

Ahmed Al Kuwaiti¹

Article info:
Received 16.12.2015
Accepted 04.03.2016

UDC – 54.061
DOI – 10.18421/IJQR10.02-03

APPLICATION OF SIX SIGMA METHODOLOGY TO REDUCE MEDICATION ERRORS IN THE OUTPATIENT PHARMACY UNIT: A CASE STUDY FROM THE KING FAHD UNIVERSITY HOSPITAL, SAUDI ARABIA

Abstract: Medication errors will affect the patient safety and quality of healthcare. The aim of this study is to analyze the effect of Six Sigma (DMAIC) methodology in reducing medication errors in the outpatient pharmacy of King Fahd Hospital of the University, Saudi Arabia. It was conducted through the five phases of Define, Measure, Analyze, Improve, Control (DMAIC) model using various quality tools. The goal was fixed as to reduce medication errors in an outpatient pharmacy by 20%. After implementation of improvement strategies, there was a marked reduction of defects and also improvement of their sigma rating. Especially, Parts per million (PPM) of prescription/data entry errors reduced from 56,000 to 5,000 and its sigma rating improved from 3.09 to 4.08. This study concluded that the Six Sigma (DMAIC) methodology is found to be more significant in reducing medication errors and ensuring patient safety.

Keywords: Six Sigma, DMAIC, Medication errors, FMEA, Poka-yoke

1. Introduction

Hospital is the most essential service industry. Nowadays people are more solicitous about risks and patient safety in healthcare environment. They are much concerned about the quality of health care facilities provided to them. World Health Organization (WHO) definition of patient safety established that unnecessary harm or potential harm associated with healthcare should be reduced to an acceptable minimum (WHO, 2009). Reducing the risks and

ensuring the patient safety in health care services are the most critical challenges faced by various types of hospitals. Patient safety issues are the preventable errors that can cause harm to patients. Medication errors are the one of the most important hospital risks in healthcare industry that harm the patients in various forms. It may be defined as 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. The error may be related to professional practice, to healthcare products, to procedures, to communication problems (including prescribing, product labeling, packaging and nomenclature), to

¹ Corresponding author: Ahmed Al Kuwaiti
email: akuwaiti@uod.edu.sa

compounding, to dispensing, to distribution, to administration, to education, to monitoring and to the proper use of medications (NCCMERP, 2001).

A medical error occurs when a health care provider chooses an inappropriate method of care or improperly executes an appropriate method of care. Medical errors are often described as human errors in health care (Zhang *et al.*, 2008). A 2006 follow-up to the Institute of Medicine (IOM) study reported that medication errors are among the most common medical mistakes harming at least 1.5 million people every year. It also stated that 4,00,000 preventable drug-related injuries occur each year in hospitals, 8,00,000 in long-term care settings and roughly 5,30,000 among medicare recipients in outpatient clinics (The National Academy of Science, 2006). Medication errors can occur while selecting a medicine, writing the prescription, manufacturing the formulation to be used, dispensing the formulation, administering the drug, monitoring therapy (Aronson *et al.*, 2009).

According to Ferner and Aronson (2006), there are four broad types of medication errors such as knowledge-based errors, rule-based errors, action-based errors, memory-based errors. Another study categorized the types of errors as prescription, dispensing or administration errors. Prescribing errors are defined as incorrect drug selection for the patient (Barber *et al.*, 2003). Prescriptions are the primary means of communicating medication information and instructions between prescribers and pharmacists (Kennedy *et al.*, 2011). Dispensing errors occur at any stage from the receipt of prescription slip to supply of drugs to the patient in pharmacy (Bohand *et al.*, 2009). Administration errors are the discrepancy which occurs between the drug received by the patient and the drug therapy intended by the prescriber (Gladstone *et al.*, 1995). Medication errors may be committed by both experienced and inexperienced staffs, including pharmacists, physicians, nurses, supportive personnel (e.g., pharmacy

technicians), students, clerical staff (e.g., ward clerks), administrators, pharmaceutical manufacturers, patients and their caregivers, and others (Manasse, 1989). Poor communication, improper documentation, illegible handwriting, inadequate nurse-to-patient ratios, and similarly named medications are also known to contribute to this problem.

Medication errors contribute to adverse events that compromise patient safety and place a large financial burden on health systems (Roughead *et al.*, 2013). In addition to the financial costs, individual patients and their family members were also affected physically, emotionally and psychologically when errors occur (Deans, 2005). Therefore, the implementation of preventive or corrective measures to detect, prevent and eliminate the medication errors is essential to save the human life in health care service. Top level management personnel should give more attention to the incidence of medication errors during the processes of health care services. They should also execute a systematic and continuous evaluation to identify, report and eliminate the causes of medication errors. Measures such as computerized physician order entry (CPOE) technology, avoiding the use of abbreviations, symbols and dose designations, checking the medicines and their dosages in prescription order before administration, ensuring drugs are administered to the correct patient, double-checking of medicines, etc. are widely used to prevent medication errors.

Through the application of quality improvement and safety measures in health care processes, we can reduce risks and ensure the patient safety. Apart from various measures or strategies, Six Sigma is a quality improvement program that relies heavily on statistical analysis of data. It measures quality in terms of defect rates and it should not more than 3.4 defects per million opportunities (DMPO). In Six Sigma methodology, DMAIC (Define-Measure-Analyze-Improve-Control) is the commonly

used method which involves five stages: To Define opportunities, To Measure performances, To Analyze opportunity, To Improve performances and To Control performances. It is based on original Plan-Do-Check-Act cycle (PDCA) (Stoiljkovic *et al.*, 2010). By means of DMAIC methodology, external nonconformances were reduced in several categories of medication errors such as wrong-drug selection (33%), wrong directions (49%), and SALA errors (69%). Control charts demonstrated evidence of sustained process improvement and actual reduction in specific medication error elements. (Castle *et al.*, 2005). Therefore the objective of the current study is to analyze the effect of implementing Six Sigma DMAIC methods in reducing medication errors in the outpatient pharmacy of King Fahd Hospital of the University, Saudi Arabia.

2. Methodology

2.1. Study setting

This study was conducted in outpatient pharmacy of the King Fahd Hospital of the University (KFHU), Saudi Arabia during the year of 2014. It is mandatory to reduce the risk of medication errors that occurs within the prescription dispensing process. In KFHU, the research team forge ahead with full efforts to reduce medication errors thereby increase patient satisfaction, create

safe environment and save human life. A multidisciplinary team was formed consisting of pharmacists, technicians, information technology and administrative staffs. Accordingly, several approaches have been explored and Six Sigma DMAIC approach has been finally selected to reduce medication errors in the outpatient pharmacy of King Fahd Hospital of the University. Quality tools and strategies adopted in each phase of DMAIC to reduce the risk of medication errors are described below.

2.2. Define phase

The first step in the define phase of the project was to identify the process that needs an improvement. For this study, the nature of the problem was determined to be that medication errors occurred frequently in the pharmacy causing rework and increased waiting time of the customers. The goal of this study was fixed as to reduce medication errors in an outpatient pharmacy by 20%. Then, the voice of customers' analysis was carried out in order to know the requirements of the customers at the outpatient pharmacy. The research team considered the customer's requirements as critical-to-quality (CTQs) characteristics of the process and also identified both internal and external customers to the prescription dispensing process. The external customer in this process is the patient who is receiving the finished prescription from the pharmacy.

Table 1. Summary of responses of the voice of customer with respect to priority category

Type of Customer	Voice of Customer	Priority categorization
External	Long Processing time	Medium
Internal	Difficulty to understand the handwriting that requires frequent clarification	High
Internal	Missing Information (i.e. Dosage etc.)	High
Internal	Answering the phones makes me forget what I have done and what I still need to do.	High

In order to measure the external voice of the customer, the research team reviewed the patient satisfaction survey results and its comments. The majority of those comments

were related to prolonged waiting time in the pharmacy which may be a result of the rework associated with the medication errors occurred in the pharmacy. Likewise to assess

the voice of the internal customer, a survey was distributed to the pharmacy staff. A summary of the responses of the Voice of customer (VOC) is shown on the following table 1. As a next step, the research team

evaluated the prescription dispensing process to create a Suppliers-Inputs-Process-Outputs-Customers (SIPOC) diagram for the pharmacy and it is depicted in table 2.

Table 2. SIPOC diagram showing the prescription dispensing process

Suppliers	Inputs	Processes	Outputs	Customers
<ul style="list-style-type: none"> • Patients • Pharmacy Staff • Physicians • Nurses • Drug Wholesaler 	<ul style="list-style-type: none"> • Prescriptions • Medications • Patient Information 	Steps Prescription Intake ↓ Prescription Entry ↓ Prescription Production ↓ Prescription Verification ↓ Dispensing	<ul style="list-style-type: none"> • Prescription labels • Patient Education 	<ul style="list-style-type: none"> • Patients • Families • HealthCare professionals

So, this study is aimed to reduce medication errors in the outpatient pharmacy by 20% and to enhance patient safety.

2.3. Measure phase

In Measure phase, a data collection sheet was created to obtain the baseline data in the outpatient pharmacy and to identify what types of medication errors were occurring and at which process step the medication errors occurs within prescription dispensing process. During data collection process, a

total of 250 prescriptions was taken as sample and reviewed for medication errors. The other key elements documented during baseline data collection were the process step where the error occurred (i.e. data entry, pharmacist verification, etc.), the type of error (i.e. wrong drug, wrong directions, etc., drug class (high alert vs. non-high alert), and whether or not the prescription was for a compounded medication. Out of those prescriptions audited (N=250), the number of defects found and its corresponding sigma rating is depicted in the table 3.

Table 3. Initial process capability data of medication errors reported in the pharmacy outpatient department

Type of Risk	No of Samples tested (Opportunities)	No of Defects (Defects)	DPU	Yield (1-DPO* 100)	PPM	Sigma Level
Prescription/ data entry error	250	14	0.044	94.4%	56,000	3.09
Medication available with manufacturers defect		09	0.036	96.4%	36,000	3.60
Medication not properly labeled		08	0.020	96.8%	32,000	3.35

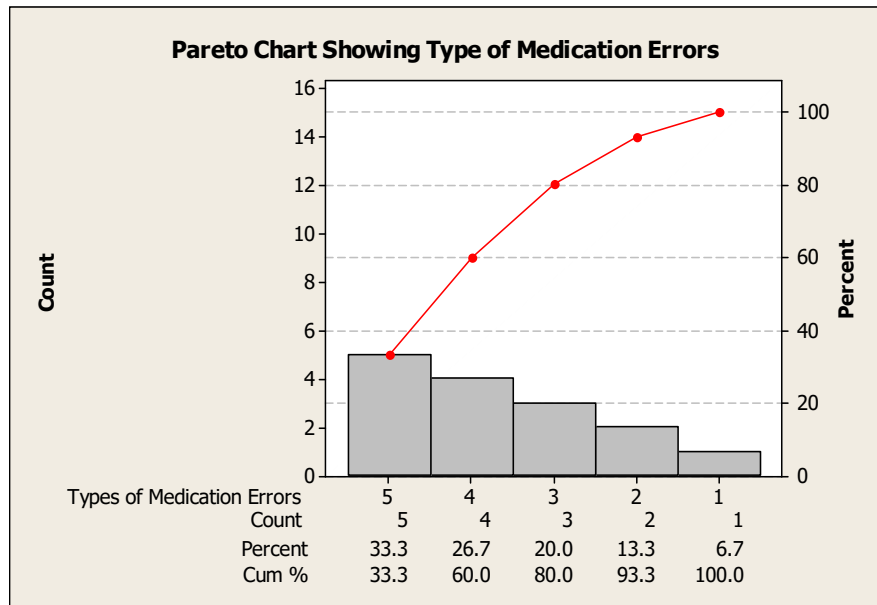
Table 3 showed that number of defects found in prescription/data entry error, medication available with manufacturers defect, medication not properly labeled are 14, 09, 08 out of 250 prescriptions respectively and corresponding parts per million (PPM) for the types of risks/errors are 56,000, 36,000 and 32,000 with sigma rating of the process as 3.09, 3.60 and 3.35.

2.4. Analyse phase

In measure phase, types and number of errors that occurred during the process and its sigma rating were collected as baseline performance. But it is critical to analyze the process in order to fix the source where high medication errors occur. During data analysis, the type of errors gathered during the measure phase was arranged in descending order to create a Pareto Chart. A Pareto chart is used to highlight the most

common source of defects or the most frequently seen defect out of data collected. The Pareto diagram showed that majority of the errors occurred during the data entry process step. Further analysis was carried out to break down the data entry errors further down into five various categories of errors (Figure 1).

Pareto analysis showed that 33% of the errors are related to wrong patient selection during the data entry process, 27% of the errors are related entering wrong medications and 20% of errors are related to wrong prescription readings. All these types of error that occur at the point of data entry are mainly due to incorrectly inputting information in the computer system. Specifically, the employees perform this process manually by reviewing the original prescription and duplicate its information while processing the prescription.



5-Wrong Patients; 4-Wrong Medications; 3-Wrong prescriptions; 2-Wrong strength; 1-Wrong Physician Selection

Figure 1. Pareto chart showing various categories of medication errors noted in the hospital

Further, a Failure Mode and Effects Analysis (FMEA) were conducted to locate the key risks within the process and is shown in table

4 (Appendix). Failure mode effects analysis (FMEA) has been used for many years in various industries to identify, anticipate and

remedy steps in a process that are likely to lead a failure (Benjamin, 2003). It is conducted based on experience with a process and assesses the failure modes and their impact on the system. It helps the research team to prioritize the risks and also develop the action plans to reduce those risks. Specifically, the FMEA focused on the types of errors that could happen within the prescription dispensing process and through that the team assessed the potential failures (types of errors that could occur) and scored according to a rating system to give each one a risk priority number (RPN). The rating system is based on three indicators; Occurrence, Severity, and Detection. The RPN is derived from multiplying each indicator together. The higher the RPN value, the greater the concern for that potential failure and action plan should be focused. After determining the RPN values, actions plans were framed along with responsibility and dates for implementation. At the very least, the action had been attempted to minimize the severity of the failure, reduce the occurrence of the failure and improve the detectability. The FMEA for the outpatient pharmacy listed all the potential failures or opportunities for medication errors to occur. From all the potential failures (medication errors) that could occur, highest RPN were associated with the data entry function in the prescription dispensing process. Specifically, the three highest ranked failure modes were related to typing incorrect information into the pharmacy computer system potentially leading to severe implications if the error reached the patient. After completing the FMEA, it has been observed that there is need to improve the data entry process step and an appropriate improvement strategy needs to be devised.

2.5. Improve phase

The Improve phase mainly involves brainstorming potential solutions with the research team and a focus team from the

pharmacies for selecting the best risk reduction opportunities, testing and evaluating the implemented actions. By including employees from the pharmacy, the risk reduction strategies would be more likely accepted by the frontline staff due to the fact that the ideas came from their peers as well.

Based on the results gathered from the FMEA, following action plans have been formulated and implemented in the outpatient pharmacy viz.

- 1) A unique identifier such as 'Patient code number' for each patient has been developed and implemented across the hospital. Also, the date of birth of the patients also used as one of the additional identifier for cross checking before entering pharmacy prescriptions in to the computer
- 2) All the physicians were provided with name seal indicating his or her name in legible manner and all the physicians are advised to use it while prescribing the drugs in pharmacy order sheet.
- 3) An barcode scanning of prescription label is provided and the data entry operators are provided with appropriate training to use it. An appropriate policy and procedure has been developed and operationalized in the outpatient pharmacy department to guide the work process in an effective and efficient manner.
- 4) An acceptable taut time is developed for each process of operation related to entering the pharmacy prescriptions.
- 5) Standardize and implement appropriate training program to reflect past experiences with medication errors and lessons learned.
- 6) Implement and operationalize 5S methodology to standardize workflow in the pharmacy and eliminate unnecessary downtime and wait time by the data entry physicians. The main purpose for completing the 5S was to find a place

for everything and to maintain everything in its place. Accordingly, the research team observed the process and identified ways to improve the data entry station in the prescription dispensing process. In this regard, an orientation program on 5S methodology had been provided to all the stakeholders involved in this process.

After implementation of all the improvement strategy for the period of 03 months, the research team assessed final process capability since it helps to determine how well a process can produce an acceptable product or service in the department and it is shown in table 5.

Table 5. Process capability data of medication errors reported in the pharmacy outpatient department after implementation of improvement strategy

Type of Risk	No of Samples tested	No of Defects (Defects)	DPU	Yield (1-DPU* 100)	PPM	Sigma Level
Prescription/ data entry error	200	1	0.005	99.5%	5,000	4.08
Medication available with manufactures defect		2	0.010	99%	10,000	3.83
Medication not properly labeled		1	0.005	99.5%	5,000	4.08

Table 5 showed that number of defects found in prescription/data entry error, medication available with manufacturers defect, medication not properly labeled are 01, 02, 01 out of 200 prescriptions respectively and corresponding parts per million (PPM) for the types of risks/errors are 5,000, 10,000 and 5,000 with sigma rating of the process as 4.08, 3.83 and 4.08. While comparing process capability at the beginning and end of the study, the research team was able to show leadership and frontline staff that the implemented improvement strategies had a positive impact for the organization. Also by measuring the process capability, the research team was able to determine if the changes made will meet the customer expectations.

2.6. Control phase

The purpose of control phase is to sustain the improvements obtained in the pharmacy prescription dispensing process. During the control phase, the investigators developed an overall control plan that describing the

required performance measures to achieve quality services and it is enclosed in table 6. The control plan will be maintained by the process owner (Pharmacy department head or supervisor) and the pharmacy staffs to make sure that the improvements made are maintained. Through this control plan, the new process can be monitored to verify sustainability. As a measure to sustain the obtained improvements, the research team utilized a mistake proofing technique so called; "Poka-yoke" to make change to a process, activity or workstation so that it cannot produce a defective product or services. Accordingly, the research team incorporated a few changes into the prescription dispensing process and prevented errors from occurring at data entry. Quality has been incorporated at the source, principally at the pharmacy. This means the right medication with the right dose for the right patient is prepared and delivered to the medication room. By doing this, errors like wrong drug and wrong dose could be prevented. The mistake proofing process that assists in decreasing the errors at

the point of data entry in the pharmacy dispensing process is the use of electronic prescriptions. Since medication errors are the most common cause of preventable injuries in healthcare, electronic prescriptions can help to reduce the number of errors associated with transcription at the point of data entry. Electronic prescriptions are automatically transmitted from the prescriber

to the pharmacy computer system. Once the prescription is in a queue in the pharmacy, the data entry technician just needs to accept the prescription and it is automatically generated in the patient's profile. This process is similar to computer provider order entry (CPOE) seen in some hospitals for inpatient medication prescribing.

Table 6. Control plan for the outpatient pharmacy dispensing process

Process Name : Prescription Dispensing				Date:	
Process Owner : Pharmacy Manager				Audit Frequency:	
Process Step	Data Description	Sample Size	Frequency of Measure	Person(s) responsible	Place of Recording
Data Entry	Medication Errors	30	Weekly	Production Pharmacist	Patient Safety Registry
Production				Pharmacist	
Pharmacist Verification				Pharmacist	
Prescription Pick-up				Pharmacy Technician	

Moreover, the pharmacy personnel should be oriented and trained to check medications labels and storage location. They should also remove expired, deteriorated, and recalled drugs. If not removed, medication might be administered to patients, which could increase a chance of patient harm. A monthly audit should be established and the records kept in the pharmacy.

3. Discussion

This study is the documentation of the effect of Six Sigma (DMAIC) methodology in reducing the medication errors in the outpatient pharmacy of King Fahd University Hospital, Saudi Arabia. This study was carried out for the period of three months. A medication prescribing error is defined as “a prescribing decision or prescription writing process that results in an unintentional, significant reduction in the probability of treatment being timely and effective or increase in the risk of harm, when compared with generally accepted

practice” (Dean *et al.*, 2000). In this study, DMAIC was applied in five phases such as Define, Measure, Analyze, Improve, and Control. During define phase, the goal of the study was set to reduce medication errors in an outpatient pharmacy by 20%. Through the voice of customers’ analysis, specifications of the customers at the outpatient pharmacy were gathered as critical-to-quality (CTQs) characteristics of the process and reported that prolonged waiting time is the major issue which might results from the rework associated with the medication errors in the pharmacy. The research team evaluated the prescription dispensing process and explained with SIPOC diagram. In measure phase, about 250 prescriptions were reviewed for various errors. Process capability showed that number of defects found in prescription/ data entry error, medication available with manufactures defect, medication not properly labeled are 14, 09, 08 respectively and their corresponding parts per million and sigma rating of the process are 56,000 (3.09),

36,000 (3.60) and 32,000 (3.35).

A Pareto chart analysis revealed that 33% of the errors are related to wrong patient selection during the data entry process, 27% of the errors are related entering wrong medications and 20% of errors are related to wrong prescription readings. Among these errors, wrong patient selection during the data entry process showed the high percentage of occurrence and it may be due to incorrect input information in the computer system by pharmacy staffs. This findings were supported by a study (Lambert *et al.*, 2010) stated that 14,247 cases of wrong drug errors happen every day in United States and most of them were caused by a wrong patient selection error. Wrong patient selection may be a result of either a slip or a mistake. It is a slip if the clinician accidentally selects the patient in an adjacent row or hits the wrong number key when entering a patient ID number (Thimbleby and Cairns, 2010). Slips are more frequent when the text is hard to read or small buttons are hard to select. Mistakes are more frequent when two patients are listed with the same first and last name (McCoy *et al.*, 2013) or inconsistent medical record numbers (from different data sources). In one study, it was reported that the most common form of prescription error as writing the wrong dose (Dean *et al.*, 2002). According to Audit Commission (2001), the most common errors on prescription charts were writing the patient's name incorrectly and writing the wrong dose, which together accounted for approximately 50% of all errors in six oxford hospitals.

Further, a FMEA analysis was conducted to study the potential risks of the process and helps to identify why a process fails and how those failures can lead to defects. By using FMEA analysis, the research team prioritized the risks and developed the action plans in order to reduce it. In continuation, potential failures were assessed and provided each with a risk priority number (RPN). The higher the RPN value, the greater the concern for that potential failure and where

action plan should be focused. Out of all the potential failures (medication errors), highest RPN were associated with the data entry function in the prescription dispensing process. Specifically, the three highest ranked failure modes were highly related to typing incorrect information into the pharmacy computer system which leads to severe implications if the error reached the patient. After completing the FMEA, it has been observed that there is a need to improve the data entry process step and an appropriate improvement strategy needs to be devised. Based on the results of FMEA, following action plans have been formulated and implemented in the outpatient pharmacy department such as considering the date of birth along with patient code number to identify the patient (Grissinger, 2008), providing the physician's seal, barcode scanning (Aronson, 2009), implementing the appropriate policy and procedures, developing acceptable taut time, implementing training programs and 5S methodology in pharmacy.

After implementation of all the improvement strategies for the period of three months, the research team assessed final process capability to know the impact of them on the process. The results showed that number of defects decreased on each type of risk or error and there is an improvement in sigma rating of the process. By comparing process capability at the beginning and end of the study, the research team concluded that improvement strategies implemented by leadership and frontline staff had a positive impact for the organization. The results showed that the reduction of parts per million in prescription/data entry error was from 56,000 to 5,000 PPM, in medication available with manufacturers defect was from 36,000 to 10,000 PPM, in medication not properly labeled was from 32,000 to 5,000 PPM and correspondingly the sigma rating (considering 1.5 σ shift) for prescription/data entry error, medication available with manufactures defect, medication not properly labeled has

improved from 3.09, 3.60, 3.35 to 4.08, 3.83, 4.08 respectively. These findings were validated by a case study which reported that there was some improvement in dispensing errors, about 230 errors per million by using Six Sigma (DMAIC) methodology (Chan, 2004). Where in another study, DMAIC was used to reduce medication errors and in addition Quality function deployment (QFD) was applied for designing a standard medication order process for all hospital units to use. Chart audits showed the improvement of percentage of order entry errors by 90% to less than 0.04 errors per bed every month after the process changes (Benitez *et al.*, 2007).

Poka-yoke is the Japanese word means "avoid mistakes". The essential idea is to design processes in such a way that mistakes are impossible to make or at least easily detected and corrected (Yang and El-Haik, 2003). In control plan, the research team made few changes in the prescription dispensing process by using poka-yoke technique in order to prevent errors at data entry. Accordingly, electronic prescriptions were followed to reduce medication errors associated with transcription at the point of data entry. Once the prescription is automatically transmitted from the prescriber to the pharmacy computer system, the data entry technician accept it and it is automatically generated in the patient's profile. This process is similar to computer provider order entry (CPOE) which is used in some hospitals for inpatient medication prescribing. Some authors stated that computerized prescribing systems, bar-coded medication systems, and cross checking by others (for example, pharmacists and nurses) can help to seize such errors (Agarwal *et al.*, 2007).

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4. Conclusion

This study of implementation of Six Sigma DMAIC methodology showed a marked reduction of medication errors in the outpatient pharmacy department. By taking into consideration, number of defects found in prescription/data entry error, medication available with manufactures defect, medication not properly labeled were reduced and correspondingly the sigma rating (considering 1.5 σ shift) has improved from 3.09, 3.60, 3.35 to 4.08, 3.83, 4.08. Specifically, the prescription/data entry error has reduced significantly which is demonstrated through the consistent and concomitant improvement of sigma rating. Also, a control plan has been developed to sustain these improvements. By reducing the medication errors, problems such as adverse drug reactions, unnecessary hospitalization, disability or death, rework, increased waiting time of patients/attenders, legal issues, cost of patient care were reduced and there will be an improvement in patient safety and frontline staff productivity.

Acknowledgment: This study is funded by the Deanship of Scientific Research, University of Dammam in the year 2014. The author expresses his gratitude to the Deanship of Scientific Research, University of Dammam for funding this project. The author expresses special thanks to Dr Arun Vijay Subbarayalu, Assistant Professor, University of Dammam for his help in completing this research work. Finally, he also thank all the team members of the directorate of Quality and Patient safety, King Fahd Hospital of the University, Al Khobar, Saudi Arabia for their support to complete this research study.

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Ahmed Al Kuwaiti

University of Dammam
Deanship of Quality and
Academic Accreditation
Kingdom of Saudi Arabia
akuwaiti@uod.edu.sa
