Medical Procedure Packs Missing Components Reduction

Ann Marie Jiménez
Master in Engineering Management Program
Dr. Héctor J. Cruzado
Graduate School
Polytechnic University of Puerto Rico

Abstract — *The project took place in a medical device company that manufactures custom procedure packs. During the pack assembly process, components may be left out of the pack which causes the assembly process to stop to rework completed packs. A rework involves a loss of productivity and additional costs to be added to the order. The objective of this project is to reduce the occurrence of missing components by understanding the process thru process observations and data collection. After understanding the current process, two areas of the process were improved to achieve a better process flow, standardized the pack assembly process, and accomplish a reduction in orders reported with missing components. As the process was improved the production output increased. The major finding of this paper concluded that manual processes standardization is required to reduce the occurrence of mistakes.*

Key Terms — *Manual Assembly, Process Flow, Process Improvement, Process Standardization*

INTRODUCTION

The project took place in a medical device company that manufactures custom procedure packs. A pack may be customized for a particular hospital or clinic, containing the exact quantity of all the instruments, drugs, and materials necessary to perform a medical procedure. The main goal of a medical procedure pack is to ease the procedure preparation. One of the critical characteristics for quality is to ensure that all components are placed in the pack. When a component left in the process bin is discovered at the end of the job, a rework process starts as completed packs need to be inspected to identify which pack is missing the item(s).

There is a cost associated with the rework as all the employees that built the pack need to open, inspect, and re-seal the packs. There is a loss in productivity as additional jobs cannot be built in the line while the rework is taking place and there is a cost associated with material as the header bags cannot be reused once opened and the wrap needs to be replaced if damage occurs during the rework.

A manual assembly process possesses challenges in the way the process is being carried out which also leads to opportunities that can be implemented to improve the current process.

The objective of this project is to reduce missing components by understanding the process and identifying gaps to implement solutions. The methodology to achieve the expected results consisted of data collection and process flow analysis. Data collection helped established a baseline of the actual process and measure progress. Process flow analysis was used to identify opportunities for improvements.

The process was measured in terms of how missing components affect productivity. To validate the project results data was taken before and after the process improvements. The data included total rework cost (labor cost + material) and a correlation between production output and orders reported with missing components.

LITERATURE REVIEW

Incorrect kit contents can result in production delays, quality costs of correcting the kit, and deficient product quality [1]. The process needs to be analyzed to determine common quality problems, its causes, and the associated quality problem type to found a solution.

An assistance system is a technical system that receives and processes information from its environment in order to support people in carrying out their tasks [2]. It is important to understand the different assistance systems available and their correlation with the process that needs to be improved. One type of assistance system is the implementation of the poka-yoke technique. The poka-yoke technique detects defects as soon as they are made, preventing faulty assemblies from being passed to the next station [3]. It is also important for getting the operators involved when designing or implementing poka-yoke techniques.

Process chart and Line layout are tools that help define the process and visualize what actions need to be implemented to improve the process. A process chart is a graphical representation of any manufacturing process or an assembly operation. It contains the sequence of all operations in the order in which they are performed and includes inspections, time allowances, and materials used in any business process – from the arrival of raw material to the final product [4].

For the process improvement to be successful it needs the management commitment and more importantly the feedback and participation of the line employees. Together, managers and workers learned to take the initiative not just for identifying problems but also for developing better processes for fixing problems and improving products [5].

In order to identify, implement and sustain process improvements there needs to be a clear analysis and understanding of the process, implement assistance systems that fit the process and ensure there are management commitment and line employees' engagement to ensure the sustainability of the improved process.

ANALYSIS

A data collection file was created to help establish a baseline of the actual process and measure how the process develops as opportunities for improvements are identified and process changes are implemented. A process observation form was developed to document the process observation, define the current process, and analyze process flow to identify opportunities for improvements.

Data Collection

Data were collected to establish the baseline of the process and measure results after process improvements. Two data tables were created to document every time an order is found with a missing component. Table 1 shows an example of the data collected used to document the cost incurred every time a rework is performed due to missing components.

Table 1
Missing Component Rework Cost

Date	Rework Time (Min)	Labor Cost ($)	Material Cost ($)	Total Cost ($)
24-Aug-20	45	$112	$21	$133
24-Aug-20	65	$161	$39	$200
24-Aug-20	70	$174	$24	$198
25-Aug-20	35	$87	$21	$108
25-Aug-20	10	$25	$28	$53
26-Aug-20	180	$446	$200	$646
26-Aug-20	10	$25	$40	$65

The second table shows a relationship between the production output and the orders found with missing components. Table 2 shows an example of the data collected to summarize the production line's performance at the end of the shift.

Table 2
End of Shift Summary

Date	Total Missing Components	Total Orders	Total Rework Hrs.	Total Rework Cost ($)
24-Aug-20	5	44	3.0	$530
25-Aug-20	4	49	2.0	$161
26-Aug-20	5	39	4.2	$910
27-Aug-20	4	41	2.5	$136
28-Aug-20	6	33	5.5	$271
31-Aug-20	4	44	2.5	$433

Process Observations

The production process has five main steps, as shown in Figure 1. The process observations focused on the setup and assembly process and took place at different time intervals for three weeks.

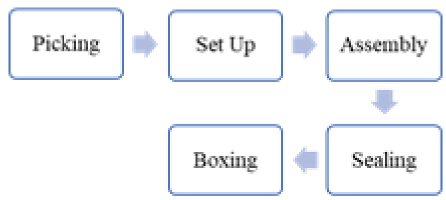

Figure 1
Production Process Flow

The Setup and assembly processes were observed to identify gaps and propose opportunities for improvements. The main activities identified during the set-up process includes:

- Verify components against the bill of materials.
- Pre-count of components.
- Place components in bins for the production line.
- Wait time until space is available to work on the next order.

The Set-up observations concluded that there was a downtime in the process and that additional responsibilities can be added to the set-up process. The assembly process observations identified the following main steps:

- Assign components to be placed in the tray by the employee.
- Distribute components between stations.
- Each station work in batches.
- There is no sequence when placing the components in the tray.

Assembly line observations concluded that the process was not standardized and each operator worked differently. Figure 2 and Figure 3 show two different ways of how the components are placed in the pack.

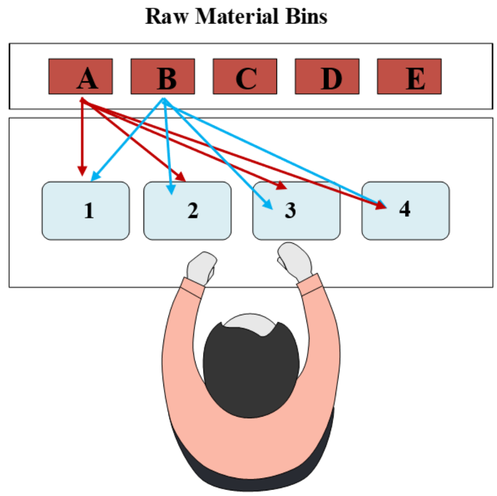

Figure 2
Placement Diagram for Station 1

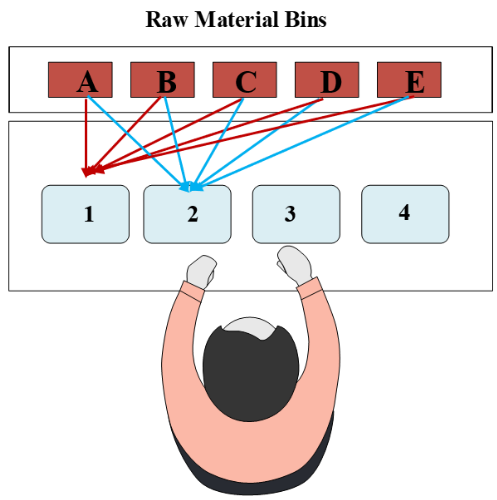

Figure 3
Placement Diagram for Station 2

Process Improvements Implementation

Opportunities for improvements were identified and shared with the production manager and supervisors. It was also shared with the operators to get additional feedback before implementing the recommended changes.

Additional responsibilities were added to the setup process since during the shift they have a waiting period between the orders. New responsibilities ensure that the lines are balanced by distributing the placement of the items equitably.

The set-up process is now determining how many stations will be needed to run the order and dividing how many items each operator place in the pack. Since this is done ahead of time the set-up process is doing a better job ensuring each station has an equal number of items to place.

The assembly process was standardized to ensure all stations pick and place the same quantity of items and follow the same assembly process. Before the new process, the operators were not following any assembly sequence and built the pack in batches. This was creating a bottleneck between the stations. The following points summarized the process improvements implemented in the assembly process:

- Work is balanced between stations. Each station picks and places a similar number of items in the pack.
- One-piece flow process. One pack is built at a time.
- Raw material items are placed in an intermediate bin in batches of five. Items are pick in order and place in the pack. After the fifth pack is built, the intermedia location should be empty.
- The first pack to be completed is the one closest to the next stations.
- Added a visual queue to identify which is the fifth tray leaving the station.

Figure 4 shows how the assembly flow was improved by standardizing how components are placed in the pack. A batch of 5 raw material items is placed in the intermediate orange tray and then the operator picks and places one of each item in the pack that is closest to the next station. A red cone is placed on the line every five packs to indicate which is the last of the 5 packs that are being worked by the operator. This visual queue is the trigger that the operator uses to ensure the intermedia orange tray is empty and ready to be replenished.

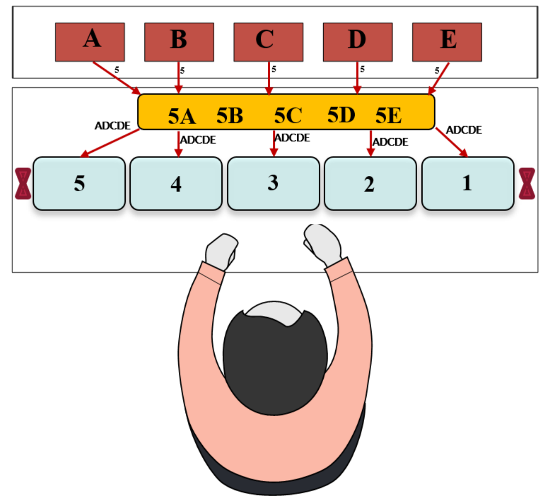

Figure 4
New Process Placement Diagram

Results and Discussion

The Process improvements implemented in the setup and assembly process had a direct impact on productivity. Figure 5 shows the correlation between missing components and production output. A positive trend can be observed in the production output as reported orders with missing components decrease.

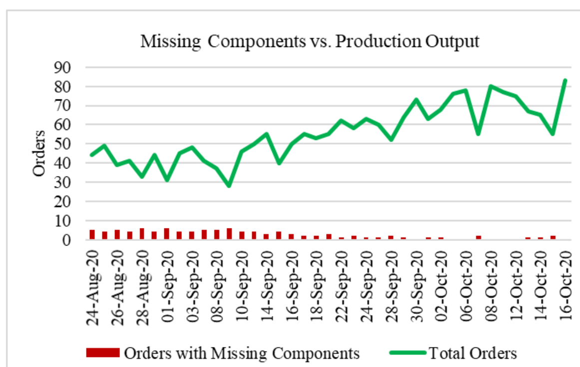

Figure 5
Missing Components vs. Production Output Trend

The additional tasks added to the set-up operation had a direct impact on the assembly line. It provided a better process flow as items are being divided equally between the assembly stations. It also improved the set-up process by eliminating the downtime between orders.

The new process flow implemented in the assembly line contributed to a reduction of missing components orders, a reduction in rework cost, and an increase in production output as there is more production time available as the rework hours decrease.

Table 3 shows a summary of the process performance before and after the process improvements in terms of orders reported with missing components, rework cost, lost rework hours, and production output.

Table 3
Process Performance Summary

	Before Process Improvements	After Process Improvements
Missing Components Orders (Average)	4.7	1.3
Lost Rework Hours (Average)	3.3	1.1
Rework Cost ($) (Average)	383	75
Production orders (Average)	41	63

CONCLUSION

Missing components reduction and increase in productivity were achieved by following a methodology that consisted of data collection, process observations, and process improvements. Data collections helped to establish the actual process performance and to compare achieved results after process improvement implementation. The process observations were key in identifying opportunities to improve the current process.

The major finding of this paper concluded that manual process standardization is required to reduce the occurrence of mistakes. By implementing a standard sequence of how components are picked and place in the pack helped to develop a uniform process flow between all the stations.

The important implication of process standardization is the good documentation of the new process to ensure correct training for new employees.

Another key aspect of the project was developing the understanding that to achieve success during the process improvement implementation it was important to get feedback from the employees during the current process observations and before implementing the new changes. The employee's involvement facilitated the transition to the new process.

REFERENCES

[1] Fager, P., *et al*., "Quality Problems in Materials Kit Preparation", *Division of Logistics and Transportation, Chalmers University of Technology, Sweden*, 2014, pp 1-8.

[2] Hinrichsen, S., *et al.*, "Assistance Systems in Manual Assembly", *Industrial Engineering Lab OWL University of Applied Sciences, Lemgo, Germany*, 2016, pp 3-12.

[3] Manivannan, S., "Improve Productivity with Poka-Yoke", *Assembly Magazine Article*, 2007, pp 1-3.

[4] Yerasi, P., "Productivity Improvement of a Manual Assembly Line", *A Thesis Submitted to the Office of Graduate Studies of Texas A&M University in partial fulfillment of the requirements for the degree of Master of Science*, 2011, pp 22-23, 29-30.

[5] Sirkin, H.L., *et al*., "Fix the Process, Not the Problem", *Harvard Business Review*, July–August 1990 Issue, pp 1-16.