Warehouse Inventory and Material Process Flow Improvement in a Compounding Pharmacy

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Abstract *— Pharmaceutical inventory management aims to improve the control over critical raw materials and its traceability, when used in the compounding of total parenteral nutrition (TPN) and reduce waste of expired materials. A compounding pharmacy dedicated for patient specific TPN products uses a variety of drug additives and components and raw materials that vary in final product quantity usage day after day. Improving inventory performance through lean Six Sigma approaches has been the objective of this research. By implementing Lean methodology with DMAIC tool, the material process flow in the Compounding Pharmacy has been able to reduce stock cost, material waste, diminish documentation errors and has effectively controlled and monitored the raw material inventory.*

Key terms *— inventory management, Lean Six Sigma, process flow improvement, waste reduction*

INTRODUCTION

Pharmaceutical industries have been seeking to maximize quality throughout their process and finished products. Inventory process improvement is a necessary approach to provide an efficient system of the control and monitoring of raw materials used during the production process of patient-specific total parenteral nutrition in a compounding pharmacy. There are many approaches deemed to improve inventory management and process flow to minimize costs and waste. "Six Sigma and lean concept have become two of most popular methodologies for improving productivity, quality and business performance" [1]. These concepts can be applied to any company, including pharmaceutical and manufacturing industries, for continuous improvement of processes. "Lean methodology aims at waste reduction in process while Six Sigma aims at reduction of process variation" [2]. "Lean Six Sigma focuses on eliminated non-value added waste from process in order to streamline production, improve quality and gain customer satisfaction in the long term" [3]. The Lean Six Sigma utilizes the DMAIC tool (Define, Measure, Analyze, Improve, and Control phases) to ensure that the process is fully analyzed in order to determine the causes to the problem. This analysis uses qualitative and quantitative data if available, to get to the root cause of the problems identified.

The lean Six Sigma concept has been utilized in this research to determine the assignable causes of the inventory process flow variations and implement actions that shall control, and trace inventory used in a compounding facility.

METHODOLOGY

In the compounding pharmacy facility, a cool room warehouse is used to store critical and most used raw materials under controlled temperature and cleaning controls. Raw materials located in the cool room warehouse is based on a fixed-time period mode, where inventory is counted weekly. The quantities of materials used differentiate daily as the production process is not a manufacturing process were quantities are fixed and it depends on shifting demands. The raw materials are stored in racks labeled with the content of the materials and the expected quantities of stock in the area. A material handler receives the raw materials and then stores them in the cool room warehouse. However, a deficiency in organization of which product lot number was received first to be used first versus which was received last, has been a problematic method in terms of process flow and waste.

Furthermore, the documentation and traceability of raw materials used during daily production has been a point of focus in internal audits because traceability of some materials such as disposables was not granted. The approach of this research is to use the DMAIC methodology to determine the root cause of the events and identify effective solutions that can be implemented to prevent recurrence of material waste and documentation errors.

Define Phase

During this phase, a project charter (table 1), was developed to include the problem and goal statement, scope and objectives. The process was also defined in order to understand the flow of materials from the delivery to the Cool Room Warehouse until its use in the Compounding Room.

Table 1
Project Charter

CURRENT SITUATION	PROJECT TITLE
• Poor organization in cool room warehouse • Poor process flow • Material waste not used and expired • Documentation errors in material lot/ expiry date used • Traceability of materials used not efficiently established	Warehouse Inventory and Material Process Flow Improvement in a Compounding Pharmacy
PROJECT GOAL	**PROCESS SCOPE**
• Implementation of improved system within 30 days • Optimize traceability of materials • Drive consistency adequacy and thoroughness in tasks • Reduce costs in waste	• Raw materials inventory • Materials process flow • Traceability
BARRIERS TO SUCCESS	**KEY ACTION**
Commitment to FIFO & Segregation Optimized inventory management software	• Gemba walk • Process Flow Chart • Fishbone Diagram • 5S • Cost Analysis

The project scope is to establish an improved process to reduce material waste, human errors in documentation and effectively monitor and track all raw materials used for the finish product. The goal is to prevent any deviations in procedures related to traceability of materials and to improve the inventory system in a short time line.

A Gemba Walk was performed to observe the work process flow. Raw materials process flow occurs from the cool room warehouse, where the materials are unpackaged from their primary package, transfer to a Decontamination Room where materials are disinfected. Furthermore, materials are then transferred via a Pass-thru hatch to the ISO 8 grade cleanroom “Dispatch Area” to be temporarily stored in dedicated bins in the racks. An operator in the “Dispatch Area” prints a list of materials to be used during the compounding process in that particular day. This may contain multiple lot numbers of the materials stored temporarily in the “Dispatch Area” as per the introduction of the materials from the Decontamination Room, thus causing that the FIFO (first in first out) methodology not be followed and use of several lots during the production.

During the day of production, the raw materials located in the “Dispatch Area” are disinfected and transferred via a Pass-thru hatch to the ISO 7 Compounding Room to be used for the preparation of the total parenteral nutrition. The pharmacist in the ISO 7 Compounding Room receives the materials and signs the list of materials previously modified by the operator and distributes the materials to the pharmacy technicians to start the production process in the ISO 5 laminar flow hood cabinets.

In this area, the secondary package of the raw materials is then removed and disinfected to be introduced in the critical area. The compounder used in this production process is linked with a system software where critical raw materials (components/additives) are traced. Although the compounder captures the critical raw materials used via a bar code scanning process, it leaves out the traceability of the main container and disposables used throughout the compounding process. The following are the deficiencies identified during this process:

- Poor organization in cool room warehouse
- Lack of adherence to procedures

- Poor process flow
- Material waste not used and expired
- Documentation errors in material lot/ expiry date used
- Traceability of materials used not efficiently established

Measure Phase

A process flow was developed to understand the inventory and material flow process by steps and identify which activities were adding value to the process and which ones were not (figure 2). By identifying areas that do no add value, opens areas of improvements to eliminate waste and human errors. This process flow only outlines the involvement of materials and not the entire compounding production. Understanding how inventory flows in the company's warehouse, clears any obstacles that do not add up, minimize/eliminate excess on all resources and create a process standardization, enabling a continued inventory flow.

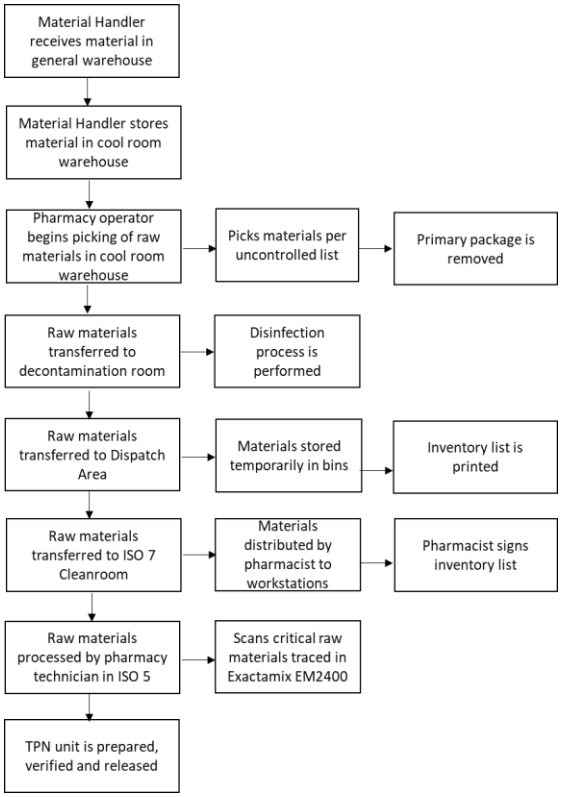

Figure 2
Material Process Flow Chart

The process flow chart identified several factors of the problem. First, the steps for picking materials using an uncontrolled list caused inventory flow problems, as multiple lots can be picked versus using one lot at a time. Second, the printing of the inventory list once the materials are temporarily stored in the Dispatch Area contains the different lot numbers of the materials to be used. The operator performing the task was documenting all the lot numbers in the area, rather than transferring one lot of the material until it was consumed completely. At the end of production, materials that were not used were returned to the Dispatch Area to be consumed the next day.

This process caused materials with earlier expiration dates to be left behind, leading to waste and the traceability of the materials used per day not being granted.

Data was collected for different materials that where left expired and a graph (figure 3) of material waste cost over time was generated from September 2019 until May 2020.

Figure 3
Material Waste Cost Over Time

Analysis Phase

The focus of the analysis step was to determine factors that significantly contributed to the problem. During the analysis phase of this research, an Ishikawa fishbone diagram (figure 4) was used to identify the root cause of the inefficient inventory and process flow in the pharmacy. Different factors were identified reviewing the process flow, procedures and documentation of forms during a production day.

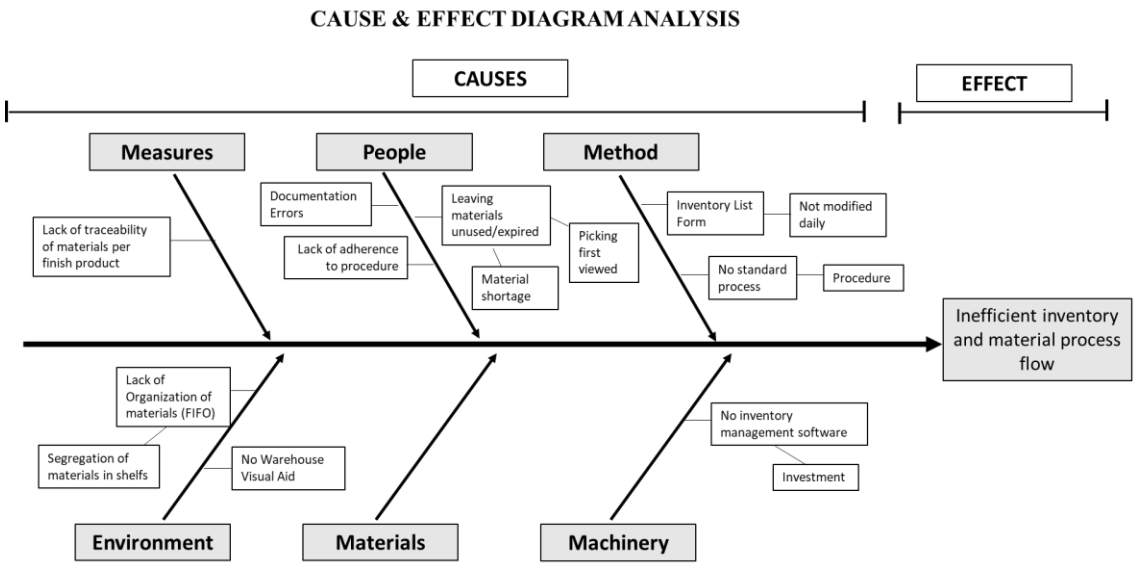

Figure 4
Fishbone diagram

The main causes were branched to sub-causes, as seen in the fishbone diagram in figure 4. The sub-causes identified were related to measures, people, method and environment which interrelated causing an inefficient inventory and material process flow in the pharmacy. The sub-cause under machinery were not taken into account at the moment of implementing immediate actions for the proposed timing of thirty days, because of the development of a software and its validation were considered for future improvement project.

Further analyzing the inventory, an evaluation of all material cost items was performed (figure 5), resulting in 65% on nutrient drugs for its high quantity purchase and prices, followed by 15% raw materials used for the preparation of the compounded products and subsequently 10% for microbiological culture media for the environmental and personnel monitoring and disinfectants. It has been identified that the most impact of materials that have been left unused due to the segregation and identification of the lot number/expiration date were microbiological culture medias, disinfectants and raw materials. These items have resulted in material waste due to expiration, when not used as per FIFO concept.

Figure 5
Total Material Cost Percentage

Improve Phase

In order to improve the inventory and material process flow, several recommendations and measures were taken. Following the Lean building blocks such as “5S (workplace organization and standardization), visual controls, point-of-use storage (POUS), standard work, streamlined layout, working in teams, and autonomous maintenance (part of total productive maintenance) can all be constituents of introducing a planned implementation effort” [4]. The 5S system in the cool room warehouse requires for an area where it is sorted, set in order, shine, standardized and sustains throughout time. To achieve this, the

implementation of visual controls such as material lots that are in use and that should not be used yet indicates the operators the status of the system. Operators will visually detect which material lot number should be continued to use, preventing the mix up of different lot numbers during same day production. This system will also prevent further waste of materials that are left to expired by not using them once received as per FIFO's concept. Identification of the incoming material in the Cool Room Warehouse with visual aids containing "In Use," "Next in use" and "Do not Use" will help the operator to follow the FIFO (First in first out) concept and dedicate in transfer those materials that are in use and in same lot prior to changing lots.

Streamlining the material flow and the documentation of the material lots in use during the production day captures the traceability effectively of raw materials (drug additives, components, container and disposables) for a patient specific product. The standardization of this process and training will consistently meet the specifications outlined in the procedures audited by quality.

The creation of a dedicated form as per established procedure, to document all materials to be used in the production day, including the Type of material, Lot and Expiration Date will trace all raw materials used during the compounding production per day, rather than having an uncontrolled weekly edited form. The new controlled form shall be verified by the pharmacist to confirm that the materials documented in the form are in fact the materials to be used in the production. Quality Department shall audit daily the forms documented by the pharmacy personnel to assure that it is in compliance with the established procedure. A weekly monitoring of the inventory in the warehouse will also assure that materials are not left to expire.

Control Phase

Following the improve phase and the implementation of actions, quality department has audited all forms containing the traceability of materials to assure conformance to established criteria. The effectiveness of these actions shall be measured in terms of deviations to procedures in relation to nonconformances detected. For a period of three months, no non-conformances related to not documenting traceability of all materials used during production day shall occur. A Material Waste Cost Analysis for the following months shall detect if the actions taken have controlled the inventory issue defined previously.

RESULTS AND DISCUSSION

During the course of identifying the causes of deficiency in inventory management and material process flow, several factors were identified and mitigated following lean Six Sigma methodology. The implementation of visual aids to help identify with material lot numbers are in used and which ones should not, has significantly reduced the waste in materials unused/expired.

Moreover, the implementation of a controlled form for the traceability of all raw materials used for the production of the TPN units has been effective and assures, with the revision of a pharmacist, that all raw materials and additives used in the compounding process performed per operator in each ISO 5 environment and Compounder is traced. This procedural form add consistency to the process performed.

Since the implementation of visual aids and an audited controlled form for traceability, no deviations have been identified. Moreover, no waste related to unused/ expired materials have been detected during walk-throughs in the warehouse and in waste cost analysis performed by operations management.

CONCLUSION

The existing inventory and material process flow was analyzed, and improvements proposed. From the research conducted, the deployment of lean Six Sigma methodology in the organization has provided the identification of factors that contributed to the deficiency observed within the inventory organization, raw material process flow

and documentation of each lot/expiry used. The decision to review this process was due to observations identified within internal audits related to deviations to procedures, where traceability of all raw materials was not granted. The simple actions implemented for organizing and standardize the documentation for traceability of all materials used for the compounding of the total parenteral nutrition has been reliable and effective in mitigating the deviations previously identified and the costs in waste of unused materials. It is suggested that in the future, an inventory system software be used to facilitate the counting of inventory and record the traceability of all materials in a better effective manner.

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