

Improving the Production Process for a Medical Device Manufacturing Company using Monte Carlo Simulation

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Author Note: Jazmin Furtado, Taiylar Mastey and Sara Menke are class of 2016 graduates of the United States Air Force Academy. Gerardo Gonzalez, Jesse Pietz and Joseph Wilck are operations research faculty members at the United States Air Force Academy. This work is a result of a year-long operations research capstone project conducted in collaboration with a medical manufacturing company.

Abstract: This work studies a medical product development, assembly, and packaging company that uses a paper-based method to track jobs through their assembly process. The paperwork often has errors, which must be corrected before distribution, causing delays in manufacturing and shipment and resulting in lost time and money. The project team analyzed the company's production process to identify areas for improvement. Through statistical analyses of the company's process data, the team established error categorization, location, and probability of occurrence. In order to address sources of error, the project team diagrammed the company's manufacturing floor and created a list of issues within each step of the manufacturing process as well as potential solutions to these problems. The team created a simulation of the manufacturing process and used this tool to analyze potential process changes to decrease the number of employee hours wasted in order to fix discrepancies. The simulation proved to be an invaluable tool that helped the company better understand their process. It helped to identify which jobs create the most errors, how many errors occur per month, and how much money the company loses on time spent correcting the errors. Eleven potential solutions were considered, but two of them appeared to yield the best results. Implementing a total quality management (TQM) system would conservatively reduce error counts by 71.3%. Implementing a start quantity to the company's electronic system would conservatively reduce mean hours wasted from 22.60 to 21.73 hours per month and mean salary lost from \$519.82 to \$499.80 per month. Using insights from the simulation, the project team then coordinated with management to decide whether error rates or time and salary spent to correct errors were more important to address. As of this writing, as a result of this study, the company is taking steps to implement a TQM system in order to decrease errors in their job tracking process.

Keywords: Medical Manufacturing, Process Improvement, Simulation, Total Quality Management

1. Introduction

This project was conducted in collaboration with a United States-based medical manufacturing company. Since the company wishes to remain anonymous, it will be referred to as ABC Medical Manufacturing (ABC) for the remainder of this article. ABC produces many different medical devices that have applications in biopsy, critical care, drug delivery, imaging, sedation, surgery, and much more. ABC has received a regional award for excellence in the manufacturing sector by a business association. The company has about 400 employees and is relatively small in the medical manufacturing industry. However, they pride themselves in providing a cost effective and safe alternative to manufacturing in Asia and Mexico. Part of ABC's mission is to provide customers with extraordinary service. These customers are Fortune 20 medical device companies.

ABC manufactures products used by medical professionals all around the world. The company must ensure their products are safe to use. The U.S. Food and Drug Administration (FDA) regulates how these devices are to be manufactured. ABC must document several things in order to follow regulations. The details of what must be documented are purposefully omitted here because they have no import in this study. It might seem tedious, but it is necessary to ensure product safety and quality. There are several things that an operator needs to document as they work on a product. Sometimes, there are paperwork errors due to incomplete or inaccurate documentation. ABC does not allow any product to ship without perfect

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documentation, so any errors caught at the final inspection must be corrected. This requires backtracking through the production line to correct the error. Sometimes the errors cannot be corrected and the whole order must be scrapped and reprocessed. If ABC can minimize their errors, they would save time and money, make their process more efficient, as well as ship product to customers in a more timely manner.

The overall production floor of ABC consists of Assembly and Molding, which is where the majority of errors occur. Operators train and work on either the Assembly floor or the Molding floor with no crossover. Each floor has several work stations. These work stations can be set up to do multiple different operations, allowing ABC to be versatile in the products they produce. Parts go back and forth between Assembly and Molding until the product is complete. Errors must be caught before the product is shipped so there are no violations of regulations.

1.1 Problem Statement

ABC’s recording system is paper-based. The paper-based system coincides with an Enterprise Resource Planning (ERP) system, but all jobs are routed through both systems. The operators that produce products at ABC are required to understand every part of the paper trail (called a “job sheet”) and they are also required to understand the importance of the ERP system. As jobs are routed through the production floor, the job sheet and ERP system become more prone to errors. Problems include sections not being filled out, inaccurate counting of parts, and the paperwork being misplaced. The paper-based system does not always match the electronic system and requires reconciliation. The result of this is an inefficient system where approximately \$1,700 per month in labor is lost. A visual representation of the build process at ABC is represented by Figure 1.

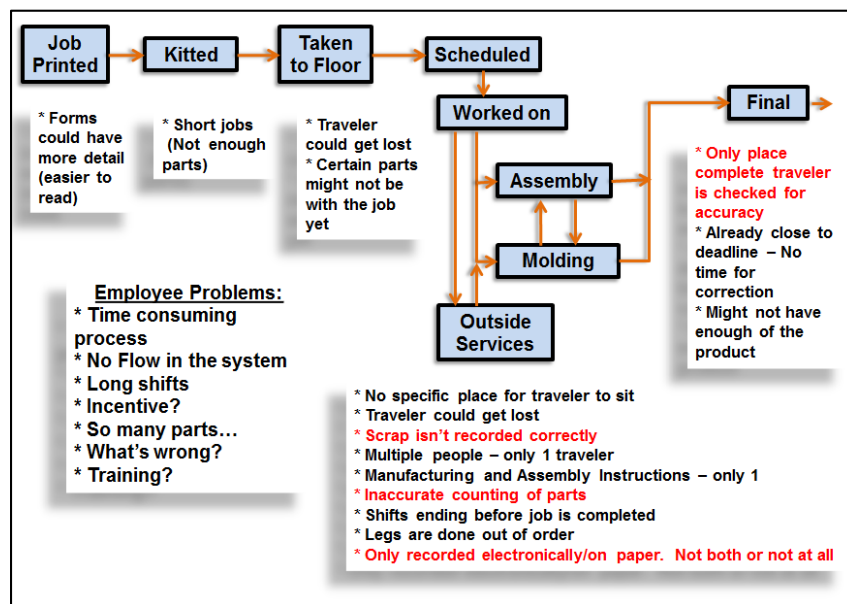


Figure 1. Fishbone Diagram of Build Process at ABC Medical Manufacturing

Below each station in the build process is a list of possible issues that could occur at that specific station. The four problems highlighted in red text are the main problems that the project team and ABC decided to focus on for this project. All of the problems presented in Figure 1 were determined through employee interviews and communication between the project team and ABC management (refer to Section 2.1 for interview details).

One main problem with the process is that scrap recording can be error prone at any step. This is an important problem to fix because scrap causes the company to lose anywhere from \$23,000 to \$64,000 per month. Two more large problems are the inaccurate counting of job parts and the inconsistent recording of information on paper and in the ERP system. Both of these problems are important to fix because they contribute to overall profit and company success. The last major problem is that the only place the entire completed job is checked for accuracy is right before it gets shipped.

Most of the errors in the process occur when the job sheet reaches the production floor and the jobs are in Assembly or Molding. Although there are many problems for Assembly and Molding, it is understood that most of their respective problems have significant overlap of potential solutions. Nonetheless, the focus of the study remains on the four issues that were described in red text from Figure 1, keeping in mind that continued findings may unintentionally alleviate issues out of our scope. The purpose of this study is to implement changes in ABC's process which will lead to minimizing cost and wasted employee time for ABC.

1.2 Related Work

Denny, King and Wilck (2004) studied the process of gold bath electroplating for a company. The team developed an easy to use electronic tool that tracked "bath chemical levels and [determined] chemical adjustments to keep the baths within specifications." Although the actual manufacturing process for electroplating is different from the process of our group's medical manufacturing process, Denny, King and Wilck used root cause analysis to understand the manufacturing process. Their fishbone diagram broke up the errors in plating into three categories: employees, procedures, and communication. Then, they listed all the causes of errors and their resulting effect on the process. In our study, a similar approach was taken to diagram the manufacturing process at ABC.

Johnson et al. (1993) present a method for bringing together the paper and electronic worlds through a new hybrid paper user interface technology. The system that the paper describes is called XAX. This system allows users to use paper to track things and then scan the paper into a computer based system. After the document is scanned, the computer program is able to correct for skew, locate check boxes on a form and determine if they are checked or not. Saving this data allows it to be recalled and modified later. This research is important because ABC is open to switching to a completely electronic system. Improving ABC's current paper system could fix several problems, but if performance is still unsatisfactory, switching to a computer based system could be the best solution. However, that could be too expensive and a system similar to the one presented in the article could be the solution.

Singer and Vogus (2013) model error prevention methods in a hospital to create a safety culture. They identified electronic medical records as a technological internal action for better safety, human resources and training as a managerial internal action for better safety, and accreditation as an external action for better safety. This model was an effort to inform policy makers and practitioners of better practices to improve their safety (quality). This article is relevant because the internal actions (technological and managerial) and external actions (FDA regulations) are factors ABC encounters within their industry.

Huang et al. (2012) discuss the application of lean and six sigma methodologies to healthcare to continuously improve quality. They studied the impact of these methodologies and advances in areas where high service quality is paramount. They found that organizational implementation of these methodologies is required for them to be most effective at reducing cost, which includes team building, personnel training, administrative strategy changes, and waste reduction. This article is relevant to ABC because the organizational changes recommended in the article are possible solutions for ABC.

Powell, Riezebos, and Strandhagen (2013) present research on ERP systems and how they can be effective drivers for quality initiatives, including lean, in a pull production environment. This research included case study examples for small and medium sized companies. They found that relying on the ERP system to support pull production is important to reach lean and quality goals within the organization. This research and case study implementations are relevant to ABC because ABC is medium sized company in a pull production environment.

Jahangirian et al. (2010) review several different articles on the use of simulation in manufacturing and business applications. The review evaluated different kinds of simulation being used, including discrete-event, Monte Carlo, and systems dynamics. This information was useful to the project team since a simulation model was built to compare alternatives for ABC.

Guo, Li, and Wilck (2011) present research on sharing information with supply chain partners, with particular attention to inventory. This research included evaluating the capabilities of ERP systems and other sources for Electrical Data Interchange. This work is relevant to ABC because it shows that ERP systems can be used for both internal and external supply chain needs with respect to the information being shared during the manufacturing process.

Nahmias and Olsen (2015) provide a textbook that provides descriptions and modern usage of many of the issues related to the ABC manufacturing system, including job shop, pull system, ERP, quality control, simulation, facility layout, control, and operations.

The United States Air Force's Lean Six Sigma program provides a framework to analyze ABC's problem. This program is commonly known as the Air Force Smart Ops for the 21st Century (AFSO21) Playbook (2008). AFSO21 gives Air Force members an eight step problem solving method as a guideline to solving problems.

1.3 Organization

The remainder of this article is organized as follows. Methodology describes the methods that were used to complete this project. The first step in methodology describes how data was collected from interviews and how visual representations of the ABC processes were created. Next in methodology is a description of how the data received from ABC was used to determine a baseline for our project. After the baseline was established, a simulation was built to determine which errors cause the most monetary loss. Finally, the results and discussion section describes the potential solutions that were presented to ABC and how each affected the time and money lost each month due to the errors that operators make during the manufacturing process. The conclusions section describes where ABC is at today and how the team's simulation helped and will continue to help the business remain successful.

2. Methodology

2.1 Manufacturing Process and Initial Interviews

The first step taken in this project was to understand ABC's manufacturing process. The project team was immersed in the multi-step process of a job from start to finish by touring the administration, Assembly and Molding floors, and the Quality Assurance sections of ABC. Additionally, the project team conducted interviews with the employees of the production floor, in order to gain perspective from non-management employees. It was important to learn how the operators on the production floor felt about their work process. From these interviews, the project team learned about problems the employees faced and what areas of the production floor were most problematic. The interviewed employees included operators from Assembly, production, clean rooms, and Molding. Their experience ranged from 2 weeks to 17 years; they were of multiple ethnicities, varying age groups, and both genders. Questions posed were about the job sheet and the training that each employee received. Some of the problems discussed with the employees included not enough room to write on the job sheet, having too few lines to write on, confusing directions, no written specifications on the job sheet, and job sheet routing. Most of the employees agreed that training materials and use of the job sheet could be improved.

The information from interviews combined with information gained from touring the manufacturing process became the blueprint for the visual representation diagrams created to describe the problem statement. First, the project team developed a diagram that explained the overarching problems that could occur at every checkpoint in the entire manufacturing process, which is shown in Figure 1. After conducting employee interviews and talking with ABC management, the project team further studied the Assembly and Molding processes. From there, we created two other diagrams that addressed specific problems that could occur at each individual checkpoint within Assembly and Molding. These rough diagrams aided the project team with listing potential problems within the process and develop possible solutions along with pros and cons for each of these solutions. These diagrams are not presented in this article for the sake of brevity and because they are similar to the high-level process diagram given in Figure 1.

2.2 Initial Data Analysis

After conducting the initial process analysis, ABC management agreed to provide the project team with some data to establish a baseline from which to measure any improvements. The data was collected by an individual who monitored the production floor and provided additional oversight to review the job sheets at periodic intervals. Therefore, the data may not be entirely representative of an unaffected production floor. Therefore, it is reasonable to expect that true error rates are greater than those observed in this data collection effort. The team aimed to find patterns within the errors from the job sheets to determine which problems were most common. The data obtained consisted of a detailed list of problems encountered amongst the job sheets during the times the employee was working. This data consisted of the date of record, the job/product number, the process step in which the problem was found, and a description of the discrepancy (as seen in Table 1).

Table 1. Sample of One Entry in Raw Data File

Date	Product	Process Step	Discrepancy
30-Oct-15	XYZ	WC-OP 50	QTY, Date, Employee Number were not filled out.

The data contained information on nine days spanning from 29 October 2015 to 20 November 2015. Using descriptive statistics, a rough baseline of specific problems in ABC’s job sheets was established. Within these nine days, there were 37 discrepancies recorded. The project team categorized the errors into four groups: 1) incorrect quantities documented; 2) missing information; 3) incorrect formatting (unnecessary spaces on the job sheet, i.e. in the quality assurance (QA) Audit operation, there is a section for shipping which is unnecessary); and 4) incorrect process completion (error with process step order or correct completion of the parts). After obtaining descriptions for each of the process steps the team made the assumption, subsequently validating it with ABC, that there were five general categories of process steps used in ABC’s production floor: 1) prep; 2) assembly; 3) molding; 4) testing; 5) QA shipping.

These data provided a baseline of types of problems ABC experiences as well as where the problems occur. Generally, on the days of error recording, there was an average of 4.1 errors while each recorded job averaged 1.3 errors. The cost of these errors depends on its type and where it occurred. The rest of the data analysis classified each error and is summarized in Figure 2.

Among the 37 errors, most occurred during Assembly and Shipping. This was in agreement with what the company claimed, for Assembly requires much more manpower than Molding and therefore houses more mistakes. Also, QA/Shipping is where many mistakes are discovered since it is at the end of the manufacturing process. This is not necessarily where the mistakes are made, but it is where many are found which require the company to backtrack to their origin. This is important because the company wants to decrease the number of errors found at this point and increase the accountability at the earlier steps, resulting in faster response and fix times as well as saving time and money.

It is to be noted that the two most common types of errors are Category 1 (incorrect formatting) and Category 2 (incorrect process completion). Category 2 errors do not cost the company as much to fix when compared to Category 1 errors. Category 1 errors did not surface as often as Category 2 errors; however, they cost the company hours of time and thousands of dollars to backtrack and fix. Nonetheless, the project team aimed to address all the different errors, for they all affected the company’s efficiency and quality of business.

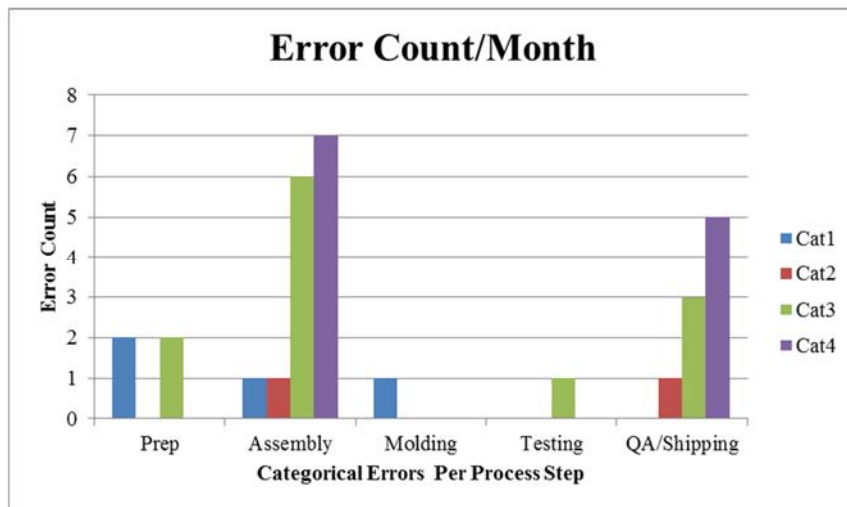


Figure 2. Discrepancy Count per Process Step and Error Category (Cat)

This information also provided a means to calculate the error rate for each process step. This would prove valuable for the project team’s simulation of the company’s manufacturing process. This would also prove useful in determining what kinds of solutions would be most beneficial, targeting specific process steps or error types.

2.3 Simulation Development

The project team created a Monte Carlo simulation in Microsoft Excel to model one month of jobs on ABC's production floor. First, the team received and modeled a single job sheet from ABC and used an arrival rate of 91.4 jobs per month, which was derived from the baseline data discussed in Section 2.2. Initially, the simulation modeled a production floor with the assumption that the same job was done 91.4 times per month.

Each job sheet that ABC uses indicates projected setup and run times for each step of the manufacturing process. For example, the job sheet indicates that crimping a wire takes 0.25 hours to setup and 4.25 hours to complete. The simulation used these times as the mean of a normal distribution with a standard deviation assumed to be 10 minutes. Distribution parameters can easily be adjusted in the simulation as new data becomes available. Each step on the job sheet was then placed into one of five categories (depicted in Figure 2): prep, assembly, molding, testing, or QA/Shipping.

Next, the probabilities of the four category errors (depicted in Figure 2) were determined for each of the five types of steps. This created 20 different probabilities in all. The probabilities were used to simulate how often each type of error occurred in each step of the job sheet. The probabilities were ultimately determined by the baseline data.

The project team used an empirically estimated binomial distribution to simulate the number of errors experienced during any particular step of the job sheet. The project team spoke with ABC management and determined numbers of hours wasted on correcting each type of error for each step category. So, if an error occurred, the specified number of corrective hours was added to the completion time for that step. The ABC management team also specified which errors were corrected by management members and which errors were corrected by operators. The wasted time by operators was summed together and multiplied by the average operator salary of \$11 and the wasted time by management was summed together and multiplied by the average management salary of \$23. Both of these dollar amounts were then added together to determine the total cost of the errors per month. Thus, as we will see in Section 3, salary lost is not simply a linear function of hours wasted, though they are very closely related.

With the simulation of one job completed, the project team acquired five more job sheets from ABC. The additional job sheets were from ABC's most manufactured products. It was assumed that each job sheet represented one sixth of all the jobs manufactured that month. The simulation was expanded to determine the number of errors, hours wasted, and salary wasted per month for each of the six types of jobs. These metrics were summed to determine the total errors, hours wasted, and salary wasted per month for all of ABC.

Once the one-month simulation was completed, the project team verified that the model was able to produce reliable results. Next, the project team presented the model to ABC in order to validate that the model produced results in a manner consistent with ABC's process. Once the simulation was verified and validated, 150 repetitions of the month were run in order to create a confidence interval with a range of 4 hours or less. This became the model for ABC's current state. The next step was to determine how changes to the system would affect the hours wasted per month.

The project team analyzed the baseline and ten different potential solutions. The potential solutions were 1) write a Manufacturing and Assembly Instruction (MAI) for job sheet creation and use; 2) implement a total quality management check system; 3) introduce better counting procedures; 4) have a maximum number of parts per job; 5) include start quantities on the job sheet; 6) add more lines to the job sheet; 7) ensure all parts of a job must stay together; 8) include a start quantity to the ERP system; 9) add more scan stations to the floor; 10) have a sign out sheet for when the job sheet is taken away from the parts. These solutions were determined by brainstorming with ABC's operators and management as well as the project team's ideas.

The project team determined how each potential solution would reduce the number of errors for each category of error for each type of step. Since there were ten potential solutions to be analyzed, ten reduction matrices were created (see Table 2 for an example matrix). The reduction matrices were used to reduce the 20 probabilities that were assigned to determine how often an error occurs in each step while the proposed solution is implemented.

The project team also determined how much time it would take to implement each solution for management and operators. Each solution takes time to implement, so the project team discussed with ABC approximately how long management or operators would spend implementing a solution. These times were added to the overall month's wasted time. This additional wasted time was also multiplied by the appropriate salary (management or operator) and then added to the total amount of money wasted per month. ABC did not have good estimates for implementation costs, so they were not explicitly included in the analysis. However, notional implementation cost is considered in the results presented in Section 3.

Table 2. Reduction Matrix for Potential Solution 1

Reduction Matrix				
Category of Error/ Process Step	Cat 1	Cat 2	Cat 3	Cat 4
Prep	10%	15%	20%	0%
Assembly	10%	15%	20%	0%
Molding	10%	15%	20%	0%
Testing	10%	15%	20%	0%
QA/Shipping	10%	15%	20%	0%

The simulation was then used to run each of the 10 proposed solutions for 150 months. The simulation output hours wasted per month, salary wasted per month and number of errors on job sheets per month. All of the metrics were compared to the baseline to determine the effectiveness of each solution.

3. Results and Discussion

The project team used the simulation to determine which category of error was most beneficial to focus on and fix. The final simulation output yielded a table of all the metrics that were used by the project team to determine which potential solution would be the most beneficial for ABC (see Table 3).

As Table 3 shows, some solutions reduced errors while increasing hours wasted and salary lost. Other solutions performed better with hours wasted and salary lost, but did not reduce the error very much. Here we focus on hours wasted and errors. Recall that hours wasted and salary lost are closely related. We include the respective 95% confidence intervals on hours wasted because several of the means were close in magnitude. The values highlighted in yellow indicate the best solution for each of the metrics that the project team analyzed. Assuming ABC cared most about the number of errors in a job, the best potential solution would be Solution 2 (implement a total quality management (TQM) system). This solution reduced mean errors from 29.74 to 8.53 errors per month. Figure 3 shows how a TQM system consistently reduced errors.

The simulation showed that even in the variation of 150 months, the highest error months with a TQM system were still less than the lowest error months of the baseline. However, a TQM system takes time to implement because everyone is constantly checking over others' work. Compared to the baseline, a TQM system increased mean hours wasted from 22.6 to 98.10 hours per month and mean salary lost from \$519.82 to \$1159.53 per month.

Table 3. Summary of Simulation Results

Proposed Solution	Mean Hours Wasted	Confidence Interval Min	Confidence Interval Max	Mean Salary Lost (\$)	Mean Errors
Baseline	22.60	21.65	23.56	519.82	29.74
1	29.56	28.52	30.61	588.57	26.98
2	98.10	97.53	98.68	1159.53	8.53
3	44.18	43.18	45.19	742.01	27.93
4	204.32	203.31	205.32	2505.68	28.07
5	42.98	41.99	43.98	988.57	27.61
6	21.93	20.95	22.91	504.30	27.57
7	421.47	420.70	422.23	4825.95	25.99
8	21.73	20.75	22.71	499.80	28.69
9	22.07	21.12	23.02	507.63	28.34
10	27.69	26.70	28.67	600.24	27.29

Assuming ABC cared most about hours wasted and salary lost, the best potential solution was Solution 8 (include a start quantity to the ERP system). This solution reduced mean hours wasted from 22.60 to 21.73 hours per month and mean salary lost from \$519.82 to \$499.80 per month. The mean errors per month was reduced from 29.74 to 28.69 errors per month, but compared to the TQM system, it was not a very large drop. It is worth noting that the hours wasted confidence intervals for the baseline and Solutions 6, 8 and 9 all overlap. Therefore, if reducing hours wasted and salary lost is the primary goal, ABC must consider implementation cost in order to select the best potential solution.

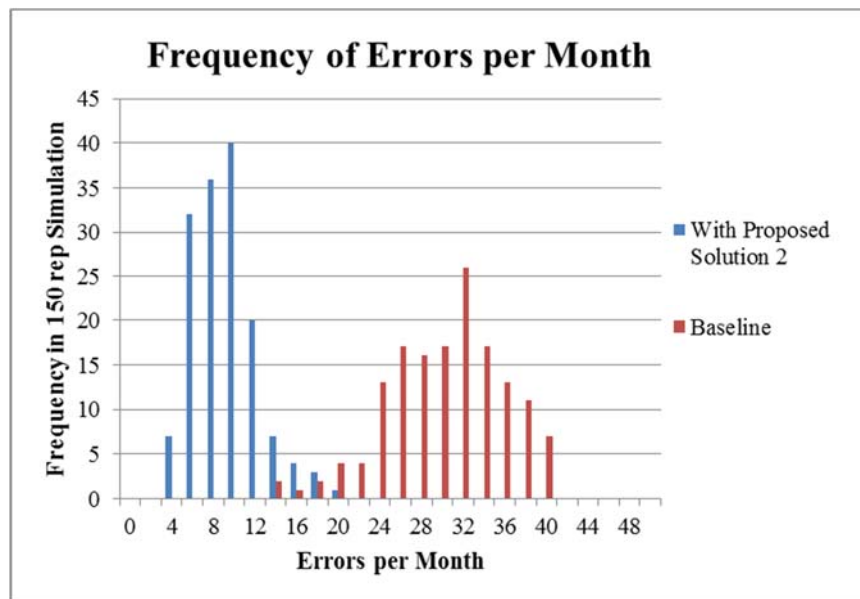


Figure 3. Frequency of Monthly Errors in 150-Month Simulation

If all three metrics are equally important, then the best potential solution would be Solution 6 (add more lines to the job sheet). This solution reduced mean hours wasted from 22.60 to 21.93 hours per month, mean salary lost from \$519.82 to \$504.30 per month, and mean errors from 29.74 to 27.57 errors per month. Not all these drops were large, but Solution 6 provided the largest drop in errors while simultaneously dropping hours wasted and salary lost. Note that all results are conservative values due to the simulation not accounting for materials, overhead, and other factors. The simulation only accounted for loss due to labor costs. Furthermore, except for the baseline, Solution 6 clearly has the lowest implementation cost of the three desirable solutions (6, 8 and 9). It only requires that lines be added to the job sheet template, while the other two solutions require ERP system changes and equipment purchases.

4. Conclusions and Future Work

ABC management had to decide which metric was most important to reduce in order to decide which potential solution to implement. The project team presented all of the metrics for each potential solution to ABC management to aid them with their decision. Ultimately, ABC decided that, because they produce medical devices that affect lives, reducing errors was the most important metric. They are currently discussing implementing a TQM system at ABC. Although this implementation will cost time and money, it will reduce errors by approximately 71.3%.

After conducting this analysis, the project team came to multiple conclusions about process improvement analysis, especially in regards to ABC's situation. First, the project team's background research on the manufacturing company and related works was critical to understanding the underlying issues. Therefore, in any process improvement analysis, insights cannot be made unless it is built from concrete, reliable, and complete knowledge of the company and all stakeholders' interests and concerns.

Next, ABC's process improvement solution is complex; there are many moving parts of the process with many nuances concerning steps and process completion. The model accurately simulates the manufacturing process, but it is limited by the available data. The project team therefore stresses the importance of ongoing, long-term data acquisition in terms of inefficiencies. This data can be used to measure the company's current state, any deficiencies, and the effect of implemented solutions.

Although the project team's model generates useful and applicable insight, there are areas for improvement which can be addressed in future works. Foremost, the model simulated the effect of implementing solutions, the project team made assumptions as to how much each solution would affect the error rate and completion time. This can better reflect reality by using error rate data collected after its implementation. This would give ABC a more accurate view of error reduction.

Additionally, based on our research on electronic systems, it would be valuable to quantify the effect of implementing a form of electronic supplementation to the current process (Johnson et al., 1993). As there are various levels at which an electronic system can be introduced into the current system up to and including converting the entire paper-based system to an electronic one.

Finally, because the company's ability to implement multiple solutions simultaneously is limited, the project team's model simulates one implemented solution to accommodate this constraint. However, if this situation were to change, it would be important to integrate multiple solutions into the model.

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