

Medication reconciliation as a strategy for preventing medication discrepancies in a tertiary care teaching hospital in south Kerala: A cross sectional observational study

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Abstract

Background: Medication reconciliation is a major component of patient safe care. An average hospitalized patient’s medication will have atleast one medication error. Among these errors 1% of errors are occurring due to inadequate medication reconciliation program. Thus through a proper medication reconciliation process these errors can be averted.

Aim and objectives: The aim of the study is to assess the medication reconciliation related medication discrepancies in a tertiary care teaching hospital setting with the help of medication reconciliation form. The objectives of the study are to assess the effectiveness of the medication reconciliation as a tool in the prevention of medication related discrepancies, to determine the most frequent types of medication reconciliation errors,

to identify the most common therapeutic groups related to reconciliation errors, to identify the most common age groups of patient related to reconciliation errors and to assess and rate the severity of medication discrepancies.

Methods: This was a cross-sectional observational study conducted in the departments of General medicine, Endocrinology, Rheumatology, General surgery, Cardiology and Nephrology in a tertiary care teaching hospital South Kerala. We took the medication history of the patients in the above mentioned departments and compared with the medication orders at hospital admission and any identified discrepancies were noted and analyzed for reconciliation errors. Univariate and bivariate analysis was used in this study.

Results: Out of 277 samples, 77 medication discrepancies were identified among study participants, with a percentage of 27.8% which is found to be highly significant ($p=0.001$). Due to lack of human resources, hospitals are struggling in the implementation of a medication reconciliation process across all levels and intensities of care. Staffing of clinical pharmacists can be valuable in performing structured medication reconciliations to prevent unintentional discrepancies at admission and reduce the risk of medication errors.

Keywords: Medication reconciliation, Medication discrepancies, Inpatients, Univariate and bivariate analysis, South Kerala.

Introduction

Several international patient safety organizations such as the World Health Organization (WHO), the Joint Commission International (JCI), and Institute for Health Care Improvement (IHI) acknowledged medication reconciliation as an important process to improve patient safety by identifying unintentional medication discrepancies at transitions of care points[1]. Medication reconciliation is the process of comparing patient's medication orders to all the medications that the patient has been taking. This reconciliation is done to avoid medication related discrepancies such as omissions, duplications, dosing errors, frequency errors, drug allergies and drug interaction. The continuity medicines information when moving from one care sector to another is medication reconciliation - the process of creating the most accurate list of medications at transition points. This takes place in three stages:

A list of medications the patient was using before transfer is developed.

The medication and dosage is checked against the new list – with a view to identifying any

discrepancies or differences. Discrepancies are determined to be intentional or not, with unintentional discrepancies changed as appropriate and intentional discrepancies documented.

Finally, this comprehensive new list and information regarding changes is communicated to the next healthcare provider.

According to the Institute of Medicine's Preventing Medication Error report, the average hospitalized patient is subject to at least one medication error per day. The medication errors represent the most common patient safety error and is the major cause of morbidity and mortality in the medical profession. More than 40 percent of medication errors are believed to result from inadequate reconciliation in handoffs during admission, transfer, discharge of patients. Many of these errors would be averted if medication reconciliation process were in place. Several lines of evidence suggest that many inpatient medication errors occur at care transition points[2]. A medication error can be defined as any error that occurs within the medication use process. The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP, 2014) describes it as –any incident, which can be prevented, which can cause harm to the patient or lead to inappropriate use of drugs, when they are beyond the control of the health professionals, the patient or the consumer. Due to lack of human resources, hospitals are struggling in the implementation of a medication reconciliation process across all levels and intensities of care. There is a need to develop strategies that target a greater number of patients vulnerable to medication reconciliation error with the utilization of available resources in an efficient manner. This selection can be made based on various

criteria such as availability of the services, involved patients or patients having certain characteristics that make them more susceptible to medication reconciliation error [12].

Methods

Definition and Classification of Medication Discrepancy, Reconciliation Error and Medication Error

A medication discrepancy is defined as any difference between medications taken by a patient prior to admission and medications ordered upon admission to the hospital. Reconciliation discrepancies were divided into two main categories: intentional discrepancies and unintentional discrepancies. Differences that were

considered as to be discrepancies are shown in Table1. Any unexplained variances between what was recorded as prescribed in admission orders and what medications were taken by a patient were considered to be unintentional medication discrepancies and were recorded as a reconciliation error. An incorrect dosing frequency that did which does not change the total daily dose of a medication was not considered to be discrepancy. The omission of drugs with long dosing frequency, eg: once monthly, were also not considered to be discrepancies. Reconciliation errors that are resulted in a change in medication order were considered to be medication error.

Types of Medication Discrepancies at the Time of Hospital Admission

Intended Medication Discrepancies	Unintended Medication Discrepancies
<ul style="list-style-type: none"> • Start of medication or modification of dosage justified by new clinical status of the patient. • Medical decision not to prescribe a medicine or to change its dose, frequency or route of administration. • Formulary/therapeutic substitution according to hospital policy. 	<ul style="list-style-type: none"> • Error of omission (untreated indication, failure to receive prescribed drug). • Modification of dose, frequency, and route of administration. • Incorrect drug. • Drug use without indication. • Therapeutic duplication. • Drug interaction.

Potential Harm Assessment of Medication Errors

NCC MERP Classification

National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Table 1, which assess and rates the potential harm to the patient. NCC MERP criteria were divided into three categories:

- 1) No error (NCC MERP Category A)
- 2) Error that did not reach the patient (NCC MERP Category B)
- 3) No potential harm (NCC MERP Category C)

- 4) Monitoring or intervention potentially required to preclude harm (NCC MERP Category D)
- 5) Potential harm (NCC MERP Categories E and above).

Ratings of medication errors for their potential harms were rated by two study pharmacists, followed by blind, independent review by consultant physician. Inter-rater reliability of harm ratings for three categories of error groups was also analyzed. There was

a substantial agreement rate between pharmacist and physician ratings [12].

PCNE Classification

During the working conference of the Pharmaceutical Care Network Europe in January 1999, a classification scheme was constructed for drug related problems (DRPs). The classification is part of a total set of instruments. The set consists of the classification scheme, reporting forms and cases for training or validation. The classification system is validated and adapted regularly. The current version is V8, which has been developed during an expert workshop in February 2016 and a subsequent specialist meeting in April 2017. It is no longer compatible with previous versions because a number of major sections have been revised. In V 8.01, a necessary code C3.5 (which had dropped out) is re- added.

ATC Classification

In the Anatomical Therapeutic Chemical (ATC) classification system, the active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.

Drugs are classified in groups at five different levels.

ATC 1st level

The system has fourteen main anatomical or pharmacological groups (1st level). The ATC 1st levels are shown in the figure.

ATC 2nd level

Pharmacological or Therapeutic subgroup

ATC 3rd& 4th levels

Chemical, Pharmacological or Therapeutic subgroup

ATC 5th level

Chemical substance

The 2nd, 3rd and 4th levels are often used to identify pharmacological subgroups when that is considered

more appropriate than therapeutic or chemical subgroup[18].

Design and study population

This cross-sectional observational study was conducted in the patients from General medicine, Endocrinology, Rheumatology, General surgery, Cardiology and Nephrology department of NIMS Medicity, Neyyattinkara, Trivandrum, which is a tertiary care teaching hospital. The patients with past medical history and of more than twenty- four hours of hospital stay from General medicine, Endocrinology, Rheumatology, General surgery, Cardiology and Nephrology departments was included in this study. The study was conducted for 6 months and 277 patients were enrolled in this study. The sampling technique used here was non probability purposive sampling.

Inclusion criteria

- Patient with past medical history and of more than twenty-four hours of hospital stay.
- Patients more than 18 years.
- Patients in General medicine, Endocrinology, Rheumatology, General surgery, Cardiology and Nephrology department.
- Patients who are able or willing to provide written informed consent.
- Patients with one or more medicines at home.

Exclusion criteria

- Patients on herbal medicines and without any medication history.
- Pregnant, lactating women and psychiatric patients.
- Patients who are not in a condition to give interviews.
- Patients who get discharged, transferred to another unit or hospital or those expire within 24 h of admission.

Study variables

- Socio-demographic and clinical factors (age, gender, chronic disease).
- Administrative factors (a type of admission, person who takes history)
- Medication-related (therapeutic group of medicine).
- Reconciliation process related factors (source of information, duration of the interview to reconcile medication list).

Ethical considerations: Written informed consent was obtained, necessary permission and clearance for the study is obtained from the scientific and ethical committee conducted in NIMS Medicity, Neyyattinkara, Trivandrum, Kerala.

Budget: The entire expense for the study will be met by the principal investigators.

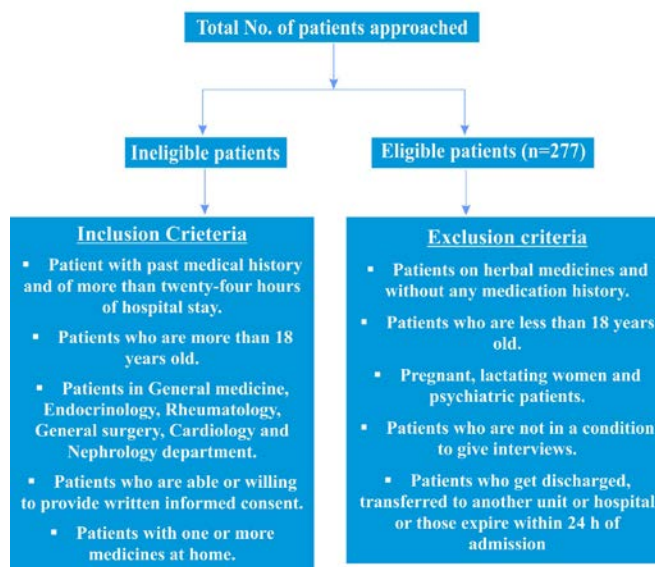
Dissemination: After the completion of research the study will be submitted to Ezhuthachan College of Pharmaceutical Sciences for project evaluation under Kerala University of Health Sciences, Thrissur.

Description of the tools used:

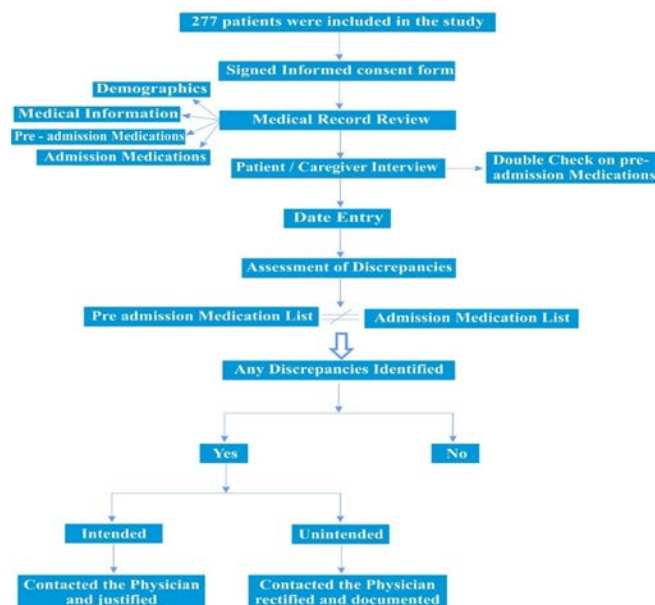
- Medication reconciliation form
- Pharmaceutical Care Network Europe (PCNE classification).
- National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP).
- Anatomical Therapeutic and Chemical Classification.

Data Collection And Analysis

PATIENT ENROLLEMENT IN THE STUDY



SCHEMATIC REPRESENTATION OF DATA COLLECTION



Result And Discussion

A total of 277 patients were enrolled in the study, from Department of General medicine, Endocrinology, Rheumatology, General surgery, Cardiology, Nephrology with past medical history of illness, medication intake and a minimum of 24 hours of hospital stay. Of the 277 participants, the mean age of participants was 59.85 (SD 12.47); with 149 patients

(53.8%) being male and 128 patients (46.2%) being female (Figure 1 & 2). A total of 77 medication discrepancies were identified among study participants, with a percentage of 27.8% which is found to be highly significant ($p=0.001$). Out of total discrepancies 63(81.81%) were unintended and 14(18.18%) were intended (Table 4 and Table 5).

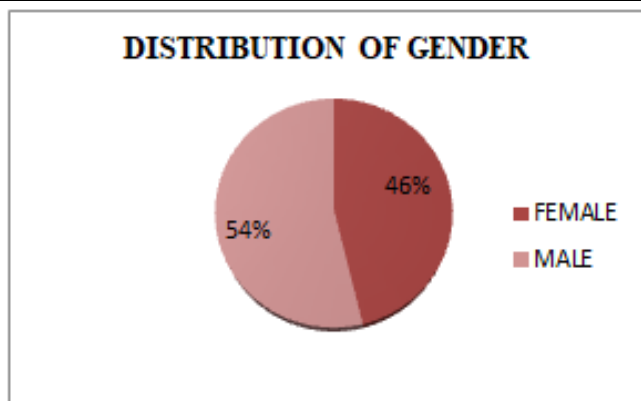
Of the 77 identified problem, interventions were reported and necessary actions were carried out. It was observed a 90% level of acceptance of the interventions. In the unintended discrepancies out of 63 (81.81%) errors, omission was the main (50.79 %) category of errors identified, followed by drug interaction (28.57 %), drug use without indication (1.58%) modification of dose frequency and route of administration (6.34%) and therapeutic duplication (11.11%).

Patient Demographics

Distribution of gender

Frequency and percentage distribution of samples according to sex (N= 277).

Sex	Number	Percentage
Female	128	46.2%
Male	149	53.8%



Pie chart representing distribution according to gender.

Distribution of discrepancies according to gender

Gender wise Distribution of Discrepancies (N=277).

Gender	Discrepancy	No Discrepancy	P-Value
Male	35(45.5%)	93 (46.7%)	0.893
Female	42(54.5%)	107 (53.57%)	

There is no significant difference between genders in terms of the occurrence of medication discrepancies. Out of 77 discrepancies male and female distribution has no significant difference ($p=0.893$). That means there is no relation between discrepancies and gender.

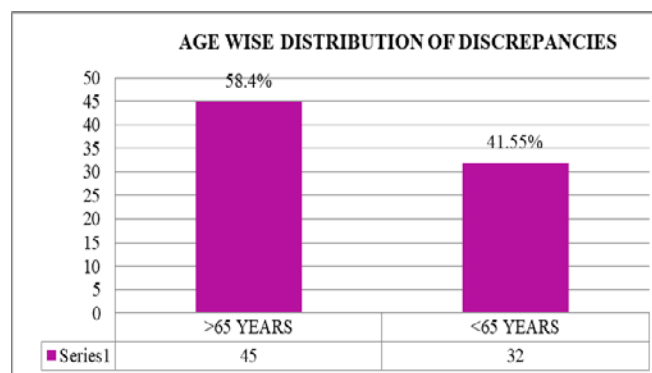
Distribution of Discrepancies according to age

Frequency and percentage, mean, and standard deviation of samples according to age in years.

Age In Year	Frequency	Percentage	Mean ± SD
>65 years	45	58.4%	59.85 ±12.47
<65 years	32	41.55%	

P value - 0.01399

Person's Chi square statistic- 6.04



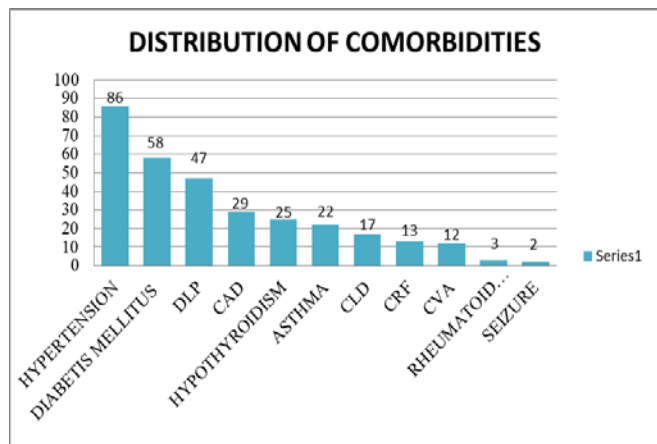
Bar diagram representing percentage distribution of samples according to age in years

Distribution of Number of medications

Frequency and percentage of sample according to number of medicines(N=277).

Number of Drugs	Frequency	Percentage
1-2 drugs	164	59.2%
3-4 drugs	39	14.07%
4-10drug	57	20.57%
>10 drugs	17	6.13%

Distribution of Comorbidities



Frequency of sample according to comorbidities (N=277)

Figure shows the distribution of comorbidities. The most frequent comorbidities were Hypertension (86), Diabetes mellitus (58) and Dyslipidemia (47).

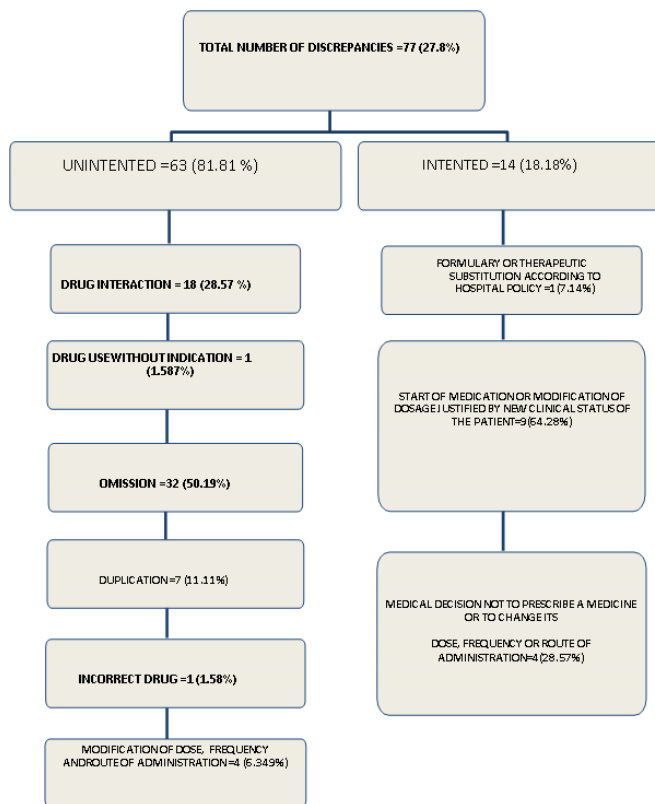
Mode of admission

Types of Admission among Discrepancies

Admission	No Discrepancies	Discrepancies	P-Value
ED	12(6.3%)	11(14.28%)	0.03
IP	188 (94%)	66(85.7%)	

Table shows that out of 77 discrepancies 85.7% are IP admissions and only 14.2% are ED admissions. There is a significant relation between the type of admission and any discrepancies. The p value is 0.03.

Medication Discrepancies

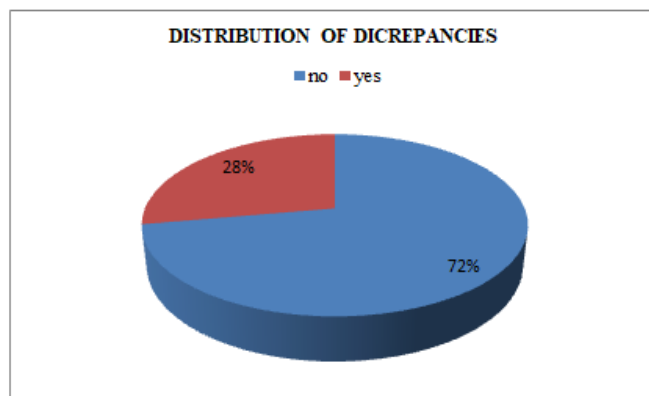


Types of Discrepancies

Distribution of Discrepancies

Frequency and percentage of distribution of discrepancies (N = 277).

Discrepancy	Frequency	Percentage	P-Value
Yes	77	27.79%	0.001
No	200	72.20%	



Distribution of Discrepancies

Out of 77 medication discrepancies were identified among study, with a percentage of 27.8%. The

proportion test reveal that this is highly significant (p=0.001).

Distribution of Discrepancies

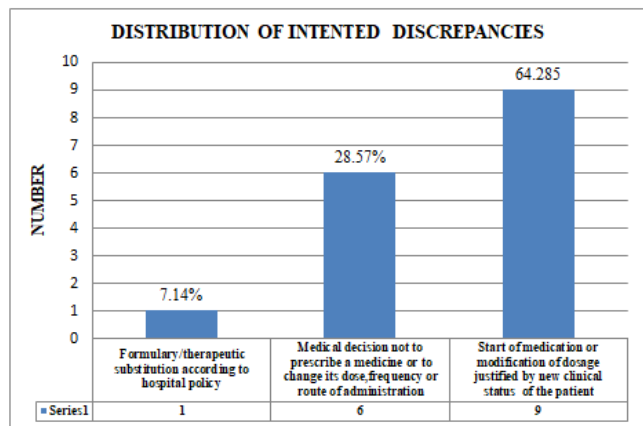
Frequency and percentage of distribution of discrepancies (N=77).

Type Of Discrepancy	Frequency	Percentage
Intended	14	18.18%
Unintended	63	81.81%

Distribution of Intended Discrepancies

Frequency and percentage of distribution of intended discrepancies (N=14).

Intended Discrepancies	Frequency	Number
Formulary/therapeutic substitution according to hospital policy	1	7.14%
Medical decision not to prescribe a medicine or to change its dose, frequency or route of administration	4	28.57%
Start of medication or modification of dosage justified by new clinical status of the patient	9	64.28%



Bar diagram representing distribution of intended discrepancies

Distribution of Unintended Discrepancies

Frequency and percentage of distribution of unintended discrepancies

(N=63).

UNINTENDED DISCREPANCIES	FREQUENCY	PERCENTAGE
Drug interaction	18	28.57%
Drug use without indication	1	1.58%
Error of omission (untreated indication, failure to receive prescribed drug)	32	50.79%
Incorrect drug	1	1.58%
Modification of dose, frequency, and route of administration	4	6.34%
Therapeutic duplication	7	11.11%

Bar diagram representing unintended discrepancies

Table 11 shows that among the intended discrepancies start of medication or modification of dosage justified by new clinical status of the patient was found to be the frequently occurring error (64.28%). Table 12 shows that omission error was the main (50.79%) followed by drug interaction (28.571%) and therapeutic duplication (11.11%) among unintended discrepancies.

Examples of Discrepancies Identified and Reported

Identified Problem	Type Of Error	Discrepancy Reported
The patient was on T. Nexito (Escitalopram) 10 mg 0-0-1 Before admission. On admission the patient was given both T. Zerodol (Aceclofenac) 1-0-1 and TAB. Nexito 10 mg 0-0-1.	Drug Interaction Aceclofenac + Escitalopram Concurrent use of Aceclofenac And Escitalopram increases the risk of GI bleeding.	Reported and TAB. Zerodol (Aceclofenac) was stopped.
The patient was on T. Rabeprazole 40 mg before admission. On admission patient was given both T. Pantoprazole 40 mg and TAB. Rabeprazole 40 mg.	Duplication Error	Reported and TAB. Rabeprazole was stopped on following days.
The patient was on TAB. Ecospirin (Aspirin) 75mg 0-0-1 before admission. The therapy was withheld during surgery and was not started after surgery.	Omission Error	Reported and T. Ecospirin (Aspirin) 75mg was continued.
The patient was on T. Cordarone (Amiodarone) 100mg before admission. On admission the patient was given both TAB. Ultracet (Tramadol + Acetaminophen) 0-0-1 and TAB cordarone (amiodarone)100mg.	Drug Interaction- Tramadol + Amiodarone increase the risk of respiratory depression.	Reported and TAB. Ultracet 1-0-1 is changed to TAB. Voveran SR 75mg 1-0-1
The patient was on T. Metformin 500mg 1-0-1 before admission. On admission the patient was not taking T. Metformin.	omission error	Reported and T. Metformin 500mg 1-0-1 was continued.
The patient was on TAB. Thyronorm (Levothyroxine) 100mcg 1-0-0 before admission. On admission the patient was not taking TAB. Thyronorm.	Omission Error	Reported and T. Thyronorm 100mcg 1-0-0 was continued.

Distribution of Discrepancies According ATC Classification

Frequency and percentage of distribution of discrepancies according to ATC classification (N=77).

Classification	Frequency	Percentage
A : Alimentary tract and Metabolism	6	7.79%
B : Blood and blood forming Organs	3	3.89%
C : Cardiovascular system	58	75.32%
H : Systemic hormonal preparations, excluding reproductive hormones and Insulin	4	5.19%
M : Musculoskeletal system	2	2.59%
N : Nervous system	2	2.59%
V : Various ATC structures	2	2.59%

Distribution of Discrepancies According ATC Classification

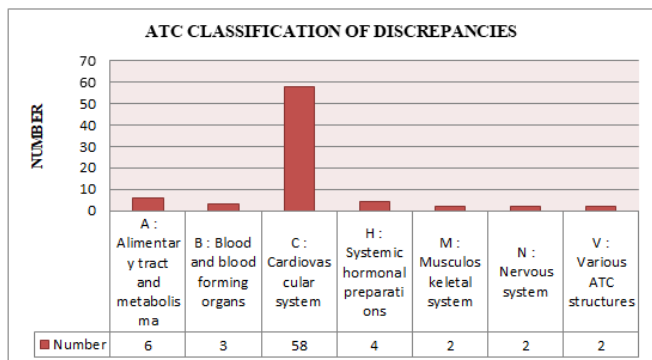


Figure shows ATC classification where patients with regimens consisting of cardiovascular drugs are more prone to reconciliation errors.

PCNE Classification for Drug Related Problems

Frequency and percentage of distribution of discrepancies according to PCNE classification (N=77).

Classification	Frequency	Percentage
Dispensing	1	1.2%
Prescribing	47	61.03%
Use	29	37.66%

Distribution of Discrepancies According to PCNE Classification

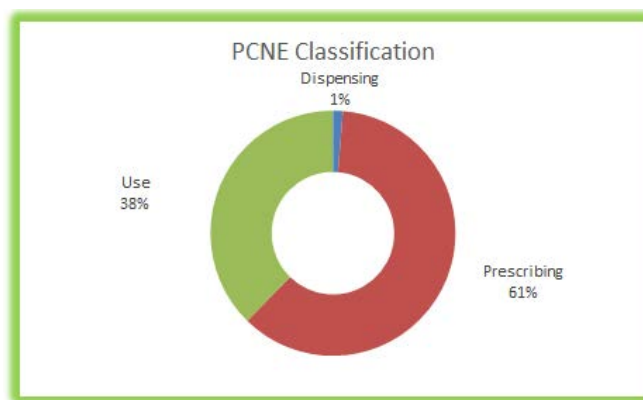
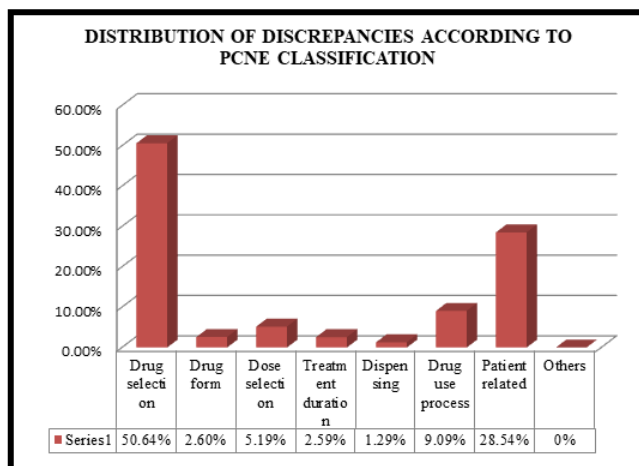


Table shows the PCNE classification for drug related problems. Among them prescribing errors are more (61.03%). The least occurring is dispensing errors (1.2%). Among these prescribing errors, error in drug selection was the common one (50.64%).

Distribution of Discrepancies in Each Classification

Frequency and percentage distribution of discrepancies in each classification of PCNE (n=77).

Classification	Sub-Classification	Frequency	Percentage
Prescribing	Drug selection	39	50.64%
	Drug form	2	2.597%
	Dose selection	4	5.194%
	Treatment duration	2	2.59%
Dispensing	Dispensing	1	1.29%
Use	Drug use Process	7	9.09%
	Patient Related	22	28.54%
	Others	0	0%



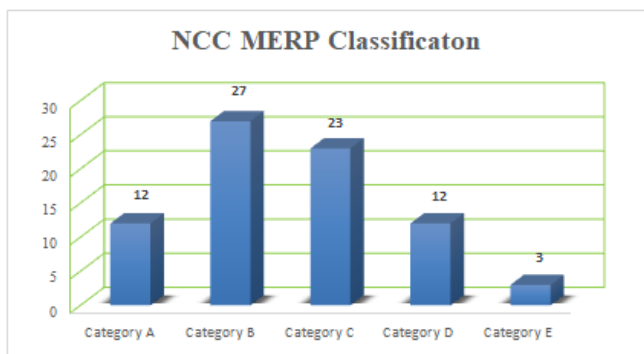
Distribution of Discrepancies in Each Classification

Medication Discrepancies According to NCC-MERP Classification

Frequency and percentage of medication discrepancies according to NCC-MERP classification (n=77).

Category	Frequency	Percentage
Category A	12	15.58 %
Category B	27	35.0a6 %
Category C	23	29.87 %
Category D	12	15.58 %
Category E	3	3.89 %

The table shows that according to NCCMERP Classification, the majority of the errors (35.06%) was classified as B category (the error occurs, but does not cause harm) followed by class C (the error reach the patient, but does not cause harm).



Medication Discrepancies According to NCC-MERP Classification

Among our study population of elderly patients, there was a high prevalence of medication reconciliation errors (57.1%). The important finding of the present study is that almost half of reconciliation errors may have had a negative clinical impact on the patients if they had remained undetected, however, the actual number of potentially harmful errors were relatively small (n=3,1.1%).

Like our findings, previous studies have reported that omission of a drug is the most common type of medication error at the time of hospital admission followed by modification of dose, frequency, and route of administration. We have found that 32 (50.79%) of

hospitalized patients have at least one drug omitted from their regimen. Doctors are known to have difficulty gaining an accurate medication history on admission to the hospital.

There are varying results from previous studies on predictors for errors in the medication history. We found that higher age (≥ 65 years), an increased number of preadmission drugs and patients on cardiovascular drug therapy are predictors of medication reconciliation errors(20,21,22).

Not all discrepancies are of equal value when it comes to the level of harm it may cause to the patient. Of the identified discrepancies, 3.89% were serious as they were associated with a potential harm/deterioration to the patient. Similarly, several previous studies conducted in Saudi Arabia and Canada found that most identified discrepancies had the potential to cause harm to the patient, being classified as serious (23). Studies conducted in Ireland and France classified most of the discrepancies as moderate or minor in seriousness (24). Hence, this potentially serious nature of most of the discrepancies necessitates the implementation of medication reconciliation services after patient admission to avoid patient harm.

Study limitations: Since medication histories were recorded by patient or caregivers interviews, the number of medication errors may have been underestimated in patients who were too ill and had no caregiver. Although we used multiple sources to reconcile medication history, however, histories recorded by patients and/or caregivers' interview may have been affected by recall bias. The classification of discrepancies into medication errors partly relies on subjective judgment by expert review of the medical record which is subject to bias and therefore we may have underestimated the number of medication errors.

High level of patients' misinformation about the medicines they use. Also, there were no prescriptions with them. So, patients' medication history quality can also be considered one of the study limitations. The presence of incomplete data due to the inadequate communication and lack of patients understanding regarding their treatment.

Conclusion and Recommendation

More than 40 percent of medication discrepancies are believed to result from inadequate reconciliation process during admission, transfer and discharge of patients. Reconciliation has the substantial potential to improve patient outcomes. Due to lack of human resources, hospitals are struggling in the implementation of a medication reconciliation process across all levels and intensities of care. Therefore, medication reconciliation on hospital admission, or at patient transition points is an important element to prevent and minimize the medication discrepancies.

The findings of the study highlight the need to identify these discrepancies in hospital setting, and support the necessity for implementing the medication reconciliation service in the country, engaging pharmacists and other healthcare providers in the process of identification and resolution of medication discrepancies. Staffing of clinical pharmacists can be valuable in performing structured medication reconciliations to prevent unintentional discrepancies at admission and reduce the risk of medication errors. Collaboration with nurses, physicians, and other health care providers on medication reconciliation is also vital. So the study reveals the impact of a pharmacist-directed medication reconciliation service on reducing the number of medication discrepancies at the time of hospital admission.

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