Implementation of Prescription Review in Hospital

Dr. Vijay Pratap Raghuvanshi[1]
[1]*Associate Professor, Department: Facilities Management, Delhi Skill & Entrepreneurship University, Delhi*

***Abstract*—Prescription Review is a technical review of the list of a patient's medicines. It addresses issues relating to the prescription or medicines; the patient does not need to be present, nor access to full notes. The medication review seeks to improve or optimize impact of treatment for an individual patient. The review is undertaken in a systematic and comprehensive way, by a competent person. Any changes resulting from the review are agreed with the patient.**

Patient safety is the ultimate goal for any Hospital. Prescription Review enables to improve the safety and quality of medication use. It ensures right medication in right dose at right time and right frequency. It helps to minimize the risk of Drug to Drug and Drug to Food interactions proactively by eliminating any potential medication harm. Therefore, it reduces drug error related morbidity and mortality.

Prescription Review was initiated in In-patient department of the Internal Medicine department as a quality initiative. Moreover, Prescription Review is a accreditation requirement in any of the hospital. Apart from reducing medication errors Prescription Review also reduce the treatment cost to the patients that may arise as a result of preventable medication errors. And more importantly these efforts will help gain patient trust and add on to patient satisfaction.

I. INTRODUCTION

Medication review is "a structured critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimizing the impact of medicines, minimizing the number of medication related problem.

Principles of Medication Review:

- All patients should have a chance to raise questions and highlight problems about their medicines.
- The medication review seeks to improve or optimize impact of treatment for an individual patient
- The review is undertaken in a systematic and comprehensive way, by a competent person.
- Any changes resulting from the review are agreed with the patient.
- The review is documented in the patient's notes. The impact of any change is monitored.

Medication errors are defined as "errors in the process of ordering, dispensing, or administering a medication, regardless of whether an injury occurred or whether the potential for injury was present" Medication errors could occur at any stage of the medication management process, including prescription, transcription, preparation and administration. The Institute of Medicine estimates that, on average, hospitalized patients are subjected to at least one medication error per day(1). Medication errors are expensive and sometimes harmful to patients (2). The Institute of Medicine estimates that at least a quarter of all medication-related injuries are preventable, and recommends electronic prescribing(e-prescribing) through a computerized provider order entry (CPOE) system as one way to reduce medication errors and patient harm (3). Hospitals are affected by similar types of errors (4), yet there is substantial variability between hospitals in how medication error is prevented. Variability in health care practice poses a significant obstacle to system-wide improvements in medication safety. Inter-hospital variability increases complexity, therefore leading to possible increase in risk of error, makes comparisons between institutions difficult, impedes the sharing of solutions and contributes to duplication of effort. Medication errors represent the most common patient safety error (5).More than 40 percent of medication errors are believed to result from inadequate reconciliation in handoffs during admission, transfer, and discharge of patients (6).Of these errors, about 20 percent are believed to result in harm (7) (8). Medication reconciliation is a formal process for creating the most complete and accurate

list possible of a patient's current medications and comparing the list to those in the patient record or medication orders. Recognizing vulnerabilities for medication errors, numerous efforts are underway to encourage all health care providers and organizations to perform a medication reconciliation process at various patient care transitions. The intent is to avoid errors of omission, duplication, incorrect doses or timing, and adverse drug-drug or drug-disease interactions. The Joint Commission added medication reconciliation across the care continuum as a National Patient Safety Goal in 2005 (9) .The Institute for Healthcare Improvement (IHI) has medication reconciliation as part of its 100,000 Lives Campaign.

The Joint Commission's standards for Medication Management (MM) are among the most rigorous and challenging for an organization to implement. To prepare a hospital for compliance, all stages of the medication use process — selection, storage, ordering, dispensing, administration, and monitoring — must be appropriately integrated into a comprehensive medication management system. If a Joint Commission survey finds that a hospital is not in compliance with a standard, the hospital receives a Requirement for Improvement (RFI). To avoid losing Joint Commission accreditation, the hospital must immediately address any RFI and submit evidence of standard compliance within 45 days.

A 2007survey (9) showed that hospitals were most likely to receive an RFI because of non-compliance with MM standards in three areas: medication storage, medication orders, and pharmacist review of orders. These are likely to remain areas of concern for the Joint Commission and should be given particular attention. Medication storage is associated with the highest percentage of RFIs.

Joint Commission standards for medication orders are among the top-10 most challenging standards, and compliance is mandatory for Joint Commission accreditation. Because surveyors use a tracer method of observation, orders are readily available for criticism. The 12 elements of performance for this standard require completeness, legibility, clear intent, and listing of special precautions when medications are ordered.

A complete order includes the patient's name, medication name, strength, route, rate, and dosing frequency. Some hospitals require that orders include a written indication for use; however, each organization is responsible for defining what constitutes a complete order. A hospital must also establish a process for clarifying orders that are incomplete, illegible, or otherwise unclear. Legibility can be enhanced with pre-printed orders. Clear intent implies the inclusion of the indication for use, precise instructions for PRN specifications, range, titrating or tapering, and requirements for resuming therapy.

Special precautions are required for verbal, telephone, and pediatric weight-based orders, and orders for LASA drugs. Verbal orders must be authenticated within a prescribed time-frame (designated by the institution within state regulations), and staff members who are authorized to accept verbal orders must be clearly identified. Pediatric orders must be carefully written, especially for medications requiring weight-based dosing and calculations. Surveyors place particular emphasis on LASA medications, and each institution is responsible for developing a list of such drugs in the facility. The Joint Commission focus list can help in compiling such a list, and drugs associated with sentinel events or adverse outcomes should also be included.

The entire staff must understand the elements of the medication ordering standard. A policy for incomplete orders must be established and implemented. All orders must be complete, legible, and have clear intent for both indication and distribution of the drug. All pre-printed orders must be complete, and precautions for LASA medications must be clearly identified.

This Medication Management and use standard requires that all medication orders be evaluated by a pharmacist prior to administration of the first dose. The five Elements of Performance require that all orders are reviewed for appropriateness, interactions, complicating allergies, and contraindications before administration. Ensuring compliance with this standard involves not only pharmacists but also physicians, nurses, and other staff throughout the hospital.

In some instances, reviews must occur in a pharmacist's absence. For this reason, the Joint Commission allows two exceptions to this standard. First, a licensed, independent practitioner (LIP) can take responsibility for the medication-use process. The scope of an LIP's responsibilities must be clearly

defined. Second, in an urgent situation such as a cardiac arrest, when the benefit to the patient clearly outweighs potential risks, a patient may receive drugs prior to pharmacist review.

For institutions lacking 24/7 pharmacy coverage, the hospital must establish processes for order review and for obtaining medications. Reviews may be performed by an offsite company or by another hospital. When the pharmacy re-opens, retrospective order reviews must be performed.

Special precautions are required for verbal, telephone, and pediatric weight-based orders, and orders for LASA drugs. Verbal orders must be authenticated within a prescribed time-frame (designated by the institution within state regulations), and staff members who are authorized to accept verbal orders must be clearly identified. Pediatric orders must be carefully written, especially for medications requiring weight-based dosing and calculations. Surveyors place particular emphasis on LASA medications, and each institution is responsible for developing a list of such drugs in the facility. The Joint Commission focus list can help in compiling such a list, and drugs associated with sentinel events or adverse outcomes should also be included.

As per JCI standard 5.1 (Medication Management and Use). (10) The licensed pharmacist, technician, or trained professional reviews each prescription or order, newly prescribed or ordered, for appropriateness or when the dosage or other appropriateness factors change. The organization defines what patient-specific information is required for the effective review of the order or prescription. This occurs prior to dispensing or prior to administration when medications are dispensed from locations other than the pharmacy. When questions arise, the individual who prescribed or ordered the medication is contacted. The process to review an order or prescription prior to dispensing includes evaluation by a trained professional of the appropriateness of the drug, dose, frequency, and route of administration, therapeutic duplication, real or potential allergies or sensitivities, real or potential interactions between the medication and other medications or food, variation from organization criteria for use, patient's weight and other physiological information and other contraindications. Those who review medication orders or prescriptions are competent to do so by virtue of education and training, as specified by privileging, or have demonstrated competency in the review process. In addition, the review for appropriateness may not be necessary or appropriate in an emergency or when the ordering physician is present for ordering, administering, and monitoring of the patient (for example the emergency department), or in interventional radiology or diagnostic imaging where the medication is part of the procedure. To facilitate review, there is a record (profile) for all medication administered to a patient except emergency medications and those administered as part of a procedure. When computer software programs are used to cross-check drug/drug interactions and drug allergies, the soft-ware is updated on an appropriate schedule.

Measurable Elements of Medication Management and Use (MMU)5.1

The organization defines the patient-specific information required for an effective review process.

1. Apart from exceptions identified in the intent, each prescription or order is reviewed for appropriateness prior to dispensing and administration
2. There is a process to contact the individual who prescribed or ordered the medication when questions arise.
3. Individuals permitted to review orders or prescriptions are judged competent to do so.
4. Review is facilitated by a record (profile) for all patients receiving medications.
5. Computer software, when used to cross-check drugs for drug/drug interactions and allergies, is periodically updated.

NABH also have guidelines to ensure medication safety. In Chapter 3 (Management of medicine) of NABH guidelines (11) MOM 4 states that documented policies and procedures guide the safe and rational prescription of medications. This standard further has various objective elements which emphasizes on norms for prescription writing. The various objective elements are as follows:

a. Documented policies and procedures exist for prescription of medications.
b. The organization determines the minimum requirements of a prescription.
   This shall adhere to national/international guidelines where appropriate. At a

minimum, the prescription shall have the name of the patient; unique hospital number; name of the drug, dose, route and frequency of administration of the medicine; name, signature and registration number of the prescribing doctor.

c. Known drug allergies are ascertained before prescribing.
It is a good practice to document drug allergies in a prominent manner in the medical record, both in OP and IP.

d. The organization determines who can write orders.
This shall be done by a doctor who at a minimum holds a MBBS qualification. The orders written by the treating doctor on the case sheet could be transcribed by another person onto the indent slip (physical/electronic). However, to avoid transcription errors, which can lead to medication errors, it is better to avoid this practice.

e. Medication orders are clear, legible, dated, timed**,** named and signed.
Only approved international abbreviations shall be used. Dangerous abbreviations shall not be used. The organization can explore the possibility of writing orders in block letters so that the issue of legibility is addressed.

f. Medication orders contain the name of the medicine, route of administration, dose to be administered and frequency/time of administration. In case of a medicine having two or more drugs (tablet/ capsule/ injection) the dose of all the individual drugs shall be written. For example, in a combination of Clopidogrel with Aspirin the dose of both the drugs shall be written as 75 mg + 75 mg or as 75 mg + 150 mg.
This is not necessary for preparations having a combination of vitamins and/or minerals. Similarly, if the combination of medication comes only in one strength, it is not necessary. In case abbreviations are used, a standardized list of approved abbreviations for medications shall be used throughout the organization.

g. Audit of medication orders/prescription is carried out to check for safe and rational prescription of medications. The scope of the audit shall include:

i. the appropriateness of the drug, dose, frequency, and route of administration;
ii. presence of therapeutic duplication;
iii. possibility of drug interaction and measures taken to avoid the same;
iv. possibility of food-drug interaction and measures taken to avoid the same;
v. requirements of this standard
This shall be done at least once a month using a representative sample size.
It could preferably be done by a clinical pharmacist. In case there is no clinical pharmacist it shall be done by the multidisciplinary committee.

II. METHODOLOGY

This study is an Interventional Study and Non-Probability Sampling method and Convenient Sampling types is used to conduct the study in the inpatient department of a private 250 bedded multispecialty hospital in India. The duration of study is 3 months.

The study tool used was Audit checklist. Prescription order of a particular date of all the patients of internal medicine (excluding ICU) during the study phase duration.

The Sample size was 40 % of the total population. 34 prescription orders were audited. Prescription order of a particular date was considered as a single opportunity and was considered as the basic unit for the study.

The over all objective of the study is to learn prescription review by the consultants in the In-patient department of Hospital, Internal medicine departments were taken for study. The specific objectives of the study are to carry out baseline study before the introduction of intervention (prescription review by the consultants), To calculate the percentage compliance to prescription review by the consultants and to find out the relationship between the prescription review and errors in prescription writing.

III. DISCUSSION AND RESULTS

The study was carried out in three phases.

1. First Phase: The first phase of the study was a baseline study for which only observation was done, no counseling or training were conducted.
2. Second Phase: The second phase of the study was preparation for training and conducting training of the stakeholders including resident doctors, Nurses.
3. Third Phase: During this phase of the study the active medical record files were audited for compliance to the prescription review and simultaneously the same files were also audited with the same check list that was used in the baseline study.

A. First Phase:

The data was collected from active patient records of the patients in the internal medicine on the audit checklist. The audit tool had total of 15 parameters out of which 10 parameters were audited from MAR sheet (Medication order and Administration Record) and another 5 parameters were audited from progress note. The MAR sheet was filled by the residents and the progress notes was filled by was filled by the consultants. The audits were done daily for two weeks after the morning rounds by the consultants were over and the residents have transcribed the medicines on the MAR sheet. Hence the data was collected prospectively. Audit parameters for the MAR sheet are Allergies mentioned, Date mentioned, Time mentioned, Drug name (capital), Legibility, Dosage form mentioned, Dose mentioned, Route mentioned, Frequency mentioned, Signature.

The Audit parameters for Progress notes are Drug name (legibility), Dosage form mentioned, Dose mentioned Frequency mentioned, Prescription reviewed by consultant (this parameter was used only for the compliance audits not for the baseline audit)

Levels of Medication Review: There are three levels of medication reviews.

Level 1: Prescription Review - It is a technical review of the list of a patient's medicines. It addresses issues relating to the prescription or medicines; the patient does not need to be present, nor access to full notes.

Level 2: Treatment Review - a review of medicines with the patient's full notes

Level 3: Clinical Medication Review - It is a face-to-face review of medicines and conditions. It addresses issues relating to the patient's use of medicines in the context of their clinical condition. The face-to-face element was deemed important because patients' views about their medication will influence whether they take their medicines and non-compliance can cause ill health and cost.

The flowchart shown in figure 1 shows the current flow in In-patient department of Internal Medicine in the hospital which was followed

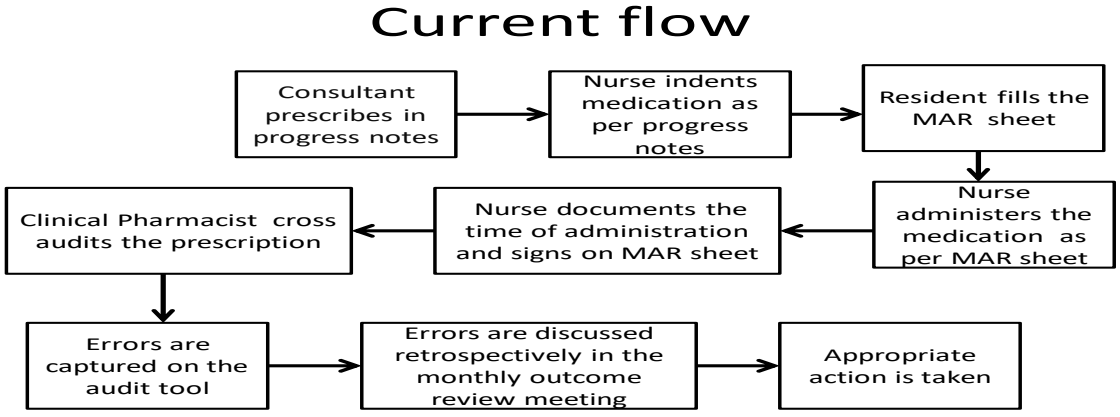

Figure 1: Current process flow in In-patient department of Internal Medicine

The following figure 2 illustrates the proposed process flow for the implementation of Prescription review by the consultants and the highlighted cells indicate the new steps that have been added to the current flow.

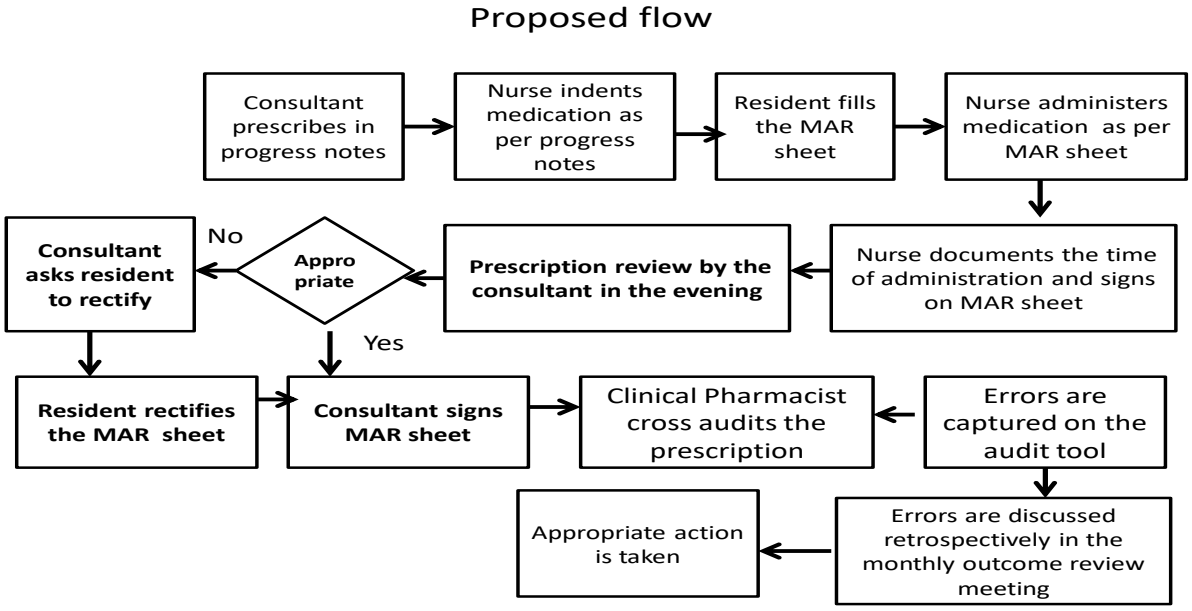

Figure 2: Proposed process flow for implementation of Prescription Review

B. Second Phase

The second phase of the study had two components

1. Preparation for training: The training modules were prepared for different stakeholders keeping in mind the training needs as well as the objective of the study. The training modules for the residents mainly focused on norms of prescription writing. The data on the errors captured during the baseline audit was also shared with them. Modules also explained about various standards in NABH and JCI related to medication safety. Apart from training they were encouraged to be the part of this quality initiative for better patient safety. The training module for the consultants mainly centered on how and when and how to do the prescription review and also about the documentation of the same. They were also made aware of the various parameters on which prescription review is to be carried out.
2. Training of the stakeholders: During this phase the intervention was introduced. All the stakeholders were sensitized about the need and importance of this new initiative.

Process of prescription Review

The consultants were trained primarily on the various parameters that are to be reviewed while carrying out the prescription review. The various parameters were:

- Appropriateness of the drug, dose, frequency, route of administration,
- Therapeutic duplication,
- Real or potential allergies or sensitivities,
- Real or potential interactions between the medications or food,
- Patient's weight
- Other physiological information and other contraindication.

The consultants were apprised that the prescription review is to be carried out during the evening rounds and incase of any discrepancy they could ask the residents to rectify it. After reviewing the prescription for the above-mentioned parameters consultants should sign the MAR sheet.

The training of the residents concentrated on various norms for prescription writing and their role in facilitating prescription review by the consultants and getting compliance to this initiative. This new project was also brought to the notice of floor manager and coordinator and nursing staff as well to facilitate the entire project.

During the training session the training for three consultants, three senior residents and five junior residents was provided.

C. Third Phase

During last phase of the study is the observation phase in which the active files were audited for compliance to the prescription review and simultaneously the same files were also audited with the same check list that was used in the baseline study. The files were audited in the morning for the signature of the consultant on the MAR sheet which was supposed to be done the preceding evening.

Data Interpretation and Analysis

This data was collected without any training or sensitization. The result of the baseline audit showed 100 percent compliance to the audit parameters for the progress notes where the prescription was written by the consultants. Whereas the parameters on the Medication orders and Administration Record sheet showed the following results which were transcribed by the residents

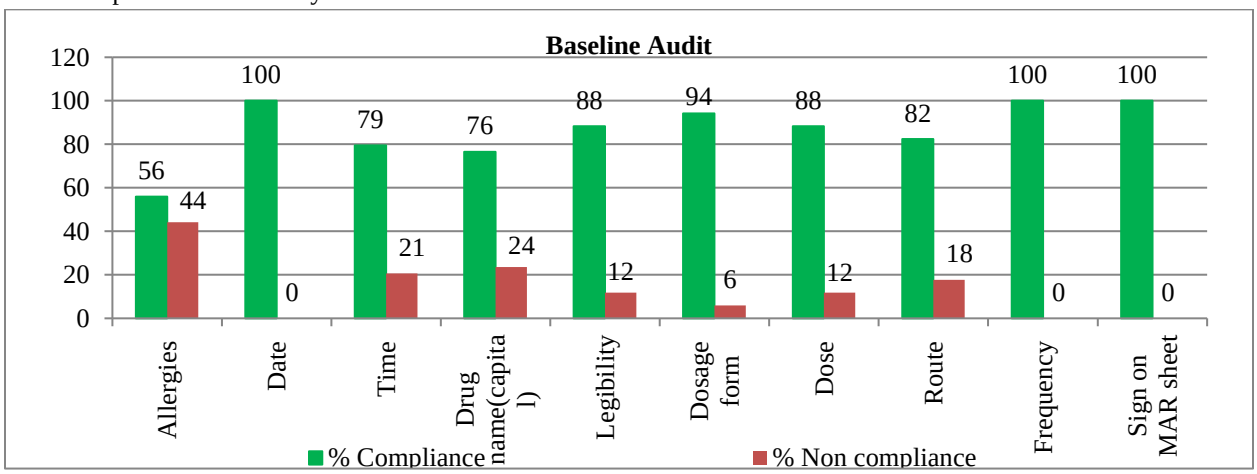

Figure 3: Findings of Baseline Audit

- As evident from the graph in figure 2 allergies were not mentioned in 44% of the total prescription orders that were audited.
- All the prescriptions were dated, signed by the resident who filled them along with the frequency of the medicine that was prescribed.
- Dosage form (like capsule or tablet) and the route of the medicine prescribed were not mentioned in 6% and 18% of the total sample audited.
- In 79 % and 76 % of the cases time was mentioned and the name of the drug was written in capitals.
- Legibility and mention of dose of the medicine prescribed was a concern with 12% of the cases out of total sample audited

Compliance Audit

The Compliance audit data was collected after conducting training sessions of all the stakeholders. As was the case with the baseline audit there was 100 percent compliance for the parameters for the progress notes. The prescription in the progress notes was written by the consultants. The findings for the parameters on MAR sheet are as following.

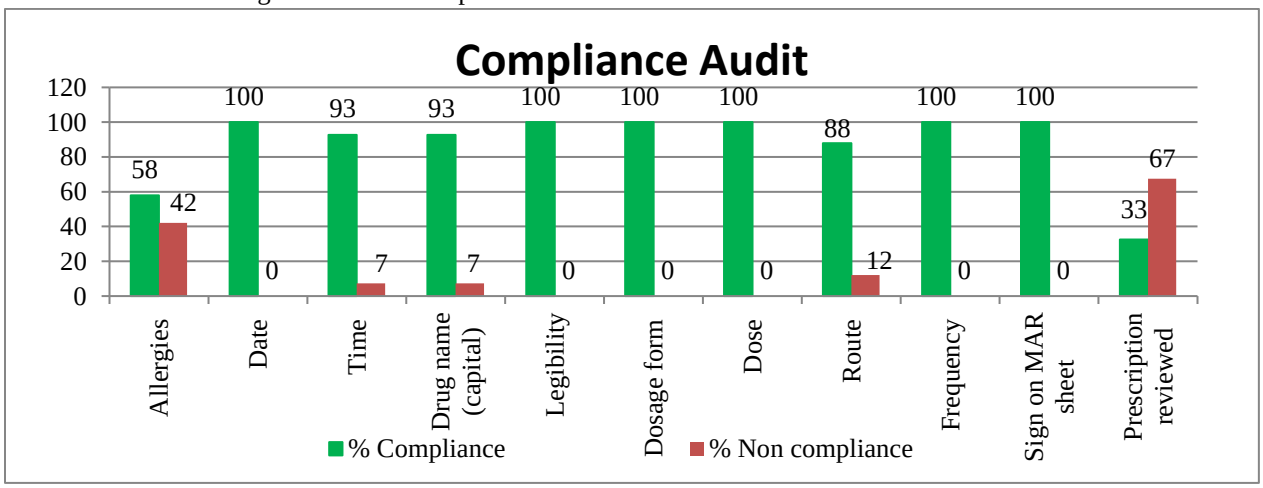

Figure 4: Findings of Compliance Audit

As apparent from the above graph in figure 3 there was 100 percent compliance for date, legibility, dosage form, dose, frequency and signature of residents on Medication order and Administration Record sheet. The Compliance to mention of Allergies and route of medication prescribed was 58% and 88% respectively. The compliance to time, drug name in capital was same that is 93% of the total sample audited. Most importantly the compliance to prescription review reached to 33% of the audited sample.

Comparison of baseline and Compliance Audit findings

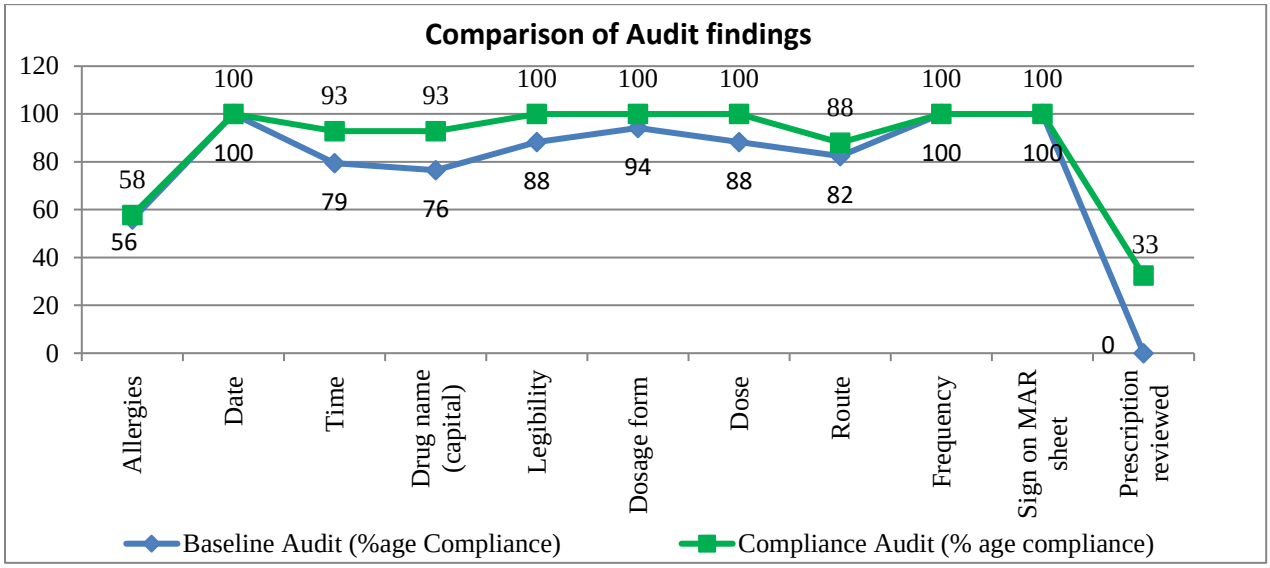

Figure 5: Comparison of Audit findings

The graph in figure 4 shows that all the parameters of audit has improved when we compared the audit results of baseline audit to that of the compliance audit. The compliance to mention of time and drug name in capital on MAR sheet increased by 14% and 17% respectively. The compliance to mentioning of date, frequency of medicines prescribed and sign of residents on the MAR sheet remained 100% in both the audits. There compliance of Legibility, dosage form and dose reached 100% showing an increase of 12%, 6% and 12% respectively.

- Prescription review by the consultants reached to 32% of the total sample audited.

EFFECT OF PRESCRIPTION REVIEW ON ERRORS IN PRESCRIPTION WRITING

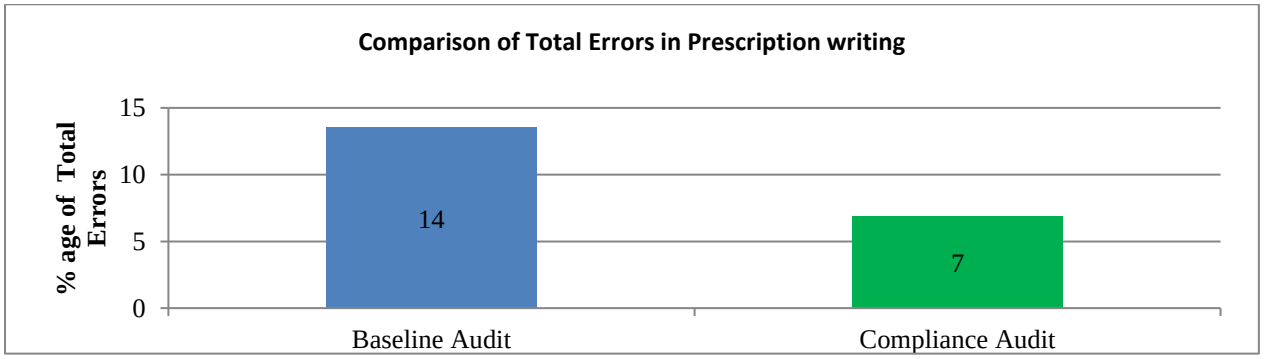

Figure 6: Comparison of Total Errors percentage in prescription writing

The graph in figure 6 shows that when we compared the errors in the base line and the compliance audit it can be concluded that with the implementation of prescription review total error percentage reduced to half. The total error entails all the types of errors made by the residents while writing on the medication order and Administration Record sheet. Another important noteworthy finding was that no error was found on the five parameters which were used to audit the progress notes. That prescription in the progress notes was written by the consultants.

Implementation of Prescription Review

Date	Number of Errors	Number of Prescriptions audited	Opportunities for errors (10 per audited prescription)	% age Errors	Number of Prescriptions reviewed	Cumulative number of prescriptions reviewed	Number of Prescriptions audited	%age of Prescriptions reviewed	Cumulative number of prescriptions audited	%age of Cumulative Prescription reviewed
7-Apr-24	8	6	60	13	1	1	6	17	6	17
8-Apr-24	4	4	40	10	1	2	4	25	10	20
9-Apr-24	4	5	50	8	1	3	5	20	15	20
10-Apr-24	2	3	30	7	1	4	3	33	18	22
11-Apr-24	4	5	50	8	1	5	5	20	23	22
12-Apr-24	5	5	50	10	1	6	5	20	28	21
13-Apr-24	7	5	50	14	1	7	5	20	33	21
14-Apr-24	2	2	20	10	1	8	2	50	35	23
15-Apr-24	0	2	20	0	1	9	2	50	37	24
16-Apr-24	7	7	70	10	2	11	7	29	44	25
17-Apr-24	0	3	30	0	1	12	3	33	47	26
18-Apr-24	1	2	20	5	1	13	2	50	49	27
19-Apr-24	4	5	50	8	3	16	5	60	54	30
20-Apr-24	1	5	50	2	2	18	5	40	59	31
21-Apr-24	2	5	50	4	1	19	5	20	64	30
22-Apr-24	2	4	40	5	1	20	4	25	68	29
23-Apr-24	2	8	80	3	4	24	8	50	76	32
24-Apr-24	2	7	70	3	3	27	7	43	83	33

Table 1: Summary of implementation of prescription Review by the consultants

COMPLIANCE TO PRESCRIPTION REVIEW

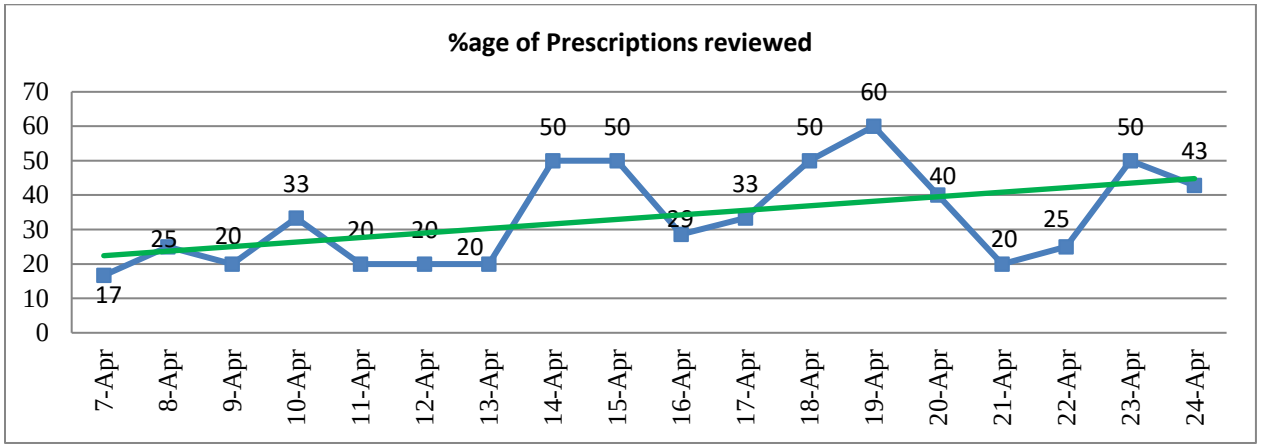

Figure 7: Trend showing compliance to prescription review

The above graph presents the compliance to prescription Review by the consultants in the form of percentage of prescription reviewed on each date as mentioned in graph. A trend line is added which shows an increasing trend of compliance to prescription reviewed.

Trend of Prescription Review Compliance Percentage and Total Error Percentage

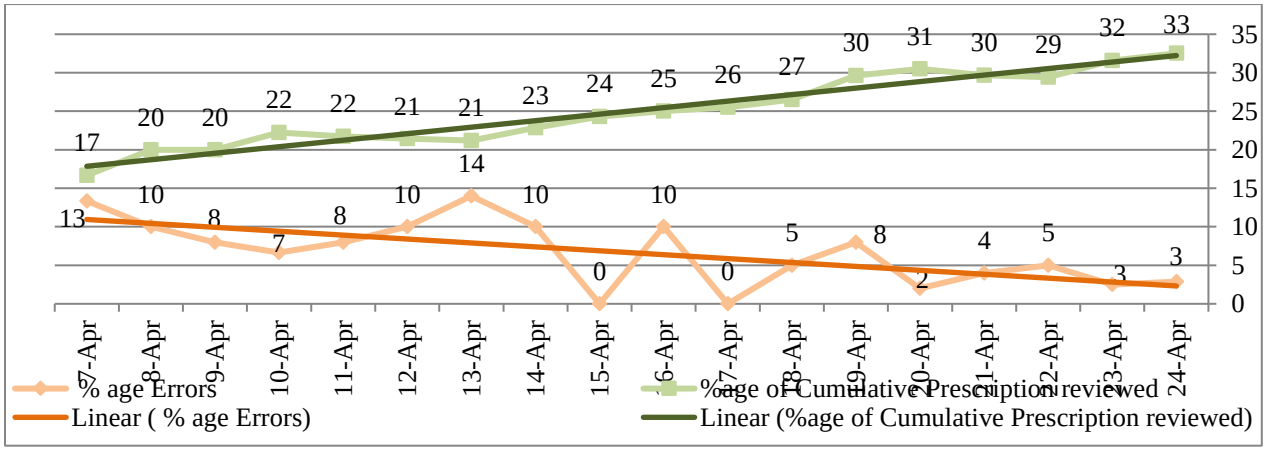

Figure 8: Trend of Prescription review compliance percentage and Total errors percentage

The above graph depicts the trend of Prescription review compliance percentage and Total errors percentage.

Relationship between Percentage compliance to prescription review & Total Error Percentage

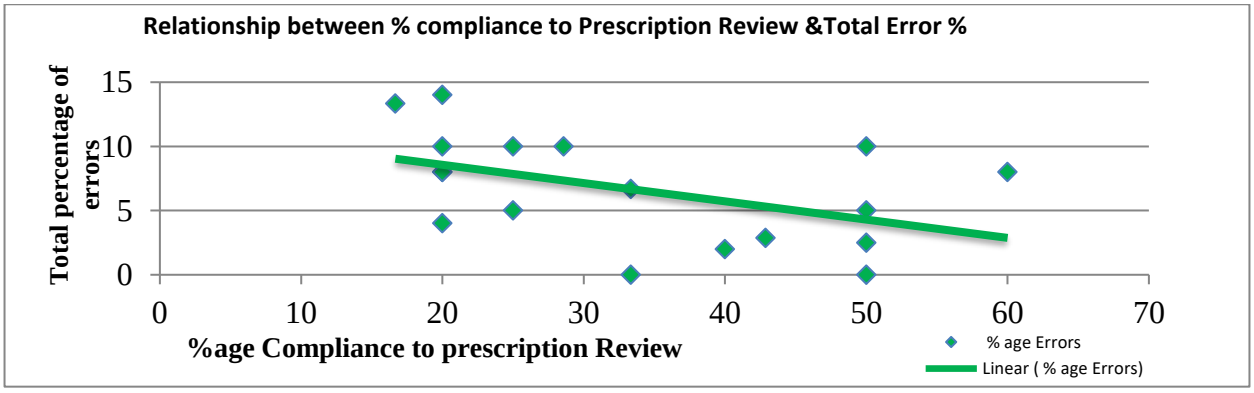

Figure 9: Relationship between % compliance to Prescription Review & Total Error %age

To see the relationship between Total percentage Error and Percentage Compliance to Prescription Review Correlation Coefficient was calculated which came out to be -0.456 which implies that the two variables have strong negative correlation. So, this can be concluded that with increase in prescription Review compliance percentage the total error percentage decreases. The p value is 0.057 which implies that the relation is significant.

III. SUGGESTIONS

To document the concerns of the consultants while prescription review existing MAR sheet was edited. The edited version of the MAR sheet had space to document the concerns of the consultants while reviewing the prescription. The use of this edited MAR sheet should be initiated which will also ensure increased compliance by addressing the concerns of the consultants regarding the appropriateness of the prescriptions.

Proper documentation of the prescription review process will ensure sustainability of prescription review in long run. Unannounced audits can be done to check the compliance after sufficient time has passed after initiation of this project in a particular department.

A separate quality indicator could be created or be integrated with medication errors and data on which should be collected department wise and discussed in monthly meetings of quality. The data gathered on this indicator could be compared across various departments. This could be done after starting Prescription Review in other departments also. The Hospital Information system (HIS) software should be doctoring friendly and proper training should be given to all staff. The use of Hospital Information system will reduce medications errors while transcribing and this will also help doctors to enter notes while they are in their consultation room. HIS with integrated software to detect drug- drug, drug-food interaction could ease out the process of prescription.

IV. CHALLENGES

There was reluctance of the concerned stakeholders to participate in the process of prescription review. The major challenge of the study was to convince the consultants for prescription review. The documentation of the prescription review process there were instances where prescription was reviewed the but forgot to sign the Medication order and Administration record sheet.

V. Limitations of the study

The prescription review carried out by the consultants is on various parameters but on the Medication order and Administration record sheet which was used in the department only signature could be documented there was no specified place for it. For the compliance phase of the study same Medication order and Administration record sheet same sheet was used therefore whether all the elements of prescription review were objectively reviewed or not was not documented. Prescription review should ideally be done by the clinical pharmacologist but there was only one clinical pharmacologist therefore consultants were counseled to do the prescription review.

REFERENCES

[1] Aspden P, Wolcott J, Bootman J, et al. Preventing medication errors. Washington, DC : National Academy press, 2007.

[2] Bates DW, Spell N, Cullen DJ, et al. 1997. The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group.

[3] Crossing the quality chasm:A new health system for 21st Centuary. America., Committee on Quality of Health Care in. s.l. : Institute of Medicine, 2001.

[4] Beyond Blame: Exploring practical approaches to the control of adverse . O'Callaghan C, Thomson B, Brown R, et al. s.l. : Victorian Drug Usage Advisory Committee, , 2002.

[5] Patient safety standardization as a mechanism to improve safety in health care. Jt Comm J Qual Saf. Rozich JD, Howard RJ, Justeson JM, et al. 2004 : s.n.

[6] Rozich JD, Howard RJ, Justeson JM, et al. Patient safety standardization as a mechanism to improve safety in health care. 2004.

[7] Gleason KM, Groszek JM, Sullivan C, et al. 2004. Reconciliation of discrepancies in medication histories and admission orders of newly hospitalized patients. Am J Health Syst Pharm.
[8] Goals., JCAHO. National Patient Safety. 2005.
[9] Maintaining Compliance with Joint Commission Medication Management Standards. By Patricia Kienle, RPh, MPA, FASHP. 2007.
[10] Joint Commission International Standards.
[11] NABH . Vol. 3 rd edition.