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A Modified Delphi Methodology to Conduct an Failure Modes Effects Analysis: A Patient-Centric Effort in a Clinical Medical Laboratory

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[AQ1]

In this article, we describe the use of an information-gathering tool, the Delphi technique, to overcome issues encountered when conducting a Failure Modes Effects Analysis as part of a Define, Measure, Analyze, Implement, Control study to improve the processes of a clinical medical laboratory. The study was conducted with the goals of reducing medical errors in the total testing process to improve patient safety, patient satisfaction, and improve the overall quality of the health care services provided by the subject hospital while meeting its Joint Commission accreditation requirements. The study found that the Delphi technique was very useful in overcoming 4 barriers encountered in conducting a Failure Modes Effects Analysis in a hospital's clinical medical laboratory and in achieving those goals.

“Things happen...[we] can't be perfect” is a recent quote from a clinical laboratory worker in a hospital when asked on a survey why the critical results of patient's tests may not be properly reported. Unfortunately, this is not an uncommon issue in providing quality patient care in today's highly competitive, highly cost-conscious health care systems. “Laboratory processes are designed on the premise that nothing will go wrong.”^{1(p32)} The importance and relevance of laboratory processes in improving the quality of clinical outcomes was emphasized by Dock when she stated that “70% of all information used by a clinician to diagnose and treat a patient comes from the laboratory.”^(p210) [AQ3]

The concepts of developing and implementing formalized approaches to providing quality products and services to customers are generally credited to the Toyota Motor Company beginning in the 1950s and continuing to today. So successful were those quality and continuous improvement methodologies in manufacturing that American companies sent teams to Japan to learn about them. Major US corporations understood the value of those tools and methodologies and, in typical American fashion, formalized

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them even further. In the 1980s, Motorola developed what it christened “Six Sigma,” which Jack Welch and GE later brought to the public’s attention through their “Black Belt” and “CI” (continuous improvement) quality programs. The gains in customer satisfaction, and in financial measures, created by these efforts were undeniable. Other industries besides manufacturing began to take notice.

The health care industry has looked at the issues of quality from a more clinical setting. Quality problems in health care cannot simply be “scrapped” or “reworked” as they can in manufacturing. Quality issues in health care can often jeopardize patient safety and lead to serious injury and death. When the nearly 300-page report “To err is human: Building a safer health system” was published by the committee on health care in America in 1999 citing the high number of serious medical errors that occur on a daily basis in the United States, it began a fresh movement towards improving quality in today’s health care systems. That same year, the national accrediting body for hospitals and other health care organizations, the Joint Commission (JC), issued its own revised mission statement which included the goal “to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations.” The JC put standards into place that required accredited hospitals to provide evidence that at least 1 performance improvement initiative was implemented annually. More than 10 years later, however, many health care systems are still struggling with the issues raised by that report, and with meeting the standards set by the JC, namely, that of determining the causes of medical errors and putting into place the systems that will prevent those errors from occurring. These struggles are created by a number of factors facing health care including how to juxtapose patient safety and care with the unique balance of clinical and business needs that managing a health care system requires, the broad range of skill levels of the workers involved, the problems of scheduling administrative priorities around critical care and clinical priorities, the 3- or 4-shift, 24-hour, 7-day-a-week working environment,

and the multiple interfaces required between a complex set of functional areas.

One methodology recognized by the JC, and designed to provide a framework by which to address such issues of quality in complex systems, is the Define, Measure, Analyze, Improve, and Control (DMAIC) steps used to implement the Six Sigma quality systems mentioned earlier. This article followed those steps in improving the processes of a clinical medical laboratory but, in doing so, determined that the traditional methods the Failure Mode Effects Analysis (FMEA) tool of DMAIC could, in and of itself, use improvement.

Specifically, this article evaluated the use of a structured communication process, known as the Delphi technique, to facilitate the implementation of FMEA, a performance improvement tool of the Analyze phase of DMAIC, in the clinical laboratory environment of one of those health care systems. Although the use of FMEA in a health care setting is not, in and of itself, unique, the use of FMEA as applied to the total testing process (TTP) of a clinical laboratory setting has not yet been well-documented nor has the Delphi technique approach taken by this project been used to date. This modified process will allow complex health care systems to more readily implement quality tools that improve patient safety, patient care, and patient satisfaction, the ultimate goal of the improvement. The second goal of the project was to assist the subject hospital in meeting its JC requirements of implementing a continuous improvement initiative.

RELATED WORK

Related work in this area appears to fall into the areas of the extent and sources of errors, determining which errors are most critical to address, and methods of preventing those errors.

As patient, or customer, satisfaction is of prime concern in the competitive environment of health care, it is crucial to understand what patients think. Surveys report that overall perceived level of medical safety being rated as excellent by only 48% of surveyed patients, 10% of patients noted they had

concerns that the “wrong” test would be conducted on them and 6% were afraid of being mistaken for another patient.²

Economic costs of laboratory error can be used to prioritize quality efforts but differ with the laboratory test. Probable costs per error can be used to identify tests with the highest costs to patients. These cost-per-error-data, when combined with test volume data and error rates by test, can help point to the tests that should receive priority in a laboratory improvement program.³ Fundamental performance measures, as the next step in aligning and maximizing laboratory improvement efforts, include customer satisfaction, turnaround times, patient identification, specimen acceptability, proficiency testing, critical value reporting, blood product wastage, and blood culture contamination.⁴ The surgical specialties, emergency rooms, and intensive care units have been previously identified as areas of risk for patient safety. Appropriate attention to system factors involved in these errors and designing system approaches help to control and eliminate many of the errors.⁵

Various tools and techniques have been employed to reduce medical errors. Implemented bar code-based positive patient identification system is used in inpatient phlebotomy. In addition, bar code technology significantly reduced the rate of specimen identification errors.⁶ Laboratories actively engaged in ongoing specimen labeling quality monitors had fewer specimen labeling errors. Establishing quality metrics for specimen labeling and deploying 24/7-phlebotomy operations may contribute to improving the accuracy of specimen labeling for the clinical laboratory.⁷

Two complementary strategies that appear to be associated with reduction of errors have been identified. The first strategy involves doing what is necessary to prevent the occurrence of errors in the first place. Health care workers must be properly educated to perform tasks with as few errors as possible. There should be written policies detailing responsibilities. The second strategy involves the assumption that errors will occur anyway. It is essential that systems designed to eliminate errors include elements of redundancy to catch those mistakes.⁸

Participating hospitals found that the Statistical Process Control spreadsheet is very suitable to monitor the performance of the sample labeling and collection and applied statistical process control charts to suit their specific needs. Statistical process control could be applied to other critical steps in the transfusion processes as a tool for biovigilance and could be used to develop regional or national performance standards for pretransfusion sample collection.⁹ Despite a mixture of both skepticism and enthusiasm in applying Six-Sigma methods into clinical laboratories, a systematic Six-Sigma approach in clinical microbiology, and other departments of laboratories, were able to improve the quality of the processes there.¹⁰

Several software applications are currently available that can aid error reduction in clinical chemistry. Both laboratory consultants and the use of information and communication technology are tools in optimizing the efficiency of laboratory medicine.¹¹

Quality management programs could be developed and improved not only looking at human error causation factor but also at human behavior that enhances system performance and other factors that affect adverse events specifically by understanding team coordination tasks that strongly affect patient care and quality management, and also how the adverse events dynamics affects provider tasks and constrains.¹² In addition, different modeling techniques, specifically discrete event simulation of system process and modeling, could be used to improve emergency services and resolve negative impact of long waiting time, thus enhancing quality of the services.¹³

As this study focused on the clinical laboratory process, it was necessary to define the set of processes involved. The set selected was based on the TTP described by McCay et al,¹⁴ which divides the steps into 3 phases, preanalytical, analytical, and postanalytical. As demonstrated by previous research, the pre and postanalytical steps still have the highest error prevalence; however, changes occurred in the types and frequencies of errors in the phases of testing.¹⁵ To improve patient safety in laboratory medicine, the focus should be on the pre- and postanalytic phases, and the concept of patient safety as a multisystem

concept must be better understood.¹⁴ The World Alliance for Patient Safety supports improvement of patient safety globally and provides a potential framework for considering the total testing process.¹⁴ Patient misidentification and problems in communicating results are recognized as the main goals for quality improvement. Each practice must examine its own total testing process to understand weaknesses and remedies.¹⁶

Preanalytic workstations are also an important tool for reducing errors. For example, the “San Bassiano hospital” experience illustrates the combination of strategic thinking, management planning, advanced information technology, and robotics which led to more reliable specimen collection and preanalytical sample handling and enhanced clinical efficiency as an integral part of the laboratory process. Errors in the total testing process thus were almost completely eliminated.¹⁷

The FMEA tool has specifically been identified in previous studies as an excellent tool for preventing medical errors from occurring. The FMEA is a technique for error detection and reduction. It was introduced within the aerospace industry in the 1960s. The FMEA may become the common standard for measurement and comparison, particularly in laboratory medicine. For example, a significant reduction of the risk priority number was obtained when applying the FMEA to blood cross-matching, to clinical chemistry analytes, and to point-of-care testing.¹⁸ The FMEA quantifies design or process risk, so high risk can be easily identified.¹⁹ In addition, it is a useful tool for not only risk identification but also for injury prevention.²⁰

The use of FMEA in health care has been recommended by organizations such as the Institute for Safe Medication Practices, American Society of Health-System Pharmacists, and The JC.²¹ It has only relatively recently been adapted to health care, but the impact has been tremendous. New processes, procedures, and care delivery methods are being “tested” to see whether there are weaknesses that could reach a patient and cause harm.²² In one use in a Children’s Hospital in Minnesota, the use of FMEA resulted in a 75% decrease in the number of

misabeled or unlabeled specimens received in the laboratory.²³ The FMEA method has achieved lasting benefits in various industries but remains untested in acute care hospitals according to some researchers.²⁴ The FMEA process includes the following elements: choose, assemble, organize, conduct, and develop.²⁵ The FMEA focuses on processes that manufacture products and involves the calculation of a risk priority number through a 3-variable equation where each variable is scored from 1 to 10. Medical device manufacturers have used this process when evaluating their equipment.²⁶ Complete review of a clinical process using FMEA requires the commitment of significant resources, but it is likely to result in valuable return on investments.²⁷ Latino notes that using FMEA in health care promotes both improved patient safety and reduces adverse outcomes which have multiple benefits to the system employing it.²⁸ The FMEA provides that proactive approach to provide both improved patient safety and improved clinical outcomes.¹

The prior research indicated that both DMAIC and its related tool FMEA have been used successfully in the medical area to reduce medical errors and improve patient safety and satisfaction but its application in the TTP was not as well-documented but is very much needed.²⁹ The current research project determined some possible reasons why this had occurred.

DEFINING THE PROBLEM— BACKGROUND, MOTIVATION AND RESEARCH QUESTION

The current study began as an exercise in process improvement using the traditional business process improvement methodology of DMAIC. This improvement was desired by the staff and management of a clinical medical laboratory operating in a medium-sized rural hospital in the Midwest. In the Define phase of DMAIC, the study reviewed the processes involved and the significance of the problems in the clinical medical laboratory. The objectives defined were to reduce the numbers of different medical errors occurring in those processes to improve patient

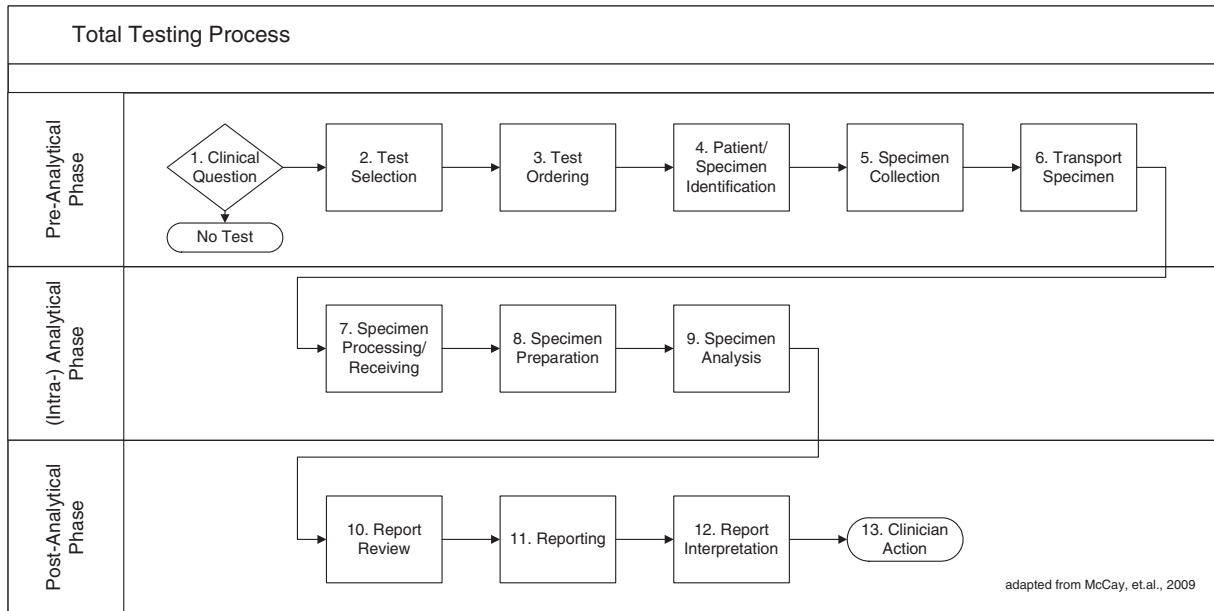


Figure 1. Total testing process steps.

safety and satisfaction as well as reducing overall costs for the hospital. Measurements would consist of the numbers of those various errors but to define those errors would first require their identification by the employees involved in the processes.

As mentioned earlier, the FMEA is considered one of the tools of the Six Sigma quality toolkit. While originally developed by the US Military right after WWII, the FMEA was also adopted by the developers of the Six Sigma methodology as a tool to assist in multiple phases of the DMAIC methodology. It was most often employed in the Analyze and Improve phases to understand problem areas and to develop policies and procedures to prevent potential errors from occurring. As this study began the Analyze phase of DMAIC, the FMEA was selected to help identify both areas of the process needing improvements as well as the actions, or Improvements, to those processes.

Several steps are involved in a traditional FMEA, the first of which is to define the topic and select a specific process to study. The general area selected, that of the clinical medical laboratory, was established in the Define phase earlier. The specific process, or set

of tasks, selected, was that of the TTP¹⁴ of the clinical medical laboratory. The TTP involves 3 major phases; preanalytical, analytical, and postanalytical. Within each major phase of the TTP are several steps, which are illustrated in Figure 1.

The steps of the analytical phase generally occur exclusively within the laboratory and are performed by laboratory personnel (technicians and technologists) whereas the steps of the pre- and postphases generally occur outside the boundaries of the laboratory and involve hospital employees and providers besides laboratory technologists. The cross-functionality of the tasks increases the complexity of the FMEA process and leads to the second step.

The second step in completing an FMEA is the selection of the multidisciplinary team to complete the process. The third step in the FMEA process involves conducting the hazard analysis in which points of failure within the process are identified, their causes, severity, and probability documented, and a hazard score calculated. Fourth, actions are developed to prevent the errors from occurring and, finally, measures are put in place to monitor the success of the action implementation. As the second step of the

FMEA began, certain issues immediately became apparent.

As mentioned, a traditional FMEA is completed by a multidisciplinary set of process owners in a team/group setting that allows for both brainstorming and group consensus to take place. The health care setting, however, presents unique challenges to this traditional methodology due to those factors mentioned earlier. Those factors included how to maintain high levels of patient safety and care while balancing the clinical and business needs of managing a health care system, the broad range of skill and education levels of the workers involved, the problems in scheduling administrative priorities around critical care and various clinical priorities, the 3- to 4-shift, 24-hour, 7 day-a-week working environment, and the multiple interfaces required between disparate complex sets of functional areas. These factors create a 4-way barrier to the group creation process required by FMEA:

1. *Vertically*: Personnel involved in the TTP process come from varying levels of authority (and skill/education levels) within the hospital environment from pathologists (medical doctors—who may also be hospital administrators), to phlebotomists (whose sole task is drawing blood specimens), to line staff with minimal formal training. This creates both difficulties in physically assembling a team as well as the possibility that lower level employees will feel intimidated discussing failure modes that may be attributable to higher level staff (eg, doctors) in a group setting that also includes those staff members.
2. *Horizontally*: The TTP process spans the boundaries of many functional areas including not only departments within the laboratory but also other various hospital departments including nursing, emergency, neonatal care, obstetrics, clinics, radiology, and many others depending on the tests needed. Again, this presents challenges in assembling & coordinating team activities.
3. *Temporally*: As the hospital operates in a 24-hour, 7-day-a-week mode, several different

shifts of employees are required with little cross-shift time available to allow full representation and participation.

4. *Clinical criticality*: Because of the nature of the business involved, patients' clinical needs trump any administrative duties or requests such as team meetings.

Combining these 4 factors, it becomes nearly impossible to assemble a dedicated cross-functional team of process owners that can meet in one place at one time for any length of time. Because of this 4-way group-forming barrier, a regular FMEA team that included any kind of viable representation was nearly impossible to accomplish for this process.

The research question then became:

How could the traditional FMEA steps be modified to facilitate accessing the combined knowledge base of process owners needed for accomplishing the intended goals of identifying potential medical errors, creating a ranked hazard score for them, developing policies, procedures and mechanisms to prevent their occurrence, implementing those policies, procedures and mechanisms and then controlling their use for sustainability with the final objective of improving patient safety, care, and satisfaction?

A unique approach was developed, using a survey-based Delphi-technique methodology, to answer that question and achieve that objective.

DELPHI TECHNIQUE

The Delphi technique has been defined as "...a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem."^{30(p3)} Its application in health care research has been documented by de Meyrick^{31(p14)} who noted that it is "well-suited to health care research," that it is flexible, so there is "no need for the respondents to be available all at the same time,"³¹ and that its anonymity "removes many of the other weaknesses of other research methods."^(p15) Mullen determined that

the Delphi technique can be used in lieu of the meeting format to avoid the problems caused by the vertical issues mentioned earlier.³² She also mentioned it had “enormous potential in many areas of health services research and practice”^{32(p49)}. Loo³³ also stresses its strategic importance as well as emphasizing the need for correct design in research adding that doing so yields a powerful information-gathering tool.

The research indicated that this tool could prove very useful in overcoming all 4 of the barriers encountered. To apply the technique, a set of 12 “FMEA Process Steps” was created for its application in this study. These process steps are illustrated in Figure 2.

ANALYZE PHASE—CONDUCTING AN FMEA USING THE DELPHI TECHNIQUE

The FMEA process steps 1 through 3 were described earlier as they constituted the rationale behind the development of the new process. The institution under study was a small rural hospital in the Midwest of the United States. The next step, FMEA process step 4, involved selecting and coordinating with the hospital and laboratory contacts. Once this was accomplished, a survey was developed to allow individuals across the 4 factors, mentioned earlier, to contribute ideas as to where and what errors occurred in the TTP, as well as to the sources, probabilities and severity of each. Open-ended questions were used asking respondents to identify and describe what kinds of errors could occur at each step of the TTP as well as possible causes of those errors and the severity and probability of each. The definitions for probability and severity were adapted from those used by the Veterans Administration for their health care Failure Mode and Effect Analyses program. A description of the definitions (errors, causes, TTP step boundaries, probability, and severity) was provided in the survey itself.

In the FMEA process step 5, surveys were distributed to all laboratory employees as well as several individual outside the laboratory including nurses and hospital administrators. Verbal instructions were

provided by either the laboratory technical supervisor (LTS) or the hospital performance improvement clinical evaluator or both. A total of 15 surveys were received back from a cross-section of employees in different departments and shifts including technologists (both laboratory technologists [CLS/MT—generally 4-year degree] and laboratory technicians [CLT/MLT—generally 2-year degree]), nurses, administrators, and staff personnel.

Following the completion of the initial survey, the FMEA process step 6 was analysis and summarization of the information including the creation of a master list of errors and hazard scores. Hazard scores are rankings based on the severity and probability of an error occurring. The higher the hazard score, the more critical the effect of the error. The study used hazard scores as described by the United States Department of Veterans Affairs. The table and associated values may be seen in Table A of the Appendix. The top 20% of errors as ranked by hazard score, plus any errors whose severity was ranked as catastrophic but were not in the top 20%, were placed on a second survey. As part of the analysis, the top 20% were ranked based on the step in the TTP. It was noted that the majority of that top percentage of critical errors identified were generated in TTP step 11 Reporting, TTP step 4 Patient/Specimen Identification, and TTP step 9 Specimen Analysis (in that order). This ranking of error frequencies may be seen in Figure 3.

This analysis helped to identify which errors, and steps, would be good candidates for improvement efforts both now and in the future.

The second survey was then redistributed in the FMEA process step 7 (refer to Figure 2) with 2 goals: (1) validate the initial consolidated hazard scores and (2) request participants to individually brainstorm to identify actions that would prevent the listed errors from occurring. Participants were instructed not to be concerned about the cost or feasibility of any recommended action, but to list any and all actions they felt could prevent the error. That second set of surveys was collected and analyzed in step 8. From this step, a master list of errors and their suggested possible preventative actions was created. A summary of that list is shown in Table 1.

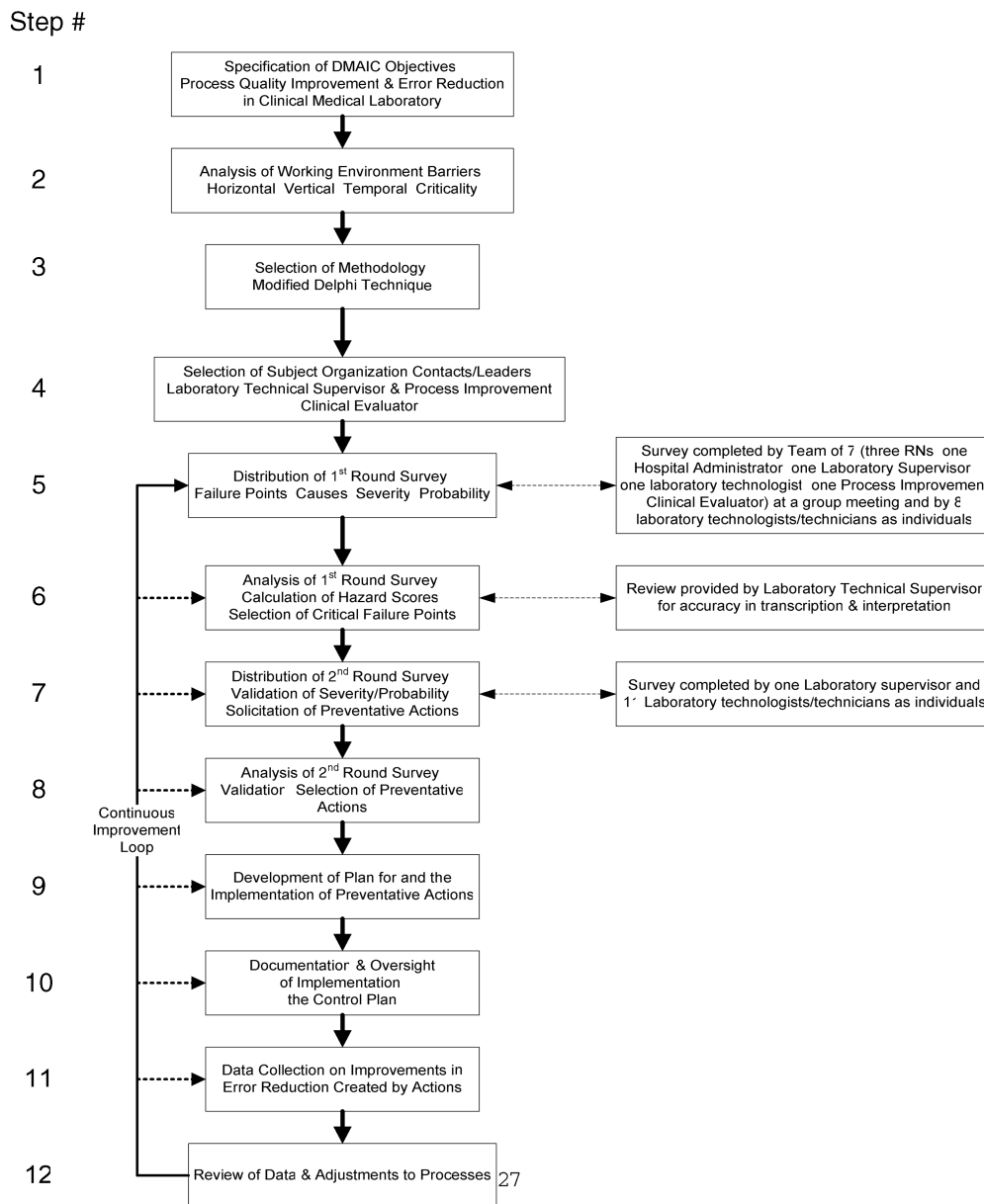


Figure 2. The Failure Mode And Effect Analysis process steps for a clinical medical laboratory using a modified Delphi technique.

Recognizing that the hospital has limited resources in terms of personnel, time, and funding, only the most critical errors, as determined by their hazard scores, were considered. The table, therefore, only includes those errors with the highest identified score of 12. The full table can be seen in the Appendix as Table B.

On the basis of the revised validated hazard scores, preventive actions for the most critical errors were selected for implementation in the FMEA process step 9. This step was performed based on inputs and participation of the laboratory technical supervisor and the hospital risk manager. Of these, the hospital contacts helped to determine which alternatives would

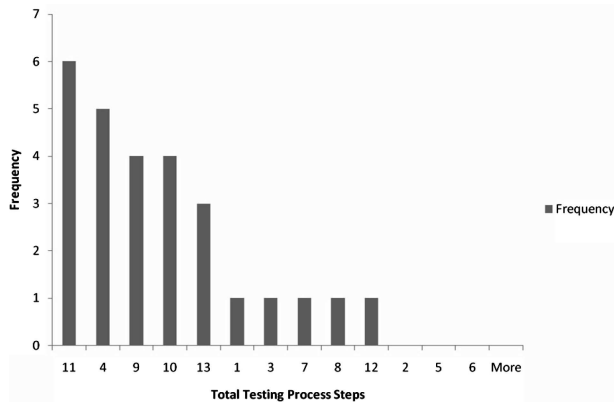


Figure 3. Error frequency by total testing process steps.

provide the most feasible and most effective preventative actions that would help to improve both patient safety and patient satisfaction.

IMPROVE/IMPLEMENTATION PHASE

The Improvement phase of DMAIC includes determining appropriate actions needed to correct process deficiencies and implementing those corrections. The plan for implementing the selected actions, the FMEA process step 9, initially involved presenting the proposed actions to the hospital contacts and then to administration for approval and selection of actions for implementation. This selection process was based on 2 criteria: both the hazard score of the identified error (the higher the hazard score the more critical the need for an error-proofed task) and the probability of success of implementing the action. It was believed that a successful implementation to prove the effectiveness of the process was as important as the criticality of the action.

The resulting selection focused on the fourth error from Table 1, “phlebotomist drawing blood from patient with no wristband.” An implementation and control plan was then developed. It was determined to develop a 2-phase implementation. In phase 1, the Performance Improvement Clinical Evaluator and the Laboratory Technical Supervisor, will initiate an audit for 2 weeks beginning approximately February 14, 2011. The audits will consist of laboratory employ-

ees monitoring the patients that they encounter for appropriate wristbands. These employees will be selected by both the LTS and the laboratory manager. This monitoring would be unannounced and performed on a random daily basis. During this audit, deviations from the current policy of wrist-banding will be noted including who, when, and why. Laboratory personnel would have spare bands with them and, if an unbanded patient is found, the error can be immediately corrected in the course of the audit.

Using the data from this audit, the LTS and the laboratory manager will make a decision as to whether enforcing the current policy (through reeducation) is sufficient or whether the hospital needs to develop new policies. New policies would be the responsibility of the LTS and would be put in place approximately 2 weeks following the decision.

Once that decision is made by the LTS and the laboratory manager, phase 2 is a 1-month follow-up audit immediately following the issuance of the new policy (or reeducation of existing). If no problems exist during time, spot audits will be conducted on a quarterly basis. If problems resurface, LTS and laboratory manager will readdress and correct and audit again in a cyclical manner. This plan was summarized in table format as seen in Table 2.

The LTS and the Performance Improvement Clinical Evaluator are also planning a secondary auditing round, following the completion of the primary implementation, to confirm the use of 2-patient identifier use (eg, wristband and patient’s statement of name, date of birth). This was an added benefit of the Delphi-enabled FMEA in that it reinforced process improvement efforts already underway.

CONTROL PHASE

One primary objective of DMAIC is to set into place proper Controls (per the last phase of the DMAIC) such that policies, procedures, and practices do not lapse back into preimplementation habits. This is the FMEA process step 10. One important aspect of this is the feedback loops associated with each of the steps in the process. A critical concept of DMAIC is that it is never a “one-time” shot at improvement but rather

Table 1

POSSIBLE PREVENTION ACTIONS SUGGESTED BY LABORATORY EMPLOYEES, NURSES, ADMINISTRATORS AND CLERICAL STAFF (MOST CRITICAL)

Hazard Score	Error	Possible Action to Prevent
12	Critical value not reported, lost report from floor to provider	<p>Be sure there is adequate staff and that they are paying attention.</p> <p>Monitor/audit to identify where errors are occurring and provide more education.</p> <p>Document errors on employee file.</p> <p>Call provider no matter what.</p> <p>Call laboratory or just reprint if lost.</p> <p>Provide a screen, similar to the laboratory, they cannot “WIZ” past and emphasize how important this could be.</p>
12	Nurse interprets report & decides caregiver notifications can wait.	<p>Educate the nurses that it is not nurse’s decision and that it is provider’s responsibility to accept these calls.</p> <p>Have a physician on call available from PM through AM (when doctors are in office/floors) to be point of contact in case provider of patient unavailable.</p> <p>Keep log of critical calls received and attempt communication with patient’s provider.</p> <p>Reassess policy for review.</p> <p>Design a better “on-call” list for laboratory result notifications. For patient type A: call X, for patient type B: call Y.</p> <p>Have a better process established through quality control officer.</p>
12	Provider misunderstands results or implications of results—orders or fails to order additional testing and/or procedures	<p>Improve communication between pathologist, laboratory, and providers.</p> <p>Provide continuing education as well as additional information or classes.</p> <p>Have additional support available for consultation.</p> <p>Schedule more frequent “Lunch & Learn” sessions between providers and the pathologist (or pathology practice).</p> <p>Provide education from laboratory pathologist on new tests or technology.</p> <p>Educate providers that they need to call the laboratory for interpretation if necessary.</p>
12	Phlebotomist drawing blood from patient with no wristband	<p>Do not draw without band and discipline/retrain in this area.</p> <p>Monitor/audit to identify areas where patients consistently not banded.</p> <p>Ask someone to arm band all patients.</p>
12	Incorrect results reported in step 10	<p>Educate, competency; identification of technologist not understanding results.</p> <p>Monitor/audit to identify where errors are occurring and provide more education. If problem is continues, let tech go.</p> <p>Document reeducation efforts to prove lack of ability to retain information.</p> <p>Make sure all results fit the clinical picture of initial diagnosis</p>
12	Clerical error	<p>Educate clerks to slow down</p> <p>Monitor/audit to identify problem areas and then provide more education in that area</p>
12	Incorrect results reported in step 11 (see also no. 19)	<p>Slow down and double-check before reporting</p> <p>Educate employees on proper procedures</p>

[AQ5]

(continues)

Table 1

POSSIBLE PREVENTION ACTIONS SUGGESTED BY LABORATORY EMPLOYEES, NURSES, ADMINISTRATORS AND CLERICAL STAFF (MOST CRITICAL) (*Continued*)

Hazard Score	Error	Possible Action to Prevent
12	Inappropriate treatment	Monitor/audit to identify problem areas and then provide more education in that area and after reeducation for the 3rd or 4th time employee needs to be let go Document the reeducation to prove lack of retraining information retained Make sure all results fit a clinical picture and/or repeat results to verify Educate/train/mentor provider Monitor and audit problem areas to identify sources of errors Remind providers that they need to listen closely to support staff Ask patient to repeat treatment plan back to doctor in own words to verify understanding and consent Provide more laboratory to provider communication on pathology level (as to what tests are important, why the testing protocol are in place, how those results should be viewed in light of patient condition) Reevaluate and reeducate providers to make them accountable

Abbreviations and definitions: Provider, physicians or physician assistants (PAs); nurses (RNs, etc), who are diagnosing and requesting/ordering laboratory services; Tech, laboratory technologist (CLS/MT—generally 4-year degree) or laboratory technician (CLT/MLT—generally 2-year degree).

a process of constant improvement. Information uncovered at each step (the FMEA process step 11) provides evidence for future areas of quality enhancement (the FMEA process step 12). Both DMAIC and FMEA are iterative processes so management should first develop a schedule of regular survey distributions to encourage constant evaluation and actions that will further improve patient care and safety. A second objective of the control plan is to provide a monitoring system for the specific actions implemented earlier. These monitoring systems would include such traditional quality control tools as statistical process control charts, a visual longitudinal tracking system.

FINDINGS

Using the Delphi technique to conduct an FMEA proved to be a very useful alternative methodology. The technique allowed for a group of 15 process owners to share their inputs and knowledge to identify

both errors and actions to prevent those errors for the purpose of improving patient safety and improving the steps within the total testing process of their laboratory. Involving that many disparate process owners would have been impossible in this setting using traditional FMEA methods.

On the contrary, there were some disadvantages noted to this process. Requiring individual inputs did create additional effort initially in that multiple instructions and much clearer instructions needed to be provided up front by those administering the surveys. Also, because the surveys were often completed away from the work setting, even though instruction was provided, individuals did not always thoroughly understand what knowledge and information they were being asked to furnish. Without the leader being physically present to provide guidance, some responses were not correctly completed.

Finally, the synergistic advantages that can be achieved in a well-designed brainstorming session may have been missed. These team synergies are hard to quantify but are, nonetheless, well-documented.

Table 2

IMPROVE/IMPLEMENTATION PLAN

Action	Responsible Person	Method of Implementing	Date to be Implemented	Control (Evidence of Continued Implementation)
1) Audit wrist-banding for errors to determine patterns and root causes	Jointly between: Performance Improvement Clinical Evaluator and LTS	LTS and Laboratory Manager will assign laboratory staff to perform unannounced random wristband checks on a daily basis over the 2-week period.	Audit to be initiated February 14, 2011	<ul style="list-style-type: none"> • Audit to be initiated for 2-weeks. During this audit, deviations from the current policy of wrist-banding will be noted.
2) Decision whether enforcing the current policy (through reeducation) is sufficient or whether the hospital needs to develop new policies.	Jointly between: Performance Improvement Clinical Evaluator and LTS	LTS and laboratory manager will assign laboratory staff to perform random unannounced wristband checks on a weekly basis over the following 1-month period..	March 1, 2011	<ul style="list-style-type: none"> • Audit regularly for 1-month. If no problems exist at that time, spot audits will be conducted on a quarterly basis. • If problems resurface, PI and laboratory will readdress and correct and audit again in an iterative cyclical manner.

[AQ6]

Abbreviation: LTS, Laboratory Technical Supervisor.

On the whole, however, it was felt that the advantages of uninhibited input from a larger number of process owners outweighed the disadvantages of not having the team synergy. The errors identified and the number of quality suggestions generated by the process, as completed, bears out that conclusion. It is believed that, as additional Delphi-enabled FMEAs are conducted at the organization, the better the process of instruction, education, and understanding of both leaders and participants will become, overcoming many of the disadvantages observed.

One further finding was that, in the process of conducting the Delphi technique surveys, which included open-ended questions as well, additional ancillary issues of interest arose. In a traditional FMEA setting, facilitators usually attempt to limit tangential discussions and issues to save time yet many of these issues may be of at least equal importance on improving the processes and hence the patient safety. Using the Delphi technique, limiting response and brain-

storming time is not as much of an issue so ancillary ideas and suggestions do not get squelched. In the course of this particular study, it was noted that the existing policy in one particular area of phlebotomy was actually too specific and should be revised to be more generalized to make it both easier to follow, more comprehensive, and more efficient.

MANAGERIAL IMPLICATIONS

This new process for conducting an FMEA is of importance to hospital administrators from the aspect that it will allow them to provide better, safer care to patients in an easier and more efficient manner than employing traditional methods while at the same time, meet their regulatory requirements set by the JC. Performing FMEAs has often been problematic, at best. This methodology allows health care process improvement teams to conduct them in a more efficient and broader manner with less disruption to

the normal workflow processes of the system. It overcomes the 4 barriers mentioned earlier and provides a formal, easily implemented structure for completing a relatively complex analysis.

LIMITATIONS AND FUTURE RESEARCH

This study did focus on an industry specific application, FMEA within the health care industry, and was even specific to a particular set of processes within one example of that industry, the total testing process of a clinical laboratory. Although this may limit its applicability to other processes within that industry or to other industries, the approach appears to lend itself to a wide range of areas. Future research needs to be done in both of these arenas to confirm this. In addition, longitudinal research needs to be done to determine whether differences exist in the long-term effectiveness of this approach versus more traditional methods of performing FMEAs, perhaps even side-by-side comparisons.

Future research will also include additional work at the subject institution. Only one specific error was addressed in the current implementation leaving 7 additional highly critical errors unaddressed. Both the Performance Improvement Clinical Evaluator and LTS are interested in performing additional root cause analysis and implementing additional preventative actions to further improve patient safety and satisfaction. Their attitude is that JC requirements are merely a starting point from which to build an ongoing continuous improvement program that will enhance both the hospital's ability to provide excellent health care solutions at reasonable costs and keep the employees involved in improving their own working environment and job satisfaction.

CONCLUSIONS

The hospital involved in this study does intend to utilize the results of this research to satisfy its quality improvement initiative requirements of the Joint Commission. A copy of this study is on file at the hospital in preparation for the next accreditation visit of the Joint Commission, which is currently

scheduled for the laboratory in the summer of 2012. The JC certifies laboratories every 2 years and health services every 39 months. As the accreditation visit usually entails anywhere from 5 to 10 people over 2 to 3 days, the process is very thorough and this study should provide excellent documentation of the hospital's process improvement efforts. The hospital managers were very pleased with the ease of administration, the lack of disruption to the normal working environment, and the honesty in answers and suggestions that the Delphi survey method provided to them.

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APPENDIX

Table A

HAZARD SCORE TABLE^a

[AQ7]

	Severity			
	Catastrophic	Major	Moderate	Minor
Frequent	16	12	8	4
Occasional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

^aAdapted from the U.S. Department of Veterans Affairs, 810 Vermont Avenue, NW—Washington, DC 20420. Reviewed/Updated Date: November 10, 2009.

Table B

POSSIBLE PREVENTION ACTIONS SUGGESTED BY LABORATORY EMPLOYEES, NURSES, ADMINISTRATORS, AND CLERICAL STAFF

Hazard Score	Error	Possible Action to Prevent
12	Critical value not reported, lost report from floor to provider	Be sure there is adequate staff and that they are paying attention. Monitor/audit to identify where errors are occurring and provide more education. Document errors on employee file. Call provider no matter what. Call laboratory or just reprint if lost. Provide a screen, similar to the laboratory, they cannot “WIZ” past and emphasize how important this could be.
12	Nurse interprets report & decides caregiver notifications can wait.	Educate the nurses that it is not nurse’s decision and that it is provider’s responsibility to accept these calls. Have a physician on call available from PM through AM (when doctors are in office/floors) to be point of contact in case provider of patient unavailable. Keep log of critical calls received and attempt communication with patient’s provider. Reassess policy for review. Design a better “on-call” list for laboratory result notifications. For patient type A: call X, for patient type B: call Y. Have a better process established through quality control officer.

(continues)

Table B

POSSIBLE PREVENTION ACTIONS SUGGESTED BY LABORATORY EMPLOYEES, NURSES, ADMINISTRATORS, AND CLERICAL STAFF (*Continued*)

Hazard Score	Error	Possible Action to Prevent
12	Provider misunderstands results or implications of results- orders or fails to order additional testing and/ or procedures	<p>Improve communication between pathologist, laboratory, and providers.</p> <p>Provide continuing education as well as additional information or classes.</p> <p>Have additional support available for consultation.</p> <p>Schedule more frequent “Lunch & Learn” sessions between providers and the pathologist (or pathology practice).</p> <p>Provide education from laboratory pathologist on new tests or technology.</p> <p>Educate providers that they need to call the laboratory for interpretation if necessary.</p>
12	Order wrong test	<p>Clarify ordering screens because it is sometimes hard to find right test for choice on computer.</p> <p>Have provider order tests directly into the computer.</p> <p>Contact provider and get verbal verification if written orders are illegible.</p> <p>Provide electronic order sheets.</p>
12	Phlebotomist drawing blood from patient with no wristband	<p>Contact provider and question orders that do not make sense.</p> <p>Do not draw without band and discipline/retrain in this area.</p> <p>Monitor/audit to identify areas where patients consistently not banded.</p> <p>Ask someone to arm band all patients.</p>
12	Incorrect results reported in step 10	<p>Educate, competency; identification of technologist not understanding results.</p> <p>Monitor/audit to identify where errors are occurring and provide more education. If problem is continues, let tech go.</p> <p>Document reeducation efforts to prove lack of ability to retain information.</p> <p>Make sure all results fit the clinical picture of initial diagnosis.</p>
12	Clerical error	<p>Educate clerks to slow down.</p> <p>Monitor/audit to identify problem areas and then provide more education in that area.</p>
12	Incorrect results reported in step 11 (see also 19)	<p>Slow down and double-check before reporting.</p> <p>Educate employees on proper procedures.</p> <p>Monitor/audit to identify problem areas and then provide more education in that area and after reeducation for the 3rd or 4th time employee needs to be let go.</p> <p>Document the reeducation to prove lack of retraining information retained.</p> <p>Make sure all results fit a clinical picture and/or repeat results to verify.</p>
12	Inappropriate treatment	<p>Educate/train/mentor provider.</p> <p>Monitor and audit problem areas to identify sources of errors.</p> <p>Remind providers that they need to listen closely to support staff.</p> <p>Ask patient to repeat treatment plan back to doctor in own words to verify understanding and consent.</p> <p>Provide more laboratory to provider communication on pathology level (as to what tests are important, why the testing protocol are in place, how those results should be viewed in light of patient condition).</p> <p>Reevaluate and reeducate providers to make them accountable.</p>

(continues)

Table B

POSSIBLE PREVENTION ACTIONS SUGGESTED BY LABORATORY EMPLOYEES, NURSES, ADMINISTRATORS, AND CLERICAL STAFF (*Continued*)

Hazard Score	Error	Possible Action to Prevent
9	Not noticing an incongruent result	<p>Provide adequate training or reeducate.</p> <p>Train employees that turn-around time is not most important measure, patient needs correct results more than timely inaccurate results;</p> <p>Calm down and slow down.</p> <p>Have a second party check result logs.</p> <p>Go at a pace that allows you to follow procedures and ask for help when needed.</p> <p>Use competency exams to ensure techs understand/recognize incongruent results.</p> <p>Provide guidance as necessary.</p>
9	Critical values not followed up on or called to floor	<p>Provide 2 people in the department on busy days.</p> <p>Follow process and do not skip steps to save time.</p> <p>Discipline and/or educate if do not follow up.</p> <p>Monitor/audit to identify where errors are occurring and provide more education.</p> <p>Remind employees that pop-up on computer screen is supposed to make you call.</p> <p>Write-up errors in employees file.</p> <p>Calm down and slow down.</p> <p>Have a follow-up discussion with competency and observed practice.</p> <p>Train employees so they understand and then remind and reinforce the notion that a quick and inaccurate result is more harmful than a delayed accurate result—quality not quantity.</p>
9	Provider acts on tests only, not whole clinical picture	<p>Establish a responsible person to ensure provider’s capabilities.</p> <p>Educate the provider on what test results mean.</p>
9	Assessment error (incorrect initial diagnosis)	<p>Establish one provider who supervises all other providers</p> <p>Less workload and involve other’s in decisions.</p> <p>Educate providers (providers need to address).</p> <p>Educational opportunities or consultation support (more continuing education and competency assessments).</p>
9	Wrong patient identified	<p>Provide opportunities for providers to destress (yoga, meditation, prayer)</p> <p>Do not draw if you cannot identify.</p> <p>Reeducate and reinforce policy to assure that employees follow protocol.</p> <p>Provide reminder to staff that they will not be disciplined for refusing to draw patients who have not been properly identified</p>
9	Inaccurate calibration, QC errors	<p>Provide further education on calibrating and understanding quality control results.</p> <p>Review of calibrations done daily by lead technologist.</p> <p>Work with manufacturer’s technical service if necessary.</p> <p>Provide classes on quality control</p>
9	Test done incorrectly	<p>Educate employees on proper procedures and that they must be followed.</p> <p>Document the reeducation to prove lack of retaining information provided.</p> <p>Provide competency tests in house to ensure same correct procedure being used by everyone and that then observe procedure being used</p>

(continues)

Table B

POSSIBLE PREVENTION ACTIONS SUGGESTED BY LABORATORY EMPLOYEES, NURSES, ADMINISTRATORS, AND CLERICAL STAFF (*Continued*)

Hazard Score	Error	Possible Action to Prevent
9	Instrument error/malfunction	Keep maintenance of instruments up to date. Replace instrument if continually having problems. Provide more time off the bench for lead techs by assigning calibration and maintenance to competent evening staff. Reeducate employees on maintenance. Monitor instrument error logs, maintenance logs, and calibrations. Review by a second tech in same day to make sure troubleshooting done. Call manufacturer's technical services. Review maintenance policy. Check of competency and additional education as needed combined with observed practice with annual/quarterly evaluations; Provide more familiarity with instruments. Call over others as time permits to observe procedures when someone is fixing equipment. Develop a policy on what to do next if analyzer's calibration fails.
9	Skipping the report review in step 10	Provide training so that all techs are familiar with calibrations; Train employees better to pay attention; Provide discipline when errors made. Monitor and audit problem areas to identify sources of errors. Educate staff to follow procedures. Educate staff on how those results should be viewed in light of patient condition
8	Specimen not centrifuged right. Others not mixed before running	Slow down and do the process as the procedure calls for. Pay attention (there are many disruptions in chemistry) and slow down. Provide education or reeducation on mixing tubes. Put up a reminder flag to check specimen integrity by the centrifuges and analyzers. Have the supplies needed to check for clots by the centrifuges/aspiration stations centrifuged, mix, prep, sample, correct before running. Do a "Stop, look, listen" and follow up with observed practice and annual/quarterly assessments. Inform everyone how each clinic's tubes should be handled.
8	Bubbles in sample. Clots in sample. Analyzer picks up wrong volume	Check each sample before analyzing Train employees and emphasize to them to follow the process. Check all tubes in hematology for clots prior to being analyzed. Place applicator stick by analyzer sampling areas to check containers that are likely to have clots that will affect testing (example: microtainers). Check the coagulation tubes for clots before centrifuging. Check all EDTA tubes for clots if results are questionable. Do a "Stop, look, listen" and follow up with observed practice and annual/quarterly assessments. Train employees so they understand and then remind and reinforce the notion that a quick and inaccurate result is more harmful than a delayed accurate result. Check each sample before analyzing

(continues)

Table B

POSSIBLE PREVENTION ACTIONS SUGGESTED BY LABORATORY EMPLOYEES, NURSES, ADMINISTRATORS, AND CLERICAL STAFF (*Continued*)

Hazard Score	Error	Possible Action to Prevent
6	Laboratory not verbally verifying patient information in addition to wristband.	Verify verbally and follow through with discipline if not done. Assure appropriate audits are in place. Have nurse or family members to also identify if patients are not able to verbalize. Leave note on employees record to reinforce policy if an employed found to have not followed procedure. Ask patients if employees have been verbally asking name and date of birth (be sure patients know they can ask staff to verify. Identify patients according to procedure and follow through with appropriate disciplinary action when procedure not followed. Inform & enforce current policy that states that all personnel will verify the wristband information by asking the patient to spell/state their name and give their date of birth if they are able. Employees should always check patient information and file an incident report if they do not. Reemphasize the importance of verbal identification and policy with employees
6	Entering wrong patient ID into computer	Hire enough staff so they are not overworked. Train employees to slow down and stay focused. Audit for patterns of mistakes. Scanning barcodes if labels were placed on tubes at patients' side. Provide better education or reeducation on the hospital wide computer system. Double check all identification numbers entered/registered (use 2nd party to verify if needed). Finish each task at hand and double check before moving on. Have other staff help in the process to lessen load of work or a particular person/area. Have 2 people in department on busy day (a laboratory "float") so we have enough staff to cover all areas so errors are less likely to occur. Make the bar code number bigger. Verify patient name after entering identification number
4	Interface problem	Improve IT's part in the process. An IT issue, enlist their help. Complete the update of the new laboratory computer system coming to the hospital as quickly as possible. Try putting computers at the laboratory's clinic/clients. Identify issues early with walk-through of systems before being put into place

(continues)

Table B

POSSIBLE PREVENTION ACTIONS SUGGESTED BY LABORATORY EMPLOYEES, NURSES, ADMINISTRATORS, AND CLERICAL STAFF (*Continued*)

Hazard Score	Error	Possible Action to Prevent	
3	Nurses not banding a patient.	Band all the patients at registration. Confirm patient identification with nurse. Track patients with no bands for first 3 days of each month (who, where, when involved) to identify if random error or if attributable to a specific department or person. Provide appropriate disciplinary action. Educate nurses on appropriate procedures.	
3	Reports printing to areas not monitored (EMR or printer).	Have a designated person to armband patients Provide adequate staff. Take nonmonitored printers out of system. Monitor where reports are being sent. Remove unnecessary printers so laboratory employees can not use from hospital computer system. Double check where laboratory's reports are being printed; update list of printers—verify numbers; Check electronic record over printed record. Have reports automatically print—take the human error out; automatic printout to right area;	[AQ8]
	Other Suggestions:	Continuing education within laboratory all the time is important. Communication is major issue within laboratory and also with other departments. Lack of respect for laboratory when there have been major issues with certain employees and those issues are looked at by outside departments of incompetence of laboratory in general. Please do not ignore competency documentation. Limits need to be set on how long problems can continue without severe consequences. Because of ongoing issues with incompetent techs, we have lost respect from outside of our department, which will never be gained back until we deal with those employees. Ask the ER staff for direct feedback on this as comments are received from them constantly. Have departments do surveys of other department's performances (ie, emergency room vs laboratory, intensive care unit vs pharmacy). Discuss the results at staff meeting. Do shadowing. Have a representative from one department shadow another department staff member for a half to one full shift to understand procedures undertaken in that department. For example, an ER nurse that is shadowing a staff member in the laboratory might understand why specimen integrity is so important and why some tests are fast and others long. Every department in the hospital must follow procedures. Write a procedure if you need to. Educate and do competency testing. Use appropriate disciplinary action when necessary.	[AQ9]

(continues)

Table B

POSSIBLE PREVENTION ACTIONS SUGGESTED BY LABORATORY EMPLOYEES, NURSES, ADMINISTRATORS, AND CLERICAL STAFF (*Continued*)

Hazard Score	Error	Possible Action to Prevent
		<p>A main problem is having a solid system of flow. Evaluation of “lean” like processes to have in place. Increase focus of job, eliminate distractions, and time management. Multitasking education, as well as time-management education is highly needed. Addressing work problems (bench day & bench work, not supervisory tasks).</p> <p>Make 50 lashes with a wet noodle a mandatory punishment for all minor offenses.</p> <p>I believe communication from supervisors is the key. Who should be getting specimens from clinic-enough staff to cover departments with fewer interruptions (phone calls, leaving station to draw blood outside the laboratory, going to get STATS from clinic & leaving chemistry unattended). No one should fear asking a question or for help – our experiences are very valuable and can be used to educate the laboratory staff.</p> <p>There should be a better work flow in the laboratory, some techs, clerks multitask while others can’t or won’t. All of the additional elements (reviewing clinic orders, going to the clinic to get specimens, etc.) may need to be more controlled regarding who does what.</p> <p>To ensure good difference/change stain weekly-better yet automatic differential staining-so all slides are good quality.</p>

[AQ10]

Abbreviations and definitions: Provider, physicians or physician assistants (PAs); nurses (RNs, etc), who are diagnosing and requesting/ordering laboratory services; Tech, laboratory technologist (CLS/MT—generally 4-year degree) or laboratory technician (CLT/MLT—generally 2-year degree).

Title: A Modified Delphi Methodology to Conduct an Failure Modes Effects Analysis: A Patient-Centric Effort in a Clinical Medical Laboratory

Authors: Peter B. Southard, Sameer Kumar, and Cheryl A. Southard

Author Queries

- AQ1: Please provide the highest academic degree(s) of the authors.
- AQ2: Please check whether the affiliation and corresponding authors address are OK as set. Please confirm whether the complete affiliation of all the 3 authors is the same. If not, then please provide the affiliation of Cheryl A Southard.
- AQ3: Please cite a reference for the quoted matter by Dock (“70%... laboratory”).
- AQ4: Reference 21 could not be verified. Please provide publisher location (and author names, if any) for the reference.
- AQ5: Please confirm whether “see also no. 19” refers to a section in Table 1. Please provide the section.
- AQ6: Please define PI in Table 2.
- AQ7: Please provide a copy of the letter granting permission for Table A in the Appendix. Also, please provide complete reference details
- AQ8: Please define EMR, EDTA, and IT.
- AQ9: ER and ICU has been expanded as emergency room and intensive care unit in Table B of the Appendix.
- AQ10: “diff” has been changed to difference in Table B of the Appendix. Please check.