ABSTRACT

SEASTRUNK, CHAD STEPHEN. Algorithm to Systematically Reduce Human Errors in Healthcare (Under the direction of Dr. Timothy Clapp.)

The purpose of the research was to develop an algorithm to permanently reduce human errors in the healthcare industry. The algorithm will be able to be applied to all healthcare organizations and provide a preventative approach to errors. The research involved looking at past methods of error reduction/prevention. Certain methods proved to be useful in generating the algorithm like the Healthcare Failure Modes and Effects Analysis while others like Root Cause Analysis proved to only have limited success. The algorithm takes a three phase approach to reducing errors. Phase One identifies the potential error producing situations. Phase Two uses error proofing principles and known solution directions to generate solutions while Phase Three uses a new method developed called Solution Priority Number to rank and evaluate the solutions. Throughout the algorithm many worksheets have been developed to aid in a team's progression through the process. Two case studies were performed. The first case study followed a traditional team through the error prevention process while the second case used the algorithm. When comparing the two cases the team using the algorithm finished the process in shorter time, produced more effective failure modes, and generated a richer set of solutions to error proof the process.

Algorithm to Systematically Reduce Human Errors in Healthcare

By

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I would like to dedicate this to my wife Rachel.

Biography

Chad Seastrunk began attending North Carolina State University in the fall of 2000. Before entering the College of Textiles he was awarded the Centennial Scholarship. At the College of Textiles at North Carolina State University he pursued an undergraduate degree in Textile Engineering. Upon graduation, he entered into a Masters program in Textile Engineering.

Acknowledgements

I would first off like to thank God for giving me the ability to perform this research. I also need to thank my wife Rachel for standing with me through this entire process. My family has also given me support without I would have never made it this far. I would also like to thank Dr. Clapp my advisor for guiding me through the research and Dr. Nakajo, Dr. Godfrey, Dr. Joines, Dr. Thompson, Mike Ferguson, and Jonathan Cook. I also would like to thank all of my fellow students in the Textile Engineering Department for making my graduate experience one I will always remember.

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1.0 Introduction

Processes or tasks in any industry will be prone to errors. These errors can be caused by the system that controls the process or they can be made by the human performing the process or task. A systems error is something that can normally be fixed once and then it will not occur again. For example, a computer program calculated the wrong value because of a code error. Once the error in the code is fixed, the problem is solved because the computer will only perform the tasks requested. The same can not be said about human errors. People can be told the correct procedure and often times know it, but because of a complex system, the right thing may not always get done.

Most process improvement techniques change how the human acts or performs a certain task, but this can prove ineffective. Error proofing is different in that it aims to change the work operation for the human(s) performing the operation. Changing the work operation instead of the worker produces a more effective change. With the old way of thinking, a lot of training is needed for every new worker, but imagine a workplace where the operations have been changed so that even the new worker can perform as if they had been there for years.

In healthcare, human errors not only affect the quality and efficiency of the healthcare organization but they also have an effect on patient safety. Healthcare is different from most other types of organizations in that the processes are working on humans and not inanimate parts. A single defective part in a manufacturing setting can cost the company a small amount of money, but a defect in healthcare can cost a patient their life. In many cases these errors are not made with an attempt to harm someone but can lead to that result. Error proofing is a very effective way to permanently reduce these errors that are prone to occur.

Many industries, especially healthcare, take a reactive approach to process improvement: they wait until errors occur before they try to fix them. One obvious problem with this line of thinking is that errors do occur and will only be fixed after the consequences are suffered. Allowing these errors to occur can lead to serious quality issues or in a healthcare setting cost a patient's life. Another problem with this methodology is that it forces everyone to focus on one event or occurrence. In a complex

system the error may happen again, but have a different cause, making it difficult to achieve a permanent solution.

A cycle of resolving problems is very frustrating for any organization. Another problem that most have with process improvement is how to hold the gains once a change has been made. In these organizations, people can be efficient problem solvers because they keep solving the same problem over and over again. Resolving problems over and over could be the result of trying to change the human action and not the operation, so the error never goes away permanently. All of these reasons are why a proactive and not reactive approach to reducing errors is needed.

Developing a systematic process for the healthcare industry is needed. The systematic approach would not just provide short term answers to their errors but would lead to a permanent reduction in these errors and thus eliminate the cycle of resolving problems.

1.1 Plan of Action

To achieve a systematic approach, a series of methods will be applied in order to achieve the permanent error reduction needed. A three phase approach involving 1) identification of potential error producing situations, 2) applying error proofing principles to generate solutions, and 3) selecting and evaluating the error proofing solutions will be used. With this approach, no adverse event has to occur for the process to take place; therefore it is completely preventative. Research is needed in the beginning to identify which high risk area will be the focus of the team's efforts.

In phase one, identifying potential error producing situations, a team would generate a list of what could potentially go wrong. A proactive approach to potential errors must be implemented. In this phase using tools such as Root Cause Analysis (RCA) or a Failure Modes and Effects Analysis (FMEA) can be used to identify potential errors. Using a FMEA is now required by Joint Commission for Accreditation of Healthcare (JCAHO) to identify failure modes in selected critical areas [1].

After identifying all of the potential errors, the next phase is to generate solutions from the set of potential error producing situations. Phase two is where applying error proofing principles and proven Solution Directions (SD) will prove useful. It is important to remember when generating solutions to change the work operation and not the human. Proven solution directions show how others have solved similar problems in the past. Using what others have done to solve similar problems will increase the likelihood of success in solving the specific problem.

Phase three is the solutions evaluation and selection phase. Phase three is often overlooked because it is normally a subconscious step instead of an actual selection process. In this phase, solutions will be evaluated and then selected. People may try to evaluate the solutions in phase two, but that would be incorrect. In the solution generation phase, solutions are only to be generated, not evaluated. By spending the time to evaluate solutions as they are listed during Phase Two will to lead wasted time. Losing this time may lead to a potentially novel or innovative solution from ever being discussed.

1.2 Thesis Statement

The healthcare industry is a very complex and tightly knit system which makes it essential for a systematic approach to permanently reduce error. An algorithm taking a three phase approach of 1) identifying potential error producing situations, 2) generating error proofing solutions, and 3) evaluating and selecting solutions will be developed for permanently reducing errors in health care and can be used by all healthcare providers.

2.0 Literature Review

Hospitals are designed to care of the sick and the injured. They are places where people go to improve their health. Not everyone who goes to a hospital leaves with an improvement in their health. The nurses or doctors do care about their patients; their primary concern is for providing high quality care to each of their patients. Why do medical errors happen? Every year, people die due to medical errors and the problem is larger than most people realize. Between fifty to one hundred thousand people die due to medical errors [2]. This total is greater than all the people that died due to motor vehicle accidents, breast cancer, and aids [3].

Are the healthcare organizations doing anything about the errors? The fact of the matter is that they are. Previously, the focus on how to reduce errors had been placed solely on the shoulders of the individual healthcare provider. The first approach to handling error has been to punish the employee in some way for making the error. This type of punishment could be a verbal speech given by the supervisor or being suspended from work. The problem with this line of thinking is that it implies that the worker committed the error intentionally and can simply choose not to do it the next time. Trying to bring about a permanent change in the workplace through these types of methods can never be accomplished.

Training the healthcare providers better through continuing education, quality improvement classes, or recertification programs has also been used [4]. The emphasis of all these of the options is to change the healthcare provider and how they perform their job. The reason they do this is to ensure that "patients should not be harmed by the care intended to help them [4].” The limitation in training is that the worker can only remember what he/she has been taught for a short amount of time. Even the most skilled worker can make an error.

Applying Six Sigma principles can be a part of a successful action plan to reduce errors in a healthcare organization. Part of the resistance to Six Sigma is that to be truly successful it needs to be instituted across the entire organization [5]. Only when the organization begins to internalize the Six Sigma methodology can the greatest gains be seen.

2.0.1 Root Cause Analysis (RCA)

A popular choice among hospitals has been to use a methodology called Root Cause Analysis (RCA). RCA has been used by many hospitals to investigate their Adverse Events or Adverse Drug Events (ADE) [6]. The Institute of Medicine has even identified specific areas in which RCA can and should be used [4, 7].

Data for RCA can be collected in a variety of ways. "Factual evidence derived from data gathering activities is the basis for all valid conclusions and recommendations from a root cause analysis [8]." Data can be divided into four main categories: people, physical, paper, and position. Physical data of the error needs to be preserved in case it needs to be analyzed many times. Paper data can be written or electronic and will often show management breakdowns. Position data refers to people or items at the scene of the incident that could be used to determine a cause of failure. Data obtained from people would be from ones who were eye witnesses or participants in the failure. When performing a RCA it is important to know all of the areas where data can be obtained so the root cause can be found [8].

RCA takes the approach of asking the five "Whys" to the adverse event that occurred. The goal of asking the group these questions is to drill down to determine the exact cause of the problem. A set of core answers can be reached: insufficient training, insufficient time, carelessness, and simple human error. When one of these answers has been reached, the team can stop asking the question "Why" [9].

RCA has some limitations in its methodology that causes it to not be the ideal methodology for all healthcare providers. The first limitation is that it takes a reactive approach to the error. In healthcare, one error can cost a patient their life. Another drawback involves how to generate and implement solutions to the root causes of the problem. Some researchers [9] mention error proofing or fail-safing as options to solve root causes but no examples or systematic method of deployment is mentioned for either.

2.0.2 Failure Modes and Effect Analysis (FMEA)

The FMEA started the paradigm shift away from reacting to errors and to the beginning of preventing the errors from occurring [10]. The methodology originated in the automotive industry as a way to assess and prevent potential defects in their parts [11]. The FMEA is an analytical tool used by an engineer or team to assess potential

failure modes and their causes and can be viewed as the thought process that an engineer would go through when developing a part or process.

The methodology in the FMEA has started to branch out into many specific forms to apply to a wide variety of users. The FMEA can be a process FMEA, design FMEA, system FMEA, or machine FMEA to name a few [10]. With all these different types of FMEA a user from many industries can perform this analysis to prevent errors at their job.

Performing a FMEA can be done by an individual or by a team. For some FMEA's that involve an entire process or multiple systems an entire team of people would be recommended in order to be thorough [10]. The first step to be is to visually map the process. The process map will serves as a representation of what happens step by step through the entire process. Identifying areas of failure or failure modes is the next step. Mapping the process is important because the different steps in the process will be examined and failure modes from the steps will be determined.

The FMEA provides a way to rank order the failure modes on a three parameter scale: severity, chance of the error occurring, and probability of detecting the error. These parameters are ranked on a 1 to 10 scale. By multiplying the three parameters together a Risk Priority Number or RPN is generated [11]. A higher RPN would indicate that the failure mode needs to have a solution and action plan generated. The RPN provides a means to rank the failure modes from most critical to least critical.

The limitation in the FMEA comes after the most critical failure modes have been identified. According to the FMEA, an action plan is to be developed on how to decrease the probability or improve the detection around the failure mode. The action plan has a member of the team assigned as the responsible member to see the action plan through [11]. Once implemented, the score is then reassessed to be able to show how much improvement has been made. The improvement can be judged on the overall reduction of the RPN number. However, no systematic method for generating solutions is provided in the FMEA methodology. The team must rely on random solution generation method based on the team's specific experience and knowledge

2.1 Phase One: Identification of Error Producing Situations

Identify potential error modes can be complicated. Most systems in healthcare analyze adverse events. Even the more progressive systems will only analyze the close calls at best [1]. The problem with this mindset is that for these two systems to start working a patient either has to be hurt or almost hurt. Taking action against an adverse event and learning from it can give valuable information, but it can not be the only line of defense against errors.

The engineering community has been using the Failure Modes and Effects Analysis or FMEA to accomplish a proactive approach to dealing with errors. The problem with the FMEA is that is was designed to look at defective parts or equipment. In healthcare they are generally looking at entire processes, performed by human operators that affect the life of a patient. All too often when a healthcare organization performs an FMEA, the severity score always becomes a ten [1]. The reason for this is that errors in healthcare can either lead to the death of the patient or cause no harm.

The National Center for Patient Safety (NCPS) began to investigate all types of methodologies that took a proactive approach to identifying errors in processes [1]. The NCPS identified the Hazard Analysis and Critical Control Point Principles (HACCP) that was being used for the US Department of Agriculture. This was originally developed by the Food and Drug Administration to protect food supplies [1]. The HACCP has seven steps to consider: conduct a hazard analysis, identify critical control points, establish critical limits, establish monitoring procedures, establish corrective actions, establish verification procedures, and establish record keeping and documentation procedures [12].

The NCPS looked at their own RCA process to determine if there were any steps or methods contained that could be beneficial for the development of a new process. The RCA process had a Safety Assessment code matrix to prioritize events [1]. This matrix would rank events based on their severity and their probability. The matrix ranked both of these parameters on a one to three scale.

After viewing the FMEA, HACCP, and RCA, a new method was developed using the best parts of all three methodologies. Concepts from the industry FMEA model were used to satisfy the proactive approach needed in the healthcare industry. The decision tree model from the HACCP was used. The RCA process lead to the development of a

new Hazard Score Matrix with a 1-4 scale for severity and probability and will be used. The new method developed was called the Healthcare Failure Modes and Effects Analysis (HFMEA) [1]. Figure 2.1.1 shows the HFMEA and their concepts and concepts of the other processes viewed. The HFMEA aimed to create a proactive approach to dealing with errors that included understandable healthcare definitions.

Concepts Employed	HFMEA™	FMEA	HACCP	RCA
Team membership	•	•		•
Diagramming process	•	•	•	
Failure mode and causes	•	•		
Hazard Scoring Matrix	•			•
Severity and probability definitions	•	†		•
Decision Tree	•		•	
Actions and outcomes	•	†		•
Responsible person and management concurrence	•	†		•

* *HFMEA, Health Care Failure Mode and Effect Analysis; FMEA, Failure Mode and Effect Analysis; HACCP, Hazard Analysis and Critical Control Point; RCA, root cause analysis.*

† *Although these components are present in FMEA, they were substantially modified in the HFMEA™ model.*

Figure 2.1.1 HFMEA Concepts [1]

The HFMEA can be broken down into five simple steps: define the topic, assemble the team, graphically describe the process, conduct a hazard analysis, and produce actions and outcome measures [1]. The HFMEA uses worksheets similar to the ones found in the industry FMEA process. The worksheet used by the HFMEA with explanations of each section can be found in Figure 2.1.2.

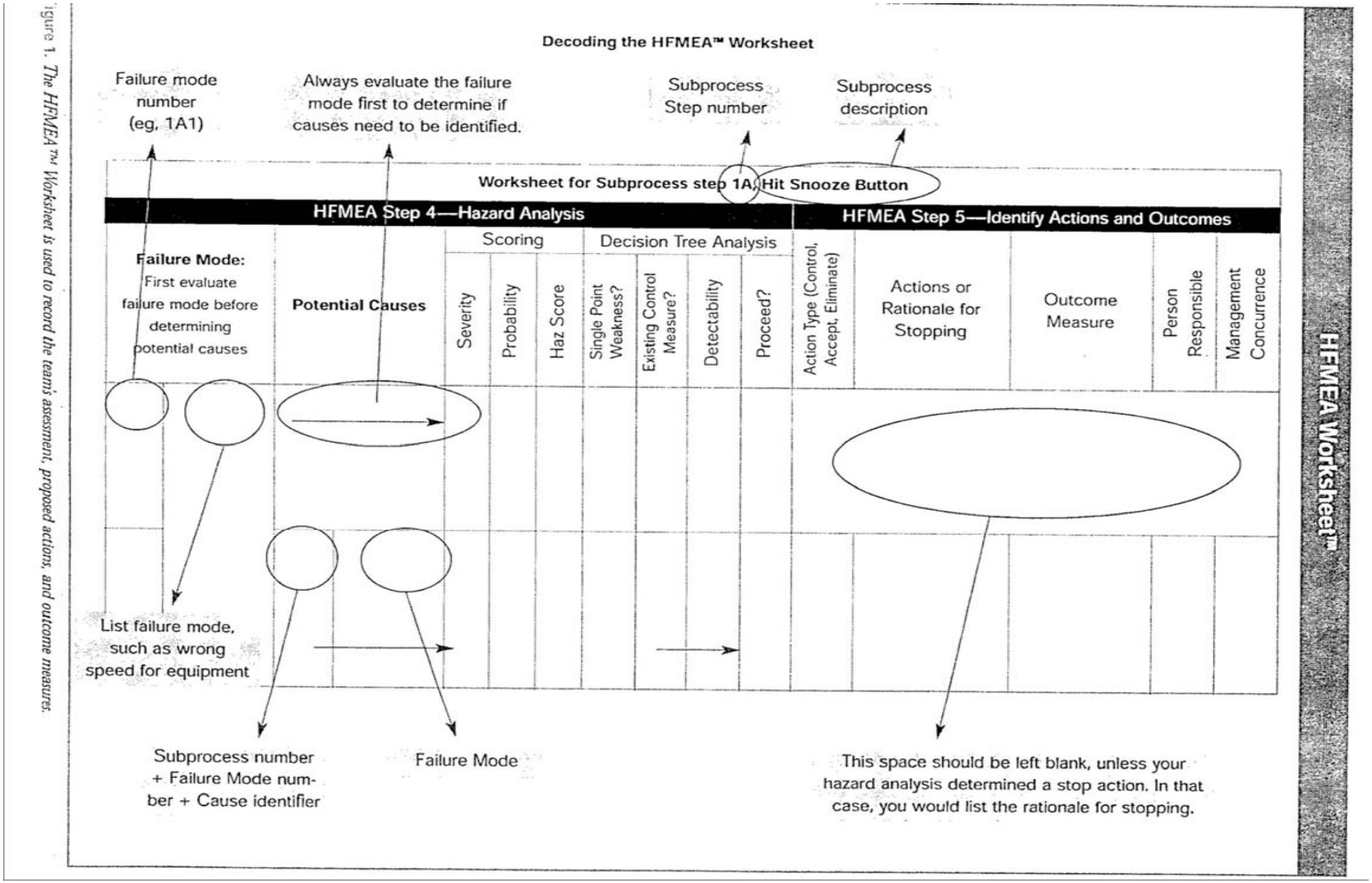


Figure 1. *The HFMEA™ Worksheet is used to record the team's assessment, proposed actions, and outcome measures.*

Figure 2.1.2 HFMEA complete worksheet [1]

Even with all the methodologies that the HFMEA draws from it is still lacking a very important step at the end. It lacks a systematic method to go forward and error proof the process through generating solutions. In step five of the HFMEA the most that is recommended is to put a person responsible to seeing the action through for the failure mode in question. The FMEA and HFMEA both have this flaw and that they tell the user to identify areas to improve (failure modes) and ask the user to put people responsible and set dates for the completion of the improvement. This drawback can lead to projects that do not fully error proof the process as it was intended to be.

2.2 Phase Two: Generating Solutions

Developing solutions is a part of every process improvement team. When problems are identified, solutions to those problems are generated. Most of the teams that generate solutions do so using an informal brainstorming technique. Team leaders encourage their members to think outside the box or out of their own realm of knowledge, but the team leaders never really facilitate the members to do so. Solutions are often generated without really knowing how the solution was discovered or what type of effects a solution of that type will bring.

2.2.1 Error Proofing, Poka-Yoke, and Mistake Proofing

Error proofing has been given many titles throughout the years: mistake proofing, foolproofing [13], poka-yoke [14] [15], etc. All of these names carry the same methodology: change the work operation to fit the human being. However, error proofing has been applied primarily to manufacturing processes.

Nakajo and Kume, in the late 1980's, studied over one thousand error proofing solutions [13]. They found that five principles existed that categorized all of the solutions. These five principles are elimination, replacement, facilitation, detection, and mitigation. The manufacturing community utilized the detection principle the most as computers and other advanced technology came available. Each of the principles was then divided into sub-principles to make it easier to understand how to mistake proof the process. Figure 2.2.1.1 shows the five principles and their sub-principles in a chart format.

Dr. Nakajo also found in manufacturing that there are common error modes found throughout the manufacturing solutions [16]. Identifying the common or generic error makes it easier to generate proven solutions. If the same type of error is happening at different points throughout the process, one solution or type of solution may be able to solve multiple problems. Table 2.2.1.2 shows a list of some of the common error modes found in manufacturing.

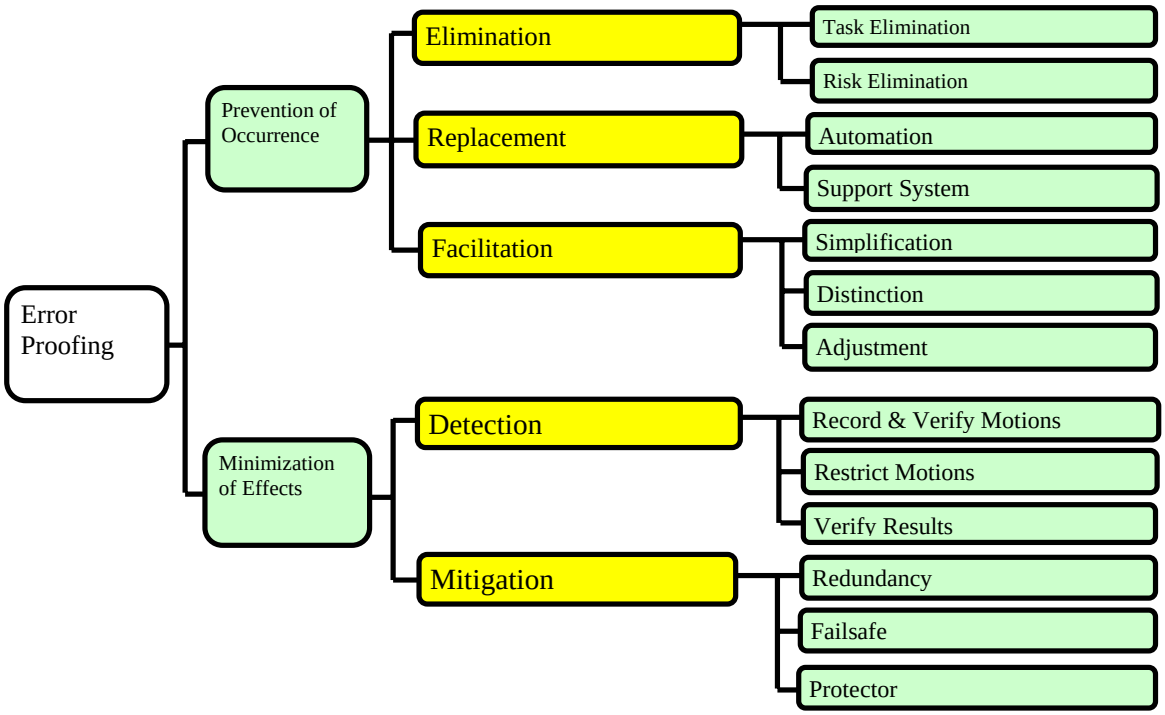


Figure 2.2.1.1 Error Proofing Principles and Sub-Principles

Table 2.2.1.2 Common Error Modes found in Manufacturing

Error Modes
Omission
Excessive Repetition
Wrong Sequence
Early/Late Execution
Incorrect Identification/ Selection
Incorrect Counting/ Calculations
Overlooking
Misreading/ Misunderstanding
Miscommunication/ Insufficient Communication
Incorrect Transcription/Typing
Incorrect Orientation/ Positioning
Unintentional Touching/Sticking
Slipping

The key with both the error proofing principles and the common error modes will be to see how they both apply to the healthcare industry. The knowledge that can be gained from using both of these tools to error proof the process would be something that healthcare currently does not use or have. A similar research study of known healthcare solutions must be performed in order to provide data to prove whether or not these methods will work in healthcare.

2.2.2 Theory of Inventive Problem Solving (TRIZ)

The Theory of Inventive Problem Solving or TRIZ was developed by Genrich Altsthuller in the 1940's. Altshuller was a patent clerk and inventor that studied over 200,000 patents and determined that only a few types of novel solutions were being developed across all fields of work [17]. He was able to determine that the "engineering system is not a random event but is governed by certain parameters [18]." From this conclusion he realized that creativity could be taught. The goal of TRIZ is to find the truly novel or innovative solution, even if it lies outside of the normal realm of thinking. The TRIZ methodology will help direct the mind into an area that would not have been previously thought [19]. A list of Altshuller's major solution generation techniques can be found below in Table 2.2.2.1.

Table 2.2.2.1 TRIZ Methods [18]

Levels of Innovation
Contradictions
40 Inventive Principles
39 Engineering Parameters
Four Separation Principles
Ideality
76 Standard Solutions
Patterns of Evolution
ARIZ (Algorithm of Inventive Problem Solving
Substance-Field Analysis

The 40 Inventive principles provide a way to guide the mind into a known direction that has produced proven solutions [20]. This is exactly what the healthcare industry needs to direct their minds away from the way things have always been and into a possibly new direction. The key will be to find out if the inventive principles apply to the healthcare industry.

2.3 Phase Three: Evaluating and Selecting Solutions

When evaluating solutions, determining what solutions are good enough to be implemented can be difficult. The difficulty lies in what is important when evaluating a solution. To be thorough, the team must not only consider what it perceives to be important but what management finds important. The solution evaluation phase is one that many people rush over, believing that it is not as important as the steps they took leading up to this point. But in fact, this stage may be one of the most important for any process.

Whether the team realizes it or not everyone employs some type of solution selection process. Even if the team chooses the first solution it comes up with, there process is one of selecting the first solution that they use [21]. Another popular form of solution selection could be the trial and error method. Implement a solution and try it if it fails put another one into place. The problem with this line of thinking in healthcare is that another mistake could mean another patient's life.

The method that teams use can vary depending on who is leading the team or who trained the team on how to perform the process improvement process. There are a few categories that solution evaluation and selection process can fall into. Table 2.3.1 lists several common solution evaluation methods.

Table 2.3.1 Solution Selection and Evaluation Types [21]

Type	Definition
External Decision	Concepts are turned over to the customer, client or some other external entity for selection.
Product Champion	An influential member of the product development team chooses a concept based on personal preference.
Intuition	The concept is chosen by its feel. Explicit criteria or trade-offs are not used. The concept just seems better.
Multi-voting	Each member of the team votes for several concepts. The concept with the most votes is selected.
Pros and Cons	The team lists the strengths and weaknesses of each concept and makes a choice based upon the group opinion.
Prototype and test	The organization builds and tests prototypes of each concept, making a selection based upon test data.
Decision matrices	The team rates each concept against pre-specified selection criteria, which may be weighted.

Pugh's concept evaluation method, is a popular perception-based method [22]. With the Pugh concept selection, the team weighs different ideas or solutions against a reference. They weigh the ideas with a preset list of selection criteria [21]. After the first phase of the process is complete, the solutions are looked at to see if they are to proceed with the solution or combine it with another. Once this is completed, the solutions are then scored based on a weighted system of the selection criteria and one solution will come out with a higher score than the others [21]. That solution is the one that the team will select.

The FMEA that is used so widely among the non healthcare industry has a solution evaluation tool in it that people may not realize. The tool is the fact that in the FMEA once an action plan for a failure mode is set, the team rates what the new RPN number would be for the failure mode [11]. The process of ranking the new RPN number shows how effective the solution is.

The problem is that the healthcare industry needs a simple systematic way to evaluate their solutions. A method that can incorporate what management thinks through when they evaluate the solutions. Pugh's method provides a complex set of matrices that may not be necessary for the healthcare industry, while the FMEA provides no systematic method for ranking the solutions. A new method must be developed.

2.4 Conclusion

After reviewing all of the systems and methods, certain methods have shown specific methods that could be useful. An algorithm can be put together to provide a complete three phase approach to reducing human errors in healthcare. For phase one, identifying potential errors, the HFMEA method of identifying potential errors will be used to guide the team. In phase two, generating solutions to error proof the work process, error proofing principles traditionally used for manufacturing will be tailored to fit a healthcare environment. Solution evaluation methods such as trial and error or the Pugh Concept Matrix method of evaluating solutions will not fit the three phase approach. A simple and practical solution evaluation method will need to be introduced. Other directed brainstorming activities can and will be inserted to optimize the three phase approach. The algorithm will permanently reduce human errors and will be easily used by all healthcare providers.

3.0 Algorithm for Reducing Errors in Healthcare

The Algorithm for reducing human errors in healthcare can be implemented by all healthcare providers. Its approach will be simple enough that with a little training, someone from a healthcare organization could lead a team through the algorithm. This algorithm will aim to permanently reduce the errors in the process.

3.1 Phase 1: Identification of Error producing situations

The HFMEA, as previously discussed, provides a good framework to find the areas in which errors most commonly occur. The HFMEA process contains easy to understand healthcare definitions as well as provides procedures of its own. The HFMEA focuses on a work process that is a high risk area as either determined by the publications from the Joint Commission or by the organization's own detection of serious events. Stepping through the algorithm, a team or team leader will be filling out different worksheets to catalog the journey through the error proofing process. Some of the worksheets are from the HFMEA while others are completely new. All of these worksheets can be found in Appendix I. The algorithm only uses the HFMEA to generate areas in the process where errors may occur.

3.1.1 Scope of the Project

Defining the scope is very important and if the scope is too large, the project will either take an extreme amount of time or may never be finished. The scope is best defined by upper management and then conveyed to the team leader. Upper management will be able to best define what results they expect from the project. Before the team is formed someone must be able to convey where the starting and ending points of this process will be. It is the team leader's responsibility to keep the team's focus on the task and to not let "scope creep" happen. "Scope creep" is when the project being performed becomes larger from the addition of additional tasks or goals and will lead to the project taking a large amount of time or never finished.

3.1.2 Formation of the team

Forming the team for a project can almost be as difficult as the project itself. Forming the team is important because the project will only be as good as the members

and leader from which it is made. In healthcare it is essential to form a multi-disciplinary team. The key to forming a good team is to insure that all employees from every aspect of the work process are represented. In the healthcare industry doctors, nurses, secretaries, managers, pharmacists, and even upper management may need to be involved in order for the team to succeed. The function of the multi-disciplinary team is to have knowledge of the entire work process. Having a member of upper management present allows for feedback from the top about scope issues and when selecting solutions. Forming the team can make or break the project before it even starts.

After members of the team have been selected, a way to increase efficiency in the team is to divide the members into sub groups or committees. A sub group allows the team leader to divide out specific work tasks to be performed between meetings. Dividing out work to specific groups not only increases the efficiency of individual meetings but also of the entire error proofing process. Using the process map generated in a couple of steps can provide natural cuts of how to divide people into sub groups.

3.1.3 Selecting a Team leader

Selection of a team leader is critical for insuring the efficiency and effectiveness of the team's performance. The team leader serves as the driver for the error proofing process and team members will feed off of him/her. The team leader must have excellent facilitation skills and a good working knowledge of the error proofing process. Clinical knowledge of the process is helpful, but a team member with clinical knowledge can be selected as a co-leader.

3.1.4 Process Mapping

Process mapping is the visual representation of the process being examined. The process is broken down into major steps and then into sub-process steps. Doing this eliminates the complexity of the process map. Identification of all the steps in the work process is very important. Leaving out a major step in the process can lead to missed error proofing situations and can allow errors to still occur in the process. Trying to identify the major steps at a high enough level can prove to be difficult. If the process is beginning to identify too many steps, one of two things has happened. Either "scope creep" has occurred or the process steps are not at a high enough level and may actually

be several groups of sub-process steps. It is the team leader's responsibility here to take a step back and see if those steps could all be included under a single major step heading. An example of the process mapping worksheet can be seen in Figure 3.1.4.1 and in Appendix I.

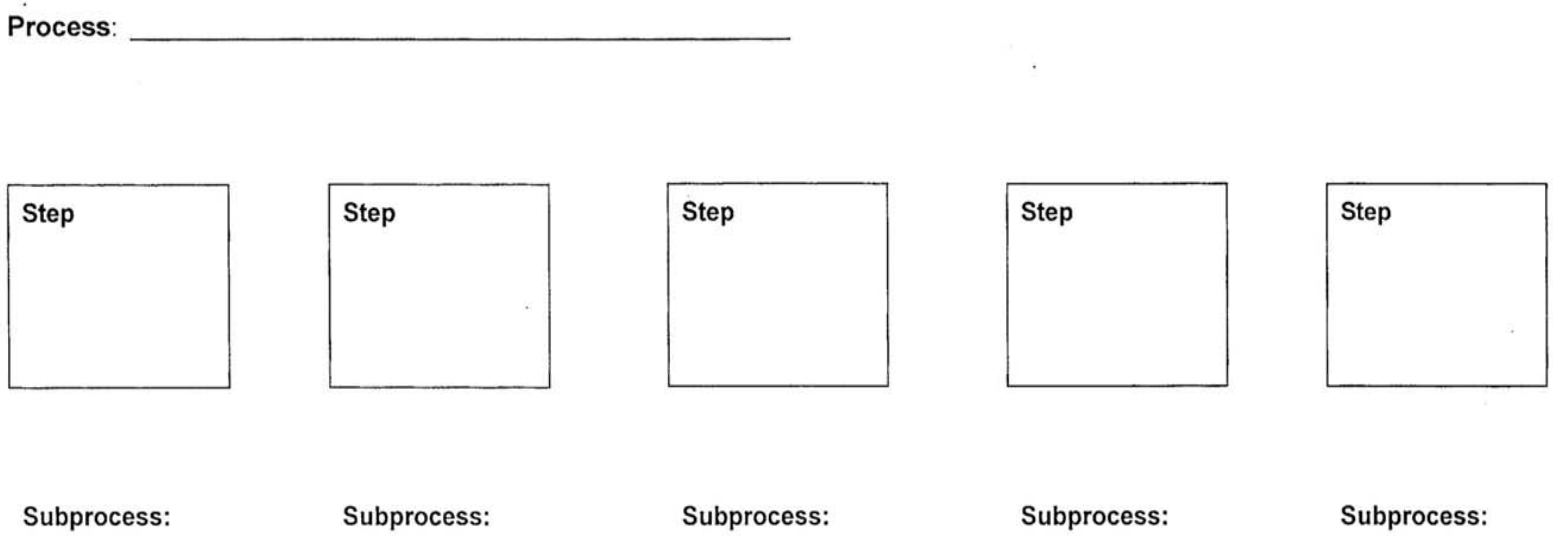


Figure 3.1.4.1 Process Mapping Worksheet

Formulating the exact words of a sub-process can be difficult and extra help may be needed to identify all of the sub-process steps. To help with the identification of sub-process steps, a simple worksheet has been developed to help health care providers identify their sub-processes. This worksheet is not included in the HFMEA, but was developed for the purpose of this algorithm. The worksheet contains generalized healthcare sub-processes worded to give the team a better understanding of what is happening in this sub-process step. Applying this worksheet in the team's meetings will speed up the process of identifying sub-processes and allow the team to derive sub-processes that may not have been thought of previously. The worksheet can be discussed by the team leader and distributed as a handout. The worksheet of generalized healthcare sub-processes can be found in Figure 3.1.4.2 and in Appendix I.

3.1.5 Identifying Potential Failure Modes

Identifying the failure modes involves listing each potential failure modes from the sub-process steps. It is critical to document all the failure modes, even if a member of the team believes it does not happen frequently. The failure modes are what the team will use to generate solutions so every possible potential failure mode should be listed. The team leader needs to make sure that when they are discussing potential failure modes, they do not linger on the causes of the potential failure modes. At this stage no scoring of the failure modes has occurred. The team should avoid wasting time discussing causes of a failure mode that may not be critical.

When generating failure modes it is important for the team leader to steer the activity clear of finger pointing and blame. Having members of the team identifying areas where they personally commit errors in the process can sometimes be difficult. It is essential here for the leader to remind the team that they are only trying to identify "potential" errors or failure modes. Discussing what could go wrong instead of just pointing fingers at one another can create a friendlier environment.

Failure modes are what the team will use to develop solutions. A more clearly stated failure mode has an increased chance of generating a successful solution. Because this can be a difficult task for the team, a generalized healthcare failure mode

Generalized Healthcare Subprocesses

Generalized Subprocess		Examples of Subprocess
Prescribing	Visit/see	Visit patient on the floor; see patient prior to surgery.
	Assess/evaluate	Assesses patient; evaluate home medications.
	Review/screen	Review chart; review order; screen allergy/drug interaction.
	Consult/discuss	Consult pharmacist; discuss with Radiology MD.
	Choose	Choose procedure; choose system for entry; choose mode of delivery.
	Calculate/score	Calculate dose; assign score.
	Prescribe/transcribe/write	Prescribe medication order; transcribe medication order; write order.
	Enter	Enter order into computer; enter allergy information into computer
	Order/give	Order medications verbally; give directions.
	Feedback/repeat	Provide feedback to MD; repeat order
	Document/complete/sign	Document medications; complete note; sign form
Administration	Identify/clarify	Identify patient; Identify resources; identify needs; clarify IV status.
	Arrange/coordinate/establish	Arrange transporter; coordinate timing; establish time.
	Prepare	Prepare patient; prepare medications
	Set up/program	Set up device; program device.
	Obtain	Obtain medications; obtain flow sheet.
	Label/produce label	Label medications; produce labels for medications.
	Verify/check/confirm	Verify order; verify syringe; check medication; confirm room availability.
	Administer/apply	Administer medications; administer PCA; apply probe.
	Perform	Perform procedure.
Monitoring	Monitor/observe	Monitor patient; observe patient
	Respond/intervene	Respond to alarm; perform intervention.
	Adjust/manage	Adjust regimen; manage pain.
	Change/turn on/turn off	Change cartridge; turn on alarm; turn off alarm.
	Discharge/transition	Discharge patient; transition to oral medications.
Communication	Report	Provide report to floor
	Notify/page	Notify RN that exam/procedure completed; page MD.
	Communicate	Communicate expectations.
	Gather/get	Gather allergy information; get information from family.
	Answer/inform/update/support	Answer questions; inform patient; update family; support family.
Others	Pick up/return	Pick up slip; return chart.
	Place	Place form in chart; place allergy information on armband.
	Take/send/deliver	Take medications to bed; send order to pharmacy; deliver medication to unit.
	Receive	Receive order; receive medications.
	Transport	Transport patient.

Figure 3.1.4.2 Generalized Healthcare Sub-processes

worksheet has been developed. The worksheet will assist the team in stating the failure mode clearly but help them identify more failure modes. The worksheet includes a list of questions that can be read by the team leader to direct the team's thinking to an area of failure that may have not been discussed. An example question would be with the key word Omission: What part of the sub-process is prone to be omitted? The complete list of these questions can be found in Figure 3.1.5.1 and in Appendix I. These questions will provide an atmosphere of failure mode thinking for the group.

The failure modes that are suggested need to be categorized in a table format. The HFMEA provides a failure mode scoring sheet to assist in this process. The algorithm will not use the entire worksheet used for the HFMEA. This sheet is what the team leader will use to document the failure modes, record their scores, use during decision tree analysis, and to list potential causes. An example of this sheet can be found in Figure 3.1.5.2 or in Appendix I.

General Failure Modes – Questions for Listing Failure Modes

Question: ***What can go wrong?***	Examples of Failure Modes
Omission: What part of the subprocess is prone to be omitted?	• Omitting necessary steps in the preparation of a medication • Forgetting to switch on a humidifier in a respirator • Forgetting to return flow quantity after processing an additional medication
Excessive Repetition: What part of the subprocess is prone to be excessively repeated?	• Re-executing the finished work • Adding the same liquid twice into the mixture
Wrong Sequence: In what wrong sequence can the subprocess be executed?	• Filling an order without entering allergy information, patient weight, etc. • Proceeding care before producing the patient ID
Early/Late Execution: What execution can be early or late?	• Beginning work earlier/later than specified • Giving a medication in the wrong time
Incorrect Identification/Selection: What object of the subprocess, e.g., patient, medication, equipment, document etc, is prone to be selected or identified incorrectly?	• Giving a medication to the wrong patients • Choosing the wrong dose or the wrong syringe • Wrong-side surgery
Incorrect Counting/Calculating: What objects of the subprocess can be counted, measured or calculated incorrectly?	• Counting medications incorrectly • Miscalculating quantity of drugs and overdosing
Overlooking: What information, risk or failure/error is prone to be overlooked?	• Overlooking patient's allergies • Overlooking abnormal values displayed in a system • Not noticing information on drug-drug interactions or patient's other medicines
Misreading/Misunderstanding: What misunderstanding or misreading is prone to occur?	• Misreading medication orders • Misunderstanding status of the equipment • Misunderstanding bed availability
Incorrect Decision: What incorrect decision is prone to occur?	• Misjudgment of discharge criteria
Miscommunication: What miscommunication is prone to occur?	• Miscommunicating current status of patients in transition • Insufficiently notifying to other caregivers • Disagreement between the care team
Incorrect Transcription/Entering: What transcription/entering error is prone to occur?	• Making a mistake in transcription of doctor's instructions • Making a mistake in entering patient information into computer systems
Incorrect Route/Orientation/Positioning/Setting: What route/orientation/positioning/setting error is prone to occur?	• Operating controls on a defibrillator based on the understanding of different defibrillators • Connecting tubes/valves incorrectly
Unintentional Touching/Sticking/Splashing: What can be unintentionally touched, stuck or splashed?	• Unintentionally touching equipment switches • Being splashed with a toxic substance • Sticking needles in hands
Hazardous Movement: Where What movement can cause harm (slipping, falling etc)	• Slipping on the floor • Falling
Not Available: Who/what is prone not to be available?	• MD not available • Equipment/room/medication not available
Hardware Failure/ Incorrect Information: What hardware failure or incorrect information provision is prone to occur?	• Equipment failure or expired medication • Incorrect patient information system record
Unexpected Patient Reaction: What unexpected patient reaction is prone to occur?	• Unexpected patient reaction

NOTE: 1) Apply the above questions to each subprocess. 2) If the related latent risks are found, add the corresponding failure modes to the subprocess making their expressions specified for the subprocess.

Figure 3.1.5.1 Generalized Failure Modes

HFMEA Step ____ Subprocess ____ : _____

HFMEA Step 4 - Hazard Analysis									
Failure Mode		Scoring			Decision Tree Analysis				Potential Cause
		Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure ?	Detectability	Proceed?	

Figure 3.1.5.2 HFMEA Worksheet for Failure Modes

3.1.6 Scoring and Selecting Failure Modes

The last part of Phase One is the scoring and selecting of the failure modes. Unlike an FMEA, the HFMEA only uses two scoring parameters (Probability and Severity) and a decision tree analysis to evaluate the failure modes. The HFMEA ranks these parameters on a 1 to 4 scale. The severity factor is broken up into patient outcomes, visitor outcomes, staff outcomes, equipment or facility, and fire. The probability rating remains the same throughout. An example of the patient outcome table for severity and the probability rating is shown below in Tables 3.1.6.1 and 3.1.6.2.

Table 3.1.6.1 HFMEA rating for Patient Outcomes [1]

Score	Description
1	***Minor*** **patient outcome: No injury, nor increased length of stay, nor increased level of care**
2	***Moderate*** **patient outcome: Increased length of stay or increased level of care for 1 to 2 patients**
3	***Major*** **patient outcome: Permanent lessening of bodily functioning, disfigurement, surgical intervention required, increased length of stay for 3 or more days, increase level of care for 3 or more patients**
4	***Catastrophic*** **patient outcome: death or major permanent loss of function, suicide, rape, hemolytic transfusion reaction, surgery/procedure on the wrong patient or wrong part of body, infant abduction or discharge to wrong family**

Table 3.1.6.2 HFMEA rating for Probability [1]

Score	Description
1	***Remote*: Unlikely to occur** **(may happen sometime in 5 to 30 years)**
2	***Uncommon*: Possible to occur** **(may happen sometime in 2 to 5 years)**
3	***Occasional*: Probably will occur** **(may happen several times in 1 to 2 years)**
4	***Frequent*: Likely to occur immediately or within a short period (may happen several times in one year)**

Scoring all the failure modes involves taking each of the two numbers from probability and severity and multiplying them together to give a number between 1 and 16. The scores are then examined on the Hazard scoring matrix from the HFMEA. The Hazard scoring matrix is shown in Table 3.1.6.3. In the hazard matrix, scores of eight or greater are highlighted because they will effect which questions are asked in the decision tree analysis.

After scoring, the team proceeds to decision tree analysis. In decision tree analysis the team assesses the scores of the failure modes (probability multiplied by severity) and then asks three questions: 1) is the failure mode a single point weakness?; 2) is there an existing control measure?; and 3) is this detectable?. The answers to the questions will determine which failure modes will be examined in Phase Two of the algorithm Generating Solutions. The decision tree analysis is shown in Figure 3.1.6.4.

Table 3.1.6.3 Hazard Scoring Matrix [1]

Probability — Severity

Failure Mode → Effect (Hazardous Event)

Probability of Failure Mode	Severity of Effect			
	Catastrophic **(4)**	***Major*** **(3)**	***Moderate*** **(2)**	***Minor*** **(1)**
Frequent **(4)**	**16**	**12**	**8**	**4**
Occasional **(3)**	**12**	**9**	**6**	**3**
Uncommon **(2)**	**8**	**6**	**4**	**2**
Remote **(1)**	**4**	**3**	**2**	**1**

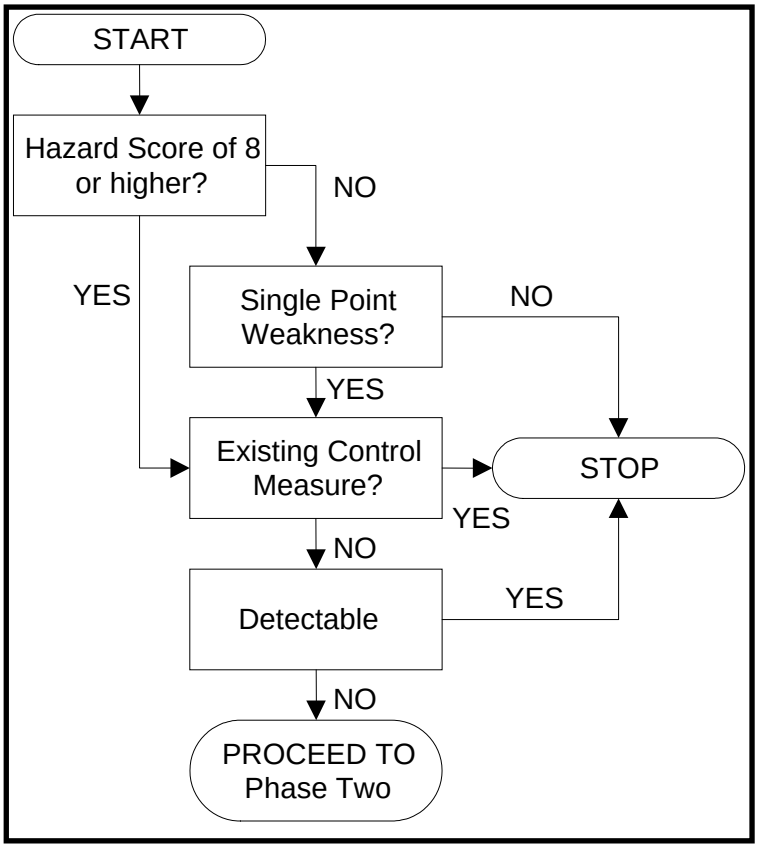


Figure 3.1.6.4 Decision Tree Analysis [1]

All failure modes that make it to the “Proceed to Phase Two box” will have potential causes generated for each of them. Once the potential causes have been generated for those failure modes, they are ready to go to Phase Two: Generating Solutions.

There are notes about scoring to consider before moving forward. Explaining scoring and decision tree analysis needs to be done slowly by the team leader to make sure everyone on the team understands it. Going through definitions of a single point weakness and examples of different levels of scoring is very helpful to the team.

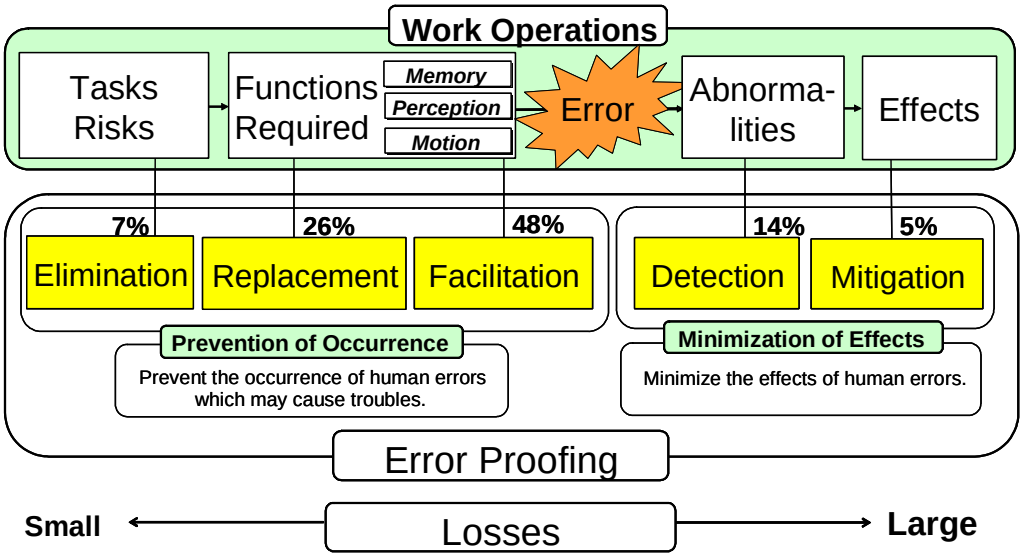
Every healthcare organization is different. The scoring system may not fit, as is the case more often with the probability than severity, making a change that fits the organization may be necessary. A change can not be made unless it will be instituted by the entire organization. When deciding on what failure modes to proceed with, some organizations will actually focus on everything that has a severity of 4 or a hazard score greater than 8, just to be thorough. Depending on the size or scope of the project, this could be a good or bad idea. Making a decision like this falls upon the shoulders of the team leader of the project.

3.2 Phase Two: Generating Solutions

In Phase Two of the algorithm, the areas that can potentially produce errors have been identified. The generation of solutions to permanently reduce or eliminate those errors starts. In Phase Two a deviation is made away from HFMEA process and moves toward a more systematic approach to generate solutions. The first step a team takes after identifying failure modes is to brainstorm possible solutions. In Phase Two, a systematic approach will be laid out to produce more solutions and more innovative solutions than traditional brainstorming can accomplish. Error proofing principles previously used to categorize manufacturing solutions will be used in healthcare. TRIZ principles will be used to provide solution direction techniques. The two will be shown how they relate to one another through research conducted about actual solution to healthcare problems. A database of known healthcare solutions will also be an additional process improvement tool.

3.2.1 Error Proofing Principles

The first part of Phase Two revolves around five error proofing principle: 1) Elimination 2) Replacement 3) Facilitation 4) Detection 5) Mitigation. The first three of these principles deal with preventing the error from occurring while the last two are measures that take effect after the error has occurred. Error proofing aims to change the work operation and not the person performing the operation to achieve a permanent change in errors. Below, Figure 3.2.1.1 illustrates the five principles and how they relate to preventing an error. The percentages come from research, done by myself and Professor Nakajo, and contained in the error proofing database, that myself and Professor Nakajo created, and relates how many solutions from the over 700 in the database fall into that specific principle.



Note: The percentage indicates the ratio of examples corresponding to each principle in healthcare.

Figure 3.2.1.1 Error Proofing Principles

The first principle, Elimination, aims to remove any operation that is prone to human error from the process. This principle aims to eliminate the tasks or risks associated with the error. Eliminating tasks can be seen as taking a step out of the process completely or eliminating a type of handoff of information from one person to the other. Many times eliminating a step causes a process or equipment design to be changed drastically or a complete culture change to take place. Eliminating the error from ever happening again can prove to have the biggest reward. Eliminating the error may have large side effects to the process that need to be considered, but the reward of eliminating the error can be greater.

The second principle in the error proofing process is Replacement. Replacement involves replacing the human operations with more reliable machines and methods. Replacement can occur either through automation or a support system. Automation will use a machine to automate the process and take the human aspect of it completely out. By using a support system, the operator or person performing the task has a checklist to replace relying on their memory alone. Replacement should be used in moderation because replacing everything at once can lead to problems. In the work process, only the

error prone sections of it are focused on and replaced; do not just replace for the sake of replacing.

The third principle, which is the most often principle used by healthcare providers, is Facilitation. Here the operation or task the caregiver is performing is made easier. Certain tasks can be prone to error just by the way they are designed. Having an operator perform this flawed task will only result in the operator committing an error. Facilitation's goal is to simplify the task; it is required to create a distinction so the right choice can be made, or to adjust some part of the job to make it easier to perform. The reality of these types of solutions is that their cost is generally very small but, as a single solution, their effectiveness can also be small. This type of solution should be used along with others to truly achieve the permanent result desired.

The fourth principle, Detection, goes from the area of preventing the error and into the minimization of the error's effects. In the healthcare industry, these types of solutions are good, but most organizations try to focus on the first three principles so that the error is actually prevented. Detection is trying to make all abnormalities caused by a human error visible so that action can be taken to correct that error. These abnormalities can be detected by recording the actions performed in a task or by checking the results. The keys to detection are that the earlier the error is caught the smaller the cost will be and, that most times some type of computer or hardware will play a role in the detection of errors.

Mitigation is the fifth and final principle and aims to reduce or lessen the effects of the error by adding in redundancies or methods that can absorb part of the effect so the patient does not see it. In Mitigation a type of failsafe may be put into the process. When detecting an abnormality in the dose of medication to the patient, the system would shut itself off and not administer the dose without an override.

These five principles are not just to be used in Phase Two of this algorithm, but could also be applied to the workplace. Can eliminating some part of a task reduce the occurrence of an error? Internalizing the principles will make the team more effective. As shown these principles are useful not only in generating different types of solutions, but also in helping the team gain a better understanding of the solutions that were generated.

3.2.2 Solution Directions

The next step in Phase Two is a tool that will allows the team to systematically generate error proofing solutions that will produce the change required by each of the principles discussed above. As discussed earlier, Altshuller [17] developed a systematic way of thinking called "TRIZ" or the Theory of Inventive Problem Solving. In his work he developed a set of proven solution directions that help direct the mind out of its own personal solution space and into a new direction to where a truly innovative solution lies. This steps applies some of his proven solution directions commonly found in healthcare solutions and uses them to direct the team through a systematic brainstorming exercise to produce not only more but better solutions.

Some examples of the solutions directions used can be found in Table 3.2.2.1. The error proofing principles and solution directions have direct correlation to the other. This was confirmed by the research done for the error proofing database that showed how each specific solution directions applied directly to the error proofing principles. With this knowledge a list of questions that applied the solution directions was developed to aid the team in its systematic brainstorming exercise. This list of questions is a great tool to be used by the team leader when generating solutions. By having the leader read out the question can spark a team member to come up with an innovative solution. The team leader can also pass the sheet out to each individual team member and have them write their own solutions down in the space provided. The team leader can then document all of these new solutions after the meeting. Another option would be to email the form to all the members before the meeting and have them fill it out before the meeting even starts. The complete list of questions can be found in Figures 3.2.2.2 and 3.2.2.3 and in Appendix II.

Table 3.2.2.1 Solution Directions

Solution Directions	**Examples**
Trimming	Eliminate hand-offs; eliminate manual data entry
Self Elimination	Broken pills do not roll; pill trays
Standardization	Make asymmetrical part symmetrical; one size fits all
Unique Shapes/Geometry	Electrical outlets; pill shape; symbols
Copying	Duplicate forms; blood ID barcodes
Prior Action	Pre-measured dose; supplier supplies 100 % inspected parts; pre-printed form
Flexible Films or Thin Membranes	Medicine bottle safety seal; rubber gloves
Color	Color-coded charts, zones, medicines
Combining	Patient records; medicine capsules with fast and slow release
Counting	Count the number of instruments before closing the incision
Automation	Automatic dispensing of medications

Step __ Subprocess __ : _____

Failure Mode ___ : _____

Principles	Question	Solution
Eliminate Tasks/Risks	Trimming - Can we eliminate the error-prone process or harmful objects?	
	Self Elimination - Can the harmful action or object eliminate itself?	
	Prior Action - Can we do something beforehand to eliminate the error-prone process or harmful objects?	
Replace Error-Prone Human Operations	Automation (Automatic Inspection) - Can we automate the process to solve our problem?	
	Prior Action - Can we do something beforehand to support human operations?	
	Combining - Can we combine (bring together/closer) two or more things to automate or support human operations?	
Facilitate Human Operations	Trimming - Can we trim similar or confusing things to facilitate human operations?	
	Standardization - Can we standardize the process to facilitate human operations?	
	Copying - Can we use redundancy to facilitate human operations?	

Figure 3.2.2.2 Worksheet One for Solution Generating Questions

Facilitate Human Operations (Continue)	Prior Action - Can we do something beforehand to facilitate human operations?	
	Flexible Films or Thin Membranes - Can we use flexible films or thin membranes to facilitate human operations?	
	Color - Can we use color to facilitate human operations?	
	Combining - Can we combine (bring together/closer) two or more things to facilitate human operations?	
Detect Abnormality	Counting - Can we count something to detect abnormalities in the human operations or their results?	
	Self Elimination - Can we let people notice abnormalities by themselves?	
	Standardization - Can we standardize the process to detect abnormalities?	
	Unique Shape/Geometry - Can we use shapes (1D, 2D, or 3D) to detect abnormalities in the human operations or their results?	
	Automation - Can we automatically inspect something to detect the abnormalities in the human operations or their results?	
Mitigate Effects	Trimming – Can we trim a part of harmful objects to mitigate the effects?	
	Copying - Can we use redundancy to mitigate the effects?	
	Prior Action - Can we do something beforehand to mitigate the effects?	
	Standardization - Can we standardize the process to detect abnormalities?	

Figure 3.2.2.3 Worksheet Two for Solution Generating Questions

Table 3.2.2.4 shows how many solutions fell into each principle and solution direction from the research done for the Error Proofing Database. Highlighted boxes will show which solution direction is used most frequently in each principle. This chart also helped in developing the list of questions for the team mentioned above. Certain solution directions where chosen for the question even at a low number because there where not as many solutions for that particular principle or solution direction. In the database, solutions were categorized to certain principles and solutions directions.

Table 3.2.2.4 Error Proofing Principles with Solution Directions

Principle \ Solution Direction	Trimming (7%)	Self Elimination (7%)	Standardization (20%)	Unique Shape/Geometry (2%)	Copying (Redundancy) (5%)	Prior Action (23%)	Flexible Films or Thin Membranes (2%)	Color (5%)	Combining (23%)	Counting (1%)	Automation (7%)	Total
Elimination (7%)	29	12	4	0	0	12	0	0	4	0	1	62
Replacement (26%)	1	0	17	2	7	108	0	1	67	0	25	228
Facilitation (48%)	28	0	104	3	16	55	9	35	107	0	0	357
Detection (14%)	0	44	20	9	0	2	2	0	3	6	24	110
Mitigation (5%)	2	0	13	0	17	7	1	0	0	0	1	41
Total	60	56	158	14	40	184	12	36	181	6	51	798

3.2.3 Error Proofing Database

The last tool in Phase Two is the Error Proofing Database. Looking at what others have done to solve similar or same problem can help the team generate or find a proven solution to the error prone problem. The error proofing database allows searching by operation or by the error proofing principle, as shown in Figures 3.2.3.1 and 3.2.3.2.

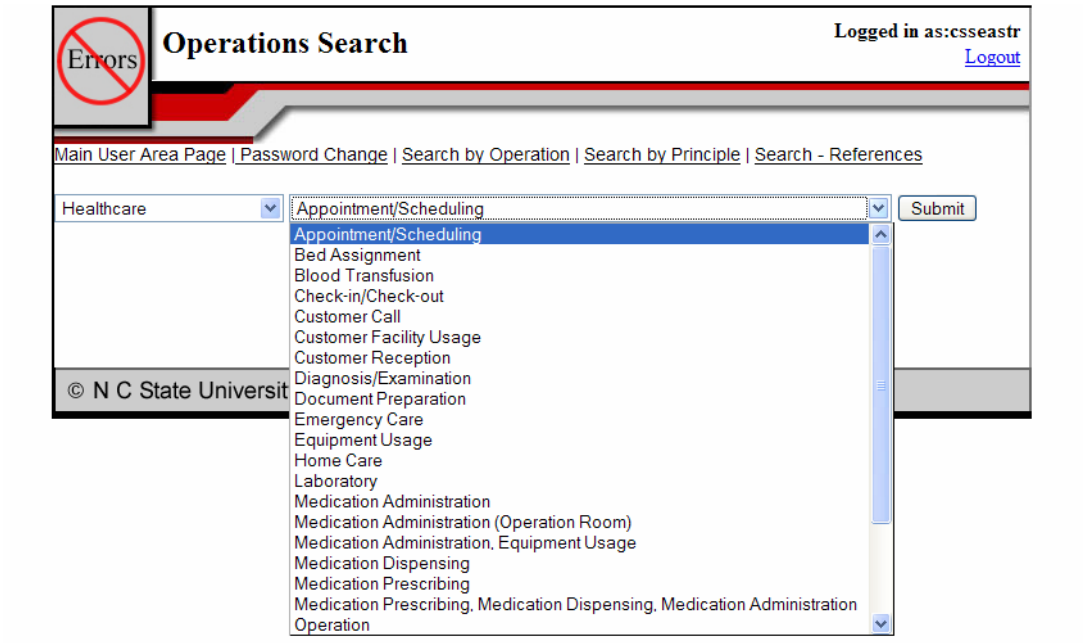


Figure 3.2.3.1 Search by Operation

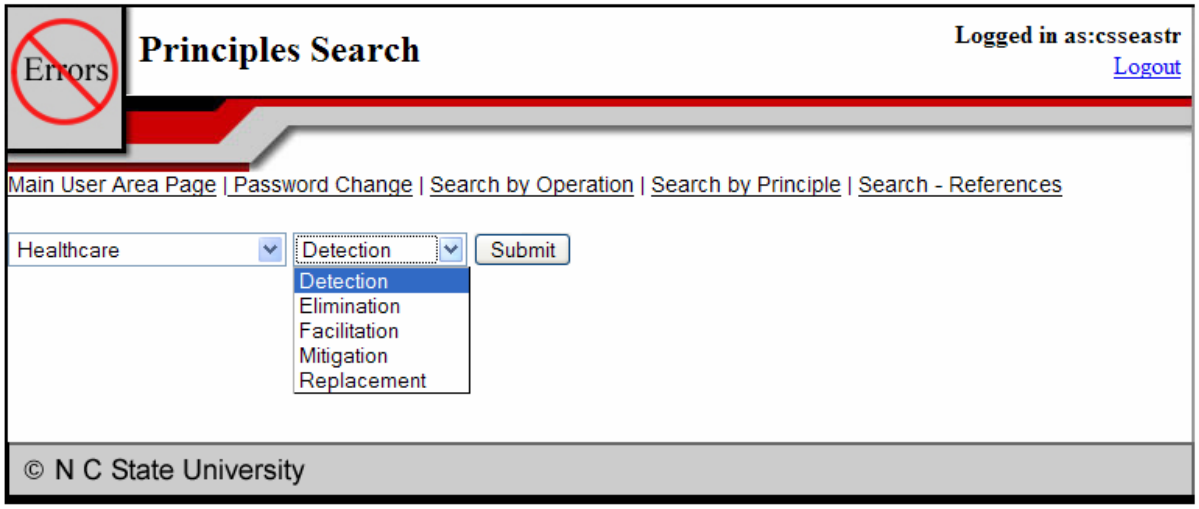


Figure 3.2.3.1 Search by Principle

Once a database search has been submitted, a list of solutions to solved problems will come up. From there a specific solution can be picked and its contents can be viewed as seen in Figures 3.2.3.3 and 3.2.3.4.

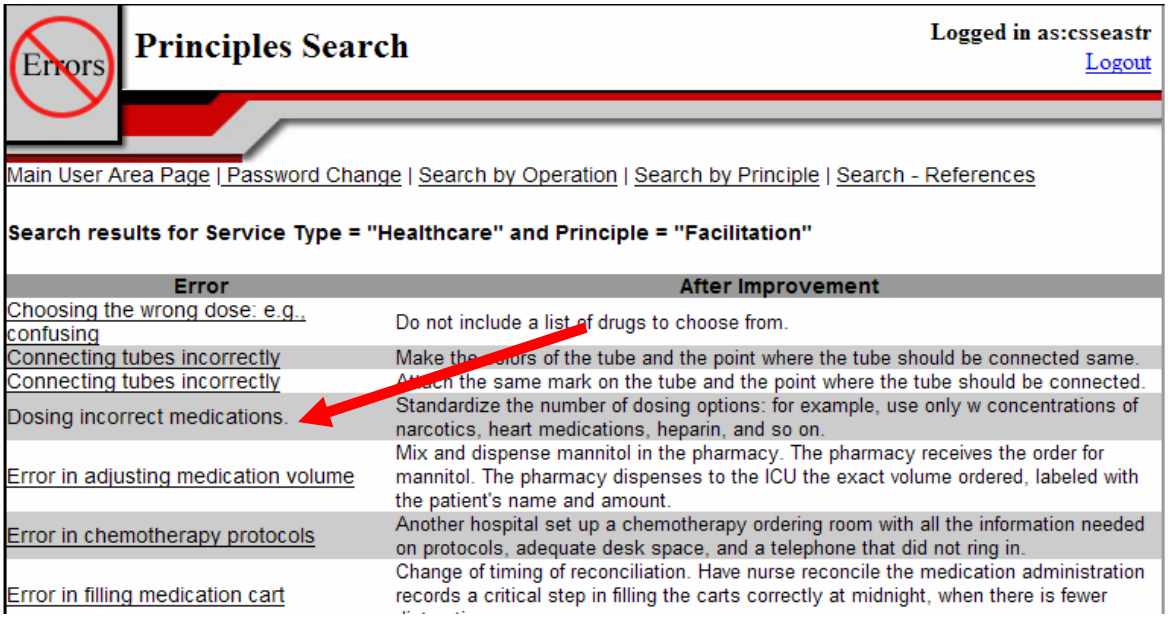


Figure 3.2.3.3 Selecting an Error

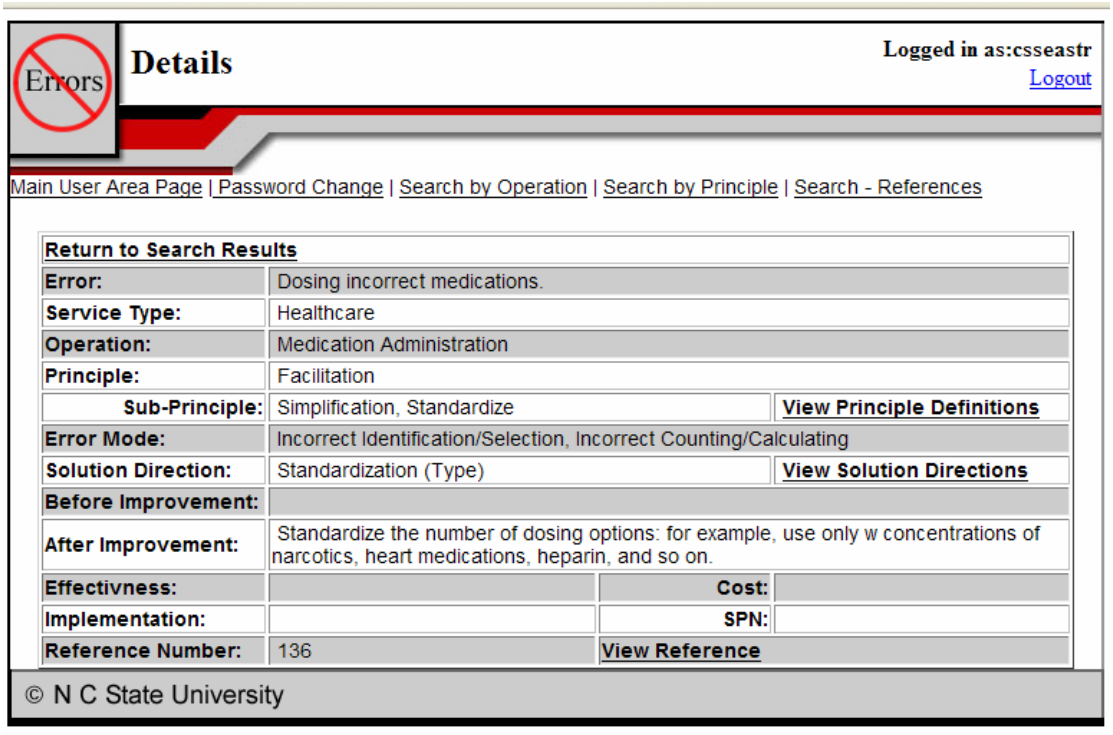


Figure 3.2.3.4 Detailed Results of Error

This database provides the team with an opportunity to find an example that may help solve the problem but also allows the team to know the reference where the error came from. They can click on the View Reference tag and see what article, journal, or book that the example came from. This not only gives credibility to the solution but allows the user to find out what hospital published the study and may provide the ability to contact them. The database also allows one to search through the references by type of examples they yielded.

Phase Two, Generating Solutions, guides the team through a systematic process of generating innovative solutions. A key in this phase for the team leader is to have the team only generate solutions and not spend time on evaluating them. This can lead to wasted time and potentially not allow a solution to be discussed because of a lack of time. The goal of Phase Two is to develop a complete and rich set of solutions that will provide the team with options on how to error proof the process permanently.

3.3 Phase Three: Evaluating and Selecting Solutions

Phase Three involves evaluating and then selecting the solutions. With the large list of solutions developed by Phase Two, how is the team going to know which solution is better than another solution? Phase Three's goal is to provide the team with a simple and logical way to rank solutions. The tool used here is completely new and is called the Solution Priority Number (SPN) number. It looks similar to how the RPN number is calculated for the FMEA. The SPN takes into account what most managers think about when they are deciding upon a solution: how much will it cost, how difficult will it be to implement, and how effective will it be. The SPN takes into account all three of these parameters and rates them on a simple 1 to 3 scale. The scoring boxes for each of the three criterions can be seen in the next three Tables (3.3.1 -3.3.3).

Table 3.3.1 Effectiveness Scoring

Score	Definition
3	**Very Effective**: *Probability* can be eliminated and reduced to 1, or *Control Measure* or *Detectability* can be changed to "Yes."
2	**Effective**: *Probability* can be reduced; however, *Hazard score* is still more than 8, and *Control Measure* and *Detectability* remain to be "No."
1	**Ineffective**: *Probability* can not be reduced, and *Control Measure* and *Detectability* remain to be "No."

Table 3.3.2 Cost Scoring

Score	Definition
3	**Low**: Within daily operation budget. No specific budget is needed.
2	**Moderate**: Unit level budget is needed.
1	**High**: Hospital level budget is needed.

Table 3.3.3 Implementation Scoring

Score	Definition
3	**Easy**: No training is needed. No resistance is expected.
2	**Moderate**: Training course is needed. Some resistance is expected.
1	**Difficult**: Culture change is needed. Strong resistance is expected.

The three tables provide a simple and effective way for the team to employ management thinking to their solutions. A perfect score here for the solutions would be a 27 (remember here that higher is better). After ranking all of the solutions, it will be much easier to go back through them all and select which ones to implement. The selected solutions will then have an action plan developed and the team leader will select a person responsible to see that plan through.

There are some key notes about evaluating solutions; some of the solutions regardless of their score may be implemented. Some solutions may have scored lower but are easy to implement, cost nothing, and provide a small benefit. These solutions may need to be implemented along with other solutions to truly error proof the process. In most cases just one solution alone can not error proof the failure mode or sub-process step. These types of easily instituted solutions can be implemented right away while others will need a more developed action plan to get fully into the system.

Certain solutions will sometimes have a high cost associated with them but would be easy to implement and by highly effective. These type of solutions need to be mentioned to management as they are the ones who can help in overcoming the cost issue. It is important to tie each solution back to each and every failure mode it impacts. Some solutions may impact more than one failure mode and, if that is the case, a higher cost can then be spread between a few divisions making the solution more appealing to management.

Phase Three's goal is to create an easy and effective way to categorize the set of solutions and tie them back to the failure modes that they affect. One type of action plan will not work for all solutions. Each solution needs to be evaluated and have its own plan of implementation.

4.0 Case Studies and Results

Over the course of a year I studied two teams of people from local Hospitals conducting an FMEA analysis as well as an HFMEA. I was also joined in these meetings by Professor Takeshi Nakajo of Chuo University in Japan. The hospital contained over 500 beds. The hospital had performed several traditional FMEA's in the past to meet the JCAHO (Joint Commission for Accreditation of Healthcare) requirement. For the purpose of this case study, team A will be the one conducting the traditional FMEA and team B will be the one using the Error Proofing Algorithm.

The roles I played on each of the teams were vastly different. For team A, I merely sat and observed the FMEA process while on team B, I played a much more active role in helping the leader guide the team through the algorithm. Through the year, Professor Nakajo and I studied both teams, making observations on what tools could be used to further enrich the team's participation as well as find opportunities in which the process could be completed in a shorter amount of time.

4.1 Case Study A: Traditional FMEA

For team A, I was merely an observer and did not play a very active role. Team A had the task of tackling the use of contrast in two areas: the Cath Lab and radiology. Contrast media is what is injected into the body in order for x-rays to be displayed. The team was comprised of members from Hospital X and its sister Hospital Y in hopes that the FMEA would be useful to both hospitals. After the first few meetings it was realized that the OR (Operating Room) also needed to be included in the process.

Team A's leader did not have a medical background. The leader had an industrial engineering background and had worked in the Hospital X for a few years, but had no official medical training. The leader of the team did, however, have a substantial knowledge of the FMEA process as well as good leadership qualities needed to guide a team. The team was comprised of members from the three affected areas of both hospitals as well as representatives from the pharmacy. All areas brought in technicians or nurses so that the people with the hands on experience of using contrast were present in each meeting. The only area who brought a form of executive leadership was the radiology department. The regular meeting time for the group was every Monday after lunch for one hour rotating meeting locations from Hospital X to Hospital Y. Before the process began, the leader of team A gave a brief overview of the FMEA process using examples from previous FMEA conducted at Hospital X.

Even though team A was following the traditional FMEA format, a change in the RPN scoring was made to make it more health care applicable. The definitions for the severity, occurrence, and detection had been slightly modified such that they pertained to healthcare operations. These scoring sheets can be found in Appendix III. No other changes were made so the group proceeded through the FMEA process following the standard order of procedures as described in traditional manufacturing FMEA.

With the meetings occurring every Monday baring holiday or some special exception, the leader of team A would have to put together a brief agenda as well as update any changes made to the FMEA documents, i.e., process flow diagram, scoring of failure modes, etc. With the frequent meetings, there was much to be done by the leader to prepare for the next meeting. The leader would assign homework to specific group members in order to make the process more time efficient.

At the beginning of each meeting, a recap was given of what happened at the meeting before, and sometimes an introduction to FMEA principles had to be given because a new member had joined. The first task of the group was to tackle the OR and Cath Lab because they were viewed to be smaller and less complicated processes than the radiology department. Both of these departments were studied simultaneously depending on who was at each of the meetings. The amount of work accomplished at each meeting really depended on who was actually able to be there. The more members of a department that were present meant more work could be accomplished in that meeting. It took roughly five months of meetings to get both of these departments to the action plan phase of the FMEA. Once these two departments were finished, their members of FMEA team stopped coming unless asked to come and give an update.

Once the Cath Lab and the OR had gone into the action plan phase the group began to turn its focus to the radiology department. Since the entire group had developed a better knowledge of the FMEA process things ran a little smoother through the radiology section than through the other two areas. Members of the radiology department had been attending meetings since the very beginning so their knowledge was greater. What became complicated with the radiology department was that it was divided into sections. It took as long to complete as the previous two combined.

One problem that team A had during the FMEA process was having all the members attend. Though this is a common problem throughout the healthcare industry, it is a crucial problem that must be solved. The nurse and technician's primary job is to care for patients, so if supervisors are not very motivated then they will not let their people attend the meetings. Sometimes this problem could be the result of an emergency case that they can not leave.

Team A was not only having a problem with attendance in general, but also with having the correct people at the right time. There could have been 10 members present but if none were from the Cath lab and the topic of the day was the Cath lab then minimal progress was made.

The meeting place and frequency could have also provided some problems. Having the meetings occur every week posed difficult for some. Since there were representatives from Hospital X and Hospital Y at the meetings the location of the

meeting would rotate from one hospital to the other. Even though the meeting would be at a particular hospital, it would not necessarily mean that all members from that hospital would show up.

All of the above problems were personnel related. The next few problems discussed are related to the FMEA process directly. The first problem was "scope creep." The initial project was to evaluate the areas of use of contrast media. It then developed into two areas, then three areas, and then to three areas at two different hospitals. Many steps would be done at one hospital and not at the other, leading to larger than expected process flow diagrams.

The process flow map's main purpose is to identify all the steps of the process and then identify potential failure modes from those steps. What commonly happens in the FMEA with a highly complex process with many handoffs is that the team loses itself in the map. The process flow should not be something that is hard and complicated but merely a roadmap. Another problem for team A was that they began discussing problems with a step before establishing the whole process. The leader in team A did a good job of keeping the team motivated on the task at hand but discussing problems as the steps come up is a common error that does often happen.

Brainstorming is a very important step in the FMEA process whether it is brainstorming solutions or potential failure modes. Team A could have improved in each of these areas. When trying to identify failure modes or solutions sometimes having a directed brainstorming activity can prove to be very useful to the team. The difficulty can be in expressing failure modes in words in a failure mode phrase, i.e., *Omission* of a document. The other problem in failure modes that team A would encounter was trying to solve the failure mode before evaluating it with an RPN score. This is where the leader of team A stepped in and kept the team on task.

When it comes to generating solutions, the goal is to get people to think outside of their normal realm of thinking. A pharmacist may come up with a pharmaceutical solution to the problem, but the team leader needs to encourage them to go beyond their normal set of solutions. As with failure modes, the leader of team A had to keep the team on track and not evaluate solutions as they where brought up and continue to brainstorm more solutions.

The last opportunity for improvement for team A is if the leader was both experienced in clinical areas as well as the FMEA process. This did not hold the team back in any way, but could have been a definite plus for the team.

4.2 Case Study B: Algorithm for Reducing Human Errors

Team B's task was dealing with the recording and use of allergy information. Team B performed an HFMEA with the algorithm to help them along with the process. With this team I played a more active role in the meetings by helping them out if they had questions about the steps of the HFMEA, a tool in the algorithm, and would also meet between meetings with the leader of team B as needed. This team was composed of the Medication Safety Committee at Hospital X. The committee did have a few members from Hospital Y, but with this group there was not as much difference in the policies from one hospital to the other. The committee took on the job of completing the HFMEA.

Having the committee already in place was as a huge advantage for team B because there was already a planned meeting time, once a month from 12:30 to 2:00 with lunch provided at Hospital X. The medication safety committee was already formed as a multi-disciplinary team so no new members had to be added. The leader of team B did have a medical background and is currently in Nursing Administration. Team B's leader did have experience in leading teams, but had never conducted an HFMEA or FMEA before. Because of this, I played a much more active role in the meetings.

The algorithm tools used in the process were healthcare general failure modes, error-proofing principles, solution directions, and solution priority number. These tools will be discussed as they were used by the group. Other than the insertion of these tools at specific points during the HFMEA process, everything remained the same from the HFMEA.

The meetings took place at an existing committee meeting time, so the meetings did not just involve the error proofing process. The meeting had lunch provided, so the meeting usually started around 10 minutes late to give everyone who needed to talk that day a chance to finish eating. The first part of the meeting involved reviewing the minutes from the last meeting and discussing the agenda for the current meeting. Next, a monthly update of adverse drug events would be discussed and intervention would be planned if needed on a case by case basis. Special updates by team members would take place and then they would begin where they left off in the error proofing process. The leader of team B would always do a good job of recapping where they were at in the HFMEA process.

In the beginning of the process, the team leader needed help outside of the monthly meetings for Professor Nakajo and myself to educate her on the HFMEA process and discuss the next steps for the team. This type of meeting would normally occur once between the meetings and then a few questions would be asked through email as they came up. We would also help the leader of team B with corrections to the HFMEA sheet as needed. The leader for team B would have some work besides meeting with us for each meeting and that work would involve updating the documents and finishing scoring items in an effort to speed up the process. The leader and other members would do most of the outside work, but the entire team at the next meeting would then review all changes made.

Because of the leader's hard work to internalize the error proofing process, the meetings ran quite smoothly. A positive action made by the leader was that, in between meetings, the leader would relay reading material to help the team understand where they were going and discuss the next steps before the meeting even happened. This added efficiency to the team and allowed them to accomplish more in the meetings because everyone would know what is going on without a lengthy recap.

The first few meetings had problems with getting the team engaged in this new process. The team leader did a great job of getting everyone involved and participating by creating a relaxed atmosphere where anyone could speak up if they had a question. One difficulty that the team had initially was creating the process flow chart. This chart for the HFMEA greatly differs than the spaghetti diagram that often results from the FMEA. With the HFMEA, the process flow diagram is broken down into major steps and a list of sub-process steps would describe the activities inside each main step. This eliminates the complexity of the chart. The problem that team B was not thinking at a high enough level to get those major steps. What took place for team B is that they ended up listing a lot of the sub-processes or sub steps first. Professor Nakajo or I would then have the team take a step back and ask if all of those sub steps could be grouped to become a major step. Once they saw the first process step, the other two steps were much easier to define. Because of this confusion between steps the Generalized Healthcare sub-process sheet was developed to help teams.

The next phase in the process was to identify failure modes. There was a bit of turmoil at this step for a couple of reasons. The first problem was that there was confusion discerning between a failure mode and potential cause for the failure mode. Many times a lot of potential causes would be listed and that group of causes would make the group to realize that it came from one failure mode. This is where the worksheet of Generalized Failure Modes from the Algorithm was helpful. The general healthcare failure modes direct the team into a mindset of failure mode thinking and have them list the failure modes in a standard way i.e. Omission of daily report. This type of thinking did not just happen right away, the leader of team B, Professor Nakajo, and I had to keep reinforcing this point and have them use the worksheet tool. Once the team internalized this way of thinking, the meetings became much more productive. The potential benefit here for future teams is that these members already adopted this way of thinking.

The second reason for some problems with this step was that, when a potential failure mode was agreed upon there was an urge by some team members to begin to list all the causes of a failure mode. This is bad because the failure mode in question may not even be critical. Listing the potential causes comes after the scoring of the failure mode. In this instance a good team facilitator is the best way to keep the team on track. With a large team this can be hard to do, but a good team leader can keep the team focused by reinforcing that the particular failure mode was well thought out and keep the team on task to identify more before discussing it.

The team proceeded to scoring the failure modes after generating the failure modes. The team did a thorough job identifying failure modes, resulting in many failure modes to score. The team leader knew that if they tried to score every single failure mode as an entire group it would take a few meetings to complete this one task. What she decided to do was score the first few failure modes as a group and pass out the sheets that explained the scoring system so that the entire group knew how to do it. Shortly after that meeting a small group meeting was called and more failure modes were scored. Even with that extra meeting, not all of the failure modes were finished scoring. The group leader decided to finish the rest alone. Since the leader did have a clinical background the leader was qualified to do this alone.

The next step in the HFMEA process, decision tree analysis, is a hard one for a lot

of people in healthcare and for team B to grasp at first. The hardest part of this step is trying to explain the concept of a single point weakness. The best way to do this seems to be to use a practical example instead of just giving a definition. Trying to find an example that applies to the team specifically will always work the best. Professor Nakajo and I met with the team leader about this subject between meetings in order to coach the leader on this subject. Once the idea of decision tree analysis was presented to the team, a similar strategy to the failure mode scoring was used in that the leader did a lot of the decision tree analysis outside of the meetings to improve efficiency. The revised copy would then be sent out before a meeting and the team would review it for errors.

Another problem that occurred during the failure mode process was that team members would want to list solutions to the failure modes right away. The reason the team does not want to do this is the same as why listing potential causes first is bad: because the failure mode may score low and not even be examined. This leads to time spent on something that is not the most important.

Generating solutions was a step that was thoroughly enjoyed by the team. In this step, such tools as using error proofing principles and solution directions were helpful. When using the error proofing principles the team looks at each failure mode and determined if an item could be replaced or eliminated. The team leader would try to direct the brainstorming of solution on specific error proofing principles to insure that all possible solutions are recorded. The team leader does this in order to try to develop solutions outside of every ones personal solution area and get them to think outside the box. The members had fun generating outrageous ideas, but some ideas proved to be useful.

It is important for the leader to not criticize any solutions; this time is for brainstorming solutions and not for evaluating. The team enjoyed the use of the error proofing principles and solution directions to help generate more solutions than normal. This step was a long one in that the leader could not do this work without the team. The point of generating solutions is to have a multi-diversified team that can come up with many solutions, generating solutions on an individual basis is not recommended.

A common thing that will happen when generating solutions is that one will find that a few solutions address many failure modes, as was the case with team B. Most of

the time these solutions tend to cost more financially or cause a drastic culture change. It is important to keep track of how many areas each solution would affect and keep this in mind when going to management with recommendations for solutions to be implemented.

Evaluating the solutions is a step that is missed in many groups because there has not been a standard or easy way to evaluate them. Team B used the SPN or Solution Priority Number to help them identify which solutions where the best to use. The rating of the solutions was completed quickly because many of solutions where used over again. The team leader thought, in order to speed things up, the group should meet in two weeks instead of a month in order to complete the last few. The SPN allowed the team to find what solutions where more valuable than others, and they identified some easily instituted solutions that could be implemented immediately.

One thing the leader of team B did when presenting the solutions to management and others was relate each solution back to the failure modes it affected. This is so important because others who have not lived in the HFMEA process can see exactly what areas the solution will target. Many times this will lead to a much easier approval process by others.

With every team certain things could have be improved; with team B it would be to meet more than once a month. Because it was an existing committee everyone would show up every month but bi-weekly meetings earlier on in the HFMEA could have decreased the time in which it took to complete the HFMEA. In the beginning, a month was more appropriate as the team leader may have needed more coaching to understand better what was going on at the next meeting.

4.3 Results

In this summary, a comparison will be made between the two case studies. The whole process will be analyzed to view such things as how many sub-processes, failure modes, solutions, and solutions per failure mode were developed. The amount of time spent in meetings and the length of time to completion will also be evaluated for both groups.

Just to recap each group, team A was the contrast media group that performed the FMEA and team B was the group that performed the HFMEA on the collection and use of allergy information. Team B also used the algorithm tools such as the Healthcare General Failure modes sheet, Error proofing solution questions, and the SPN or solution priority number.

Team A's FMEA took eight months to complete with meetings every week, with the exception of holidays, for 1 hour each meetings. For team A, the actual meeting time total is greater than 30 hours. Team B met basically monthly until the end when meetings became bi-weekly. Even though the meetings were one and a half hours long, the first thirty minutes of the meetings were on issues other than the HFMEA so the HFMEA portion lasted around an hour. Team B's meeting time to completion was then just greater than ten or eleven hours.

When it came to the amount of time spent outside of meetings, each leader had their share of work to do in order to prepare for the next meeting. Team B's leader did meet with Professor Nakajo and I on occasion between meetings but not enough to outweigh the drastic time to completion mentioned above. Team B, overall, had a much shorter time to completion hour wise than team A. What this shows is that with all bi-weekly meetings the HFMEA could have been done over the period of about 4 to 5 months.

The next set of comparisons will be using Table 4.3.1 below. Team A and B are being evaluated not only for the quantity of failure modes and solutions, but also being judged by normalizing the numbers based on their process size. It would be unfair to compare two things for the amount of solutions if one team had significantly more failure modes. From the table below team B's use of the algorithm tools shows them having a much larger set of failure modes and solutions. This is so important is because to truly

error proof a system or work task, one must think about all the things that could potentially go wrong. Having more failure modes and solutions achieves this goal. The second thing is that one wants to identify as many possible solutions to the problem and generate those truly innovative solutions. Using tools to guide and expand the teams thinking, new and helpful failure modes and solutions will result.

Table 4.3.1 Results of each teams activities

Team	[1] Number of Sub-process	[2] Number of Failure Modes	[2]/[1]	[3] Number of Critical Failure Modes	[4] Number of Summarized Failure Modes	[5] Number of Solutions	[5]/[4]	[6] Number of Selected Solutions
A	37	68	1.8	44	44	35	0.8	35
B	9	44	4.9	36	36	151	4.2	53

A simple five month plan to deploy the algorithm is listed below in Figure 4.3.2. This is a beginner plan in which the team will learn about all aspects of the algorithm and complete the process with results. This plan requires an outside source to be able to teach the algorithm to the team if no one in the organization can lead it. By reading through this algorithm, someone inside the organization could follow this plan and be successful. As an organization becomes more familiar with the process, it will run faster and not require as much time to explain each phase.

Month 1 (1/2 Day)	1. Specific Charge (Stating Scope, Team, Primary Members/Associates, Meeting Schedule)	1hr *
	2. Overview of Error Proofing Process	1hr
	3. HFMEA 3.1 Process Mapping	2hr
Month 2 (1 Day)	Team Presentation (Process Mapping)	2hr
	3.2 Failure Modes Identification	2hr
	3.3 Hazard Analysis	2hr
Month 3 (1 Day)	Team Presentation (Failure Modes Identification & Hazard Analysis)	2hr
	4. Solution Generation (Lecture & Exercise)	4hr
Month 4 (1/2 Day)	Team Presentation (Solution Generation)	2hr
	5. Solution Evaluation and Selection	2hr
Month 5 (1/2 Day)	Major Reportout with Action Plan	2hr

* Approximate time

Figure 4.3.2 Plan of Action

4.4 Discussion of Results

Opportunities for improvement of many types were present in each of the teams. Many of the problems were discussed in the sections for case study A and B, but below will be a complete summary of the areas that could use some improvements based on observing both groups. These areas are ones that will relate to most healthcare organizations and not just the hospital observed.

The first area relates to the members and the meetings. Some problems related to these subjects could be:

- Finding a meeting time that will work for everyone.
- Having members arrive on time for meetings.
- Even if members of the meeting are present, having the right members present that are actively involved in the process in question.

This area would not just apply to healthcare but to all types of teams for any organization. Some possible solutions to these problems could be:

- Team leader should use subgroup meetings efficiently.
- Have a flexible time between meetings.
- The team leader should be taking on tasks as well as delegating tasks to team members between meetings in order to decrease the time that it takes the FMEA process to be done.
- Be well prepared for the meetings.

The next area for improvement is one that many healthcare organizations may not have a direct answer. Each team needs a leader who possesses a good knowledge of FMEA, a good clinical experience, and necessary team facilitation skills. Even though there may not be one person that fills this role, assigning co-leaders to the group or having core members in the team may be a possible answer. It may also be beneficial for the team leader to receive some outside learning experience to enhance his or her knowledge.

Defining and containing the scope of the project is typically very difficult. “Scope creep” is a common ailment that tends to make projects last longer than they normally should. In a health care setting focusing on a specific area, based on ISMP reports or experienced Adverse Drug Events (ADE), can help select the area to examine.

A lack of standardization of clinical processes happens more than one might think in a hospital. Many times in a meeting a process will be discussed and two or three different ways of doing the process will come up. Many times the broad picture of the process is the same, but the details of the steps may come in different orders. This is where the HFMEA and its broad high level process steps and having the sub-processes listed underneath can be helpful. Instead of creating a complex diagram having lines all over the place, sub-processes should simply be listed under the process steps. Another area that deals with clinical processes is the lack of understanding of the specific steps of an entire process. Everyone on the team has their specific area of expertise or specialization, so it is important to utilize their knowledge and not just rely on one person.

Whether the HFMEA or FMEA is being used, there are certain problems that relate to failure modes that occur for both groups. The areas for improvement are:

- Reluctance to document actual level of error occurrence or problems within the healthcare providers own processes.
- Understanding of the concepts of failure modes. (Differentiating failure modes from causes and effects.)
- Prematurely and excessively discussing possible solutions before identifying high risk failure modes.

Most of these problems need to be solved directly with leader involvement. The areas above deal with the atmosphere that the team leader is setting for the meeting, how well the leader can explain complex ideas, and their ability to lead a team. Nobody on a team wants to put blame on themselves for a problem. The team leader really needs to change the atmosphere to one of learning and not of blaming. Some possible solutions to these areas would be:

- Use the Healthcare General Failure Modes for listing failure modes.
- The team leader should guide the team members to focus on listing failure modes.
- Team leader should make team members comfortable to brainstorm failure modes by inhibiting evaluation/ criticism and managing time effectively.

Another topic that can sometimes be confusing to a team is how to really score the failure modes. Teams can often go off on tangents trying to argue whether a failure mode

is a five or a six on a particular rating scale. What is often done in this situation, if the leader can catch it quick enough, is rating it in between the two areas, making it five and a half. A solution to this type of problem is having clear definitions for severity, probability, and chance of detection. The HFMEA already reduces the scoring scale of the FMEA from ten down to a scale of four. This smaller scale can prove to be easier to pick up since definitions are clearer cut and there simply are not as many choices.

Within a team every member needs to feel comfortable enough to speak up, not only when identifying failure modes but when identifying solutions as well. No matter how far fetched the idea may be, it is still important to record that idea and make everyone feel involved. The team leader also needs to be careful not to let the team get stuck on a single solution but keep generating more. Solutions such as staff education and employee training come up frequently and should not be the answer to every problem. Some solutions to this area of problems are:

- Use the Solution Generation Questions.
- The team leader should guide the team members to focus on generating solutions.
- Team leader should make team members comfortable to brainstorm solutions by inhibiting evaluation/criticism and managing time effectively.
- Use the Solution Priority Number to evaluate and select the generated solutions. If team members understand that the generated solutions will be evaluated by an objective method, they can feel freely to generate solutions.

One of the most crucial areas in the whole process is having management agree to implement solutions. What can cause this to be such a problem is that, in the solution evaluation phase, everyone in the room may agree to a solution and then that solution goes to management in another meeting. This can lead to a series of meetings, some with management and others with the group but most of the time both sides never completely meet. A solution to this would be to have management involved at least the solution evaluation phase to reduce this problem and allow solutions to be implemented sooner.

5.0 Conclusion

Failure Modes and Effects Analysis's do not have to take an excessive amount of time. The use of the algorithm greatly decreased the normal time to complete the process and provided a better set of solutions to permanently reduce the errors in the process. Team B was an ideal example of how well the algorithm worked. Team B not only produced more failure modes and solutions, but the team members came away with a new line of thinking to be used in their everyday work.

6.0 Future Work

This algorithm, if completely generalized, could be used in many other industries besides healthcare. The frame work for the algorithm could remain the same but new generalized worksheets would need to be developed. The use of the HFMEA would need to be changed as well. Certain aspects of the HFMEA and FMEA could be used to create a general failure identification method that could be used across all industries with only the scoring scales changing.

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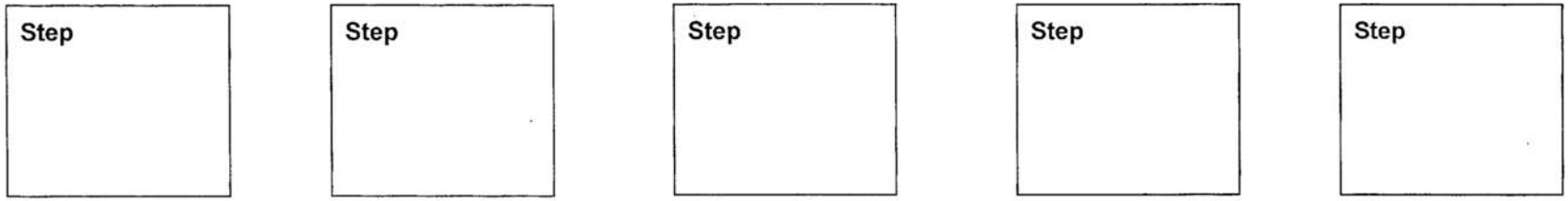
Appendix I: Phase One Tools

Process: _____



Subprocess: Subprocess: Subprocess: Subprocess: Subprocess:

Generalized Healthcare Subprocesses

Generalized Subprocess		Examples of Subprocess
Prescribing	Visit/see	Visit patient on the floor; see patient prior to surgery.
	Assess/evaluate	Assesses patient; evaluate home medications.
	Review/screen	Review chart; review order; screen allergy/drug interaction.
	Consult/discuss	Consult pharmacist; discuss with Radiology MD.
	Choose	Choose procedure; choose system for entry; choose mode of delivery.
	Calculate/score	Calculate dose; assign score.
	Prescribe/transcribe/write	Prescribe medication order; transcribe medication order; write order.
	Enter	Enter order into computer; enter allergy information into computer
	Order/give	Order medications verbally; give directions.
	Feedback/repeat	Provide feedback to MD; repeat order
	Document/complete/sign	Document medications; complete note; sign form
Administration	Identify/clarify	Identify patient; Identify resources; identify needs; clarify IV status.
	Arrange/coordinate/establish	Arrange transporter; coordinate timing; establish time.
	Prepare	Prepare patient; prepare medications
	Set up/program	Set up device; program device.
	Obtain	Obtain medications; obtain flow sheet.
	Label/produce label	Label medications; produce labels for medications.
	Verify/check/confirm	Verify order; verify syringe; check medication; confirm room availability.
	Administer/apply	Administer medications; administer PCA; apply probe.
	Perform	Perform procedure.
Monitoring	Monitor/observe	Monitor patient; observe patient
	Respond/intervene	Respond to alarm; perform intervention.
	Adjust/manage	Adjust regimen; manage pain.
	Change/turn on/turn off	Change cartridge; turn on alarm; turn off alarm.
	Discharge/transition	Discharge patient; transition to oral medications.
Communication	Report	Provide report to floor
	Notify/page	Notify RN that exam/procedure completed; page MD.
	Communicate	Communicate expectations.
	Gather/get	Gather allergy information; get information from family.
	Answer/inform/update/support	Answer questions; inform patient; update family; support family.
Others	Pick up/return	Pick up slip; return chart.
	Place	Place form in chart; place allergy information on armband.
	Take/send/deliver	Take medications to bed; send order to pharmacy; deliver medication to unit.
	Receive	Receive order; receive medications.
	Transport	Transport patient.

HFMEA Step ___ Subprocess ___ : _____

HFMEA Step 4 - Hazard Analysis									
Failure Mode		Scoring			Decision Tree Analysis				Potential Cause
		Severity	Probability	Haz Score	Single Point Weakness?	Existing Control Measure ?	Detectability	Proceed?	

General Failure Modes – Questions for Listing Failure Modes

Question: ***What can go wrong?***	Examples of Failure Modes
Omission: What part of the subprocess is prone to be omitted?	• Omitting necessary steps in the preparation of a medication • Forgetting to switch on a humidifier in a respirator • Forgetting to return flow quantity after processing an additional medication
Excessive Repetition: What part of the subprocess is prone to be excessively repeated?	• Re-executing the finished work • Adding the same liquid twice into the mixture
Wrong Sequence: In what wrong sequence can the subprocess be executed?	• Filling an order without entering allergy information, patient weight, etc. • Proceeding care before producing the patient ID
Early/Late Execution: What execution can be early or late?	• Beginning work earlier/later than specified • Giving a medication in the wrong time
Incorrect Identification/Selection: What object of the subprocess, e.g., patient, medication, equipment, document etc, is prone to be selected or identified incorrectly?	• Giving a medication to the wrong patients • Choosing the wrong dose or the wrong syringe • Wrong-side surgery
Incorrect Counting/Calculating: What objects of the subprocess can be counted, measured or calculated incorrectly?	• Counting medications incorrectly • Miscalculating quantity of drugs and overdosing
Overlooking: What information, risk or failure/error is prone to be overlooked?	• Overlooking patient's allergies • Overlooking abnormal values displayed in a system • Not noticing information on drug-drug interactions or patient's other medicines
Misreading/Misunderstanding: What misunderstanding or misreading is prone to occur?	• Misreading medication orders • Misunderstanding status of the equipment • Misunderstanding bed availability
Incorrect Decision: What incorrect decision is prone to occur?	• Misjudgment of discharge criteria
Miscommunication: What miscommunication is prone to occur?	• Miscommunicating current status of patients in transition • Insufficiently notifying to other caregivers • Disagreement between the care team
Incorrect Transcription/Entering: What transcription/entering error is prone to occur?	• Making a mistake in transcription of doctor's instructions • Making a mistake in entering patient information into computer systems
Incorrect Route/Orientation/Positioning/Setting: What route/orientation/positioning/setting error is prone to occur?	• Operating controls on a defibrillator based on the understanding of different defibrillators • Connecting tubes/valves incorrectly
Unintentional Touching/Sticking/Splashing: What can be unintentionally touched, stuck or splashed?	• Unintentionally touching equipment switches • Being splashed with a toxic substance • Sticking needles in hands
Hazardous Movement: Where What movement can cause harm (slipping, falling etc)	• Slipping on the floor • Falling
Not Available: Who/what is prone not to be available?	• MD not available • Equipment/room/medication not available
Hardware Failure/ Incorrect Information: What hardware failure or incorrect information provision is prone to occur?	• Equipment failure or expired medication • Incorrect patient information system record
Unexpected Patient Reaction: What unexpected patient reaction is prone to occur?	• Unexpected patient reaction

NOTE: 1) Apply the above questions to each subprocess. 2) If the related latent risks are found, add the corresponding failure modes to the subprocess making their expressions specified for the subprocess.

Appendix II: Phase Two Tools

Step __ Subprocess ___ : _____

Failure Mode ___ : _____

Principles	Question	Solution
Eliminate Tasks/Risks	Trimming - Can we eliminate the error-prone process or harmful objects?	
	Self Elimination - Can the harmful action or object eliminate itself?	
	Prior Action - Can we do something beforehand to eliminate the error-prone process or harmful objects?	
Replace Error-Prone Human Operations	Automation (Automatic Inspection) - Can we automate the process to solve our problem?	
	Prior Action - Can we do something beforehand to support human operations?	
	Combining - Can we combine (bring together/closer) two or more things to automate or support human operations?	
Facilitate Human Operations	Trimming - Can we trim similar or confusing things to facilitate human operations?	
	Standardization - Can we standardize the process to facilitate human operations?	
	Copying - Can we use redundancy to facilitate human operations?	

Facilitate Human Operations (Continue)	Prior Action - Can we do something beforehand to facilitate human operations?	
	Flexible Films or Thin Membranes - Can we use flexible films or thin membranes to facilitate human operations?	
	Color - Can we use color to facilitate human operations?	
	Combining - Can we combine (bring together/closer) two or more things to facilitate human operations?	
Detect Abnormality	Counting - Can we count something to detect abnormalities in the human operations or their results?	
	Self Elimination - Can we let people notice abnormalities by themselves?	
	Standardization - Can we standardize the process to detect abnormalities?	
	Unique Shape/Geometry - Can we use shapes (1D, 2D, or 3D) to detect abnormalities in the human operations or their results?	
	Automation - Can we automatically inspect something to detect the abnormalities in the human operations or their results?	
Mitigate Effects	Trimming – Can we trim a part of harmful objects to mitigate the effects?	
	Copying - Can we use redundancy to mitigate the effects?	
	Prior Action - Can we do something beforehand to mitigate the effects?	
	Standardization - Can we standardize the process to detect abnormalities?	

Appendix III: Case Study Materials

DETECTION RATING SCALE

Rating	Description	Definition
10	No chance of detection	There is no known mechanism for detecting the failure.
9 8	Very Remote/Unreliable	The failure can be detected only with thorough inspection and this is not feasible or cannot be readily done.
7 6	Remote	The error can be detected with manual inspection but no process is in place so that detection left to chance.
5	Moderate chance of detection	There is a process for double-checks or inspection but it not automated and/or is applied only to a sample and/or relies on vigilance.
4 3	High	There is 100% inspection or review of the process but it is not automated.
2	Very High	There is 100% inspection of the process and it is automated.
1	Almost certain	There are automatic "shut-offs" or constraints that prevent failure.

Adapted from: The Basics of FMEA, Productivity, Inc. Copyright 1996 Resource Engineering, Inc.; Goodman, S.L., Design for Manufacturability at Midwest Industries, Harvard Business School, *February 2, 1996 Lecture;* Wheelwright, S.C.; Clark, K.B., *Revolutionizing Product Development: Quantum Leaps in Speed, Efficiency, and Quality*, The Free Press.

OCCURRENCE RATING SCALE

Rating	Description	Potential Failure Rate
10	Certain probability of occurrence	Failure occurs at least once a day; or, failure occurs almost every time.
9	Failure is almost inevitable	Failure occurs predictably; or, failure occurs every 3 or 4 days.
8 7	Very high probability of occurrence	Failure occurs frequently; or failure occurs about once per week.
6 5	Moderately high probability of occurrence	Failure occurs about once per month.
4 3	Moderate probability of occurrence	Failure occurs occasionally; or, failure once every 3 months.
2	Low probability of occurrence	Failure occurs rarely; or, failure occurs about once per year.
1	Remote probability of occurrence	Failure almost never occurs; no one remembers last failure.

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SEVERITY RATING SCALE

Rating	Description	Definition
10	Extremely dangerous	Failure could cause death of a customer (patient, visitor, employee, staff member, business partner) and/or total system breakdown, without any prior warning.
9 8	Very dangerous	Failure could cause major or permanent injury and/or serious system disruption with interruption in service, with prior warning.
7	Dangerous	Failure causes minor to moderate injury with a high degree of customer dissatisfaction and/or major system problems requiring major repairs or significant re-work.
6 5	Moderate danger	Failure causes minor injury with some customer dissatisfaction and/or major system problems.
4 3	Low to Moderate danger	Failure causes very minor or no injury but annoys customers and/or results in minor system problems that can be overcome with minor modifications to system or process.
2	Slight danger	Failure causes no injury and customer is unaware of problem however the potential for minor injury exists; little or no effect on system.
1	No danger	Failure causes no injury and has no impact on system.

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