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Effectiveness of Medication Management Process Using FMEA Approach-Arba Minch Government General Hospital-Ethiopia

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Abstract: ***The study was designed as observational and analytical research. In every hospital, irrespective of their standards medication errors remain the continuous phenomenon. The high possibility of medication faults lead to fatal consequences and chances for patient morbidity or mortality. The purpose of undertaken this study was to minimize or progressively eliminate the medicament errors and meaningfully improve and ensure patients safety by applying Failure Mode Effective Analyses (FMEA) approach in the inpatient area of Arba Minch Government General Hospital, Arba Minch, Gamo zone, SNNPR region, Ethiopia. The study carefully investigated the (a) failure modes, (b) the causes for process collapse and (c) its effects on patients. The possible ratings were properly assigned based on scales provided by the Institute for Healthcare improvement. The key respondents were carefully selected based on medication management process in each area. The likely respondents were selected according to convenience sampling method. The primary and secondary data were collected from the convenient sources. The primary data collected through conducting face to face discussions and direct observations with the medical officer (MO), pharmacist, nurse supervisor and an administrative officer of the Arba Minch Government General hospital. The study was administered in four phases involving process mapping, identifying failure modes, prioritizing of failure modes through 'RPN' and suggestions to minimize or eliminate the failures. The key errors finding in the investigation were (a) prescription errors (b) Dispensing errors and (c) Drug administration errors. The significance of the study was prominently used FMEA tool to carefully formulate Healthcare policies and necessary procedures to typically prevent medication errors and improve Quality of effective medication in a cost- effective way.***

Keywords: FMEA, Quality management, medication management process, continuous quality improvement, medication errors

1. Introduction

Medication has been around 3,000 years, and the costs of healthcare are enormous across the world (James and Hammond, 2000). The health services across the world struggled to provide care to people when they are unwell and assist them to stay comfortably. The accessible and competent primary care is essential to attain the universal health coverage and support the community. Even though the hospitals work hard to adequately provide safe and high quality care, but sometimes people are unintentionally harmed. The unsafe health care has been candidly acknowledged as a global challenge (WHO, 2016).

The condition of the safe and patients care remain comfortably a major priority and understanding the degree and nature of harm is absolutely essential because the millions of people across the world depending on primary health care services. As possible as reduce the harm represent obligation and it is very essential. The quality health care avoids hospitalisation and unsafe health care leads to complex illness, injury, unnecessary hospital care and sometimes causes disability and even death (WHO, 2016).

1.1 Medication errors

The medication errors are predominantly occurred based on the hospital setting and the type of clinical problems encountered, classes of medicament used and organization of services in primary care are differing from one another. Therefore, the risk caused and solutions required in primary cares may differ from those in hospital settings. A medication error can 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 healthcare professional, patient, or consumer"(National Coordinating Council for Medication Error Reporting and Prevention).

Reducing medication errors is one of the utmost priorities in every country with primary emphasis on improving the patient safety. Minimizing the adverse drug events and medication errors considerably represent the significant goal in the health care sector. It is acknowledged that even competent and well caring professionals equally can commit mistakes. In the past, most of the medication errors were occurred due to negligence and inadequate systems made serious mistakes by health care providers. The medication errors can occur during any stage of the medication process. The possible ways to happen medication errors are drug prescription, feeding information into computer system, drug preparation or dispensed or given to or taken by the patient. Every so often medication errors can lead to dreadful harmful results to the patients like Death, Life threatening situation, Hospitalization, Disability and Birth defect.

1.2 Factors Contributing to Errors

There are several factors influencing the medication errors and it makes become risk of patients' life such as work environment, Interruptions, inadequately trained staff, sleep deprivation, language barriers, medicine sound-alike names, and lack of data concerning a patient. Apart from these, there are some other factors like Ordering, Administrative, Transcription, and Dispensing errors.

1.3 Medication management

The fundamental reason for grabbing medicines by individual is to improve quality of life. Medication management is a service designed to support individuals manage their medications so they can pursue their medicines punctual, all the time, and avert the dangers of incorrect medication administration. When patients are not feeling well or using multiple medications, it is absolutely essential to obtain right medications at exact times but it will be very difficult. If medications are untaken properly, the quality of life does not improve and turns down in many cases. That is why the medication management is getting more prominent attention now a day because it can support to get right treatment, ensure correct time to take medicines to individuals and ensure the quality of medication.

1.4 Benefits of Medication Management

The medication management is an important tool for ensuring the health and managing health care costs of individuals. The following benefits typically derived out of effective and efficient medication management.

1) Better outcomes for the patients.
2) Less stress for the patients and their families. Everyone can be comfortable knowing medications are being distributed and taken correctly.
3) Less money spent on related health care costs such as emergency room visits and hospital stays
4) Reduced illnesses and deaths due to medication noncompliance or drug interactions

1.5 Medication management process

The medication management process represent effective strategies devised to minimize errors and make the the system self-reliable by ensuring prevention of errors and detection at subsequent stages. The FMEA is a systematic proactive tool to indentify the probable errors and the reasons for the process getting fail at various steps and prioritize them according to their severity and devise risk reduction strategies to improve patient safety. Lack of effective medication management process remains a critical concern, which affects the lives of people in a country. The FMEA is a systematic proactive risk assessment tool developed by the US Navy's bureau of Aeronautics and is widely used by "National Aeronautics and Space Administration"(NASA) and the US Department of Defense in the quality management of military and aerospace applications. This approach is recently initiated to use in hospitals.

The study was conducted in Southern Nations Nationalities and Peoples' Region (SNNPR), Gamo Gofa zone, Arba Minch town at the south-west part of Ethiopia. In this zone, the population is growing rapidly at an annual rate of about 3%, which in addition is accommodating many migrants from rural area to urban area due to drought. The zone has three government hospitals, 55 health centers and 468 health posts. Communicable diseases and nutritional problems are a major health hazard in the region and account for the majority of health problems. The health institutions in the zone are under staffed and less equipped. Arba Minch Government Hospital is one of the oldest Zonal hospitals in the region presently serving for the people and it was primarily established about 40 or more years ago for a much lesser population.

1.6 FMEA approach

The FMEA approach focuses on 'system design' rather than a single incident such as in Root cause analysis (RCA). RCA is retrospective and dissects a case, while FMEA is prospective and dissects a process. The Application of FMEA in healthcare institutions is a recent innovation used to make complex Medication management process simple, to achieve service excellence and Continuous efforts to improve quality of the health service delivery system. FEMA approach is a proactive risk assessment tool, which enables to recognize the steps in the process, identifying and prioritizing of errors and also understanding the severity of the failure effects, the chances of occurrence of failure and the possible detection of failure mode. FMEA was used to test the reliability and safety of engineering systems. FMEA has also been proved as an effective tool for analyzing drug administration in pediatric wards, Lago et al, (2012).

1.7 Statement of the Problem

The hospitals remain symbols of humanitarian efforts for community welfare, accountability for performance, and were of little concern. Today, however, people are increasingly concerned with hospital's performance and quality service delivery. According to the Institute of Medicine (IOM), Kohn et al. (1999) conducted a study that stated around 100,000 Americans die each year because of medication errors and negligence by nurses and doctors and the economic loss in US is around $29 Billion. Much of the Arba Minch community is economically poor, backward and illiterate and lack of medical expertise, poor work ethics and negligence represent the primary causes of medication errors in Arba Minch Government General Hospital, Arba Minch, Ethiopia.

1.8 Objective of the Study

The key objective of the study was to investigate and examine the flow of medication management process, possible failure modes, reason for process failure, and its effects on patients, prioritize failure modes and possible suggestions for

prioritized failure modes in the inpatient ward using **FMEA** approach with reference to Arba Minch Government General Hospital.

1.9 Significance of the Study

This study was undertaken to initiate a quality improvement across the Government Hospitals in Ethiopia by understanding the medication management process at Arba Minch Government Hospital. The people across the world are suffering from without availing a quality medicament and efficient cares in hospitals. Since medication errors have high risk impacts and fatal consequences involving mortality, the significance of the study is considered critically important in the present context. Therefore, this study attempted to provide feasible suggestions for the upgrading medication management process and it can be used as a model across Ethiopia.

2. Research Methodology

The study carefully considered the treatment and medication conditions for inpatients in Arba Minch Government hospital. The healthcare remains a primary concern for the development of society and mostly the Hospital acquired infections (HAI) could destroy the sheer fabric of community. This study was framed as an observational and analytical study conducted in the inpatient area of Arba Minch Government General Hospital, Ethiopia. In this investigation, the respondents were selected only those who involved in medication management process at the hospital. The key respondents were selected according to convenience sampling method. The primary and secondary data were collected from the existing sources. The Primary data was collected through conducting face to face discussions and observations with various employees of the hospital like medical officer (MO), pharmacist, nurse supervisor and an administrative officer. Since there was less availability of secondary data sources, the researcher gathered them from limited published and unpublished books and research journals.

3. Discussion and Analysis

In the discussion and analysis part, the possible occurrences of medication errors had been discussed in detail. The medication management processes were explained by process steps and map, FMEA approach, Severity, (s) Occurrence, (O) and Detection (D) of failures and FMEA matrix analyses conveniently presented through tables.

3.1 Steps involved in Medication Management Process

The medication management process is very imperative and the sequence of steps used to make effective and efficient of health care services. The Qian, Siyu & Yu, Ping, (2013), stated in their study that the health care workflow should understand essentially by designing optimal technologies as a first step that enable the staff to complete the intended task faster and better. In addition prescribing multiple or high risk medicines by older people in nursing homes receives the potential threat to increase medication error rate. In the medication management process, the prescription, Pharmacy and drug administration are playing a vital role and they had been explained below in detail.

3.2 Prescription

The prescription of medicine by a Doctor triggers a chain of process work flows, aimed at serving the patient in an efficient and cost effective way. It is essential to place policies and procedures in healthcare facilities. The duty of the hospital is to provide the appropriate medication, for the proper symptoms at the right time, and patients have the right to receive, Baker et al, (2010).

The medication management process flow started with the physician, who prescribes the medicines in a 'Prescription Paper' which contains the Patient's name, Drug name, Dosage form, strength and Duration. The physician is usually a Medical Intern or a junior medical practitioner. The physician simultaneously updates the "Order Sheet" which is a piece of sheet kept in the "Individual patient folder" and has his complete details including ward no, bed no, the conditions, vital signs and the timing for the medication. The patient gets admitted in the inpatient ward.

3.3 Pharmacy

Followed by the prescription step, the second process started from pharmacy in which the relative/attender of the patient goes to the pharmacy with the 'Prescription' to collect the medicines. The pharmacist retains the prescription in his folder and checks for the Stock. If there is no availability then the pharmacist writes down the prescription in a piece of paper, and the attender of the patient has to purchase them from pharmacy outside hospital. If the medicines are available, a bill book called "Auditable pharmacy transaction system" which contains the name of the patient, drug details, dosage, strength and mainly its retail price is provided as a 'proof of receipt.' The medicines are put in a 'plastic pouch', which contains a front label with patient details, name of the drug and its timing (morning, afternoon, evening, night).

3.4 Drug Administration

The third step in the medication management process is once the medicines are dispensed from the pharmacy and they are brought to the patient bedside, the duty of the nurse starts. The nurse has to cross check the medicines with the 'order sheet' written by the physician. The nurse also transcribes this information into a "Medication administration record" (MAR) form, which contains the name, dose, route and frequency of the drug with columns for the time to provide drug, date and signature. Every time the nurse administers the drug, and she has to update the 'MAR' and countersign it properly. When the shift changes the duty nurse is aware of the medicine being given to the patient. The MAR is also maintained in the

Individual patient folder. The nurse also maintains a "patient history log book", which contains the patient details, drug changes and its timing for administration as a reminder for the shift nurse. During the consultation rounds of the physician, if there are any drug changes or stoppages recommended by them the Order sheet gets updated by the nurse. The nurse also maintains a "Progress note" for each patient, which records how the patient progresses or recovers within a particular time.

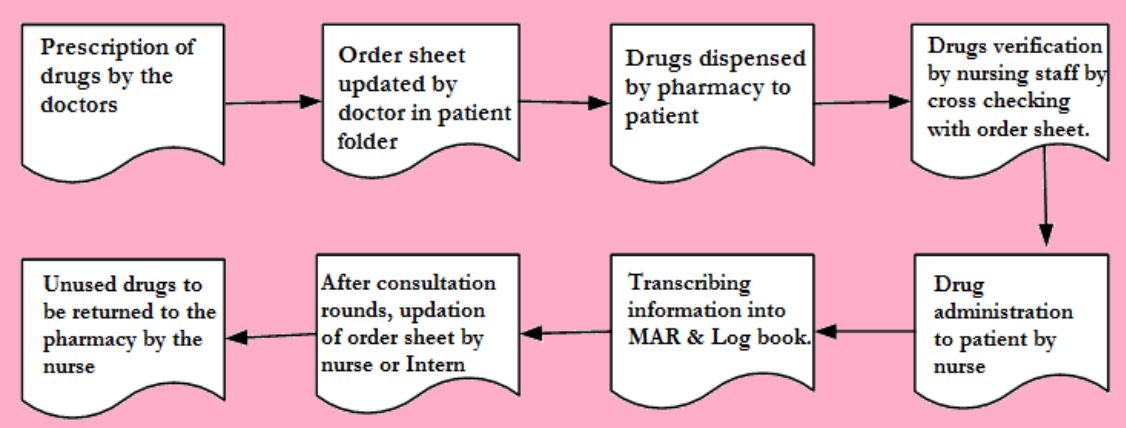

Figure 1: Process Map of Medication management process
Source: Primary data

3.5 FMEA Approach

FMEA is a proactive method to recognize where and how a process would fail and consider their consequences which include the (1) Process steps, (2) What might go wrong? (Modes of failure),
(3) Reasons for failure (causes of failure), and (4) Impacts of failure (effects of failure)

FMEA does not require a specific case or adverse event. FMEA focuses on system design rather than a single incident, whereas Root Cause analysis (RCA) is case based and does not ensure to eliminate all the possible factors for the failure. Moreover since there were no records maintained on medication errors at Arba Minch Government Hospital, it is almost impossible to do RCA on medication management.

3.6 FMEA Analysis

The Failure Mode Effect Analysis was conducted in four phases involving process mapping, identifying failure modes, providing ratings for the severity (S), occurrence (O) and detection (D) of failure modes based on a 1-10 rating scale provided by Institute for healthcare improvement. The Risk priority number (RPN) was generated by multiplying the values assigned to [severity x occurrence x detection]. The failure modes were identified through direct observation and the study population involved hospital inpatients, nurses administering drugs, and transcribing information into MAR, physicians prescribing drugs and finally pharmacists dispensing drugs. The ratings for severity, occurrence and detection were provided individually by the doctor, nurse and pharmacist and after final consultation with the administrative officer, the ratings were decided on a consensus basis. There were no inpatient records maintained regarding the details of medication failure, irregularities observed or preventive/corrective action reports. So the information collected was entirely based on face to face discussions. According to the Institute for Healthcare Improvement, the severity, frequency and detection rates were presented in detail below in the tables.

Table 1: Severity rating scale

Rating	Criteria/Risk	Description (severity of failure)
10	Dangerously high	Failure could cause terminal injury or death of patient
9	Extremely high	Failure could cause regulatory non compliance and long time disability
8	Very high	Failure cause patient health to seriously affected and has to return for major correction
7	High	Failure seriously affects patients health leading to high patient dissatisfaction
6	Moderate	Failure causes disruption of patient activities of daily living leading to dissatisfaction
5	Low	Inconvenience of patient and provider with failure being detected
4	Very low	Inconvenience at subsequent function; minor rework, failure detected and corrected at subsequent step of process
3	Minor	Slight inconvenience at next function; minor rework, failure detected and corrected at next step of the process
2	Very minor	Slight inconvenience at delivery; minor rework, failure detected and corrected at delivery
1	None	No noticeable defects

Source: Institute for Healthcare Improvement

Table 2: Frequency rating

Criteria/Risk	Rating	Description (probability of failure)
Dangerously high	10	Failure is almost inevitable. More than one occurrence per day
Extremely high	9	One occurrence every three to four days
Very high	8	High. Repeated failures, one occurrence per week
High	7	One occurrence every month
Moderate	6	Moderate. Occasional failures, one occurrence every three months
„	5	One occurrence every every six months to one year
„	4	One occurrence per year
Low	3	Low . relatively few failures, one occurrence every one to three years
Very low	2	One occurrence every three to five years
None	1	Remote. Failure is unlikely, one occurrence in greater than five years

Source: Institute for Healthcare Improvement

Table 3: Detection rating

Rating	Criteria/Risk	Description (detection of failure)
10	Absolute uncertainty	Controls will not or cannot detect the existence of failure. No known controls available to detect failure mode
9	Very remote	Controls will probably not detect the existence of failure mode. Control achieved with indirect or random checks only
8	Remote	Controls have a poor chance of detecting the existence of failure mode
7	Very low	Controls have a low chance of detecting the existence of failure
6	Low	Controls may detect the failure
5	Moderate	Controls may detect the existence of failure mode. Error likely to be detected after service delivery
4	Moderately high	Controls have a good chance of detecting failure mode. Error detection at service delivery
3	High	Controls have a very good chance of detecting failure mode. Error detection at subsequent steps
2	Very high	Current controls almost certain to detect the failure mode. Process automatically detects the failure mode.
1	Almost certain	Current controls almost certain to detect the failure mode. Reliable detection controls are known with similar processes. Process automatically prevents further processing.

Source: Institute for Healthcare Improvement

Table 4: FMEA matrix

F.M No	Process	Failure mode	Causes	Effects	S	O	D	RPN
1	Prescription of drugs	Incorrect drug prescribed, Route, dose, frequency not mentioned	Abbreviation, mental slip or negligence	Delay in administration of drug	5	5	3	75
2	Order sheet updation	Drug is copied wrongly, allergies not mentioned	Extra work pressure of transcription leading to error	Wrong drug/dose given to patient	5	3	3	45
3	Drugs dispensed by pharmacy to patient	Wrong medicine/dose/ form/ labelling mistakes	Negligence of pharmacy	Strong effect on patient's health may result in death	8	8	6	384
4	Drug verification by nursing staff once drug reaches patient bedside	Drug not cross checked with order sheet filled by the physician	Mental slip, heavy workload, fatigue, negligence	Wrong drug/dose given to patient	6	8	6	288
5	Drug administration to patient by nurse	Incorrect administration time, missing dose to the patient	Miscommunication between shift nurses, negligence, work fatigue	Delay in patient recovery/progress	6	9	6	324
6	Transcribing/ documentation of MAR and Log book	Erroneous documentation, Missing documentation in Log book and MAR	Mental slip, heavy workload, fatigue, negligence, miscommunication between shift nurses	Delay in administration of drug	6	6	6	216
7	After consultation rounds, updation of order sheet by the nurse or intern	Stopped drugs are continued and the patient shows no improvement sign	Miscommunication between shift nurses and negligence	Wrong drug/dose given to patient, delay in progress of patient	6	5	6	180
8	Unused drugs to be returned to pharmacy	Drugs overstocked at patient bedside	Negligence	May lead to overdose and fatal consequences	6	8	7	336

Source: Primary source

The preceding FMEA table showed clearly the Risk Priority Numbers and they were calculated based on severity, occurrence and detection ratings. According to the table value the risks were prioritized respectively 384, 336, 324, 288, 216, 180, 75 and 45. Therefore, the highest risks must be given priority and initiate prompt corrective actions to ensure the patients safety and quality medication services offered by hospitals.

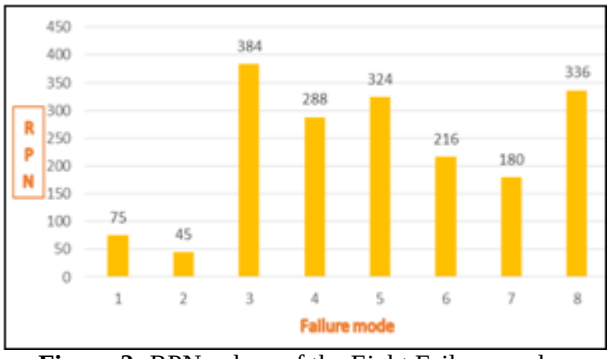

Figure 2: RPN values of the Eight Failure modes
Source: Primary data

The above bar diagram clearly depicted the Risk Priority Numbers based on the FMEA matrix table given below.

1) FM 3- Wrong medicine, dose/ Form dispensed by the pharmacy (RPN- 384)
2) FM 8- Unused drugs not returned to the pharmacy from the patient (RPN- 336)
3) FM 5- Incorrect drug administration to patient by missing dose and timing (RPN-324)

3.7 Medication Errors identified through FMEA Matrix

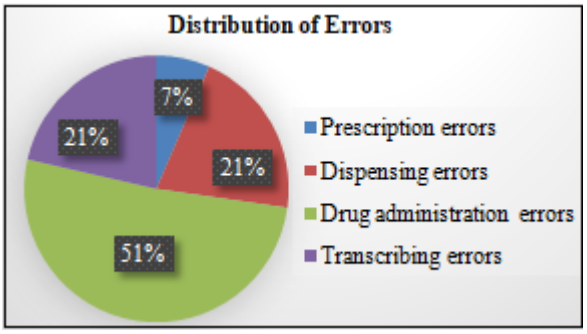

Figure 3: Percentage distribution of medication errors
Source: Primary source

3.7.1 Prescriptions Errors

The prescription errors (7%), which originate from the physician's prescription paper and some of the significant errors occurred at this state in the medication process that (1) Illegible handwriting (2) Incorrect drug prescription (3) Wrong dosage of drug (4) Use of abbreviations instead of clear writing and (5) Route, frequency and duration of medicine not mentioned

3.7.2 Dispensing Errors

The dispensing errors (21%), which originate, when drugs are dispensed from pharmacy such as (1) Wrong medicine provided to the patient by the attender/pharmacist (2) Incorrect dosage/form dispensed (3) Labeling issues in the medicine pouch and (4) "Out of Stock"

3.7.3 Drug Administration Errors

The drug administration errors (51%), which arose, when nurses administer the drug to patients like (1) Drug at the patient bedside, not cross checked against Order sheet (2) Incorrect administration time (3) Unused or stopped drugs not returned to pharmacy resulting in continuation of administering the same drug and (4) Dose missed but documented.

3.7.4 Transcribing Errors

These transcribing errors (21%) were predominantly occurring when transcribing the order sheet into Medication administration record and patient log book. It can also be called, 'Documentation errors'. This kind of errors frequently happened in the following ways that (1) Dose administered, but not documented into MAR and Log Book (2) If change of medicines, Order sheet not updated after doctor consultation rounds (3) Erroneous documentation and (4) Allergy Undocumented in Log Book.

4. Conclusion of the Study

Eight failure modes have been identified at each step of the medication management process from (Table 4). Meticulous attention has to be given to the dispensing of medicines by pharmacy (FM3-RPN-384) and the drug administration stage of inpatient care. The distribution of errors is more towards drug administration by nurse (51%), so rules and procedures have to be established. Because of time constraints and procedural implementation issues in Government hospitals, the post study was unconducted and which can be an area of study for subsequent researchers. As Ethiopia is scaling towards greater heights through its Growth and Transformation plan (GTP II) with its National health policy in "Creating Wealth through Health", it sums up everything important about health. The Research will add great impetus to the Health policy for the Government Hospitals in Ethiopia, thereby setting quality excellence and Benchmark in the African Continent.

5. Recommendations

Based on the findings of the study, the following suggestions were forwarded to hospital administration.

- Prescription from Doctors to be written only in Uppercase with no abbreviations or short form used. This usually results in major confusion and time delay.
- The current 'prescription paper' lacks mandatory fields to be filled by the Doctor. So a prescription sheet with mandatory fields such as Route, Frequency, Duration of drug, Dosage, Form must be prepared and printed for use.
- Healthcare Information Systems (HIS) implementation will solve most of the issues related to medication management. The doctor will be aware of the stock of medicines available in the hospital and can prescribe accordingly.
- The major problem with pharmacy is "Out of stock" situation at most times and the availability of medicines is only 60% of the time. Patients have to buy medicines from private pharmacies outside the hospital, where the price is very high, and most patients could not afford the cost of medicines. Good forecasting software has to be installed along with HIS, so the PFSA (Pharmaceutical fund and

supply agency) is well aware of the demand of medicines and can procure the medicines well in advance.

- The pharmacy uses the concept of "Bin card" for Stock management, which is a manual method of updating stock; when medicines are picked form the rack and refrigerator. Barcode scanners are to be implemented at the Point of Sale (POS).
- Nurses have to adhere to the 5 Rights of medication administration which includes "Right medicine, Right route, Right dose, Right time and Right patient." Awareness programme on the 5 Rights of medication administration needs to be conducted.
- To ensure timely administration of drug, a 'movable medication cart', with separate drawers to store medicine for different patients is to be installed. Unused medicines can be removed from the patient bedside and returned to pharmacy. This is a 'Just in Time' Lean Concept which is used in Toyota production System (TPS).
- Training programs on Quality and Communication skills are to be regularly conducted among the hospital staff. A monthly best performer award should be given, and the name and photo can be displayed which will serve as a motivation for others.
- Random audits are to be conducted by Head nurse and Medical administrator in the Inpatient ward and pharmacy every month. The Audit should check into documents such as MAR, Log Book and Patient folder for any discrepancies. If any irregularities are found, a Corrective action report should be maintained, which should be re-checked during the next audit for the actions taken.
- Becoming an ISO 9001:2008 Certified Health care system. The ISO certification establishes all standards, rules, procedures and processes to be followed, which helps in maintaining a globally recognized quality management system.

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