Implementing Six Sigma Tools to Reduce Formulation Errors in a Compounding Pharmacy

Author: Elisha S. Jiménez Acosta
Advisor: María García Sandoval, Ph.D.
Master in Manufacturing Competitiveness

Abstract

Formulation errors are medication errors that occur when a prescribed mixture is not performed as per the required medical order. Formulation errors in compounded total parenteral nutrition units represent an inherent risk to the safety of the intended patient. A 46.43% increase in the metrics incidence associated with formulation errors was identified in a patient-specific compounding pharmacy. This project aimed to comprehend the effects of implementing six sigma tools in the compounding pharmacy's order entry process by focusing on reducing the incidence of the metrics associated with formulation errors by 50%. By applying the DMAIC methodology, the incidence in the metrics of formulation errors has been reduced, thus reducing the number of formulation non-conformances and external complaints.

Introduction

The compounding of TPN units is a complex process that involves many manual tasks. One of the most critical tasks during the compounding process is the order entry task, which requires transcribing a medical order to the system that will communicate with the compounder. This manual process has been identified as prone to human error, causing an inherent risk for formulation errors. The DMAIC concept has been utilized in this research project to define and improve the root causes that led to a high incidence in the metrics related to formulation errors in a compounding pharmacy. This project focuses on improving the order entry, first verification, and second verification process of the TPN order to reduce the incidence of the metrics associated with formulation errors by at least 50%.

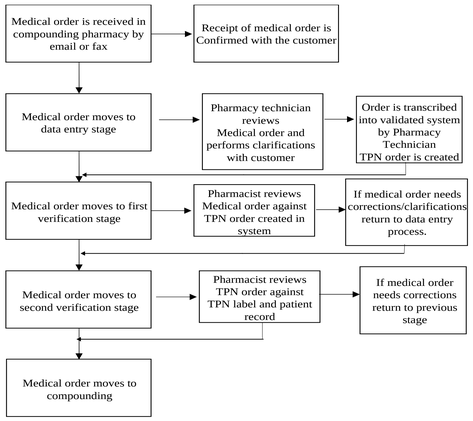
Background

A high incidence of input critical incidents has been noted in the compounding pharmacy. Input critical incidents are a metric evaluated by the quality department that describes in-process incidents that, if not detected internally, will result in formulation errors (i.e., dosage errors, an incorrect ingredient added, missing ingredients). It has been identified that for Q3 2022, the amount of input critical incidents equaled 53, higher than the amount of 25 reported in Q2 2022.

This design project aims to implement six-sigma tools to reduce the amount of input critical incidents, thus parallelly reducing the complaints and investigations raised because of formulation errors (incorrect doses, incorrect units, incorrect drug) during the data entry process.

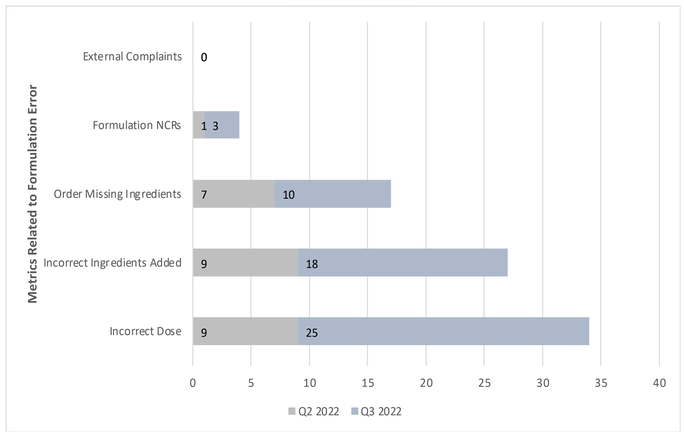
Methodology

DEFINE



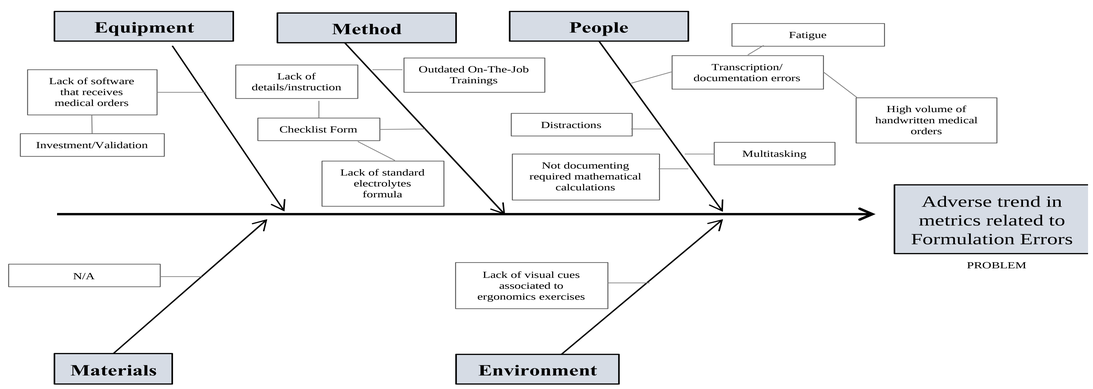
Order Entry Workflow Process

MEASURE



Metrics related to formulation errors for Q2 2022 and Q3 2022 were measured for recurrency

ANALIZE



Causes for the adverse trend in formulation metrics were identified in the fishbone diagram's people, environment, and method portion

IMPROVE

- Revision and update of On-the-job trainings
- Re-training of pharmacy staff
- Creation of data entry checklist, revision of verification checklist
- Implementation of eye break and ergonomic exercises visual cues in data entry process

CONTROL

- Revision of patient record prior to release
- Process audit

Results and Discussion

Six Sigma methodology was implemented to efficiently identify all the assignable causes related to a high incidence of formulation errors in the compounding pharmacy. Several causes were identified, and corrective actions were implemented for Q4 2022. The placement of visual cues in the order entry area to remind pharmacy personnel of the frequency of eye breaks and ergonomic stretches increased personnel participation in ergonomic exercises and consequently reduced the occurrence of fatigue in personnel.
On the other hand, re-training personnel on the updated on-the-job training, revised procedure, and forms has significantly reduced the number of input critical errors identified for Q4 2022.
The implemented actions were able to efficiently reduce the metrics related to formulation errors in Q4 2022 by 64% compared to Q3 2022. Input critical errors were reduced significantly, and no formulation nonconformances or deviations were identified in Q4 2022.

Conclusions

A high incidence in metrics related to formulation errors was observed in the compounding pharmacy for Q3 2022. In response to this, the order entry stage of the compounding process was studied, and corrective actions were implemented. This project aimed to reduce the incidence of metrics related to formulation errors by at least 50%. The Six Sigma methodology was executed during this project and helped identify several factors that led to a high incidence of in-process formulation errors. Corrective actions tailored to the leading causes for formulation errors were implemented for Q4 2022. The implemented actions effectively reduced the incidence of formulation errors (including in-process formulation errors) by 64%.

Future Work

Further improvements were identified but were out of this project's scope; it is suggested that software capable of communicating with customers to receive medical orders electronically is implemented in the future. This software will reduce, in a more effective and controlled manner, the metrics related to input critical errors by eliminating handwritten medical orders.

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