IV Bag Fill Volume Project

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Abstract *— Accurate filling of intravenous (IV) bags is a critical aspect of healthcare, ensuring patients receive the precise medication dosage while minimizing wastage and reducing costs. The existing IV bag filling process often suffers from excessive solution filling volumes, increasing expenses. This paper aims to optimize the IV bag filling process by identifying and minimizing waste while enhancing efficiency. The objective is to develop a robust and reliable process that ensures accurate IV bag filling, reducing waste and increasing cost savings. The Lean Six Sigma DMAIC methodology is employed in this project. Measurement techniques are utilized to gather data and assess the existing process's strengths and weaknesses. The data is then analyzed to identify the root causes of waste and inconsistencies. Based on the analysis, targeted improvements are implemented to enhance the IV bag filling process. These solutions aim to achieve accurate and consistent filling volumes, thereby reducing waste and costs.*

Key Terms *— IV Bag, Process Capability Index, Process Performance Index, Standard Operating Procedure.*

INTRODUCTION

In the healthcare industry, IV (intravenous) are a fundamental component of modern medical practice and are used in a wide range of healthcare settings, including hospitals, clinics, and ambulatory care centers. IV bags are used extensively to administer fluids, medications, and nutrients to patients. IV therapy is one of the most common medical interventions, with over 90% of hospitalized patients requiring IV access at some point during their stay [1]. Filling these bags with the right amount of solution is crucial for patient safety and well-being. A useful approach is to consider IV fluids as a drug/medication [2]. Standardized procedures to ensure correct IV bag filling process help to prevent adverse events .However, the IV bag filling process has its challenges.

To begin with, the IV bag filling process involves several steps. First, the solution is mixed in a tank and then transferred to the filling machine. The accuracy of measuring and mixing the solution is crucial to ensure the correct dosage and concentration [2]. The filling machine then fills the bags (see Figure 1) with the solution and seals them, taking care to avoid any air bubbles or contamination during the process. Finally, the filled bags are inspected for quality control before being sent out for use in patient care. These measures may include double-checking procedures by trained personnel to minimize errors.

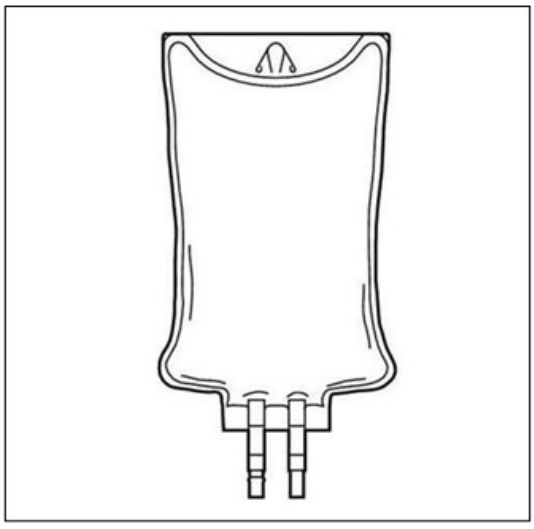

Figure 1
IV Bag Sketch

The filled weight in our current process suffers from excessive solution filling volumes. To address this issue, the filled volume reduction project was initiated. The project aims to maximize the capacity of mixing solution tanks by reducing the amount of solution during the filling process.

METHODOLOGY

The DMAIC (Define, Measure, Analyze, Improve, Control) method, originally developed in the manufacturing industry, has been widely adopted by various healthcare organizations to enhance patient safety and improve healthcare delivery. [3] DMAIC methodology is a structured problem-solving approach widely used in process improvement initiatives. In the context of optimizing the IV bag filling process, each phase of DMAIC can be explained as follows:

Define: The Define phase focuses on clearly defining the project's scope and objectives. The stakeholders involved in the IV bag filling process are identified. Their requirements and expectations regarding accurate medication dosages, waste reduction, and cost-effectiveness are gathered and considered. The project's scope is explicitly defined as the IV bag filling process, outlining the key areas and parameters to be addressed.

Measure: The Measure phase involves collecting data to establish a baseline and measure the performance of the IV bag filling process. Key metrics and indicators, such as filling volume accuracy, wastage rates, and cost analysis, are identified and measured. Data is collected from historical records, to establish baseline metrics, and serve as quality or safety indicator [4]. This data provides insights into the current state of the IV bag filling process and serves as a benchmark for future improvements.

Figure 2
Filling Nozzle

Analyze: In the Analyze phase, the collected data is analyzed to validate the causes of errors, deviation, delays, waste, or other etiologies of defects in the process. [4] As well as, identify opportunities for improvement within the IV bag filling process. Statistical analysis techniques using Minitab® ® are applied to pinpoint the factors contributing to inconsistent filling volumes and excessive waste (see Figure 2). Understanding the underlying causes, potential solutions, and improvement strategies can be identified and prioritized.

Improve: Based on the analysis conducted in the previous phase, the Improve phase focuses on implementing solutions to address the identified problems or opportunities. Is essential to brainstorming and using clear communication about potential solutions. This may involve introducing automated filling systems, optimizing filling parameters, standardizing procedures, or enhancing training programs. The solutions should be tailored to the specific needs and requirements of the IV bag filling process. Piloting and testing the proposed improvements are essential to validate their effectiveness and feasibility before implementing them on a larger scale.

Control: The control phase is crucial to achieving sustainable change. This phase ensures that the improvements achieved in the IV bag filling process are sustained over time. This phase involves developing and implementing control measures to monitor and manage the process. Standard operating procedures (SOPs) are crucial for establishing and managing quality control and quality assurance systems, acting as a pathway to success by facilitating the achievement of high-quality processes, procedures, systems, and skilled personnel, ultimately resulting in high-quality products.[5]. SOPs may be modified to incorporate the improvements and ensure consistent adherence. Ongoing performance measurement, quality assurance checks, and staff training are integral to the control phase to maintain the gains achieved and continuously improve the IV bag filling process.

ANALYSIS

One year's historical data from multiple manufacturing codes can be analyzed using Minitab® ® to identify the potential codes that maximize the filled weight. Minitab® ® is a statistical software that can analyze data and provide insights into the factors that affect the IV bag filling process. The manufacturing codes that produce the most accurate filled volume can be identified by analyzing the data, and the filling process can be adjusted accordingly.

The first step in using Minitab® ® is to input the historical data from the various manufacturing codes. Once the data is inputted, Minitab® ® is used to analyze the data and identify patterns or trends to help us optimize the filling process.

The potential codes that produce the most accurate filled weight can be identified by analyzing the data, and the filling process can be adjusted accordingly. Statistical software can help us optimize the filling process and ensure that patients receive the correct dosage of medication or fluid.

The Capability Analysis in Minitab® is a statistical tool used to assess the capability of a process to meet specified tolerance limits. It provides measures such as Cp, Cpk, Pp, and Ppk, which indicate how well the process performs within the given specifications.

In this project, a Capability Analysis for four different codes was performed: 2G3504, 2G3576, 2G3577, and 2G3579. The following is the breakdown of the analysis for each code:

- Code 2G3504:
  - Sample size: 27,615
  - Mean fill volume: 53.19 ml
- Code 2G3576:
  - Sample size: 149,400
  - Mean fill volume: 53.18 ml
- Code 2G3577:
  - Sample size: 74,590
  - Mean fill volume: 103.6 ml
- Code 2G3579:
  - Sample size: 19,060
  - Mean fill volume: 103.6 ml

To perform the Capability Analysis, Minitab® calculates various statistics based on the provided data. The key metrics obtained from the analysis include the following:

- Cp (Process Capability Index): Cp measures the potential capability of a process to meet the specifications, assuming the process is centered. It compares the total process spread (6 standard deviations) to the specification width. Cp values greater than 1 indicate that the process can meet specifications.
- Cpk (Process Capability Index, considering centering): Cpk measures the actual capability of a process, considering both spread and centering. It considers the difference between the process mean and the target value. Cpk values greater than 1.33 indicate that the process can meet specifications.
- Pp (Process Performance Index): Pp measures the potential capability of a process to meet the specifications, assuming the process is centered. It compares the total process spread (6 standard deviations) to the specification width. Pp values greater than 1 indicate that the process can meet specifications.
- Ppk (Process Performance Index, considering centering): Ppk measures the actual capability of a process, considering both spread and centering. It considers the difference between the process mean and the target value. Ppk values greater than 1 indicate that the process can meet specifications.

Using the sample size, mean fill volume, and specification limits (if available), Minitab® calculates these capability indices for each code, allowing you to evaluate the performance of the corresponding process.

RESULTS

After gathering data and analyzing the IV bag fill process, the results have shown significant opportunities for improvement. The process was

carefully examined to identify critical codes that can be maximized to optimize the fill weight target. This analysis recommends a new fill weight target based on its financial benefit and process capability (see Table 1).

To begin with, it is essential to understand the IV bag fill process in detail. This process involves filling IV bags with a specific amount of fluid. The fill weight target is critical in this process as it determines the amount of fluid filled in each bag. The goal is to achieve a consistent and accurate fill weight target each time to ensure the IV bags meet the required specifications.

Table 1
Potential Codes and Savings

Code	Mean fill	Target reduction	New fill target mean	Ave. Yearly Demand	Addional bags/year with reduction	Cost/bag filled	Cost Saving/year with reduction
2G3504	53.19	0.8	52.39	1,440,000	21,989	18,386	$ 40,428.85
2G3576	53.18	0.8	52.38	9,800,000	149,675	1.3294	$198,978.54
2G3577	103.6	0.8	102.8	3,200,000	24,903	1.3921	$ 34,667.08
2G3579	103.6	0.8	102.8	740,000	5,759	4.6189	$ 26,599.11

In the Capability Analysis performed for the given codes, the results indicate the following:

- Code 2G3504:
  - It could potentially have a fill volume reduction of 0.8 ml, resulting in a new fill volume of 52.39 ml.
  - The Cpk value obtained for this code is 1.36. See Figure 3.

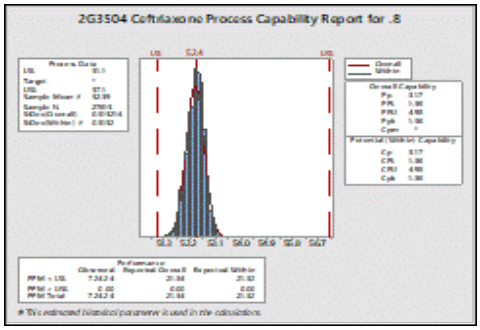

Figure 3
Code 2G3504

- Code 2G3576:
  - It could potentially have a fill volume reduction of 0.8 ml, resulting in a new fill volume of 52.38 ml.
  - The Cpk value obtained for this code is 1.66. See Figure 4.

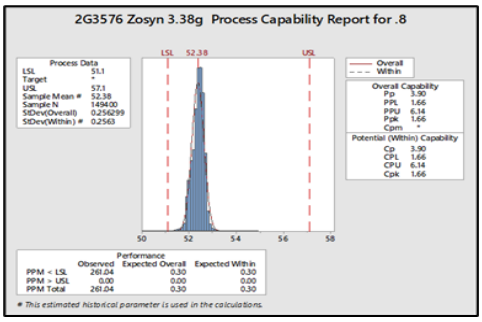

Figure 4
Code 2G3576

- Code 2G3577:
  - It could potentially have a fill volume reduction of 0.8 ml, resulting in a new fill volume of 102.8 ml.
  - The Cpk value obtained for this code is 2.14. See Figure 5.

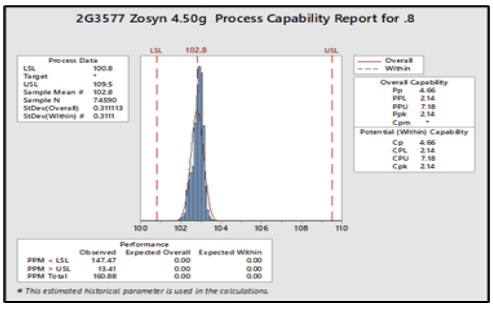

Figure 5
Code 2G3577

- Code 2G3579:
  - It could potentially have a fill volume reduction of 0.8 ml, resulting in a new fill volume of 102.8 ml.
  - The Cpk value obtained for this code is 1.76. See Figure 6.

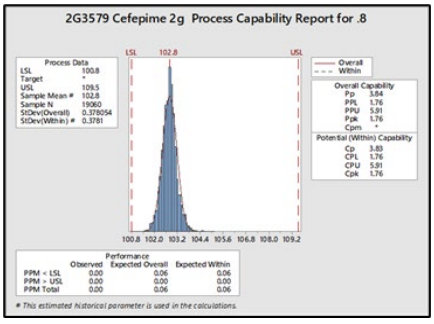

Figure 6
Code 2G3579

The Cpk value is a key metric used to assess process capability, considering both the spread and centering of the process. In this analysis, all the codes evaluated have Cpk values greater than 1.33, considered a standard in the industry. This indicates that the processes associated with these codes can meet the specified requirements.

The recommended fill weight target was based on the financial benefit and process capability. The financial benefit of the recommended fill weight target was determined by calculating the cost savings associated with reducing the amount of fluid used in each bag for a total potential savings of $300,673. The process capability was determined by analyzing the data to ensure that the recommended fill weight target was achievable and consistent with the required specifications. Based on the results obtained from the analysis, the cost benefits associated with each code are as follows:

- Code 2G3504:
  - It will result in additional production of 21,989 bags per year.
  - This will lead to a cost saving of $40,428.85.
- Code 2G3576:
  - It will result in additional production of 149,675 bags per year.
  - This will lead to a cost saving of $198,978.54.
- Code 2G3577:
  - It will result in additional production of 24,903 bags per year.
  - This will lead to a cost saving of $34,667.08.
- Code 2G3579:
  - It will result in additional production of 5,759 bags per year.
  - This will lead to a cost saving of $26,599.11.

Among these codes, code 2G3576 stands out as the top priority for the project due to its significant cost-saving impact. It has the highest potential for additional bag production, resulting in a substantial cost saving of $198,978.54 annually.

Focusing on code 2G3576 would likely provide the most significant financial benefit to the project or organization when considering resource allocation and decision-making.

CONCLUSION

In conclusion, the accurate filling of IV bags is crucial to patient care, ensuring proper medication administration while minimizing waste and associated costs. The current process often needs help with excessive solution-filling volumes. By applying the Lean Six Sigma DMAIC methodology, this study aims to optimize the IV bag filling process, leading to enhanced accuracy, reduced waste, and improved cost-effectiveness.

The project involved conducting a Capability Analysis using Minitab® for four codes: 2G3504, 2G3576, 2G3577, and 2G3579. The primary objective was to evaluate fill volume reduction's benefits in producing more bags with the same amount of solution in the mixing tank, ultimately benefiting patients.

The analysis revealed that implementing a fill volume reduction of 0.8 ml across the codes could substantially improve bag production. Code 2G3504 could generate an additional 21,989 bags per year,

while code 2G3576 could yield an impressive 149,675 additional bags annually. Code 2G3577 and 2G3579 also showed notable increases in bag production, with 24,903 and 5,759 additional bags per year, respectively.

These increases in bag production not only result in higher output but also offer significant cost savings. The project estimated cost savings of $40,428.85, $198,978.54, $34,667.08, and $26,599.11 for codes 2G3504, 2G3576, 2G3577, and 2G3579, respectively.

Overall, the fill volume reduction initiative demonstrates its positive impact on the production process, enabling the production of more bags while maintaining the required solution amount. By maximizing the use of resources, this approach helps optimize efficiency, reduce costs, and ultimately benefits patients by ensuring an adequate supply of bags for their medical needs.

It is important to note that while the financial and production benefits are evident, it is essential to consider other factors, such as product quality, feasibility, and regulatory compliance, before implementing the fill volume reduction strategy. Nonetheless, the results highlight the potential for significant gains through process optimization, emphasizing the importance of continuous improvement efforts in delivering better outcomes for the organization and the patients it serves.

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