Original Article

Drug Related Problems Identified by Clinical Pharmacist in a Tertiary Care Hospital in South India: An Observational Study

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ABSTRACT

Introduction: Drug related problems (DRP) negatively impact the quality of life of the patient and increase the burden of illnesses in terms of economic and social factors. In order to reduce medication errors, adverse reactions, and length of stay, pharmacy services must identify and classify potential DRPs. The goals of this study are thus to identify DRPs by reviewing medical orders (MOs) given to each patient, and to analyses DRPs using PCNE classification. **Materials and Methods:** This study was conducted in eight medical wards in a multispeciality hospital using prospective observational cohort research. Pharmaceutical Care Network Europe's version 9.1 classification system (version 9.1) was used to identify and classify potential DRPs based on the patients' medical orders. **Results:** A total of 394 patients were admitted to the hospital wards for treatment of a variety of clinical conditions during the study period. From the total cohort, 190 (48%) medical orders were detected with DRP. A total of 324 DRPs were detected and classified among 190 patients using PCNE 9.1. Among them, drug-drug interactions (16.3%) account for the highest prevalence followed by incomplete drug treatment (15.4%), documentation error (12.3%), monitoring errors (13.8%). **Conclusion:** The current study emphasizes the importance of reporting DRPs to patients in order to provide better health care and advocates the significance of clinical pharmacists in pharmaceutical patient care.

Keywords: Drug related problems, Medication errors, PCNE classification, Clinical pharmacists, Pharmaceutical patient care.

INTRODUCTION

The pharmacy profession has progressed beyond traditional roles such as compounding and dispensing medication to become a highly regulated profession that focuses on direct patient care. In clinical pharmacy, the philosophy of pharmaceutical care is embraced as an approach to promoting the safe and effective use of medication, improving patient care, and educating patients and healthcare providers on medication safety and effectiveness.[1]

Drug related problems (DRP) are defined as events or circumstances associated with drug therapy that interfere with or alter desired health outcomes.[2] In all types of healthcare, whether at home, in long-term care, in community pharmacies or in hospitals, DRP are considered adverse events.[3]

This high incidence of DRP negatively affects the quality of life of the patient and increases the economic and social burden of illnesses. A pharmacy service's first step toward preventing patient harm is to detect and classify potential DRP.[3,4] The identification and classification of potential DRPs by pharmacy services is crucial in reducing medication errors, adverse reactions, and length of stay, thus preventing patient harm.[5]

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There have been several strategies developed for detecting DRPs, including pharmacist review of medication orders (MO), computerized physician order entry (CPOE), and clinical decision support programs that allow the clinical pharmacist to actively participate within the healthcare team.[6-8] In spite of DRP's clinical and economic importance, very few studies have examined the incidence, types, and causes of DRP in hospitalized patients. Clinical pharmacists' impact on reducing DRP rates at the patient level has been extensively studied in developed countries. In India, there are very few studies showing the value of clinical pharmacist recommendations. Previous studies from India addressed polypharmacy associated DRP,[9] DRP in patients with cardiovascular diseases,[10-11] drug-related hospital admissions,[12] and DRPs among chronic kidney disease patients.[13]

From December 2000 to June 2001, postgraduate students from the pharmacy practice department of JSS Medical College Hospital, Mysore, India, conducted a study to detect DRP in six medical wards. The study was the first to involve pharmacy professionals in pharmaceutical patient care and to report DRP.[14] Despite being a notably populated country, India has very little data on reported DRP and the recommendation to address them. This study is therefore an attempt with objectives; 1) To detect DRP by reviewing all medical orders (MOs) issued to each patient in various departments of a general teaching hospital, 2) Systematically analysed and compared DRP in various clinical departments using PCNE classification.

MATERIALS AND METHODS

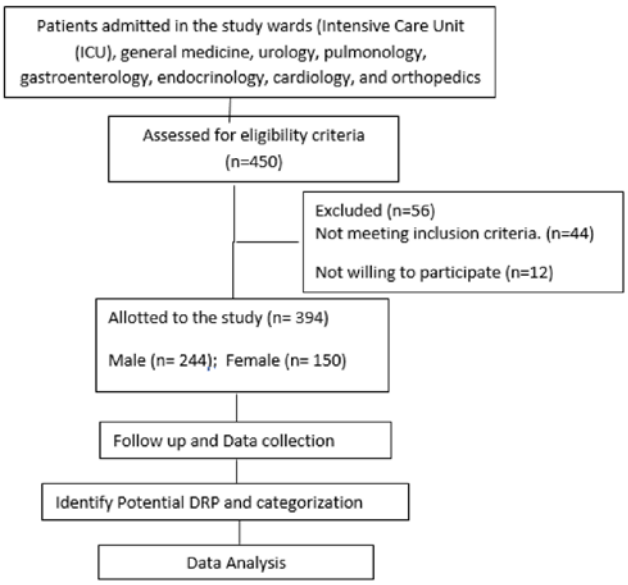
Study settings and duration: The study was conducted at RVM Institutes of Medical Sciences and Research Center at Lakshmakkapally, Medak District, Telangana. The hospital has 800 beds, and the study took place in the Intensive Care Unit (ICU), general medicine, urology, pulmonology, gastroenterology, endocrinology, cardiology, and orthopaedic wards. The study lasted 6 months between October 2020 and March 2021.

Study Design

This was a prospective observational cohort study conducted at the study hospital with prior ethical approval by the institutional human ethical committee at Geethanjali College of Pharmacy with approval number, GCPK/IEC/NOV 2020-21/B01. Before including in the study, written informed was taken from study subjects.

Inclusion Criteria

Patients of both sexes older than 18 years of age who were hospitalized for more than 24 hr in the study departments. Patients with cancer chemotherapy regimens, transplant recipients, pregnant women, Ophthalmology, Dermatology, ENT and Gynecology patients and patients hospitalized with COVID-19 were excluded.



Flow Chart for Methods

Data collection and Analysis

Study participants were followed from admission to discharge throughout their hospital stays. Patients' data were collected by pharmacy students (investigators) and potential DRP were identified. For the initial collection of data from qualified prescriptions, a pre-structured data collection form was used, followed by an Excel sheet for analysis. Patients' demographic information (age and gender), diagnosis, as well as information about their medications (drug name, dose, duration of treatment, prescribing physician, and dispenser) is collected on data collection forms.

The drugs were classified according to the ATC system.[15] The DRP were defined according to the definition of Pharmaceutical Care Network in Europe: "An event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes", http://www.pcne.org.[2] Potential DRP are identified and classified according to their types and causes using Pharmaceutical Care Network Europe's classification system (version 9.1). Drug interactions are checked using a drug interaction checker that can be found on Drugs.com.[16]

Statistical analysis was performed using Microsoft Excel. We performed descriptive statistics such as the following: frequencies, Percentages were calculated for the required data. Histograms, such as bar graphs and pie charts, were used to display the data. Wherever possible, cross-tabulations were performed on the data.

RESULTS

During the study period, 394 patients were admitted to the hospital wards intended for treatment of various clinical conditions. From the total cohort, 244 males and 150 females received the pharmaceutical care service. Among them, 190 (48%) patients (Male 42.6%; Female 57.3%) case sheets were detected with DRP. Mean age was 46.7 years [SD = 23.6; min = 18, max = 89]. The mean number of prescribed drugs per patient on the respective ward was 4.6± 1.8 drugs/patient [min = 3, max = 18]. The majority of patients were admitted to the general medicine ward (121) followed by cardiology (64) (Table 1). From Figure 1, DRP were found highly reported in the gastroenterology ward (68.2%) followed by cardiology (54.6%).

Pattern of DRP

Among 190 patients, 324 DRP were identified and classified according to PCNE 9.1. In the process of evaluation for drug selection by the prescriber intended for the clinical treatment, 193 (59.5%) DRP were identified. Inappropriate combinations with minor to major effects were observed and reported as drug-drug interactions (16.3%). Inappropriate drug formulations were prescribed for 7 (2.1%) patients. Inadequate dose/high dose without proper instructions were observed in 3 (0.9%) patients. Treatment duration errors were found in 2 (0.6%) patients. Dispensing errors were observed in 23(7%) prescriptions. Errors in drug use were observed in 6 (1.8%) patients. It is worth noting that 45 (13.8%) patients who intended close therapeutic monitoring were not given the required pharmaceutical care. Documentation errors were reported in 40 (12.3%) patients and wrong direction errors in 5 (1.5%) patients (Table 2).

Table 1: Patient demographics, clinical/pharmacological risk factors.

	Total patients n (%)/(Mean±SD)	Patients with DRP n (%)
No. of patients n (%)	394	190 (48)
Gender n (%)		
Female	150 (38)	86 (57.3)
Male	244 (62)	104 (42.6)
Age (Mean±SD)	46.7 ± 23.6	
Drugs on admission (Mean±SD)	4.6± 1.8	
Clinical/pharmacological risk factors present n (%)	394	56 (14.2)
Wards		
Intensive Care Unit (ICU)	46	22 (47.8%)
General medicine	121	40 (33%)
Nephrology	26	12 (46.1%)
Pulmonology	42	21 (50%)
Gastroenterology	41	28 (68.2%)
Endocrinology	16	5 (31.2%)
Cardiology	64	35 (54.6%)
Neurology	38	18 (47.3%)
Orthopedics	21	9 (42.8%)

DRPs- drug-related problems; SD- Standard deviation.

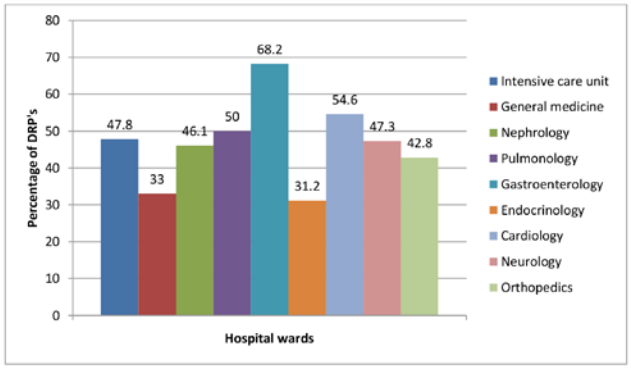


Figure 1: The relative frequency of the DRP main categories for each clinical department.

Figure 2 depicts the distribution of total DRP reported in various wards in the study hospital. From Figure 3, most of the errors in the pharmaceutical care process were found to be reported at the drug selection (dose, form, indication, combination) process.

During the study, certain adverse drug reactions (ADR's) and certain drug-drug interactions were observed. The same was depicted in Table 3 and Table 4.

Major drug-drug interactions were included in the table. This study categorizes DRP according to the errors made by health care professionals. Out of 324 DRP, the prevalence of DRP at the prescriber's level is high (63%) followed by nurses (14.1%), duty medical officers (13.8%) and dispensary pharmacists (7%) (Table 5, Figure 4).

DISCUSSION

Our study assessed the incidence of DRP among adult patients hospitalized in various medical wards of a multispecialty hospital using an open prospective

Table 2: Classification of potential Drug related problems according to PCNE V9.1.

Primary Domain	Code V9.1	Cause	Percentage of DRPs identified in patient case sheets of different hospital wards n (%)									
			ICU	GM	NP	PM	GS	ED	CD	NU	OR	Total
		Number of patients with DRP's n	22	40	12	21	28	5	35	18	9	190
Drug selection n=193 (59.5%)	C1.1	Inappropriate drug according to guidelines/formulary	5 (24.3)	7(17.5)	4(33.3)	2(9.5)	4(14.2)	0	4(11.7)	2(11.1)	0	28(8.6)
	C1.2	No indication for drug	4(18.9)	4 (8.9)	3(25)	1(4.7)	0	1(20)	6(17.1)	1(5.5)	0	20(6.1)
	C1.3	Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements	8(35.1)	5(12.5)	5(41.6)	4(19.2)	8(28.5)	1(20)	15(42.8)	4(22.3)	3(33.4)	53(16.3)
	C1.4	Inappropriate duplication of therapeutic group or active ingredient	0	2(4.7)	0	1(4.7)	2(7.1)	1(20)	2(5.8)	1(5.5)	0	9(2.7)
	C1.5	No or incomplete drug treatment in spite of existing indication	11(51.3)	13(32.8)	5(41.6)	8(38)	2(7.1)	2(40)	6(17.1)	2(11.1)	1(11.1)	50(15.4)
	C1.6	Too many different drugs/active ingredients prescribed for indication	9(40.9)	12(30)	3(25)	1(4.7)	3(10.7)	0	5(14.2)			33(10.1)
Drug form n=7 (2.1%)	C2.1	Inappropriate drug form/formulation	1(4.5)	1(2.5)	0	0	2(7.1)	0	2(5.8)	1(5.5)	0	7(2.1)
Dose selection n=3 (0.9%)	C3.1	Drug dose too low/high	0	0	0	0	0	0	0	1(5.5)	0	1(0.3
	C3.5	Dose timing instructions wrong, unclear or missing	0	0	0	0	2(7.1)	0	0	0	0	2(0.6)
Treatment duration n=2(0.6%)	C4.1	Duration of treatment too short/long	0	0	2(16.6)	0	0	0	0	0	0	2(0.6)
Dispensing n= 23 (7.0)	C5.1	Prescribed drug not available	0	3(7.5)	0	2(9.5)	2(7.1)	0	6(17.1)	3(16.6)	2(22.2)	18(5.5)
	C5.3	Wrong drug, strength or dosage dispensed	0	1(2.5)	2(16.6)	1(4.7)	0	0	0	1(5.5)	0	5(1.5)
Drug use process n= 6 (1.8 %)	C6.1	Inappropriate timing of administration or dosing intervals by a health professional	1(4.5)	0	0	0	2(7.1)	1(20)	2(5.8)	0	0	6(1.8)
Others n=90 (27.5%)	C9.1	No or inappropriate monitoring (incl. TDM)	8(37.8)	8(19.5)	5(41.6)	3(14.2)	2(40)	1(20)	16(45.7)	2(11.1)	0	45(13.8)
	C9.2	Other cause; Documentation error	4(16.2)	5(12.5)	2(16.6)	2(9.5)	0	25	0	2(11.1)	1(11.1)	40(12.3)
	C9.2	Other cause; Wrong direction	0	1(2.5)	0	1(4.7)	2(7.1)	1(20)	0	0	0	5(1.5)
	Total number of DRPs observed during the study		51(15.7)	62(19.1)	31(9.5)	26(8)	31(9.5)	33(10.1)	64(19.7)	19(5.8)	7(2.1)	324

ICU- Intensive care unit; GM-General medicine; NP-Nephrology; PM- Pulmonology; GS-Gastroenterology; ED-Endocrinology; CD-cardiology; NU-Neurology; OR- Orthopedics.

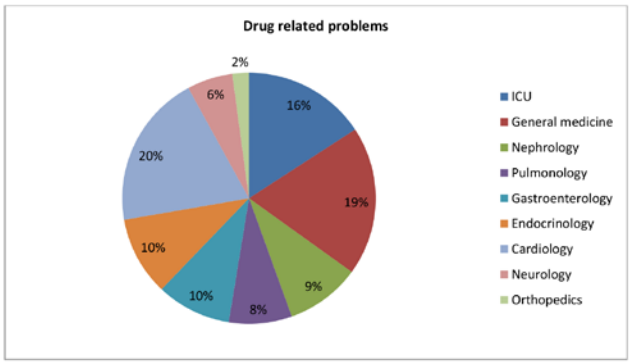


Figure 2: Distribution of total DRP's reported in various wards (*n*=324).

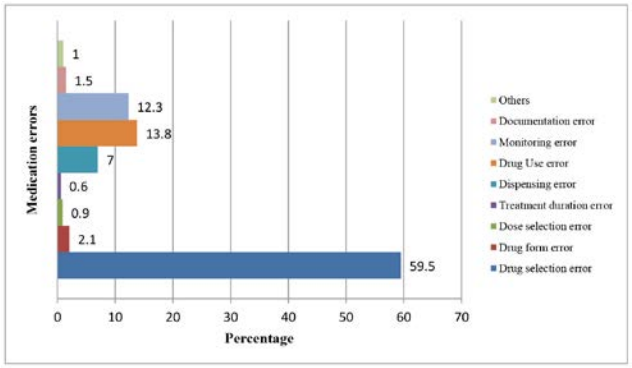


Figure 3: Distribution of potential Drug related problems according to PCNE V9.1.

cohort for a period of 6 months. To the best of our knowledge, this is one of the few studies from India that systematically analysed and compared DRP in various clinical departments using PCNE classification.

The DRP incidence in this study differed from that reported in other studies conducted at hospitals of

Table 3: Adverse drug reactions observed in during the study in the tertiary care hospital.

Departments	Total *n*=190	ADR's %
General ward	7	3.66
ICU	21	10.87
General medicine	8	4.4
Pulmonology	11	6.0
Cardiology	14	7.6

Table 4: Major Drug-drug Interactions observed.

Drugs involved	Severity	Outcome
Ceftriaxone+Heparin	Major	Increased effect of Heparin
Azithromycin+ ondensetron	Major	This combination increases the QTc interval.
Formeterol+ ondensetron	Major	This combination increases the QTc interval.
Ibuprofen+ Ciprofloxacin	Major	Increases the effect of ciprofloxacin
Haloperidol+ Promethazine	Major	Increases the sedative effects

Table 5: Drug related problems prevalence made by health care professionals.

	DRPs at levels of health professionals	DRPs n (%)
	At Prescribers level	**205 (63%)**
C1.1	Inappropriate drug according to guidelines/formulary	28(8.6)
C1.2	No indication for drug	20(6.1)
C1.3	Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements	53(16.3)
C1.4	Inappropriate duplication of therapeutic group or active ingredient	9(2.7)
C1.5	No or incomplete drug treatment in spite of existing indication	50(15.4)
C1.6	Too many different drugs/active ingredients prescribed for indication	33(10.1)
C2.1	Inappropriate drug form/formulation (for this patient)	7(2.1)
C3.1	Drug dose too low/high	1(0.3
C4.1	Duration of treatment too short/long	2(0.6)
C9.2	Other cause; Wrong direction	2(0.6)
	Duty medical officers (DMO's)	**45 (13.8%)**
C9.1	No or inappropriate monitoring (incl. TDM)	45(13.8)
	Nurses	**46 (14.1%)**
C6.1	Inappropriate timing of administration or dosing intervals by a health professional	6(1.8)
C9.2	Other cause; Documentation error	40(12.3)
	Dispensary pharmacist	**23(7%)**
C5.1	Prescribed drug not available	18(5.5)
C5.3	Wrong drug, strength or dosage dispensed	5(1.5)

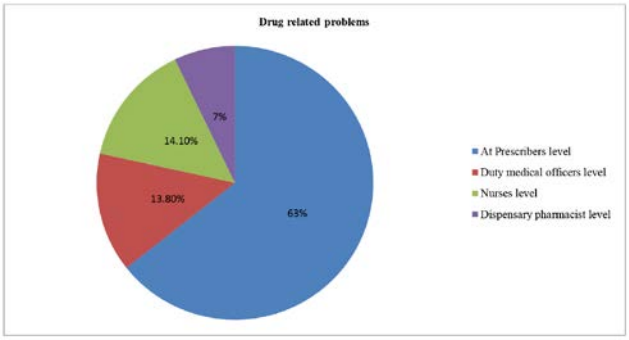


Figure 4: Drug related problems prevalence made by health care professionals.

different types of hospitals, which may be explained by the diversity of methodologies used to identify and classify DRP.[17-20]

A similar study conducted in Brazil found DRP in the review of medication orders by pharmacists who used the Pharmaceutical Care Network Europe 6.2 classification (PCNE). The most common DRPs were treatment ineffectiveness (11.5%) and treatment costs (5.90%), followed by the drug use process (18.4%) and the duration of treatment (31.0%).[21]

A structured order review (French Society of Clinical Pharmacy instrument) was used to detect DRP in a study conducted in France by using a computerized physician order entry system (CPOE). In general, non-conformity to guidelines or contra-indications accounted for 29% of DRP, improper administration (19%), drug interactions (16%), and over dosage (12%).[17]

A study in Switzerland categorizes DRP into seven classes by clinical pharmacists. There were 145 patients included in the study, and 383 DRP were identified (2.6 DRP per patient on average). As similar to our study, drug interaction was the most common DRP (21%) identified, followed by untreated indication (18%), overdosage (16%), and drugs used without a valid indication (10%).[19]

In a retrospective cross-sectional study conducted by Bayoud, T. and colleagues, they identified overdosage (30.8%) as the most frequent DRP, low dosage (17.6%), unnecessary drug therapy (17.3%), the need for additional drugs (11.6%), and the need to switch from one medication to another (12.3%).[20]

This study was notable for having conducted a MO review within various departments, as opposed to many others that concentrated on a single department or a very small number of departments, the geriatrics department being in particular focus.[22,23] Furthermore, the methodology adopted in our study was internationally recognized standards, which helped to make comparisons of the results easier.

There has been an increase in the importance of clinical pharmacy services in developing countries like India, which introduced doctoral pharmacy courses. A tremendous amount of research is being done by Pharm D students, adding literature on drug use and DRP in India. Taking into consideration the global scenario, the pharmacy council of India published the Pharmacy Practice Regulations (2015) on pharmacists' duties towards patients.[24] Developing risk stratification instruments for potentially manifested DRP and/or pharmaceutical interventions should be a part of future research in this topic, such as assessing the frequency of manifested DRP, their outcomes, and the impact on hospital costs.[3,25]

Our study added to the literature supporting previous studies and supporting the important role of clinical pharmacists in the provision of pharmaceutical care. However, there are certain limitations hence the outcomes of the interventions were not studied, which might give a complete impact on the purpose of the study. Another limitation of the study is seasonality; this is a 6-month study, the drug use may defer with seasons. Furthermore, it is difficult to generalize the results due to the study being conducted in just one hospital, even though many of the characteristics are common to hospitals around the world.

CONCLUSION

The findings of the current study emphasize the significance of reporting DRP to patients in order to provide improved health care. Pharmacists and physicians could collaborate to develop drug use guidelines and policies in developing a safer healthcare system; this study advocates for the possibility of a collaborative and joint effort.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DRP: Drug related problems; **PCNE:** Pharmaceutical Care Network Europe; **MO:** Medication orders; **CPOE:** computerized physician order entry; **ICU:** Intensive Care Unit; **ENT:** Ear, Nose, and Throat; **ATC:** Anatomical Therapeutic Chemical; **SD:** Standard deviation; **GM:** General medicine; **NP**-Nephrology; **PM:** Pulmonology; **GS:** Gastroenterology; **ED**-Endocrinology; **CD**-cardiology; **NU**-Neurology; **OR**- Orthopedics; **ADR's:** Adverse drug reactions; **TDM:** Therapeutic drug monitoring.

SUMMARY

The purpose of this observational cohort study was to identify and classify potential DRPs based upon the medical orders of patients. The Pharmaceutical Care Network Europe version 9.1 classification system was utilized. The number of DRPs identified was significant, but drug-drug interactions have the highest prevalence. Clinical pharmacists' role in pharmaceutical patient care is advocated in the current study as they emphasize the importance of disclosing DRPs to patients in order to provide better health care.

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