RCA than small centers, centers with < 4 RCA per year have higher rates of post-op complications	**Strengths:** Large dataset **Limitations:** No control group, self-reported RCA data **Critical Appraisal Tool & Rating:** John Hopkins III B*
(Kellogg et al., 2017)	None mentioned	Non-experimental	302 RCA cases reviewed, 499 solutions categorized in a large tertiary care academic medical center	Error severity category using National Coor-dinating Council for Medical Error Reporting and Prevention criteria	Types of root causes and solutions proposed	Qualitative analysis	The most commonly proposed solutions were from the weakest action categories	**Strengths:** Systematic review of reported RCAs **Limitations:** Single institution, only the most severe incidents were examined **Critical Appraisal Tool & Rating:** John Hopkins III C*
(Paul et al., 2014)	None mentioned	Quasi-experimental	35,384 patients receiving care from acute pain service in 3 hospitals	PCA – Patient Controlled Analgesia, adverse events	Adverse events	Chi square, Fisher exact	Overall event rate (2.35 to 1.47), respiratory depression (0.71 – 0.41), severe hypotension (1.34 – 0.78) decreased after	**Strengths:** Large # of patients, online reporting system **Limitations:** Potential for Hawthorne effect, safety

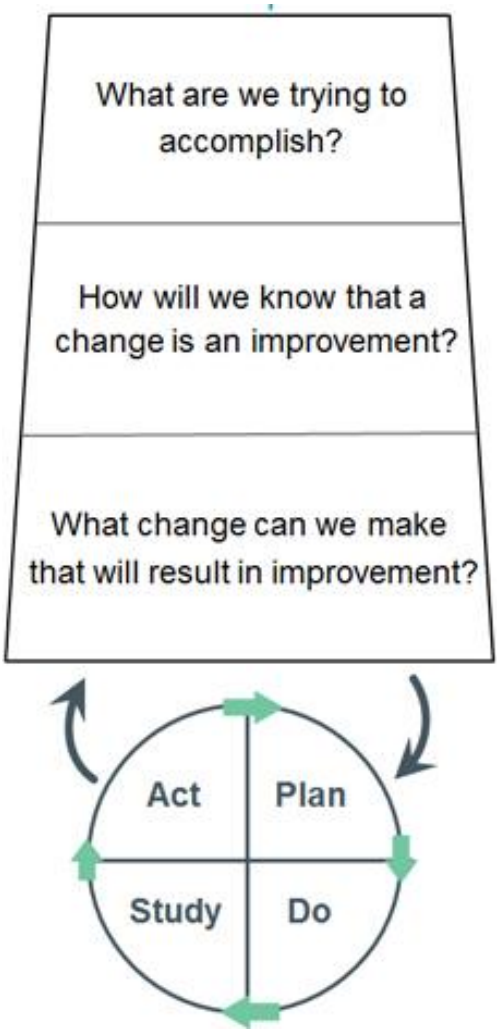
							implementing RCA	emphasis may have happened without RCA implementation **Critical Appraisal Tool & Rating:** John Hopkins II B*
(Bowie et al., 2016)	Enhanced SEA conceptual framework	Quasi-experimental	240 physicians, dentists, nurses, a pharmacist in a primary care setting	SEA – significant event analysis	Pre-post training Likert scores about attitudes toward and experiences of SEA; blame culture; and usability of guiding tools	Chi square analysis of survey scores, qualitative analysis of interviews	Developed a conceptual model for doing SFA, implemented it, evaluated use	**Strengths:** Strong research-based model for developing tools **Limitations:** Possible respondent bias **Critical Appraisal Tool & Rating:** John Hopkins II B*
(Yadav, England, Vanderkolk, & Tam, 2017)	None mentioned	Non-experimental	Adult dialysis unit at the University of Minnesota Medical Center	HD – hemo-dialysis, RO – reverse osmosis	Water cultures of HD and RO machines	No statistical analysis	Determined root cause of water contamination, implemented standard protocols, 100% of cultures met regulatory standards	**Strengths:** Good use of RCA methodology **Limitations:** Only 1 dialysis center, not all water culture was speciated **Critical Appraisal Tool & Rating:**

								John Hopkins V B*
(Sauer and Hepler 2013)	Berwick's description of embedded systems	Non-experimental	Health care coalition in Florida with nearly 2 million employees	DTP – drug therapy problem, DRM – drug-related morbidity	Drug related emergency room visits	No statistical analysis	Identified 3 themes with many subsystem influences	**Strengths:** Systematic look at RCA at multiple levels **Limitations:** Limited number/type of participants, limited number of problems evaluated, no solutions proposed **Critical Appraisal Tool & Rating:** John Hopkins V B*
(Dolansky et al., 2013)	QSEN competencies	Case study	BSN student on med/surg floor	QSEN – Quality and Safety Education for Nurses	none	No statistical analysis	Recommen-dations for change in communication, and curriculum	**Strengths:** Thorough description of RCA process **Limitations:** Case study of one error, no follow-up **Critical Appraisal Tool & Rating:** John Hopkins V A*

* - Dearhold, S. & Dang, D. (2012). *Johns Hopkins nursing evidence-based practice: Model and guidelines* (2nd ed.). Indianapolis, IN: Sigma Theta Tau International.

Appendix B

Model for Improvement



Visual presentation of the model for improvement from Langley, J., Nolan, K., Nolan, T., Norman, C., & Provost, L. (2009). *The improvement guide: A practical approach to enhancing organizational performance* (2nd ed.). San Francisco, CA: Jossey-Bass

Appendix C

The Eight Accelerators

The Eight Accelerators from Kotter, J. P. (2014). *Accelerate: Building strategic agility for a faster-moving world*. Boston, MA: Harvard Business Review Press.

Appendix D

Letter of Support

October 17, 2017

To whom it may concern,

This is a letter to show support for Lisa Duncan to implement and evaluate her DNP Comprehensive Project at [redacted]. The focus of the project will be to implement and evaluate enhanced tools for incident reporting, including root cause analysis, and training supervisors how to use the tools and how to conduct root cause analysis.

We do not give Lisa permission to use the name of our agency in her DNP Comprehensive Project Paper and in future presentations and publications.

Sincerely,

Donna Baker
Senior VP and General Counsel

[redacted]

Appendix E

Data Collection Tool

General Incident/Accident/Error Report Additional Information

☐Personal Injury/Accident/Error ☐ Property Equipment Damage Accident/Error
☐ HIPAA Breach ☐ Near Miss Event
Name of Person Completing Report _____
Incident Report Number _____

Staff interviewed to complete this report _____
Where in the building or grounds did the incident occur? _____
What was the person doing at the time? _____
During what step or part of the work did the incident occur? _____
What time of day did the incident occur? _____
Was a supervisor physically present in the department at the time of the incident? _____
What was staffing like the time of the accident? ___ Overstaffed ___ Optimal Staffing ___ Understaffed
What was staffing like the day of the accident? ___ Overstaffed ___ Optimal Staffing ___ Understaffed

Analysis of Accident Causes

Unsafe Acts that contributed directly to the incident – please note that unsafe acts are those that contribute to the incident occurrence. Equipment may refer to software applications

☐ Operating or using equipment without authority
☐ Failure to remove equipment that was broken
☐ Failure to secure against unexpected movement.
☐ Failure to warn or signal as required
☐ Failure to wear personal protective equipment
☐ Removing or making safety devices inoperative
☐ Using defective tools or equipment
☐ Not following Policy # _____
☐ Doing work incorrectly – not following steps or directions for doing work
☐ Taking an unsafe position or posture
☐ Repairing or servicing moving, energized or hazardous equipment
☐ Distracting, startling, teasing, etc.
☐ Other unsafe act _____
☐ No unsafe act

Human Factors/Causes of Unsafe Acts

☐ Unaware of things that may contribute to error
☐ Not paying attention to work
☐ Not aware of safe/correct methods to do the work
☐ Low level of job skill
☐ Tried to gain or save time - rushing
☐ Tried to avoid extra effort/workarounds
☐ Trying to do too many things at once
☐ Acted to avoid discomfort
☐ Influence of emotions
☐ Influence of fatigue
☐ Influence of illness
☐ Influence of intoxicants
☐ Defective vision or hearing
☐ Other physical impairment
☐ Unable to judge nature of human factor/causes
☐ Other human factor/cause _____
☐ No human factor/cause involved

Unsafe Conditions – please note this could relate to software

☐ Lack of or inadequate guards and safety devices
☐ Lack of or inadequate warning system
☐ Fire and explosion hazards
☐ Unexpected movement hazard
☐ Poor housekeeping hazards
☐ Protruding object hazard
☐ Clothing restricted movement
☐ Clothing interfered with work
☐ Close clearance and congestion hazards
☐ Hazardous atmospheric conditions
☐ Hazardous arrangement, placement or storage
☐ Defective tools or equipment
☐ Inadequate illumination or intense noise
☐ Other unsafe condition _____
☐ No unsafe condition

Please scan and email to Lisa Duncan upon completion

Source/Causes of Unsafe Conditions – please note this could relate to software

- ☐ Worn out from normal use
- ☐ Abuse or misuse by user(s)
- ☐ Overlooked by regular inspection
- ☐ Regular inspection was not required
- ☐ Housekeeping or clean-up failure
- ☐ Regular clean-up was not required
- ☐ Inadequate ventilation
- ☐ Inadequate illumination
- ☐ Congested space
- ☐ Unsafe design, design that allows errors
- ☐ Faulty construction
- ☐ Lubrication failure
- ☐ Exposure to corrosion or rusting
- ☐ Exposure to vibration
- ☐ Tampering or unauthorized removal
- ☐ Supervisor failure to provide instruction or supervision
- ☐ Other source cause
- ☐ Unable to determine cause
- ☐ Failure to repair faulty equipment/software
- ☐ No unsafe condition

Please answer the following questions using the above information:

How was the work supposed to occur? List steps that should have been followed to do the workClick here to enter text.

How did the work occur? List steps that were followed.Click here to enter text.

What was the reason for the variance?Click here to enter text.

If an error occurred, is this a common error? ☐ Yes ☐ No

Has the employee received training to do the work? ☐ Yes ☐ No

Root Cause:

For example, if someone was rushing, why were they rushing? If they didn't check name and date of birth, how did they get the wrong record or paperwork in their hands? How is the work or environment designed to support error-free or accident-free work?

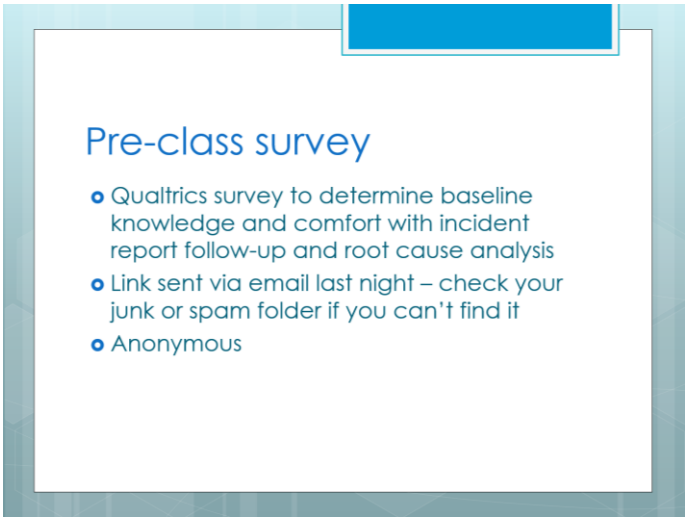
Countermeasures:

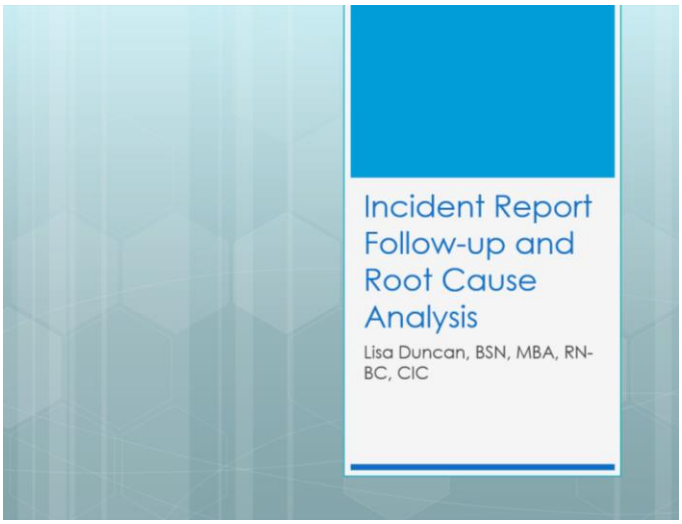
What was done to prevent this from happening again with this or any employee or patient? What systems were improved?

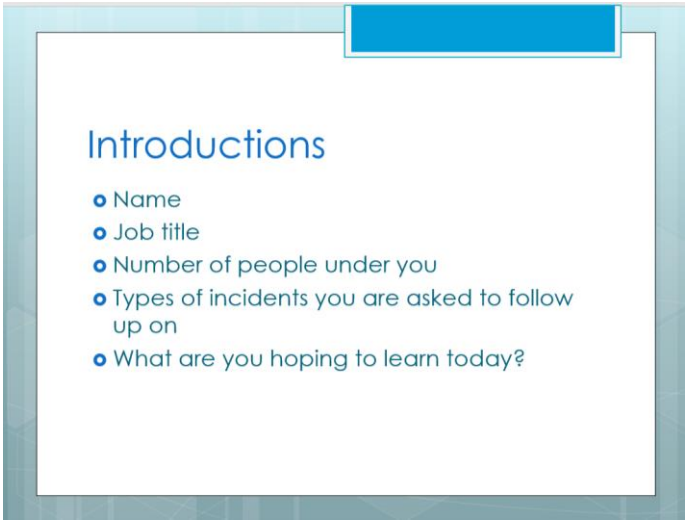
Please scan and email to Lisa Duncan upon completion

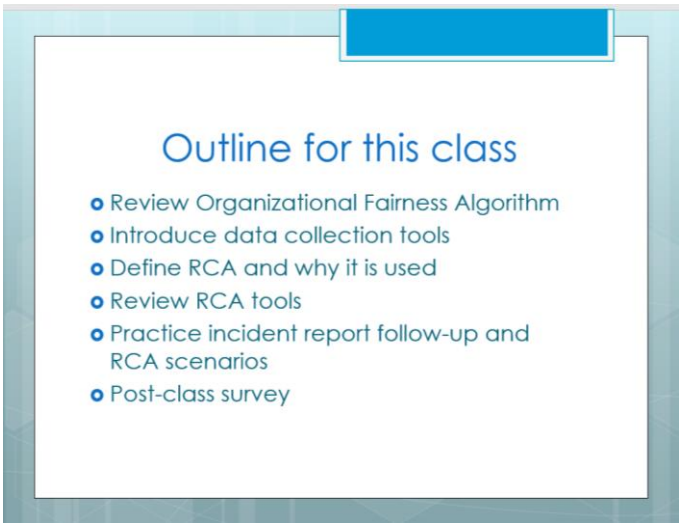
Appendix F

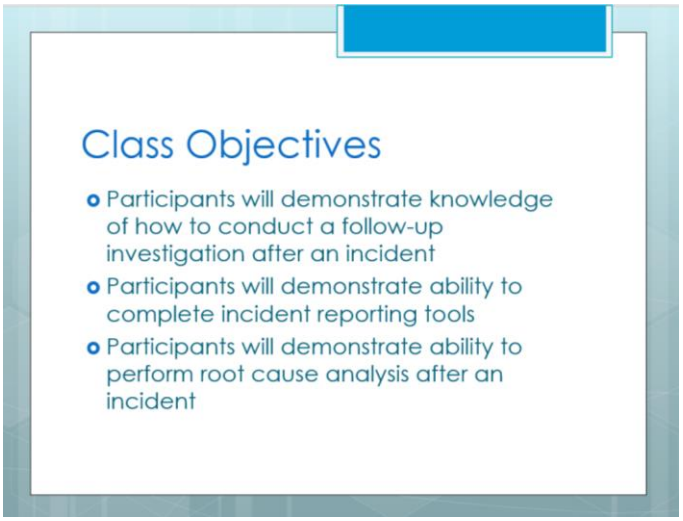
Class Materials

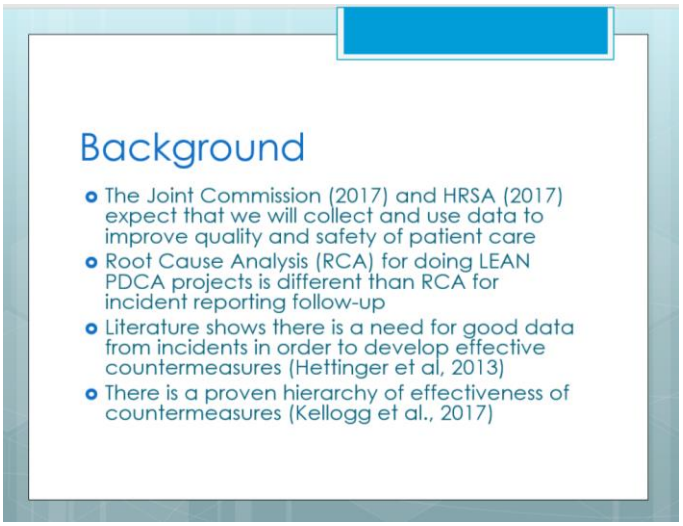






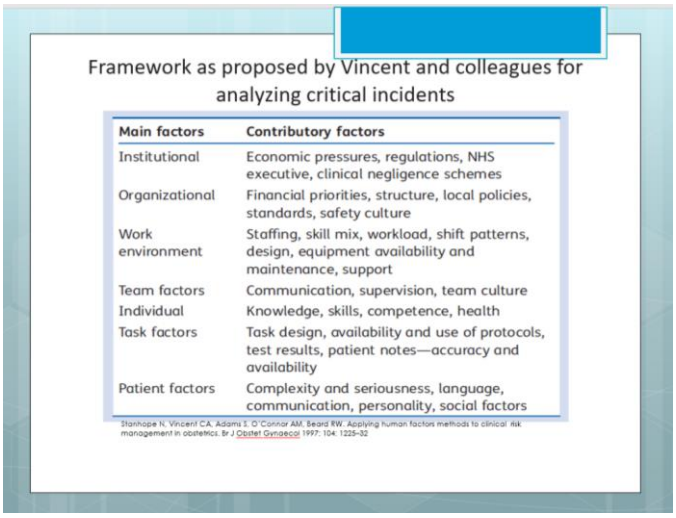

Outline for this class
Review Organizational Fairness Algorithm
Introduce data collection tools
Define RCA and why it is used
Review RCA tools
Practice incident report follow-up and RCA scenarios
Post-class survey

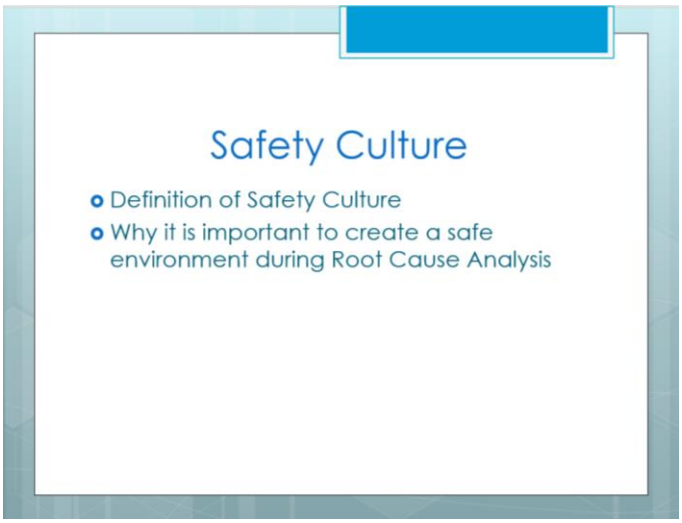

Class Objectives
Participants will demonstrate knowledge of how to conduct a follow-up investigation after an incident
Participants will demonstrate ability to complete incident reporting tools
Participants will demonstrate ability to perform root cause analysis after an incident


Background
The Joint Commission (2017) and HRSA (2017) expect that we will collect and use data to improve quality and safety of patient care
Root Cause Analysis (RCA) for doing LEAN PDCA projects is different than RCA for incident reporting follow-up
Literature shows there is a need for good data from incidents in order to develop effective countermeasures (Hettinger et al, 2013)
There is a proven hierarchy of effectiveness of countermeasures (Kellogg et al., 2017)


Organizational Fairness Algorithm
Review events for applicability
1. Assign level of intent
2. Evaluate system influences
3. Assign behaviors
4. Promote learning and improvement
5. Evaluate the individual for a history of unsafe acts
See handout (Frankel, Leonard & Shapiro, ND)

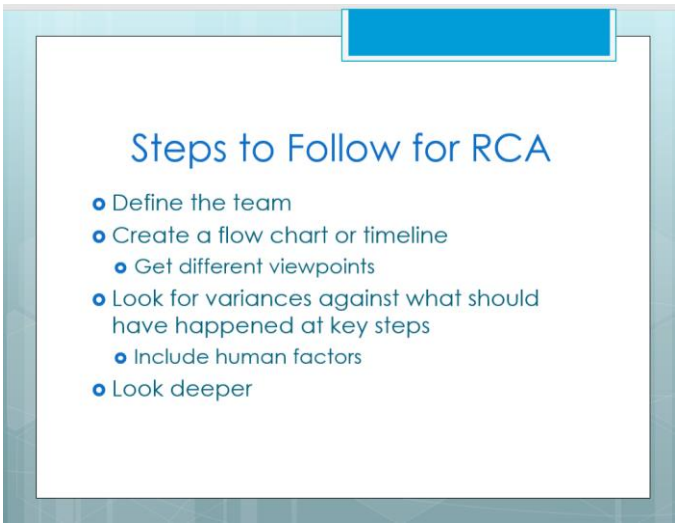

Human Factors Approach
Human behavior is influenced by outside factors that should be considered when evaluating incidents

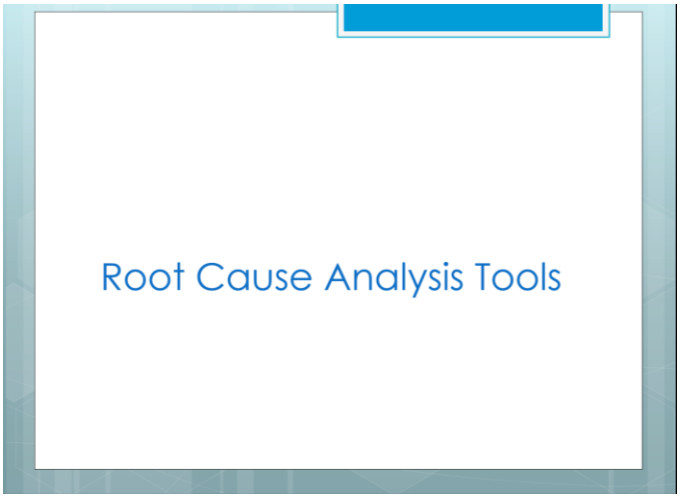

Framework as proposed by Vincent and colleagues for analyzing critical incidents
Main factors
Contributory factors
Institutional
Economic pressures, regulations, NHS executive, clinical negligence schemes
Organizational
Financial priorities, structure, local policies, standards, safety culture
Work environment
Staffing, skill mix, workload, shift patterns, design, equipment availability and maintenance, support
Team factors
Communication, supervision, team culture
Individual
Knowledge, skills, competence, health
Task factors
Task design, availability and use of protocols, test results, patient notes—accuracy and availability
Patient factors
Complexity and seriousness, language, communication, personality, social factors
Stanhope N, Vincent CA, Adams T, O'Connor AM, Beard RW. Applying human factors methods to clinical risk management in obstetrics. Br J Obstet Gynaecol 1997; 104: 1225–32

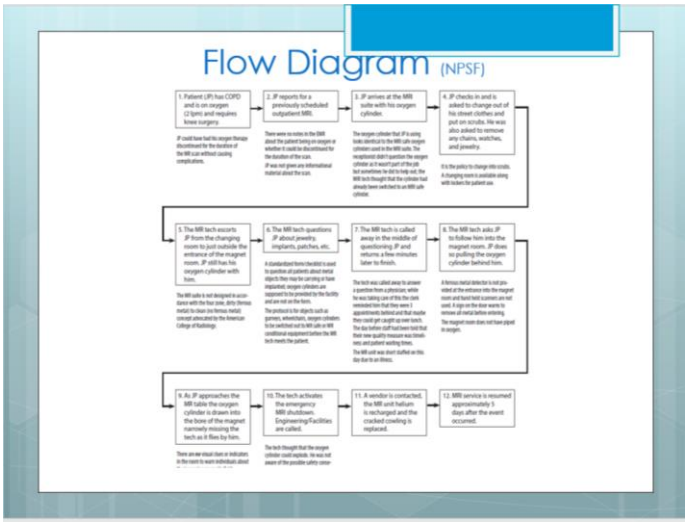

Safety Culture
Definition of Safety Culture
Why it is important to create a safe environment during Root Cause Analysis


Incident Report Tools
Tool for employee incidents
Tool for general incidents

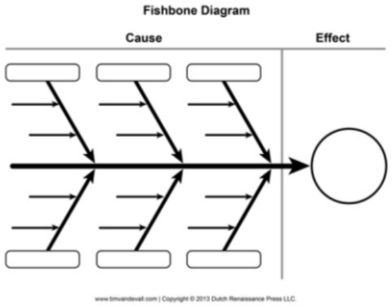

Incident Report Tools
Tool for employee incidents
Tool for general incidents


Steps to Follow for RCA
Define the team
Create a flow chart or timeline
Get different viewpoints
Look for variances against what should have happened at key steps
Include human factors
Look deeper


Root Cause Analysis Tools

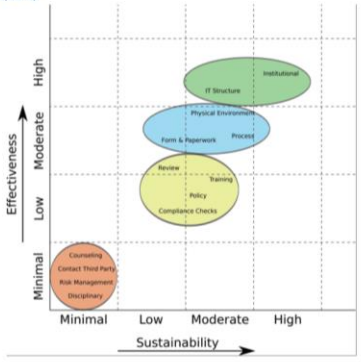

Flow Diagram (NPSF)

Fishbone Diagram



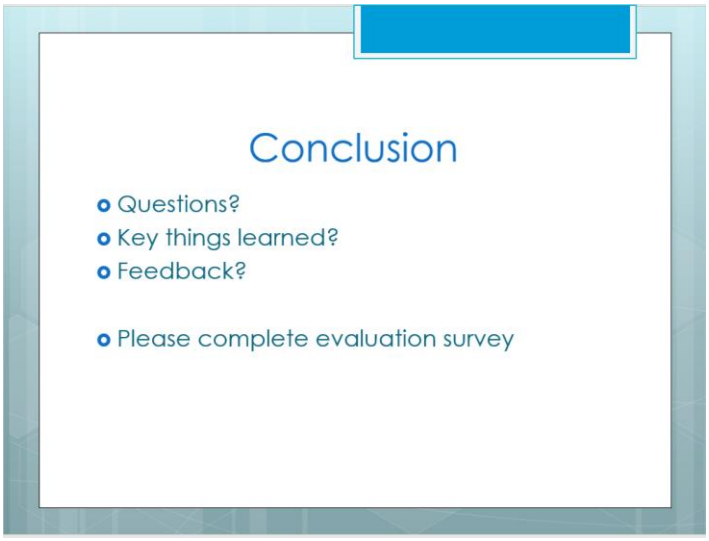
Determining Countermeasures

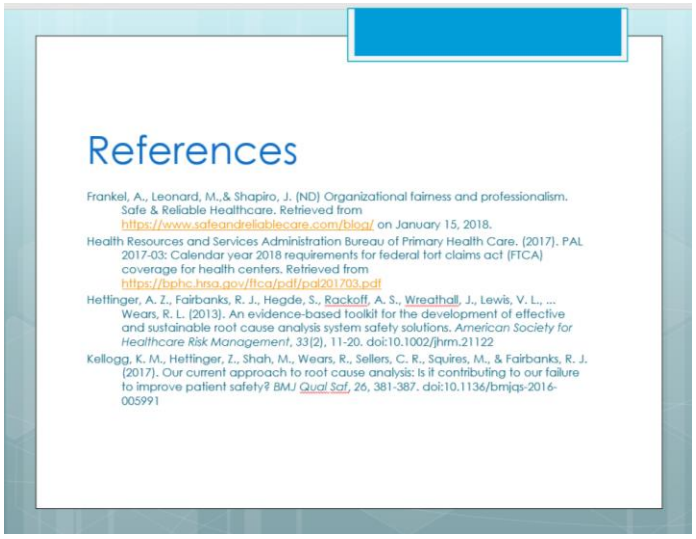
Hettinger et al (2013)

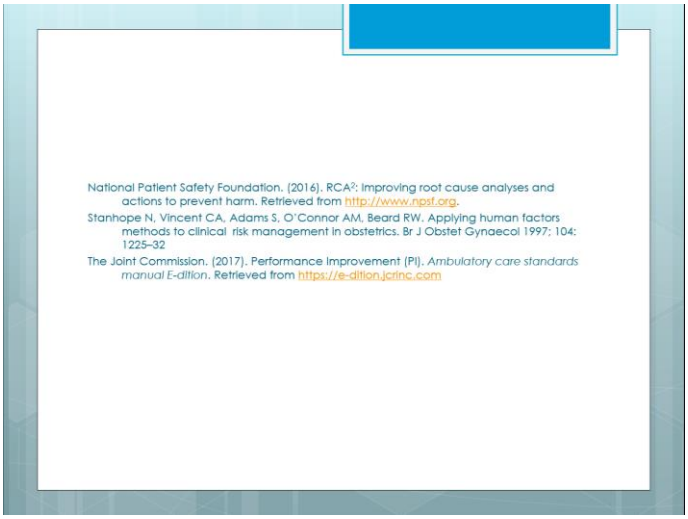


Scenarios

- Divide into groups
- Assign a "Supervisor" and roles
- Complete the investigation tool
- Write up summary of root cause and suggested actions


Conclusion
Questions?
Key things learned?
Feedback?
Please complete evaluation survey


References
Frankel, A., Leonard, M.,& Shapiro, J. (ND) Organizational fairness and professionalism. Safe & Reliable Healthcare. Retrieved from https://www.safeandreliablecare.com/blog/ on January 15, 2018.
Health Resources and Services Administration Bureau of Primary Health Care. (2017). PAL 2017-03: Calendar year 2018 requirements for federal tort claims act (FTCA) coverage for health centers. Retrieved from https://bphc.hrsa.gov/ftca/pdf/pal201703.pdf
Hettinger, A. Z., Fairbanks, R. J., Hegde, S., Rackoff, A. S., Wreathall, J., Lewis, V. L., ... Wears, R. L. (2013). An evidence-based toolkit for the development of effective and sustainable root cause analysis system safety solutions. American Society for Healthcare Risk Management, 33(2), 11-20. doi:10.1002/jhrm.21122
Kellogg, K. M., Hettinger, Z., Shah, M., Wears, R., Sellers, C. R., Squires, M., & Fairbanks, R. J. (2017). Our current approach to root cause analysis: Is it contributing to our failure to improve patient safety? BMJ Qual Saf, 26, 381-387. doi:10.1136/bmjqs-2016-005991


National Patient Safety Foundation. (2016). RCA²: Improving root cause analyses and actions to prevent harm. Retrieved from http://www.npsf.org.
Stanhope N, Vincent CA, Adams S, O'Connor AM, Beard RW. Applying human factors methods to clinical risk management in obstetrics. Br J Obstet Gynaecol 1997; 104: 1225–32
The Joint Commission. (2017). Performance Improvement (PI). Ambulatory care standards manual E-dition. Retrieved from https://e-dition.jcrinc.com

Appendix G

Pre- and Post-Class Surveys

Pre-Course Survey

Start of Block: Student Self-Assessment

Q1 How comfortable do you feel about your ability to collect additional information after an incident?

- Extremely comfortable (1)
- Moderately comfortable (2)
- Slightly comfortable (3)
- Neither comfortable nor uncomfortable (4)
- Slightly uncomfortable (5)
- Moderately uncomfortable (6)
- Extremely uncomfortable (7)

Q2 Please indicate how much you agree or disagree with the following statement: I fully understand how to undertake and lead a Root Cause Analysis

- ○ Strongly agree (1)
- ○ Moderately agree (2)
- ○ Slightly agree (3)
- ○ Neither agree nor disagree (4)
- ○ Slightly disagree (5)
- ○ Moderately disagree (6)
- ○ Strongly disagree (7)

Q3 What are you hoping to learn from this class? Be as specific as possible, and list as many aspects as you feel are appropriate.

_____

_____

_____

_____

_____

End of Block: Student Self-Assessment

Start of Block: Participant Information

Q4 What is your job title?

- Supervisor (1)
- Manager (2)
- Director (3)
- Other (4)

Q5 In which area do you work?

- Behavioral Health (1)
- Care Coordination (2)
- Dental (3)
- Medical (4)
- Other (5)

End of Block: Participant Information

Student Feedback

Start of Block: Class Evaluation

Q1 Overall, how satisfied or dissatisfied were you with this class?

- ○ Extremely satisfied (1)
- ○ Moderately satisfied (2)
- ○ Slightly satisfied (3)
- ○ Neither satisfied nor dissatisfied (4)
- ○ Slightly dissatisfied (5)
- ○ Moderately dissatisfied (6)
- ○ Extremely dissatisfied (7)

Q2 How interesting was this class?

- ○ Extremely interesting (1)
- ○ Very interesting (2)
- ○ Moderately interesting (3)
- ○ Slightly interesting (4)
- ○ Not interesting at all (5)

Q3 How relevant or irrelevant were the practice RCA projects in class?

- ○ Extremely relevant (1)
- ○ Moderately relevant (2)
- ○ Slightly relevant (3)
- ○ Neither relevant nor irrelevant (4)
- ○ Slightly irrelevant (5)
- ○ Moderately irrelevant (6)
- ○ Extremely irrelevant (7)

Q4 On a scale from 0-10, how likely are you to recommend this class to a friend or colleague?

- ○ 0 (0)
- ○ 1 (1)
- ○ 2 (2)
- ○ 3 (3)
- ○ 4 (4)
- ○ 5 (5)
- ○ 6 (6)
- ○ 7 (7)
- ○ 8 (8)
- ○ 9 (9)
- ○ 10 (10)

End of Block: Class Evaluation

Start of Block: Student Self-Assessment

Q5 How comfortable do you feel about your ability to collect additional information after an incident report?

- ○ Extremely comfortable (1)
- ○ Moderately comfortable (2)
- ○ Slightly comfortable (3)
- ○ Neither comfortable nor uncomfortable (4)
- ○ Slightly uncomfortable (5)
- ○ Moderately uncomfortable (6)
- ○ Extremely uncomfortable (7)

Q6 Please indicate how much you agree or disagree with the following statement: I fully understand how to undertake and lead a Root Cause Analysis.

- ○ Strongly agree (1)
- ○ Moderately agree (2)
- ○ Slightly agree (3)
- ○ Neither agree nor disagree (4)
- ○ Slightly disagree (5)
- ○ Moderately disagree (6)
- ○ Strongly disagree (7)

Q7 How much do you feel you learned from this class?

- ○ A great deal (1)
- ○ A lot (2)
- ○ A moderate amount (3)
- ○ A little (4)
- ○ Nothing at all (5)

Q8 What did you like most about this class? Be as specific as possible, and list as many aspects as you feel are appropriate.

_____

_____

_____

_____

_____

Q9 What did you like least about this class? Be as specific as possible, and list as many aspects as you feel are appropriate.

_____

_____

_____

Q10 If you have any other thoughts/comments/feedback on this teacher or this class, please include them below.

_____

_____

_____

_____

_____

End of Block: Student Self-Assessment

Start of Block: Participant Information

Q11 What is your job title?

- Supervisor (1)
- Manager (2)
- Director (3)
- Other (4)

Q12 In which area do you work?

- Behavioral Health (1)
- Care Coordination (2)
- Dental (3)
- Medical (4)
- Other (5)

End of Block: Participant Information

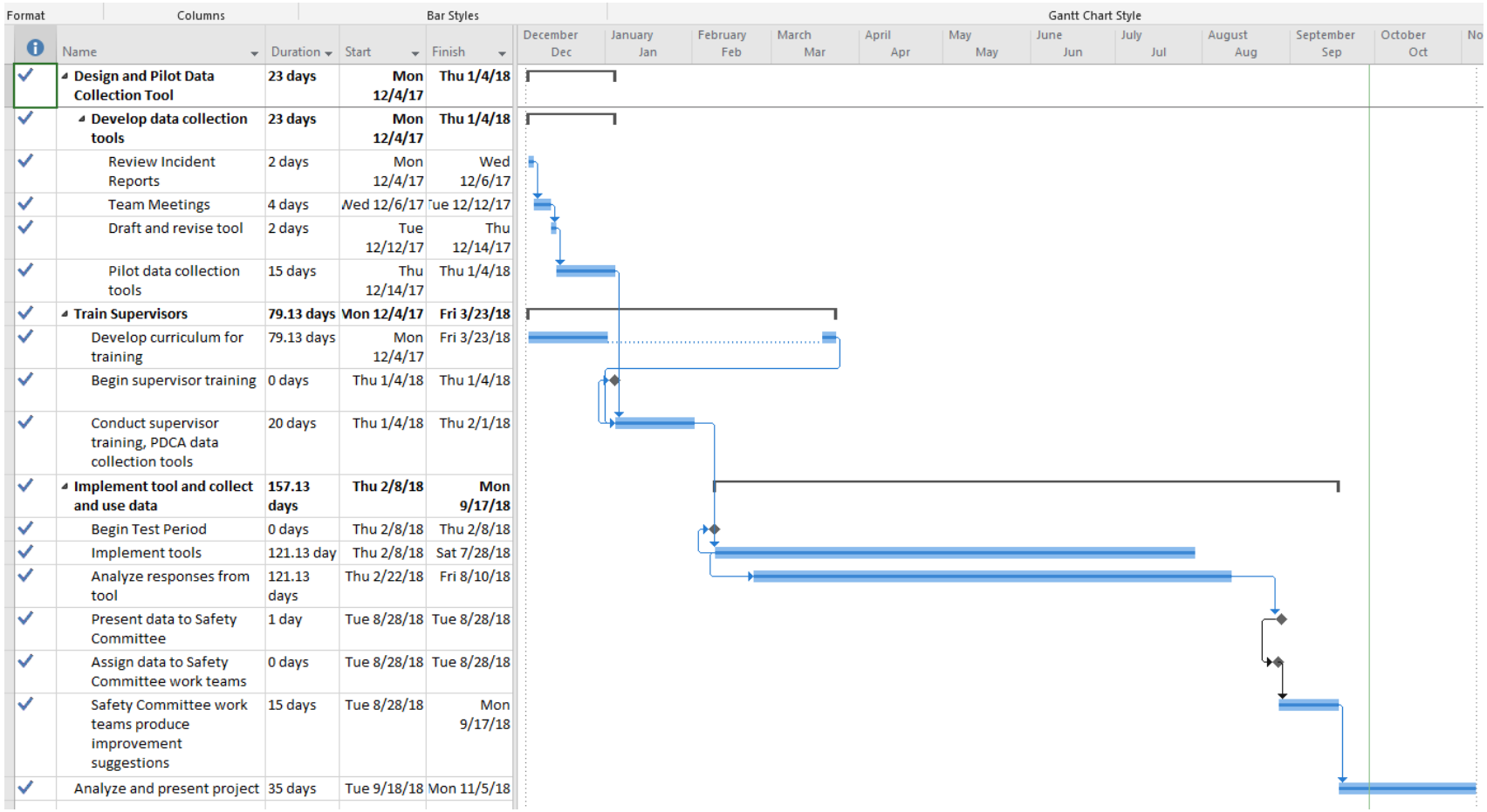
Appendix H

Gap Analysis

Area of Interest	Current Standing	Deficiency	Action Plan
Data from incident reports	Type of incident, location, frequency, job title	No place to document assessment of root cause, no underlying factors noted	Create incident report follow-up tools specific to incident type, including documentation of RCA
Supervisor knowledge of RCA	Some supervisors have received training, most of it related to large improvement projects	All supervisors need to know how to do RCA following incidents	Conduct RCA training
Changes made from incident reporting data	When incidents become high work groups may be assigned to propose solutions	Detailed information about incidents including underlying factors and RCA is not available for workgroups	Report enhanced IR data to Safety Committee and assign work groups

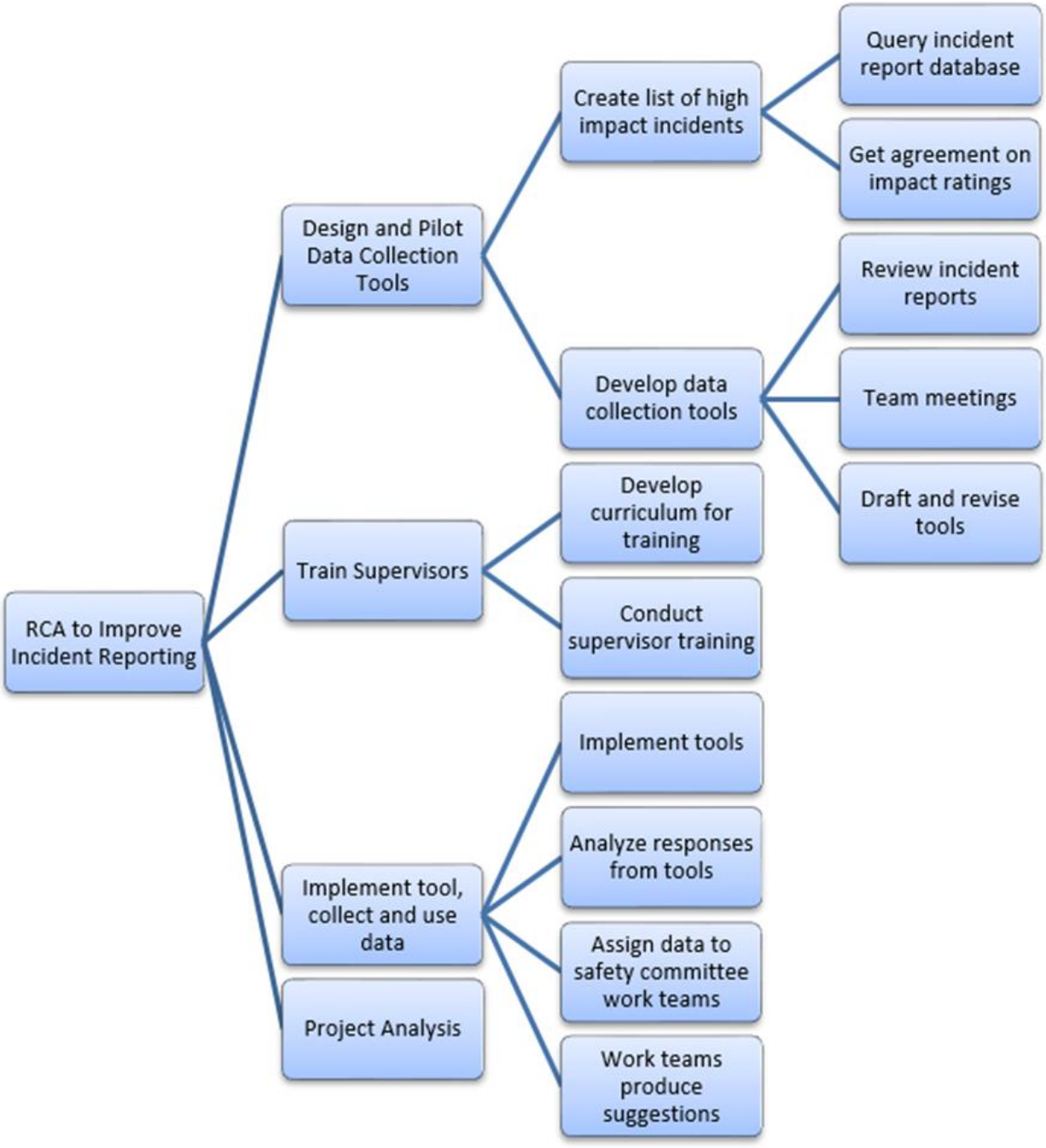
Appendix I

Gantt Chart



Appendix J

Work Breakdown Structure



Appendix K

Template for Risk Log

Risk Description	Current Level of Risk			Controls in Place	Potential Controls
	Likelihood	Magnitude	Overall Rating		
				a b c	a b c
				a b c	a b c
				a b c	a b c

Appendix L

Responsibility/Communication Matrix

PROJECT OVERVIEW

MON 12/4/17 - MON 11/5/18

% COMPLETE

100%

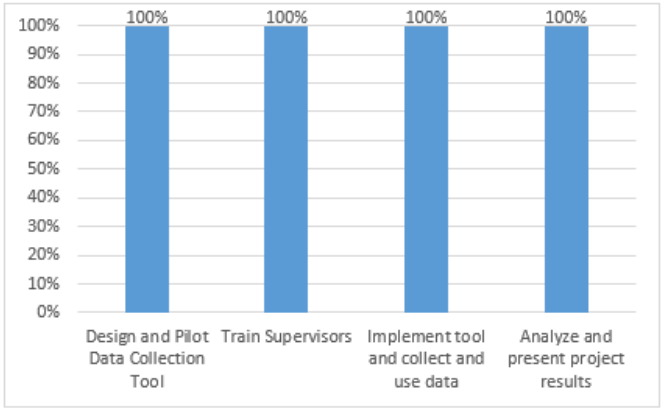
MILESTONES DUE

Milestones that are coming soon.

Name	Finish

% COMPLETE

Status for all top-level tasks. To see the status for subtasks, click on the chart and update the outline level in the Field List.



LATE TASKS

Tasks that are past due.

Name	Start	Finish	Duration	% Complete	Resource Names

Appendix M

SWOT Analysis

Strengths	**Weaknesses**
- Incident reporting system is electronic - Information entered as check boxes is collected as data point - Employees are familiar with incident reporting system - Most members of Safety Committee have many years of experience with the SO	- Multiple locations of varying size - Organizational growth in number of facilities, employees, patients - Supervisors not all familiar with how to conduct follow-up investigations - Incident reporting system does not collect information about underlying conditions
Opportunities	**Threats**
- Some evidence-based practice literature indicates that RCA is effective in finding solutions to improve safety - Alternative incident reporting systems are available from companies that have healthcare experience	- Incidents can lead to expensive worker's comp claims and increased cost of coverage - Errors can lead to legal action and increased regulatory scrutiny - Difficult to find taxonomy suitable for ambulatory care healthcare organization

Appendix N

Budget

Source of Project Cost

	PROJECT TASKS	Year 1 LABOR HOURS	Year 1 LABOR COST ($)	Year 1 ROOM USE COST ($)	Year 1 TOTAL PER TASK	Year 2 LABOR HOURS	Year 2 LABOR COST ($)	Year 2 TOTAL PER TASK	Year 3 LABOR HOURS	Year 3 LABOR COST ($)	Year 3 TOTAL PER TASK	Year 4 LABOR HOURS	Year 4 LABOR COST ($)	Year 4 TOTAL PER TASK
DEVELOP DATA COLLECTION TOOLS	Review Incident Reports	12.0	$660.00	$120.00	$780.00	260.0	$14,300.00	$14,300.00	260.0	$14,872.00	$14,872.00	260.0	$15,466.88	$15,466.88
	Team Meetings	2.0	$370.00	$20.00	$390.00	NA	NA	$0.00	NA	NA	$0.00	NA	NA	$0.00
	Draft and revise tool	15.0	$825.00	$0.00	$825.00	NA	NA	$0.00	NA	NA	$0.00	NA	NA	$0.00
	Pilot data collection tools	4.0	$220.00	$0.00	$220.00	NA	NA	$0.00	NA	NA	$0.00	NA	NA	$0.00
	Subtotal	**33.0**	**$2,075.00**	**$140.00**	**$2,215.00**	**260.0**	**$14,300.00**	**$14,300.00**	**260.0**	**$14,872.00**	**$14,872.00**	**260.0**	**$15,466.88**	**$15,466.88**
TRAIN SUPERVISORS	Develop curriculum for training	50.0	$2,750.00	$0.00	$2,750.00	12.0	$660.00	$660.00	12.0	$686.40	$686.40	12.0	$713.86	$713.86
	Conduct supervisor training	28.0	$15,120.00	$300.00	$15,420.00	8.0	$4,640.00	$4,640.00	8.0	$4,825.60	$4,825.60	8.0	$5,018.62	$5,018.62
	Subtotal	**78.0**	**$17,870.00**	**$300.00**	**$18,170.00**	**20.0**	**$5,300.00**	**$5,300.00**	**20.0**	**$5,512.00**	**$5,512.00**	**20.0**	**$5,732.48**	**$5,732.48**
IMPLEMENT TOOLS, COLLECT AND USE DATA	Implement tools	144.0	$12,744.00	$0.00	$12,744.00	52.0	$2,860.00	$2,860.00	52.0	$2,974.40	$2,974.40	52.0	$3,093.38	$3,093.38
	Analyze responses from tool	216.0	$9,504.00	$0.00	$9,504.00	30.0	$1,650.00	$1,650.00	30.0	$1,716.00	$1,716.00	30.0	$1,784.64	$1,784.64
	Present data to Safety Committee	4.8	$264.00	$0.00	$264.00	4.8	$264.00	$264.00	4.8	$274.56	$274.56	4.8	$285.54	$285.54
	Safety Committee work teams produce safety suggestions	1.0	$245.00	$180.00	$425.00	10.0	$2,450.00	$2,450.00	10.0	$2,548.00	$2,548.00	10.0	$2,649.92	$2,649.92
	Subtotal	**365.8**	**$22,757.00**	**$ 180.00**	**$22,937.00**	**96.8**	**$ 7,224.00**	**$ 7,224.00**	**96.8**	**$ 7,512.96**	**$ 7,512.96**	**96.8**	**$ 7,813.48**	**$ 7,813.48**
Project Analysis		84.0	$ 4,788.00	$0.00	$ 4,788.00	NA	NA	$ -	NA	NA	$ -	NA	NA	$ -
Subtotals		**560.8**	**$ 47,490.00**	**$ 620.00**	**$ 48,110.00**	**376.8**	**$ 26,824.00**	**$ 26,824.00**	**376.8**	**$ 27,896.96**	**$ 27,896.96**	**376.8**	**$ 29,012.84**	**$ 29,012.84**
Risk (Contingency)						37.7	$ 2,682.40	$ 2,682.40	37.7	$ 2,789.70	$ 2,789.70	37.7	$ 2,901.28	$ 2,901.28
Total (Scheduled)		**560.8**	**$47,490.00**	**$620.00**	**$48,110.00**	**414.5**	**$29,506.40**	**$29,506.40**	**414.5**	**$30,686.66**	**$30,686.66**	**414.5**	**$31,914.12**	**$31,914.12**

Appendix O

Cost Avoidance/Benefit Analysis

Term		
A	Adverse Event ("AE") Name:	**Vaccine/Medication & HIPAA Errors**
B	Absolute Increase in Mortality Rate per AE:	**0**
C	Plan for Excess Capacity:	**More Patients**
D	Additional "Pure Variable Cost" per AE:	**$679**
E	Additional "Sticky Variable Cost" per AE:	**$10**
F	Additional Gross Revenue per AE:	**$0**
G	Average Number of "Opportunity Patients" Foregone per AE:	**1.00**
H	Max Number of "Opportunity Patients" Foregone per AE:	**2.00**
I	Total Net Revenue of Average "Opportunity Patient":	**$15**
J	"Dark Green Dollars" Gained per AE Prevented:	**$704**
K	"Light Green Dollars" Gained per AE Prevented:	**$15**
L	Total Potential Gains per AE Prevented:	**$719**
M	Improvement Project Initial Costs:	**$47,490**
N	Improvement Project Recurring Annual Costs:	**$30,687**
O	Annual Opportunity Investment Rate of Return:	**3%**

Color Key:

	= Enter data into yellow cells
	= Derived / fixed value: Do not change

(Sheet protected to prevent accidental formula deletion)

IHI Adverse Events Prevented Calculator © IHI

Vaccine/Medication Errors

Resource	Units Required	Cost per Unit	Total Cost	Automatic Elimination	Pure Variable	Sticky Variable
Employee Investigation Hours	1	$17	$17	Yes	$17	
Supervisor Investigation Hours	1	$45	$45	Yes	$360	
Reviewer Hours	1.5	$150	$225	Yes	$225	
Vaccine	1	$65	$65	No		$65
Patient Visit	1	$15	$15	No		$15
Retraining Hours	3	$45	$135	Yes	$200	
				Total:	$802	$80

HIPAA Errors

Resource	Units Required	Cost per Unit	Total Cost	Automatic Elimination	Pure Variable	Sticky Variable
Employee Investigation Hours	1	$17	$17	Yes	$17	
Supervisor Investigation Hours	1	$45	$45	Yes	$360	
Reviewer Hours	1	$55	$55	Yes	$55	
Repairing Errors	1	$30	$30	Yes	$30	
Retraining Hours	1	$30	$30	Yes	$200	
				Total:	$662	$0

Average, assuming 12% vaccine/medication errors and 88% HIPAA errors	**$ 679**	**10**

Appendix P

Return on Investment Plan

Period	Number of Events	Number of Patients or Patient-Days	Period Adverse Event Rate	Period Adverse Events Avoided	Period Lives Saved	Aggregate Lives Saved	Period Dark Green Dollars Gained	Aggregate Dark Green Dollars Gained	Period Light Green Dollars Gained	Aggregate Light Green Dollars Gained	Period Cost of Improvement Work *(includes opportunity cost)*	Aggregate Cost of Improvement Work *(includes opportunity cost)*	Aggregate Return on Improvement Project ($)	Aggregate Return on Improvement Project (% of investment)
Baseline Q1	99	100000	0.001											
Baseline Q2	103	100000	0.001											
Baseline Q3	92	100000	0.001											
Baseline Q4	74	100000	0.001											
Improvement Period Q1	98	100000	0.001	1.000	0.000	0.000	$704	$703.80	$15.00	$15.00	$55,570.80	$55,570.80	-$54,867.00	-99%
Improvement Period Q2	55	100000	0.001	48.000	0.000		$33,782	$34,486.20	$720.00	$735.00	$8,140.74	$63,711.54	-$29,225.34	-46%
Improvement Period Q3	45	100000	0.000	47.000	0.000		$33,079	$67,564.80	$705.00	$1,440.00	$8,201.12	$71,912.66	-$4,347.86	-6%
Improvement Period Q4	40	100000	0.000	34.000	0.000		$23,929	$91,494.00	$510.00	$1,950.00	$8,261.95	$80,174.61	$11,319.39	14%
Improvement Period Q5	40	100000	0.000	59.000	0.000		$41,524	$133,018.20	$885.00	$2,835.00	$8,323.23	$88,497.84	$44,520.36	50%
Improvement Period Q6	40	100000	0.000	63.000	0.000		$44,339	$177,357.60	$945.00	$3,780.00	$8,384.96	$96,882.80	$80,474.80	83%
Improvement Period Q7	35	100000	0.000	57.000	0.000		$40,117	$217,474.20	$855.00	$4,635.00	$8,447.15	$105,329.95	$112,144.25	106%
Improvement Period Q8	35	100000	0.000	39.000	0.000		$27,448	$244,922.40	$585.00	$5,220.00	$8,509.81	$113,839.76	$131,082.64	115%
Improvement Period Q9	35	100000	0.000	64.000	0.000		$45,043	$289,965.60	$960.00	$6,180.00	$8,572.92	$122,412.68	$167,552.92	137%
Improvement Period Q10	30	100000	0.000	73.000	0.000		$51,377	$341,343.00	$1,095.00	$7,275.00	$8,636.51	$131,049.19	$210,293.81	160%
Improvement Period Q11	30	100000	0.000	62.000	0.000		$43,636	$384,978.60	$930.00	$8,205.00	$8,700.57	$139,749.76	$245,228.84	175%
Improvement Period Q12	30	100000	0.000	44.000	0.000		$30,967	$415,945.80	$660.00	$8,865.00	$8,765.10	$148,514.86	$267,430.94	180%
Improvement Period Q13	25	100000	0.000	74.000	0.000		$52,081	$468,027.00	$1,110.00	$9,975.00	$8,830.11	$157,344.97	$310,682.03	197%
Improvement Period Q14	25	100000	0.000	78.000	0.000		$54,896	$522,923.40	$1,170.00	$11,145.00	$8,895.61	$166,240.57	$356,682.83	215%
Improvement Period Q15	25	100000	0.000	67.000	0.000		$47,155	$570,078.00	$1,005.00	$12,150.00	$8,961.58	$175,202.16	$394,875.84	225%
Improvement Period Q16	25	100000	0.000	49.000	0.000		$34,486	$604,564.20	$735.00	$12,885.00	$9,028.05	$184,230.21	$420,333.99	228%

P	Average Baseline AE Rate:	0.001
Q	Average Improvement Period AE Rate:	0.000
R	% Reduction in Average AE Rate:	58.36%
S	Aggregate AE Prevented:	859.00
T	Aggregate Lives Saved:	0.00
U	Aggregate Light Green Dollars Gained:	$12,885
V	Aggregate Dark Green Dollars Gained:	$604,564
W	Aggregate Cost of Improvement Work:	$184,230
X	Aggregate Return on QI Investment ($):	**$420,334**
Y	Aggregate Return on QI Investment (% of QI Investment Cost):	**228%**

This analysis assumes error rates will decrease over subsequent years and patient volume will remain constant

Adverse Events Prevented Calculator from the Institute for Healthcare Improvement retrieved from http://www.ihi.org/resources/Pages/Tools/AdverseEventsPreventedCalculator.aspx

Appendix Q

Response Rates from Class Participants

Supervisors attended class	78
Supervisors completed class	75

96.15% completion rate

Class Survey Completion Rate	#	%
Supervisors completing survey before class	76	97
Supervisors completing survey after class	71	95

	General Incidents		Employee Incidents	
	#	% of those who completed course	#	% of those who completed course
Feedback responses returned for PDCA of tool	24	32	30	40
Responses returned from group work	46	61.3	64	85.3
Total completed course	**75**	**100.0**	**75**	**100.0**

	General Incidents		Employee Incidents	
	#	% of returned responses	#	% of returned responses
Completed analysis of accident causes	44	95.7	63	98.4
Completed analysis of workflow variance	25	54.3	33	51.6
Defined root cause	8	17.4	13	20.3
Total responses	**46**	**100**	**64**	**100**

Appendix R

Pre- and Post-Class Confidence Scores

	Pre		Post		Pre	Post	Change
	#	%	#	%	%	%	%
Comfort with Ability to Collect Additional Information After an Incident Report							
Extremely Comfortable	21	27.6	41	57.7	73.7	98.6	24.9
Moderately Comfortable	35	46.1	29	40.9			
Slightly Comfortable	12	15.8	1	1.4			
Neither Comfortable nor Uncomfortable	6	7.9	0	0.0			
Slightly Uncomfortable	2	2.6	0	0.0			
Moderately Uncomfortable	0	0.0	0	0.0			
Extremely Uncomfortable	0	0.0	0	0.0			
Total	76	100.0	71	100.0			

Fully Understand How to Undertake and Lead a Root Cause Analysis							
Strongly Agree	2	2.7	38	53.5	50.7	97.2	46.5
Moderately Agree	36	48.0	31	43.7			
Slightly Agree	13	17.3	2	2.8			
Neither Agree nor Disagree	12	16.0	0	0.0			
Slightly Disagree	5	6.7	0	0.0			
Moderately Disagree	6	8.0	0	0.0			
Strongly Disagree	1	1.3	0	0.0			
Total	75	100.0	71	100.0			

Appendix S

RCA Completion Rates

Responses for RCA from General Incident Reports

	Before Measurement Period		During Measurement Period		Difference
Requests Sent	26		28		
	#	%	#	%	
Completed RCA	16	61.5%	19	67.9%	6.40%

Data Collection Tools	
120	
#	%
44	37%

Appendix T

Responses from Incidents

	Total		General		HIPAA	
Forms Sent	**120**		**67**		**53**	
% of Forms Returned	**37%**		**22%**		**55%**	
Forms Received	**Total 44**		**General 15**		**HIPAA 29**	
	#	**%**	**#**	**%**	**#**	**%**
Time of Day						
Beginning of Shift	5	11.4	0	0.0	5	17.2
Middle of Shift	23	52.3	7	46.7	16	55.2
End of Shift	10	22.7	4	26.7	6	20.7
Supervisor Present						
Yes	27	61.4	11	73.3	16	55.2
No	15	34.1	3	20.0	12	41.4
Staffing						
Over	0	0.0	0	0.0	0	0.0
Optimal	37	84.1	11	73.3	26	89.7
Under	5	11.4	2	13.3	3	10.3
Employee Received Training						
Yes	38	86.4	12	80.0	26	89.7
No	0	0.0	0	0.0	0	0.0
Unsafe Acts						
Failure to take protective measures	2	4.5	0	0.0	2	6.9
Sharing PHI	5	11.4	0	0.0	5	17.2
Not following policy	4	9.1	1	6.7	3	10.3
Distracting	3	6.8	1	6.7	2	6.9
Not following directions for using tools or equipment	4	9.1	2	13.3	2	6.9
Failing to check restroom	1	2.3	1	6.7	0	0.0
Using defective tools or software	1	2.3	1	6.7	0	0.0
Taking an unsafe position or posture	2	4.5	2	13.3	0	0.0

Forms Received	Total 44		General 15		HIPAA 29	
	#	%	#	%	#	%
Human Factors						
Not paying attention to hazards	18	40.9	7	46.7	11	37.9
Lack of attention to detail	4	9.1	0	0.0	4	13.8
Tried to gain or save time	9	20.5	3	20.0	6	20.7
Tried to avoid extra effort	5	11.4	1	6.7	4	13.8
Low level of job skill	1	2.3	1	6.7	0	0.0
Influence of fatigue	1	2.3	1	6.7	0	0.0
Nails too long	1	2.3	0	0.0	1	3.4
Unable to hear	1	2.3	0	0.0	1	3.4
Unaware of job hazards	1	2.3	1	6.7	0	0.0
Unsafe Conditions						
Defective tools or equipment (EHR)	2	4.5	0	0.0	2	6.9
Hazardous placement, arrangement, or storage	1	2.3	1	6.7	0	0.0
Lack of notification when orders are created	1	2.3	1	6.7	0	0.0
Poor housekeeping hazards	2	4.5	2	13.3	0	0.0
Lack of or inadequate warning system	2	4.5	1	6.7	1	3.4
Lack of or inadequate guards or safety devices (may be electronic)	3	6.8	1	6.7	2	6.9
Source/Causes of Unsafe Conditions						
Overlooked by regular inspection	3	6.8	1	6.7	2	6.9
Unsafe design (electronic system	3	6.8	0	0.0	3	10.3
Abuse or misuse by users	1	2.3	1	6.7	0	0.0
Congested space	2	4.5	1	6.7	1	3.4
Supervisor failure to correct	1	2.3	0	0.0	1	3.4
Failure to repair faulty equipment	1	2.3	1	6.7	0	0.0

Forms Received	Total 44		General 15		HIPAA 29	
	#	%	#	%	#	%
Reason for Variance (extrapolated for some responses)						
Distraction	5	11.4	2	13.3	3	10.3
Not following instructions	5	11.4	2	13.3	3	10.3
Lack of attention	13	29.5	5	33.3	8	27.6
Working too quickly	8	18.2	1	6.7	7	24.1
Shared printers	2	4.5	0	0.0	2	6.9
Using 2 EMRs	1	2.3	0	0.0	1	3.4
Root Cause (extrapolated for some responses)						
Rushing	2	4.5	1	6.7	1	3.4
Lack of attention	18	40.9	2	13.3	16	55.2
High volume of work	5	11.4	0	0.0	5	17.2
Batched upload	2	4.5	2	13.3	0	0.0
Lack of knowledge	3	6.8	2	13.3	1	3.4
System doesn't create worklist	1	2.3	1	6.7	0	0.0
No fail safes	1	2.3	1	6.7	0	0.0
Computer system error	1	2.3	0	0.0	1	3.4

Appendix U

Number of General and HIPAA Incidents Reported

General Incidents Reported

	24 Weeks Before Implementation		24 Weeks During Implementation	
Type of Incident	**#**	**%**	**#**	**%**
Safety Hazard	23	2.8%	19	1.7%
Hazardous Chemical Exposure	1	0.1%	1	0.1%
Report of Patient/Fetal Death	4	0.5%	7	0.6%
Automobile Accident	1	0.1%	4	0.3%
Slip/Trip/Fall	27	3.3%	44	3.8%
Drug Seeking Behavior	13	1.6%	18	1.6%
Theft	3	0.4%	6	0.5%
911 Call	0	0.0%	80	7.0%
Laceration	4	0.5%	5	0.4%
Non-compliant/AMA	11	1.4%	7	0.6%
Emergency Medical Condition	30	3.7%	51	4.5%
Request to Review Care	58	7.2%	96	8.4%
Vaccine Outage	0	0.0%	3	0.3%
Allergic Reaction	2	0.2%	5	0.4%
Security Problem	23	2.8%	28	2.4%
Talked to Themselves/Heard Voices	19	2.3%	10	0.9%
Bite	0	0.0%	1	0.1%
Medication/Vaccine Error	24	3.0%	22	1.9%
Vandalism/Graffiti	2	0.2%	8	0.7%
Equipment Problem	4	0.5%	5	0.4%
Homicidal	7	0.9%	7	0.6%
Bleeding	2	0.2%	8	0.7%
Patient Suicidal Ideation	49	6.0%	74	6.5%
Mandatory Reporting	1	0.1%	17	1.5%
Reported Abuse	92	11.3%	98	8.6%
Infectious Disease Exposure	8	1.0%	9	0.8%
Seizure	6	0.7%	6	0.5%
Swilling/lump/bump	8	1.0%	9	0.8%
Seemed Confused/Disoriented/Agitated	45	5.5%	54	4.7%
Dental Procedure Complication	2	0.2%	1	0.1%
Lab/Testing Problem	21	2.6%	29	2.5%
Prescription Alteration	3	0.4%	2	0.2%
Other	318	39.2%	409	35.8%
Total	**811**	**100%**	**1143**	**100%**

HIPAA Breaches Reported

	Before Implementation		During Implementation	
HIPAA Breach Reports	**#**	**%**	**#**	**%**
Total	**60**	**100%**	**86**	**100%**

Appendix V

DNP Statement of Non-Research Determination Form

Student Name: Lisa Duncan

Title of Project:

Root Cause Analysis to Improve Incident Reporting in an Ambulatory Care Setting

Brief Description of Project:

The organization's incident reporting system does not provide sufficient data to guide clinical teams to make improvements in workflow to reduce errors. Supervisors in the organization are asked to provide follow-up information, including details about the incident that had not been included in the initial report and results of Root Cause Analysis (RCA). Supervisors do not provide a consistent level of quality of feedback and rarely provide results of RCA. Supervisors have not all been trained in conducting and documenting results of incident report follow-up, including Root Cause Analysis (RCA). The project will be done in three phases.

- Phase 1 – Design and pilot data collection tool. Review literature for taxonomy and common data elements collected with incident reporting systems, conduct team meetings to review historic incident reports and determine what additional data would have been useful to collect, then develop and pilot the data collection tool. The data tool will include a place for documentation of RCA.

- Phase 2 – Train supervisors. Hold four-hour classes for small groups of supervisors to teach them how to conduct and document RCA and how to collect data to fill out the data collection tool. Approximately ten classes will be needed to accommodate all supervisors. The classes will contain instruction and examples of real-life scenarios for participants to use to lead teams of RCA investigations and to practice documenting the findings on the incident report documentation tool. To determine the effectiveness of the class, the responses on the practice tools from one scenario will be graded to determine whether the participants are able to complete them successfully with the expected responses, including the correct documentation of RCA. The participants will be asked to complete a question regarding confidence with completing incident report follow-up, including RCA, using a Likert scale at the beginning and the end of the class to measure whether the class increased participant confidence with completing incident reports, including RCA.

- Phase 3 – Implement tool and collect and use data to develop recommendations for process improvements. Assign responsibility for incident report follow-up, including RCA, and send supervisors the data collection tool to complete and file with the incident report. Extract data from tools to aggregate and analyze. Share results with Safety Committee. The project lead is the Chair of the Safety Committee. The Safety

Committee will assign workgroups to use data to generate suggestions for workflow, documentation, or other system improvements. Collect data on number of suggestions submitted to Safety Committee.

A) Aim Statement:

This is a project to improve incident reporting data collected at [redacted] by first developing an enhanced incident reporting tool including a place to document RCA, and then teaching Root Cause Analysis and specifics of data collection needed to complete the tool to supervisors in order to improve the data collected from incident reports. By enhancing the data collected from incident reports we hope to provide actionable suggestions for improvements in workflow, staffing, training, or documentation systems.

B) Description of Intervention:

- Phase 1 Part 1 – three weeks – Review literature, hold team meetings to determine what data should be collected from incident reports, and develop data collection tool, including a place to document RCA.

- Phase 1 Part 2 – two weeks –Pilot data collection tool for certain types of incidents, and revise tool as needed.

- Phase 2 – four weeks – Conduct 4-hour classes for supervisors to learn RCA and how to use the tool to document the results of incidents. Collect responses to Likert-style question about confidence with completing incident report follow-up, including conducting RCA, before and after class. Test participant learning by evaluating responses on the data collection form after being presented with an incident scenario.

- Phase 3 – six weeks – Send tool to supervisors when incidents occur and support supervisors in filling out the tool. The data collected will be shared with the Safety Committee and workgroups will be assigned to develop recommendations for systems change. The Project Lead is the Chair of the Safety Committee and will assign the workgroups. The number of recommendations submitted to the Safety Committee will be tracked to evaluate effectiveness of the tool.

C) How will this intervention change practice?

Having enhanced documentation and RCA consistently done as a part of incident report follow-up will provide data for workgroups to analyze and use to suggest enhancements for documentation, training, or workflow. The end result will be safer care for patients and a safer environment for staff.

D) Outcome measurements:

- The supervisors will achieve a score of 90% in correct completion of the tool, including RCA, with the expected answers from a practice scenario at the end of the training session.
- The supervisors' reported confidence with completing incident report follow-up, including conducting RCA, immediately before and after taking the training class will increase by 20%.
- Supervisor compliance with using all aspects of the tool, including RCA, will increase by 20% when assigned incident report follow-up over a six week period.
- The number of systems change suggestions brought to the safety committee as a result of enhanced incident reporting will increase by 10%.

To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used: (http://answers.hhs.gov/ohrp/categories/1569)

X This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). Student may proceed with implementation.

☐ This project involves research with human subjects and must be submitted for IRB approval before project activity can commence.

Comments:

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST *

Instructions: Answer YES or NO to each of the following statements:

Project Title: Teaching Root Cause Analysis in an Ambulatory Care Setting	**YES**	**NO**
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	**X**	

The specific aim is to improve performance on a specific service or program and **is a part of usual care**. ALL participants will receive standard of care.	**X**	
The project is **NOT** designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does **NOT** follow a protocol that overrides clinical decision-making.	**X**	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	**X**	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	**X**	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	**X**	
The project has **NO** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	**X**	
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., **not** a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.	**X**	
If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: *"This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board."*	**X**	

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

STUDENT NAME (Please print):

Lisa Duncan_____

Signature of Student: 
_____**DATE_9/2/17**_____

SUPERVISING FACULTY MEMBER (CHAIR) NAME (Please print):

_____

Signature of Supervising Faculty Member (Chair):

_Dr. Marjorie Barter___DATE_9/2/17_____

Appendix W

Variance Log

Planned Work	Work Done	Reasons for Variation
Development of data collection tools specific for incident type and pilot tested before class instruction	Data collection tools generic for employee incidents and general incidents revised during instruction period using feedback from class participants	Unable to find guidance for developing tool and was given template by worker's compensation insurance provider. Insufficient feedback from team members to do adequate revisions before classes started.
Tools completed by class participants scored to determine effectiveness of training to impact supervisors' ability to complete tool correctly	Tools evaluated for completeness of each section	Class participants lacked knowledge in basic elements of incident repot process and found most value in discussion and information-sharing, so completion of the tool was not emphasized
Data collection period planned to be six weeks	Data collection period extended to 24 weeks	There were few incidents for which the project lead felt use of the tool was appropriate in six weeks. The SVPGC supported use of the tool, so the collection period extended until just before the quarterly Safety Committee meeting.
Results presented at Safety Committee will generate suggestions for countermeasures	No suggestions generated	Training only partially effective. Not all supervisors completed training. Some supervisors delegated tool completion to staff involved in incident. Safety committee members did not feel empowered to suggest organization needs to develop safety culture