DMAIC Application to Reduce Medication Errors in a Specialized Pharmacy Process

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Abstract *— Medication errors can have serious consequences for patients, and medication safety is essential to pharmaceutical care. Insight is needed into the vulnerability of the working process at specialized pharmacies in order to identify what causes error incidents, so the system can be improved to enhance patient safety. It is important to identify the causes of error incidents, so improvement can be initiated. More often, it is the actions of individuals that are considered the sole cause of error. However, two approaches to the problem of human fallibility exist: the person and the system. Medication errors are one of the major causes of deaths and injuries of thousands of patient every year in US, contributing to soaring healthcare costs. The purpose of this research is to examine what has been done to deal with medical error problems in a specialized pharmacy that works with several medications for chronic diseases, by using a DMAIC methodology.*

Key Terms *— DMAIC Improvement, Medication Errors, Safety, Specialized Pharmacy.*

INTRODUCTION

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and, nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use [1]. Medication error has been quite a severe problem in Specialized Pharmacy for a long time but very few serious measures have yet been adopted to overcome or reduce this. The pharmacist and pharmacy technician's role in medication error prevention is very important in order to avoid risks for the safety of patients. Medication incident reports signal those incidents which have actually caused harm or have had the potential to cause harm involving an error in the process of prescribing, dispensing, preparing, administering, monitoring or providing advice regarding medicines. Internal errors should be discussed among pharmacists, technicians, and clerks. To foster proactive learning, it is important to share errors occurring at other pharmacies; the most frequently reported types of medication incidents involve:

- Order entry/Wrong dose
- Omitted or delayed medicines
- Dispensed a wrong medicine
- Dispensed to a wrong patient

Specialized pharmacies are different from traditional pharmacies in coordinating many aspects of patient care and disease management. They are designed to efficiently prepare and deliver medications with specialized handling, storage, and distribution requirements with standardized processes that allow for scaled economies. Specialty pharmacies are also designed to improve clinical and economic outcomes for patients with complex, often chronic and rare diseases, with close contact and management by pharmacist. Health care professionals employed by specialty pharmacies provide patient education, help ensure appropriate medication use, promote adherence, and attempt to avoid unnecessary costs. Other support systems coordinate sharing of information among physicians treating patients and help patients locate resources to provide financial assistance with out of pocket expenditures.

Specialized pharmacies will require quality control processes and measures to ensure the accuracy and safety of the products being

distributed to patients. The specialized pharmacy places great emphasis on designing quality into a product by monitoring and controlling the patient dosage. The companies are recurring to methods to reduce operational cost but at the same time, improve the pharmacy system in order to comply with the FDA regulations. Therefore, many health care companies are recurring to Six Sigma Tools in order to achieve the desired results.

Research Description

Medication errors are common throughout healthcare and result in significant human and financial cost. There are several categories of medication errors ranging from slips and lapses to fixation errors and deliberate violations. Violations may be more likely in organizations with a tendency to blame front-line workers, a tendency to deny the existence of latent conditions, and a blinkered pursuit of productivity indicators. In these organizations, borderline-tolerated conditions of use may occur, which blur the distinction between safe and unsafe practice. A few complementary strategies are proposed which may result in minimizing medication errors. At the organizational level, developing a safety culture and promoting robust error reporting systems are key aspects to be taken into account.

Research Objectives

This research is designed to analyze the current pharmacy prescription process in order to identify the types of dispensing errors that may occur in the managed care area, dispensing area or medication pick-up area and recognize the leading causes of these errors. The objective is to propose strategies and recommendations in order to avoid or minimize such errors. To help reduce the occurrence of errors, there is a need for the pharmacy to maintain a continuous careful analysis of the errors. Another objective is the design and implementation of a strategy to maximize the quality and safety of the patient.

Research Contributions

The research discussed in this article will contribute information to the specialized pharmacy to minimize the risk of patients using incorrect medicines. In addition, the research contributes in reducing medication errors and maximizing patient safety without compromising the quality of the process. Prevention must be a priority for the pharmacy system. The goal of the research is to establish a new Standard Operating Procedure (SOP) to dispense and verify medication using an information technology with CPR+ program such as electronic prescription to reduce errors and prevent the high cost of medication errors.

LITERATURE REVIEW

Many research papers and articles were published in the last decade dealing with medical errors. The reports on medical errors revealed that more than 95,000 people die every year in the US because of the most frequent medication errors. This changes the way doctors, pharmacists and pharmacy technicians think and talk about medical errors and their consequences, with few left doubting that preventable medical injuries are a serious problem.

The articles suggest various approaches to reduce medical errors; such standardization processes, tools, technology and equipment should be standardized because variations increase complexity and consequently the risk of errors [2]. Standardized abbreviations are a very important aspect in the reduction of errors when the pharmacy staff verifies a prescription. Abbreviation misinterpretation can have adverse patient consequences. (See table 1).

Pharmacists have the legal duty to provide patients with the best care possible. Drugs have the potential to produce serious harm when used improperly, and patients are ordinarily unable to appreciate the potential harm; they therefore rely on the pharmacist's skill and knowledge. A pharmacist would be liable if he or she has breached that duty in a manner that caused harm to the patient. By tradition, long ago, courts established that the

pharmacist has the legal responsibility to take extreme care to dispense the correct medication, supply the correct dose, and provide the correct label instructions. These legal responsibilities, of course, mirror the traditional role for the pharmacist but also represent the most common source of pharmacist errors.

Table 1
Misinterpretation Abbreviations Examples

Abbreviation	Intented Meaning	Misinterpretation	Recommendations
TIW	3 times a week	Interpreted as 3 times a day	Spell Out
0.5 mg	One half mg	Read 5 mg	Use leading zero and write "0.5"
3lbs	3 pounds	Read 31 pounds	Spell out pounds

In order to be more competitive, the specialized pharmacies are recurring to Six Sigma, which is the implementation of a measurement-based strategy that focuses on process improvement and variation reduction, and the Lean Six Sigma methodology as a technique to improve manufacturing costs by eliminating the process muda. Muda is a Japanese word that means waste.

The Health Care Industry is noticing dwindling profits as there is now great competition coming from generic brands and errors within the manufacturing process. In order to improve this, many companies are attempting to increase efficiency within the manufacturing and operational processes by optimizing their resources, controlling inventory and reducing waste and errors.

By implementing traditional Six Sigma and Lean manufacturing, many companies are able to reduce waste and bring about effective change within the manufacturing process. Instead of having to rely on end-process testing, Six Sigma is enabling companies to predict and eradicate errors and therefore give a much needed boost to operational efficiency.

DMAIC is a data-driven quality strategy used to improve processes. It is an integral part of the Six Sigma initiative; however, in general, it can be implemented as a standalone quality improvement procedure or as part of other process improvement initiatives such as Lean. DMAIC is an acronym for the five phases that make up the process:

- **Define**- the problem, improvement activity, opportunity for improvement, the project goals, and customer's (internal and external) requirements.
- **Measure**- process performance.
- **Analyze**- the process to determine root causes of variation, poor performance (defects).
- **Improve**- process performance by addressing and eliminating the root causes.
- **Control**- the improved process and future process performance.

The DMAIC process easily lends itself to the project approach to quality improvement encouraged and promoted by Juran. [3]. DMAIC process structure gives the opportunity to develop and to create new thoughts and ideas based on the current process, product or services.

Six Sigma

The customer of the health care industry garners benefits from the implementation of Six Sigma. To be able to follow the results of implementation of changes and improvements, key performance indicators can be used which also emphasize the importance of choosing relevant metrics to track the impact of each Six Sigma project with regards to customer satisfaction.

General Concepts of DMAIC Methodology

A systematic approach needs to be used as a methodology to achieve the goals of the project. Since the purpose of the project is to improve the verification and dispensing procedures of a pharmacy company, the Six Sigma (DMAIC) methodology was selected. The Lean Manufacturing methodology is used to eliminate the muda (waste) and non-value activities of any process. The project will be divided into five phases

(Figure 1) following the DMAIC tool (Define, Measure, Analyze, Improve and Control). Each phase will be reviewed before continuing to the next phase.

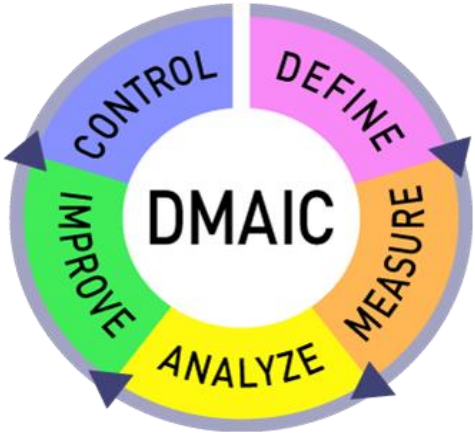


Figure 1
DMAIC Process Steps

Define Phase

The define phase is utilized to determine the direction of the project and serves as a commitment of the team members that will be working on the project. The objective of this phase is to reach an agreement with the pharmacy team members to establish a new standard operation procedure (SOP). The agreement includes the problem statement, project goal, team members, business impact and project start and end dates. As part of this phase, the deliverables include a Project Charter and a SIPOC diagram.

- **Project Charter** – Defines the scope, objective and overall approach of the project to be completed. It provides a preliminary delineation of roles and responsibilities. It serves as a reference of authority for the future of project.
- **SIPOC Diagram** – The SIPOC diagram is utilized to understand the process steps.

Measure Phase

The measure phase is used as a data gathering of the actual specialized pharmacy process to understand its current state. This phase provides a clear focus on the improvement effort by collecting information and relevant data on the current situation in the pharmacy dispensing process. One goal of the measure phase is to establish a baseline of the current pharmacy process using the data gathered in order to identify the problem. After this point, the project team's (pharmacy staff and quality assurance) efforts focus on eliminating or reducing medication errors as much as possible.

Analyze Phase

The analyze phase is used to identify the causes that affect the current process by using the data gathered during the measure phase. During this phase, the team will document potential causes of the problems that are impacting the process. In addition, the team will identify causes that are creating muda in the process which affects the pharmacy system order to increase the quantity of the process.

Improve Phase

Once the problem's root cause is brought to light, the improve phase focuses on finding a permanent solution to the medication errors problem. This is where the project team's creativity comes into play in finding an answer to a longstanding process problem. The team then tests a proposed solution through the implementation of a pilot program to test if the solution is effective and financially viable.

Control Phase

In this phase, the quality staff documents the new solution that they have created so that it can be passed on to process owners. The pharmacy staff then implements the solution according to the timeline that they have developed. Once the solution has been implemented, the Quality Control Department monitors it for several months and if it meets performance expectations it then turns it over to the process owner.

RESULTS AND DISCUSSION

The results obtained during the improvement project are discussed in this section following the systematic approach of DMAIC.

PROJECT METHODOLOGY

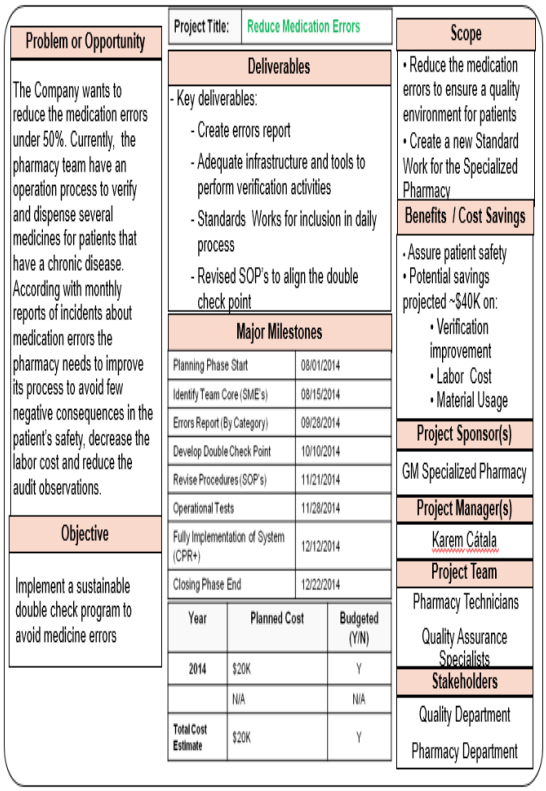
The project methodology is use a DMAIC process to reduce the medication errors in the Specialized Pharmacy

Define Phase

The customer in this process is a patient who goes to the specialized pharmacy to acquire his medication for a chronic disease. The patient has few priorities: getting the medication dispensed correctly, in a reasonable amount of time and without any medication errors.

The problem was classified by the following errors:

- Dose- Dose differs from original order.
- Drug- Wrong drug presentation differs from original order.
- Duplicate order entry- Same medication profiled twice with two different prescription numbers.
- Patient- Medication order has been profiled incorrectly on the wrong patient.



Problem or Opportunity	**Project Title:**	Reduce Medication Errors
The Company wants to reduce the medication errors under 50%. Currently, the pharmacy team have an operation process to verify and dispense several medicines for patients that have a chronic disease. According with monthly reports of incidents about medication errors the pharmacy needs to improve its process to avoid few negative consequences in the patient's safety, decrease the labor cost and reduce the audit observations.	**Deliverables**	- Key deliverables: - Create errors report - Adequate infrastructure and tools to perform verification activities - Standards Works for inclusion in daily process - Revised SOP's to align the double check point
Objective	**Major Milestones**	
Implement a sustainable double check program to avoid medicine errors	Planning Phase Start	08/01/2014
	Identify Team Core (SME's)	08/15/2014
	Errors Report (By Category)	09/28/2014
	Develop Double Check Point	10/10/2014
	Revise Procedures (SOP's)	11/21/2014
	Operational Tests	11/28/2014
	Fully Implementation of System (CPR+)	12/12/2014
	Closing Phase End	12/22/2014

Year	Planned Cost	Budgeted (Y/N)
2014	$20K	Y
	N/A	N/A
Total Cost Estimate	$20K	Y

Scope	• Reduce the medication errors to ensure a quality environment for patients • Create a new Standard Work for the Specialized Pharmacy
Benefits / Cost Savings	- Assure patient safety • Potential savings projected ~$40K on: • Verification improvement • Labor Cost • Material Usage
Project Sponsor(s)	GM Specialized Pharmacy
Project Manager(s)	Karem Cátala
Project Team	Pharmacy Technicians Quality Assurance Specialists
Stakeholders	Quality Department Pharmacy Department

Figure 2
Project Charter

A project charter was developed in the define phase with the purpose of defining the project scope and objective. The project charter defines the problem statement, goals, business impact and the team members of the project. Figure 2 presents the project charter that was developed and approved by the quality control department and Sponsor.

In addition to the project charter, a SIPOC diagram was developed in order to define the suppliers, input, output and customers of the manufacturing process related to the project. The SIPOC and the process steps diagram of actual system are defined in Figure 3.

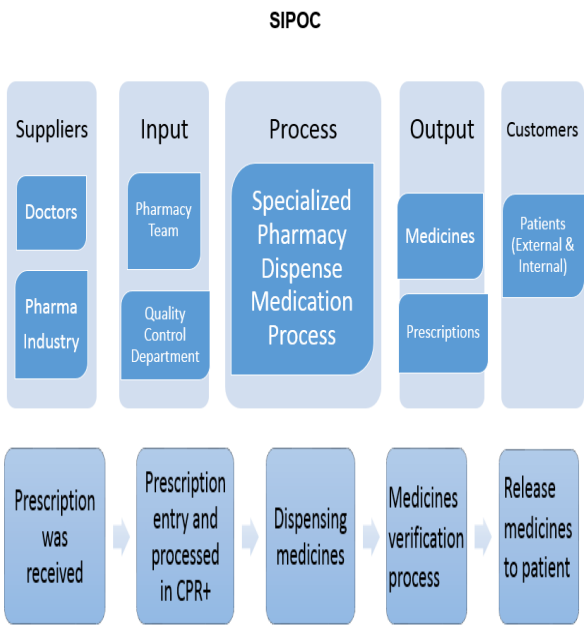


Figure 3
Pharmacy Dispense Medication Process SIPOC

Measure Phase

Since the scope of the project is to establish a new standard operation procedure (SOP) to reduce the medication errors in the dispensed and verification process, the percentage of each error type was identified in order to realize a Corrective Action Preventive Action (CAPA) of these situations by the Quality Control department.

This information was gathered through a monthly incidents report. The monthly incident reports are generated by the Quality Control Department. These reports show the most common

errors in the process of dispatching medications. Chart 1 shows the percentage which is the highest lack of double check in the verification process of prescriptions (33%). The second leading cause for errors are related to the lack of documentation for patient's allergies in the system aimed to avoid adverse effects on the health of the patient (25%). Following is the mistake of entering and processing the prescriptions in the CPR+ program (16%). Other errors that are intended to minimize or eliminate errors are incorrectly choosing the strength of medicine (7%), incorrect dose (2%), incorrect drug presentation (3%), incorrect administration route (5%) and incorrect patient selected (4%). (See Chart 1).

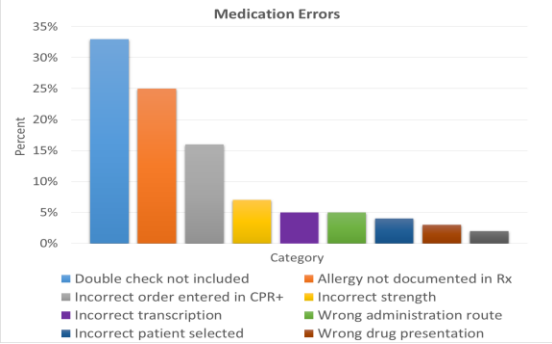


Chart 1
Causes of Medication Errors

The dispensing process was monitored for a period of (4) months in the prescription drop-off, dispense and reception point of sale area. The objective was determined based on the most common errors in dispensing and those areas that contribute a risk for the safety of the patient. The data of the monitoring period is showed on Chart 2.

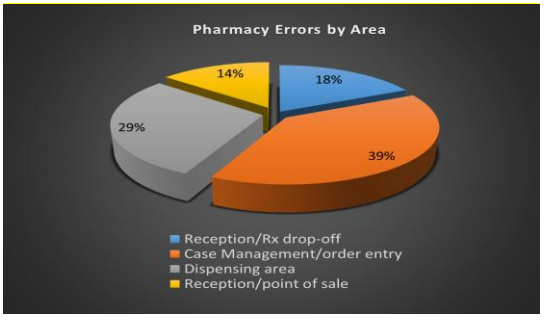


Chart 2
Pharmacy Errors by Area

The pharmacy errors by area are divided as follows:

- Case management/ order entry (39%)
- Dispensing area (29%)
- Reception/drop-off (18%)
- Reception/point of sale (14%)

Analyze Phase

The most likely causes for defects will be detected for each process step that constitutes a risk for creating medication errors, which could result in an adverse event. The Fish-Bone diagram can be used to show the most likely causes for defects. (See figure 4). The root causes for all the different types of errors could be one or a combination of the following:

- Problems with the use of personal nonconventional abbreviation.
- Distractions during the order entry process such phone calls or conversations which caused omission errors.
- Human errors which caused dispensing incorrect doses.

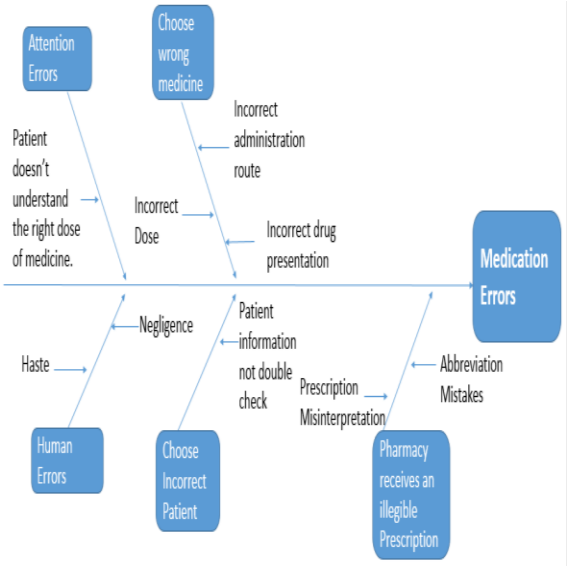


Figure 4
Fish-Bone Diagram
Defects in Pharmacy Process

- Reception/prescription drop-off:

When the reception and case management pharmacy technician receives a prescription the first errors may occur. Usually the most common error

in this area is the prescription misinterpretation. If technicians are stationed at prescription drop-off, consider creating a checklist of critical patient information, the technician should obtain it from each patient. The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy and medical condition information should be updated in the patient's record at each patient encounter and communicated to the verification pharmacist. Knowing a person's medical conditions can help the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

- Order Entry Area:

Medication safety is enhanced when technicians know medical/pharmacy terminology and drug names, especially if they enter prescriptions. New drugs are a risk because technicians, and pharmacists, may not be aware of them or recognize them early on and may instead see and select something else. Pharmacists and technicians should work together to determine the best method of distributing information regarding the availability of new drugs. It is important that the technician understands the safety features of the computer system and does not create workarounds to improve efficiency at the risk of decreasing accuracy and safety. Drugs alerts that involve medication interactions, allergies, duplications are very important.

- Filling/ Dispensing Area:

Many mix-ups during this production phase occur due to incorrectly reading a label. The problem is aggravated by confirmation bias, whereby one selects what is familiar or expected on the label rather than what is actually there. In this area the pharmacy technicians only dispense medicines without verification. The new SOP changed the responsibilities in the area to improve the actual process.

- Reception/Point of Sale:

Errors also may occur with a correctly filled prescription if it is dispensed to a patient for whom it was not intended. This error can be avoided by consistently using a second identifier at the point of sale. The person picking up the prescription should be asked to provide the patient's address or, in the case of similar names, the date of birth, and check this against the information on the prescription receipt and vial. Reviewing each prescription medication with the patient or caregiver at the point of sale provides the best final check.

Improve Phase

During the improve phase, the team decides to immediately install a new Standard Operating Procedure, in order to reduce percent of medication errors to under 50% (Chart 3). The proposed solution in a pilot program was effective and financially viable. The chart shows the comparison of percentage related to errors committed at the beginning and the end of the project. There is a decrease of 50% in this type of errors after implementing the DMAIC methodology in the specialized pharmacy dispensing process. The main mistake, which is the double check error, was drastically reduced from 33% to 10% after implementing the new SOP.

The implementation of new SOP represents an opportunity to improve a specialized pharmacy system and minimize the human errors in dispensing the medicines. In this phase the pharmacy team acquires new responsibilities such double check in different areas (fill/dispensing area, verification and reception/point of sale) and attention to the details in every area of the process.

To perform the new responsibilities the employees were trained in diverse areas of the pharmacy system. The information technology system received an upgrade. The new Standard Operation Procedures are displayed in Figure 5.

Control Phase

Standard Operating Procedures (SOP) were created for a specialized pharmacy system. The SOP are used as a tool to train the pharmacy team to performs the verification and dispense process in a standardized way in order to prevent that the process is performed incorrectly.

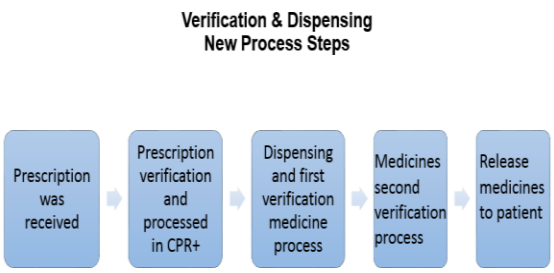


Figure 5
Standard Operation Procedure (SOP)

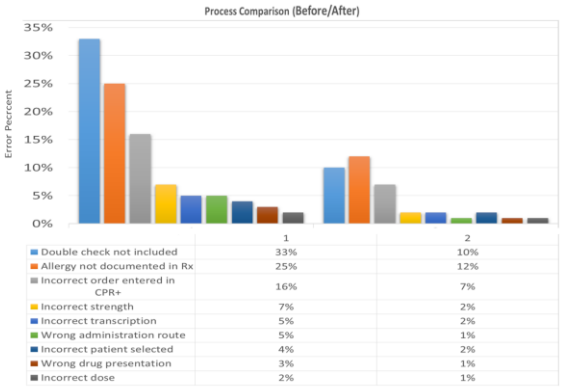


Chart 3
Process Comparison-Before/After DMAIC

Finally, the pharmacy procedure was revised to incorporate the new responsibilities and train the pharmacy staff on how the process will be performed after the implementation of the changes.

The pharmacy will perform a CPR+ program to improve the process system on a monthly basis. (See Figure 6) The CPR+ order verification tools will reduce human error in filling prescription and dispensing supplies to patients, improve inventory accuracy and save money on voided fills and wasted supplies.

As part of the control phase, a metric about the medication errors on the procedure was revised. The reduction in the last month of medication errors was minimized to under 50%. The objective was met because of the increase of quality work and procuring patient safety.

A control plan was developed to collect data on the current process and to ensure that the improvements are maintained over the long term. The plan consists of random audits, monitoring who performs the process, how often and the reaction plan if the process goes out of control.

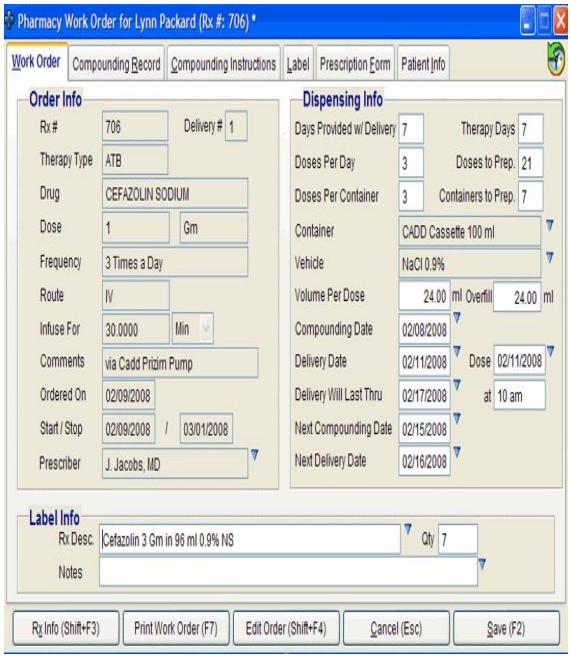


Figure 6
CPR+ Program Diagram (Update of Work Order)

CONCLUSION

The specialized pharmacy using Six Sigma on a pharmacy procedure can be improved by using tools of Lean and a DMAIC as a systematic approach. By using this approach, sources of muda on the process were identified. Performing the improvements, the goals of the projects were achieved.

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