



USE SIX SIGMA APPROACH TO IMPROVE PATIENT SAFETY AT A GENERAL HOSPITAL

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ABSTRACT

Patient safety is considered the corner stone of the high quality medical care. This study applied Six Sigma set (DMAIC) to identify root cause(s) of medication error and propose appropriate strategies to prevent medication error incidences in healthcare sections. Six Sigma's approach of problem identification, measurement, and statistical analysis, improvement, and controls plans were covered at a general governmental hospital with number of beds is 93 beds, and number of physicians is 137 physicians.

KEYWORDS: Patient safety, Six Sigma, DMAIC, medication error.

1. INTRODUCTION

Patient safety is currently an international priority in health care, as it is widely accepted that the quality of healthcare provision, in terms of reducing errors and other forms of unnecessary patient harm, needs to be improved significantly.^[1] Total Quality Management (TQM), is a methodology of management for continuously improving the quality of products and processes to meet or exceed customer expectations.^[2] On the other hand, Six Sigma is a business management strategy which seeks to improve the quality of process outputs. Integrating Six Sigma into TQM program improves the process through detailed data analysis, as Six Sigma Approach depends on using a set of tools which are known as DMAIC (Define, Measure, Analyze, Improve, and Control). Therefore, the use of Six Sigma metrics makes TQM efforts more successful.^[3,4] Previous published study used six sigma approach to improve healthcare workers safety, concluded that approach could serve as valuable serve as valuable models for other safety concerns in the health care workplace.^[5]

With its estimate that between 44,000 and 98,000 patients die in hospitals each year as the result of medical errors, the National Academy of Medicine's (NAM's; formerly the Institute of Medicine's) report To Err Is Human: Building a Safer Health System propelled a wave of activity. Health care professionals, professional societies, large employer groups, patient advocacy organizations, and researchers voiced the need to reduce the estimated high toll of medical errors and adverse events.^[6] Because a medication error is harmful event that may cause or lead to inappropriate medication use or patient harm when the medication process is in the

control of the health care professional, patient, or consumer, the achievement of six sigma methodologies, integrated into TQM, is to prevent these errors that occur in healthcare sectors, as medication errors are the most common type of medical error.^[7] In 2007, a study has shown that from 1998 through 2005, reported serious Adverse Drug Events (ADEs) increased 2.6 fold and that fatal adverse events increased 2.7-fold. Reported serious events had increased 4 times faster than the total number of outpatients prescriptions during the period.^[8] There are many types of medication errors. They include errors in prescribing, order communication, compounding, product labeling, packaging, distribution, administration, education, monitoring, dispensing and use.^[9] A cross-sectional study performed in a university hospital in Denmark to investigate the frequency and type of medication errors in each stage, revealed that frequency of medication errors was 39% for prescription, 56% for transcription, 4.0% for dispensing, 41.0% for administration and finally 76% for discharge summaries.^[10]

Prescribing errors represent the majority of medication errors. They occur as a result of a prescribing decision or prescription writing process, when there is an unintentional significant reduction in the prospect of treatment being timely and effective or an intentional significant increase in the risk of adverse result when compared with generally accepted practice.^[11] Several studies were performed to estimate the incidence of prescribing errors. In a pilot study performed to investigate the incidence of prescribing errors in hospital inpatients in one of UK hospitals, there were about 135 prescribing errors identified each week (1.5% of

medication orders written during the study period), of which 34 (0.4%) were potentially serious. The study showed a higher error rate for medication orders written during the stay of the patient in the hospital than for those written on admission or discharge. While the majority of all errors (61%) was in medication order writing, most serious errors (58%) was in the prescribing decision.^[12] In another study, pharmacists prospectively scored the number of errors of prescribing during a 4 week period at an eye hospital in UK. The errors were categorized as error of prescription writing (incorrect patient details, illegibility and incorrect format) or drug error (incorrect drug dose or timing, incorrect route of administration). Eight percentage prescription sheets had errors, 7% of them were errors of prescription writing while 1% were drug errors. The majority of errors were made by newly graduated physicians and no drug errors were made by senior doctors. The outpatients department had by far the highest predominance of errors.^[13]

2. MATERIALS AND METHODS

The study aimed to identify root cause(s) of medication error and propose appropriate strategies to prevent medication error incidences in healthcare sections by using six sigma approach.

Study setting: The study was conducted at general governmental hospital.

METHODS: Six Sigma's approach of problem identification, measurement and statistical analysis, improvement and controls plans were covered by our study. The six sigma quality improvement methodology utilized the five-step DMAIC process for every project. The following Table defines each phase of the DMAIC process:

Phase	Definition	Components
Define	Identify a project Establish the project	Identify the project. Identify the problem. Identify the objective.
Measure	Understand the current process in need of improvement	SIPOC (Suppliers, Inputs, Process, Outputs, Customers). Voice of the customer. Symptoms analyze: (Incidence of medication error): Operational definition. Define boundaries).
Analyze	Use statistical analysis to understand causes and effects in relation to the current process.	Formulate Theories & Cause-Effect Diagrams. Test Theories Data Collection. Identify Root Cause(s).
Improve	Develop a plan that can be validated by statistical data to improve the process	Evaluate alternatives. Design remedy & Design for culture. Prove effectiveness & Implement.
Control	Establish a monitoring tool or mechanisms to ensure that the process will be sustained	Design effective quality controls: Foolproof the improvement. Audit the controls.

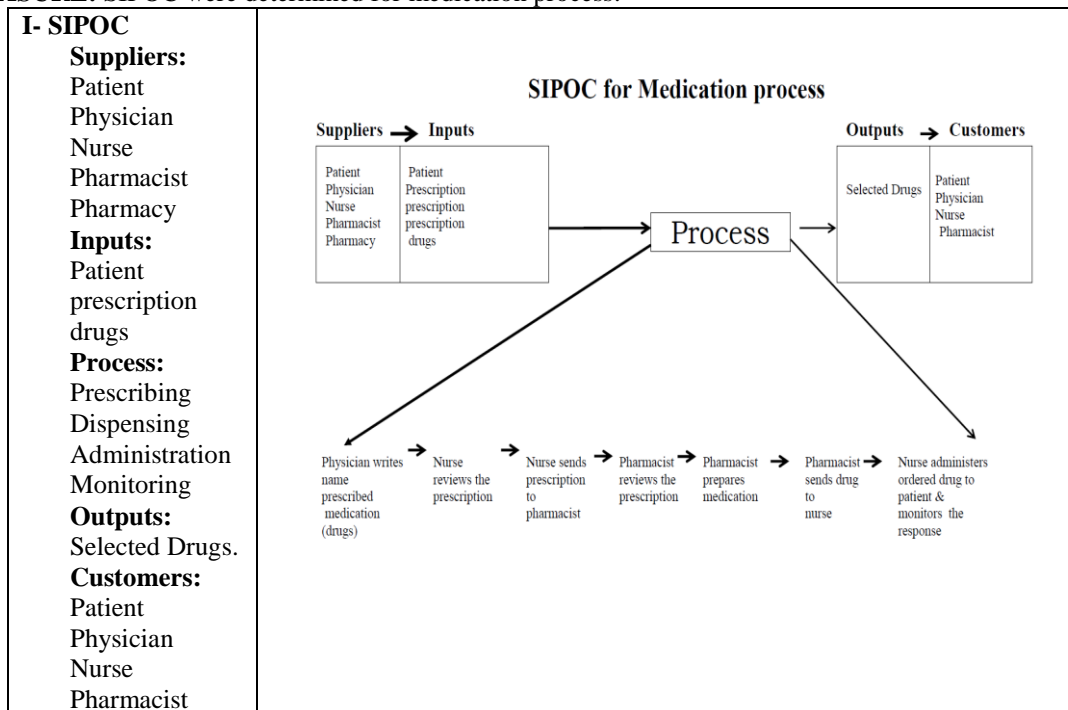
2-1: DEFINE

Problem: An informal stimulations indicated that the incidence of medication errors was 6.7 for 100 administrated medication doses, while the global standards indicated that the incidence of medication errors should not exceed 1 for 100 administrated medication doses.

Medication errors influence patients, nurses and organizations negatively; medication errors are very costly and adversely influence patients' safety and medication errors' is a global issue that causes serious harm and even death.

Objective: To propose appropriate strategies to reduce the medication error to less than 1 for 100 administrated medication doses.

2-2: MEASURE: SIPOC were determined for medication process.



II-Voice of the customer

Step 1: Develop a customer–Focused business strategy

- Assess the business needs.
- Identify customer segments.

Step 2: Listening to the VOC

- To obtain useful and valid customer information and feedback:
- Select research methods to gather customer information.
- Probe for complete understanding.

Step 3: Translating voice of the customer (VOC) into critical customer requirements (CCRs).

- Organize and verify customer needs data into CCRs.
- Determine CCR priorities.
- Identify CCR measurement and target.

Step 4: Developing measures and indicators

- Translate the CCRs into output indicators:
- Identify and select output indicators.
- Establish output performance targets.

Analyze Symptoms

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.

Medication errors are typically viewed as related to administration of a medication, but they can also include errors in ordering or delivering medication.

The medication dose must actually reach the patient. If the incorrect dose is discovered and corrected before administration to the patient, no error occurs.

Prescribing error: Mistakes made by the physician when ordering a medication. Incorrect drug selection (based on indications, contraindications, known allergies, existing drug therapy and other factors), dose, dosage form, quantity, route, concentration, rate of administration, or instructions for use of a drug product.

Dispensing error: The deviations from the physician’s order, made by staff in the pharmacy when distributing medications to nursing units or to patients in an ambulatory setting.

Administration error: The deviating from the physician's order as written in the patient's chart.

Monitoring error: Failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy.

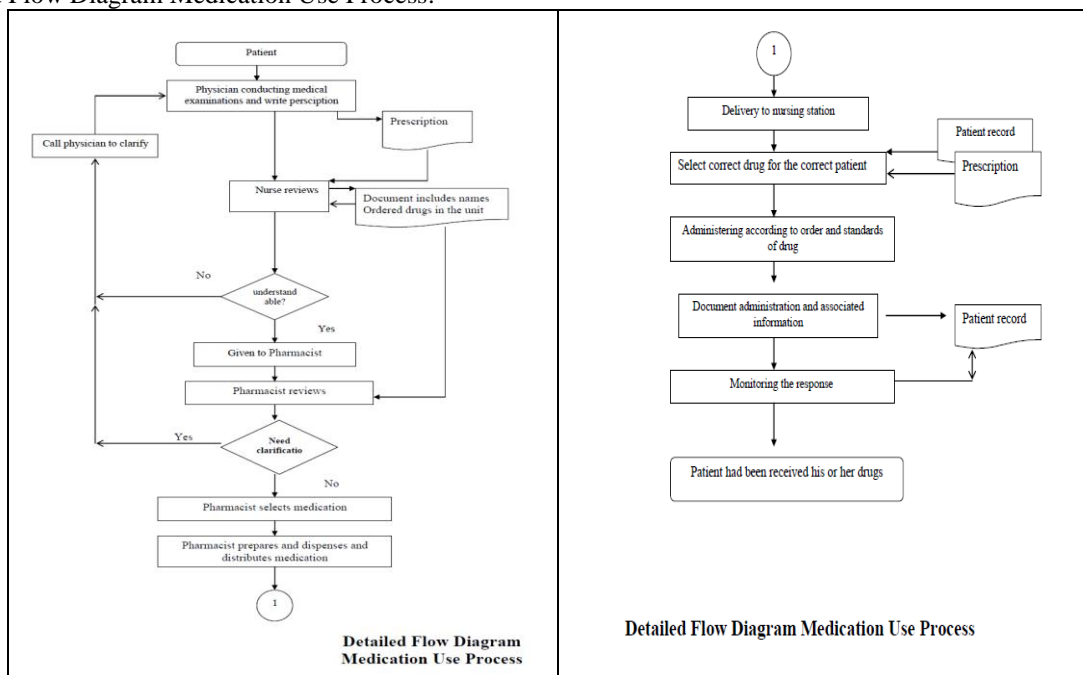
We would measure the Incident of medication error by measuring the following rates through observation methods of process or self reporting:

1. Wrong frequency prescription error rate
2. Wrong drug administration errors rate
3. Wrong dose administration errors rate
4. Wrong route administration errors rate
5. Wrong frequency administration errors rate

Define boundaries

A Process is a set of systematic activities directed toward the achievement of a specific goal.

Detailed Flow Diagram Medication Use Process.



2-3: ANALYZE

Formulate Theories through Brainstorming: Brainstorming was used to consider the full range of possible causes:

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. Abbreviations 2. Blanket orders 3. Brand names look alike 4. Brand names sound alike 5. Brand/generic names look alike 6. Brand/generic names sound alike 7. Calculation error 8. Communication 9. Contraindicated, drug allergy 10. Contraindicated, drug/ drug 11. Contraindicated, drug/ food 12. Contraindicated in disease 13. Contraindicated in pregnancy/breastfeeding 14. Decimal point 15. Diluents wrong 16. Dispensing device involved 17. Documentation inaccurate/lacking 18. Dosage form confusion 19. Drug distribution system 20. Drug shortage 21. Equipment design confusing/inadequate 22. Equipment (not pumps) failure/malfunction 23. Generic names look alike 24. Generic names sound alike 25. Handwriting illegible/ unclear 26. Incorrect medication activation 27. Information management system 28. Knowledge deficit/training Insufficient 29. Label (manufacturer's) design 30. Label (hospital's) design | <ol style="list-style-type: none"> 31. Labeling (hospital's) 32. Leading zero missing 33. Measuring device inaccurate/inappropriate 34. Monitoring inadequate/lacking 35. Non-formulary drug 36. Non-metric units used 37. Packaging/container Design 38. Patient identification failure 39. Preprinted order form 40. Performance (human) deficit 41. Procedure/Protocol not followed 42. Pump, failure/malfunction 43. Pump, improper use 44. Reconciliation-admission 45. Reconciliation-discharge 46. Reconciliation-transition 47. Reference material confusing/inaccurate 48. Repackaging by hospital 49. Repackaging by other facility 50. Similar packaging/labeling 51. Similar products 52. Storage proximity 53. System safeguards inadequate 54. Transcription inaccurate /omitted 55. Unlabeled syringe/container 56. Verbal order confusing/ incomplete 57. Weight missing/inaccurate 58. Written order confusing/ incomplete 59. Workflow disruption |
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Cause-Effect Diagrams

We categorized the causes according to process steps:

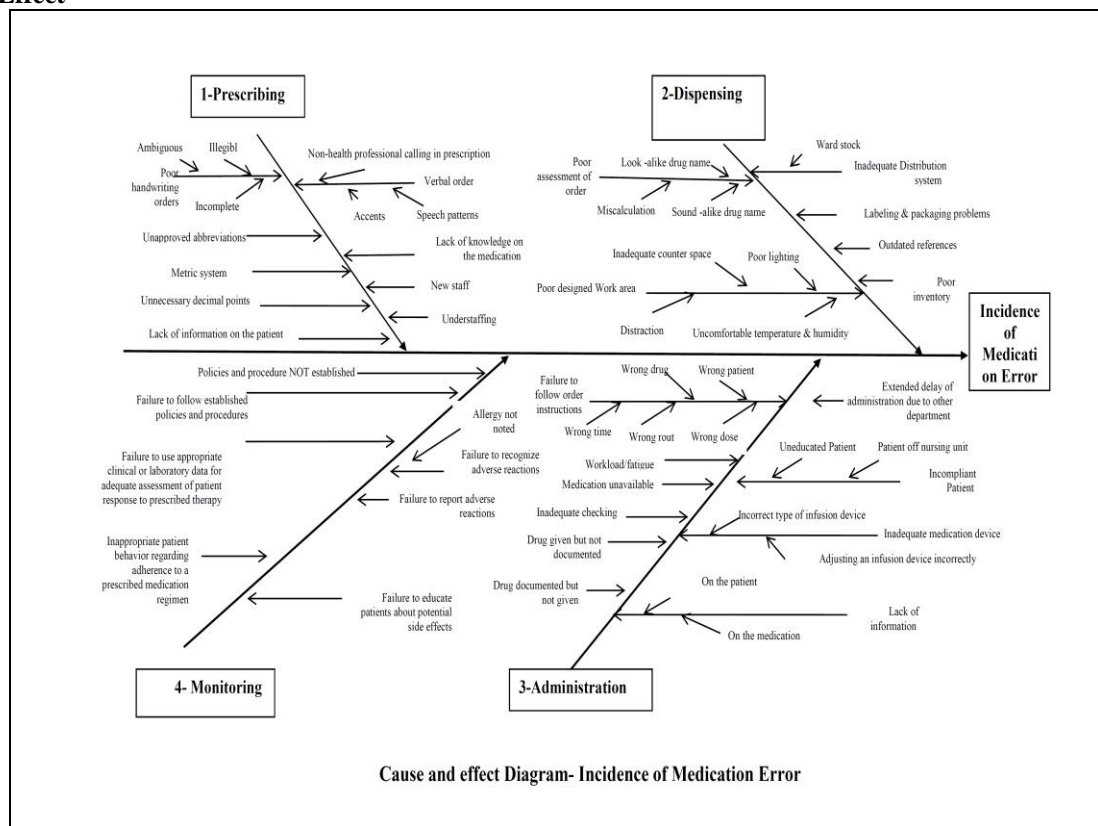
A. Prescribing

B. Dispensing

C. Administration

D. Monitoring

Cause-Effect



3. RESULTS

The data which we need, are not available, study hospitals don't have reports about the medications error and no registration system of any related data. so the method of data collection, we selected, was medication error causes- data sheet which must be filled by nurses.

Nurses play multifarious roles in medication use process

- Accurate and appropriate preparation and administration of medication
- Assessing and supporting the desired therapeutic response
- Prevention, early detection or amelioration of adverse effect
- Education of patients for participation in the management of their own medication therapy.

Nurse is the cornerstone in the medication use process; nurses involve in all process steps and understand the process.

Nurses receive orders from physicians, receive drugs from pharmacy, administrate the drugs to patient and finally monitor the response.

The purpose of the medication error causes- data sheet was to investigate "Why Medication Errors occur"; every nurse should select three causes of the sheet. One hundred and six sheets were filled and analyzed.

Pareto diagram

Data-analysis tool is Pareto diagram, to concentrate on the vital few; The goal of the Pareto is to separate the causes of problems into the vital few and the useful many.

- Contributors
- Magnitude
- Cumulative percent

The following table shows the score of each cause of medication error

Table (1): Medication Error Scores

D-Causes Related Prescribing Phase	SCORE
a. New staff	9
b. Poor handwriting orders	24
c. Verbal order	14

d. Unapproved abbreviations	22
e. Understaffing	14
f. Metric system	19
g. Lack of knowledge on the medication	7
h. Unnecessary decimal points	16
i. Lack of information on the patient	11
II)-Causes Related Dispensing Phase	
j. Poor assessment of order	12
k. Outdated references	3
l. Labeling & packaging problems	8
m. Poor designed Work area	9
n. Inadequate Distribution system	9
o. Poor inventory arrangement	4
III)-Causes Related Administration Phase	
p. Failure to follow order instructions	8
q. Workload/fatigue	15
r. Medication unavailable	10
s. Inadequate checking	6
t. Extended delay of administration due to other department (Lab levels, x-ray,.)	8
u. Incompliant Patient	11
v. Inadequate medication device	4
w. Lack of information	11
x. Drug given but not documented	13
y. Drug documented but not given	1
IV)-Causes Related Monitoring Phase	
z. Failure to recognize adverse reactions	5
aa. Failure to report adverse reactions	4
bb. Failure to educate patients about potential side effects	12
cc. Failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy	2
dd. Inappropriate patient behavior regarding adherence to a prescribed medication regimen	13
ee. Failure to follow established policies and procedures	15
ff. Policies and procedure NOT established	7

The following table shows the total score of each cause of medication error

Table (2): Pareto table --causes of medication error

cause of medication error	SCORE	Percent	Cumulative percent
b. Poor handwriting orders	24	7.5	7.5
d. Unapproved abbreviations	22	6.9	14.5
f. Metric system	19	6.0	20.4
h. Unnecessary decimal points	16	5.0	25.5
ee. Failure to follow established policies and procedures	15	4.7	30.2
q. Workload/fatigue	15	4.7	34.9
c. Verbal order	14	4.4	39.3
e. Understaffing	14	4.4	43.7
dd. Inappropriate patient behavior regarding adherence to a prescribed medication regimen	13	4.1	47.8
x. Drug given but not documented	13	4.1	51.9
bb. Failure to educate patients about potential side effects	12	3.8	55.7
j. Poor assessment of order	12	3.8	59.4
u. Incompliant Patient	11	3.5	62.9
i. Lack of information on the patient	11	3.5	66.4
r. Medication unavailable	10	3.1	69.5
m. Poor designed Work area	9	2.8	72.3

a. New staff	9	2.8	75.2
n. Inadequate Distribution system	9	2.8	78.0
t. Extended delay of administration due to other department (Lab levels, x-ray,.)	8	2.5	80.5
p. Failure to follow order instructions	8	2.5	83.0
l. Labeling & packaging problems	8	2.5	85.5
ff. Policies and procedure NOT established	7	2.2	87.7
g. Lack of knowledge on the medication	7	2.2	89.9
s. Inadequate checking	6	1.9	91.8
z. Failure to recognize adverse reactions	5	1.6	93.4
v. Inadequate medication device	4	1.3	94.7
o. Poor inventory arrangement	4	1.3	95.9
aa. Failure to report adverse reactions	4	1.3	97.2
k. Outdated references	3	0.9	98.1
w. Lack of information	3	0.9	99.1
cc. Failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy	2	0.6	99.7
y. Drug documented but not given	1	0.3	100.0
Total	318	100.0	

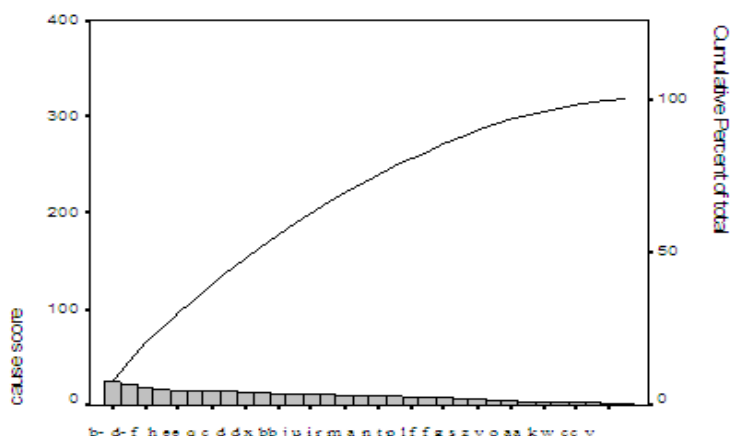


Figure (1): Pareto diagram- causes of medication error

Causes of medication error

Pareto diagram does not produce a clear picture of the vital few because each of the categories is nearly equal in the score. The data indicate no clear distinction between the categories.

All the bars on a Pareto diagram roughly the same height and It takes more than half of the categories to account for more than 60 percent of the quality effect.

Data was stratified by process steps, then we select the first phase which had the higher scores and then we grouped the causes resulted from traditional prescribing behavior of physicians (poor handwriting orders, unapproved abbreviations, metric & apothecary systems and unnecessary decimal points).

Table (3): Pareto table -cause of error during phases of medication process

Causes	SCORE*	Percent	Cumulative percent
Causes Related Prescribing Phase	136	42.8	42.8
Causes Related Administration Phase	79	24.8	67.6
Causes Related Monitoring Phase	58	18.2	85.8
Causes Related Dispensing Phase	45	14.2	100.0
Total	318	100	

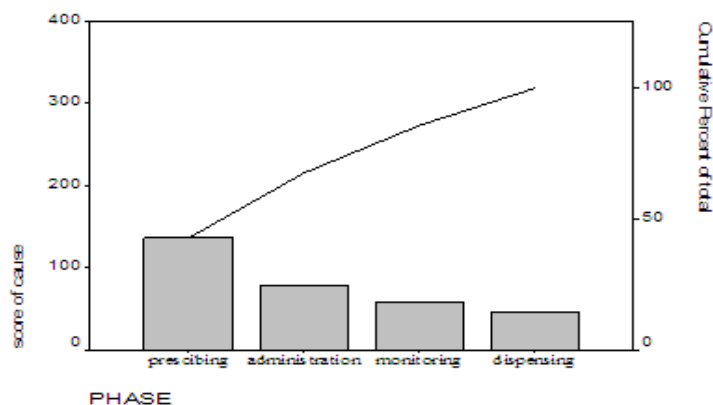


Figure (2): Pareto diagram -cause of error during phases of medication process

Table (4): Pareto Table- causes of medication error related prescribing phase

cause of medication error	SCORE	Percent	Cumulative percent
b. Poor handwriting orders	24	17.6	17.6
d. Unapproved abbreviations	22	16.2	33.8
f. Metric system	19	14.0	47.8
h. Unnecessary decimal points	16	11.8	59.6
c. Verbal order	14	10.3	69.9
e. Understaffing	14	10.3	80.1
i. Lack of information on the patient	11	8.1	88.2
a. New staff	9	6.6	94.9
g. Lack of knowledge on the medication	7	5.1	100.0
Total	136	100.0	

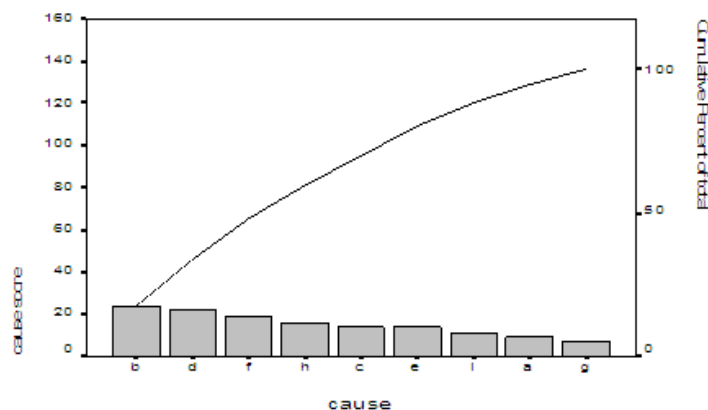


Figure (3): Pareto diagram- causes of medication error related prescribing phase

Table (5): Pareto Table- causes of medication error related prescribing phase after groping the causes related to prescribing behavior of physicians (poor handwriting orders, unapproved abbreviations, metric & apothecary systems and unnecessary decimal points)

cause of medication error	SCORE	Percent	Cumulative percent
Prescribing Behavior of Physicians	81	59.6	59.6
Verbal order	14	10.3	69.9
Understaffing	14	10.3	80.1
Lack of information on the patient	11	8.1	88.2
New staff	9	6.6	94.9
Lack of knowledge on the medication	7	5.1	100.0
Total	136	100.0	

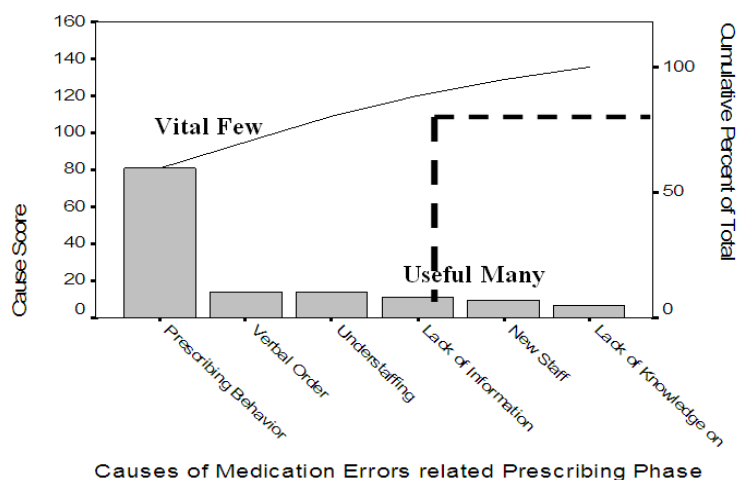


Figure (4): Pareto diagram- causes of medication error related prescribing phase after groping the causes related to prescribing behavior of physicians (poor handwriting orders, unapproved abbreviations, metric & apothecary systems and unnecessary decimal points).

Identify Root Cause(s)

Root Causes are causes resulted from traditional prescribing behavior of physicians:

1. Poor handwriting orders
 - Ambiguous
 - Illegible
 - Incomplete
2. Unapproved abbreviations
3. Metric systems
4. Unnecessary decimal points

The proposed root causes are controllable because related to one factor of the process the physicians who prescribe the drugs (prescribing behavior or practice).

4. DISCUSSION: (Improve & control steps)

4-1: Improve: Formulate Remedies through Brainstorming

1. Automation and technology (Computerization): In hospitals without computerized medication records such as electronic prescribing, electronic medication administration records, bar coding, and automated drug-dispensing systems.^[14]
2. Demands on the staff nurse: Strategies to promote greater accuracy in drug administration have to account for increased demands on nurses as hospitals downsize, declining nurse-to-patient ratios and the requirements that nurses now supervise more unlicensed assertive personnel.
3. Education & training of staff nurse: Many hospitals spent a lot of money on high-technology equipment, but not enough on educating nurses
4. Standardized general principle & practices of medication administration through six rights: Nurses attempt to ensure that the Right drug is given in the Right dose at the Right time via the Right route to the Right patient and with right documentation
5. Double check system: Double-check for every medication every time by a second person

6. Organization's Policies & Procedures: They are less expensive strategies that can be employed by the hospital to reduce medication administration errors.
7. Suitable work environment: Suitable work environments should exist for the safe preparation of drugs
8. Reporting incidence of medication error: Reporting of drug administration errors by incidence report is considered a professional and ethical responsibility of all health care providers
9. Non punitive actions: Punitive responses to drug errors foster fear and deception and have no place in current practice. Nurse' managers are responsible for ensuring that nurses and other providers are not punished for mistakes, that error reporting is encouraged, and that hiding mistakes is discouraged.
10. Empowerment: Nurses' participation in problem solving is the best way to derive strategies that will be effective and feasible. Nurses need to be involved from the unit level through the hospital policy level in decisions affecting medication administration accuracy
11. Medication Safety Committee: Every hospital should establish a medication safety committee.

According to the root causes, we summarized the remedies into strategies

Strategy (I): Improvement handwritten prescriptions by supporting traditional process for prescribing
Strategy (II): Eliminating all handwritten prescriptions by Implementing computerized order entry.

Evaluate alternatives

Strategies to Improve Medication Safety

- 1) Improve handwritten prescriptions by Support efforts to increase prescription legibility and Developing & disseminating guideline to improve handwritten prescriptions
 - Use of standard prescription preparation practices in the education and continuing education of

- physicians.
- Standardize prescription writing and prescribing rules, include purpose(guideline)
- Establish and use of standard terminology elements, e.g., units, abbreviations.
- Encourage physicians to eliminate the use of abbreviations of drug names on all prescriptions and drug orders.
 - Require physicians to include a notation of purpose (not necessarily diagnosis) on all prescriptions.
 - Require physicians to include a notation on the prescription when the patient is a child, and record the precise age of children less than 14 years of age.
- 2) Eliminate all handwritten prescriptions.
 - Use of electronic entry, hand-held computer, or other similar technology
 - Use of automated drug-ordering systems.
 - Implement physician order entry.
 - Physicians' direct computer entry of prescriptions:
 - Physician entry of prescriptions on a computer reduces transcription errors and indicates potentially problematic prescriptions. For instance, it can indicate an improper dose that is being prescribed or a drug that might interact with another medication

- the patient is taking.
- Automated hospital dispensing systems notify nurses when a drug is to be administered and allow access only to it. The systems also record what has been given and when as well as reducing delays in giving patients their medications and decreasing other administration errors.
- Bar coding hospital medications: Machine-readable labels can facilitate matching patients with their prescribed medications and documenting drug dispensing and administration.
- Computerized medication errors monitoring: Computer programs designed to screen for potential medication errors, using data from electronic patient medical records (e.g., orders for known antidotes or specific laboratory test abnormalities), cut their number and frequency.

Evaluation Criteria

- Strategy(I): Improvement handwritten prescriptions by supporting Traditional process for prescribing
- Strategy(II): Eliminating all handwritten prescriptions by Implementing computerized order entry

Table (6): Remedy selection matrix

H: High Desirability M: Medium Desirability L: Low Desirability

Criterion	Remedy 1	Remedy 2
Remedy Name	improve handwritten prescriptions	Eliminate all handwritten prescriptions
Total Cost	M	L
Impact on the Problem	M	H
Benefit/Cost Relationship	H	M
Cultural Impact/ Resistance to Change	L	M
Implementation Time	M	L
Uncertainty about Effectiveness	M	L
Health & Safety	H	M
Environment	M	L
Summery (Rate 1 for best, 2 for next, and so on.)	1.9	2.4

Selected remedy is Strategy (I) Improvement handwritten prescriptions by supporting traditional process of prescribing.

Planning

- Establishing review group (committee)
- Developing guideline for prescribing
- Disseminating guideline to all physicians through educational workshops.

Training members of review group to review prescribing orders against guideline recommendations.

Design the Remedy

The required resources:

People

review group (physician is head of the group and qualified in quality, nurse is assistant of the physician , five secretaries for hospital units and departments, and one clerk. Unit secretary in each department should be trained to review drug orders (prescriptions) against the guideline recommendation and report to group administrators.

Money

Costs of development and dissemination of the guidelines, training of medical secretary.

Time: nine weeks.

Materials

Place of review group and material needed for print the guideline and dissemination the guideline to all physicians in hospital.

Design for Culture

- Sources of resistance (barriers) and support (aids).
- Countermeasures needed to overcome barriers.

Barriers

- Shortage in nurses
- Physician acceptance
- Physician time

Aids

- Involvement & commitment of Top Management.

Counter measures

- Training of medical secretary

- Participating in developing guideline
- Educational workshops about guidelines

Prove Effectiveness

Pilot test

The strategy was implemented in the outpatient on a limited scale.

Implement

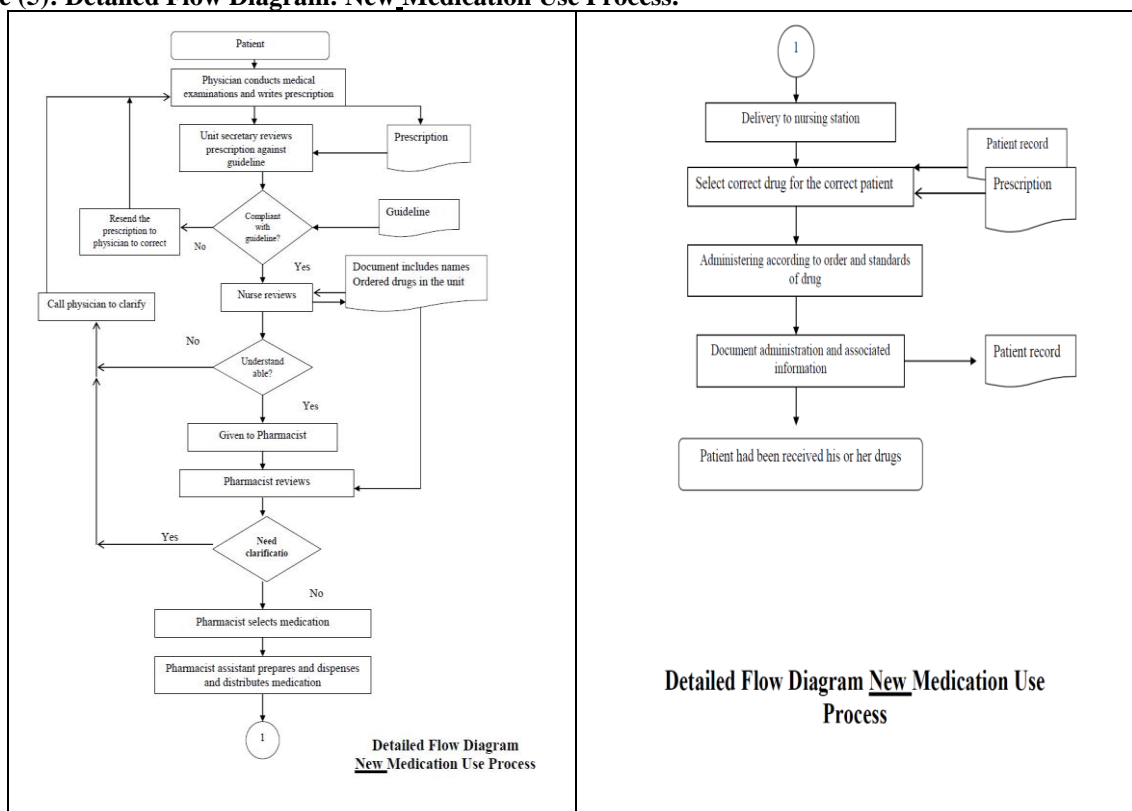
Plan

- 1) Educational workshops for physicians about Guideline Recommendations.
- 2) Training of unit secretaries on New Responsibilities that include review prescribing orders against Guideline Recommendations.

4-2: control: Design the Controls

A flow diagram of new process identifies where & when in-process measuring will be most helpful.

Figure (5): Detailed Flow Diagram: New Medication Use Process.



Foolproof the Remedy

To foolproof the remedy, feedback loops should be kept the as short as possible. A number of sheets were suggested in the control step as audit the controls. These sheets are Review Sheets against Guideline Recommendation, Daily Review Sheets, and Indicators for Guideline.

5. CONCLUSIONS

resent study Used Six Sigma Approach to Improve Patient Safety; First, we defined medication errors and determined the problem of them to set the objective of

this. Then, we moved to the measure phase. We were able to determine SIPOC for medication process, listen to The Voice Of The Customer and to define the operation with its boundaries. In analyzing step, we formulated theories through brainstorming to consider the full range of possible causes of medication error incidences and collecting data using Medication Error Causes- Data Sheet. Then, we analyzed the collected data using Pareto Diagrams to determine the Vital Few. In this step, we found that Prescribing Error Incidences occur in 42.8% to be followed by Administration Errors, monitoring Errors, Dispensing Errors, with 24.8%,

18.2%, 14.2% respectively. In prescribing error incidences the poor handwriting orders had the highest score than other sub-causes. Therefore, we compared between two strategies for this sub-causes using Remedy Selection Matrix in the improve phase of six sigma steps. The two main improvement strategies were either to improve hand writing prescriptions or to eliminate them by automation. According to this matrix, the selected choice was to support hand writing prescriptions by suggestion of an assistant sheets; Guideline Recommendations to Improve Handwritten Prescriptions to be used by the physicians working in the Hospital.

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