

Role of Clinical Pharmacist in Drug Therapy Management in a Tertiary Care Hospital

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ABSTRACT

Objectives: Drug Therapy Management is a collaborative approach between a physician and a pharmacist. Implementation of DTM in hospitals have a higher chance of reducing DRP's and increase in patients' Quality of Life. The aim of this study is to evaluate types, frequency, and ways for minimizing Drug Related Problems and identify the role of clinical pharmacist in Drug Therapy Management. **Methods:** A Prospective Observational study was carried out in a tertiary care teaching hospital in Bhimavaram. All the in-patients who satisfied the inclusion criteria were enrolled. Patient demographics and necessary clinical data was collected. MS Excel and Graphpad Prism 9 Software were used to analyze the data. Chi-Square Test was implemented to obtain significance between number of diseases, age, number of drugs prescribed, length of hospital stays with DRP's. **Results:** Among 493 cases, total of 315 DRP's were detected (mean = 2.58 DRP's per patient). The highest occurring DRP was Drug Interactions (40.6%). Antibiotics (27.54%) were found to be highly contributing. The major cause for DRP's was inappropriate combination of drugs or drugs and food (39.75%). Drug discontinuation (26.35%) was the most appropriate type of recommendation. **Conclusion:** Findings in this study signify the need of adaptation of Drug Therapy Management thereby improving healthcare system. Most of the medication errors can be prevented with the interventions of clinical pharmacist as they have broad knowledge of clinical pharmacokinetics, drug use and safety.

Keywords: Drug Therapy Management (DTM), Drug Related Problems (DRP), Clinical Pharmacist.

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INTRODUCTION

Drug Related Problems are the growing cause of many preventable errors potentially associate with increased treatment costs, in-patient admission, duration of hospital stay, decreasing quality of life, and mortality.^{1,2}

According to Pharmaceutical Care Network of Europe (PCNE), DRP is defined as "an event or circumstance involving drug therapy that actually or potentially interferes with health outcomes".³

Drug Related Problems can be observed at various stages of treatment. From the initial step of collecting past medical and medication history until last step of managing a patient.

Multiple updations and changes within the medication chart of hospitalized patients makes them more prone to Drug Related Problems.⁴

Many causes like polypharmacy, lack of proper follow up of medications, non-availability of patient history, Illegible orders, and increased patient load leads to happenings of errors like

- Drug interactions,
- Adverse drug reactions,
- Therapeutic Duplication,

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- Unnecessary Drug (without indication),
- Untreated indication,
- Failure to monitor drug concentrations,
- Incorrect dilutions,
- Dosing errors,
- Incorrect rate of expression.

Identification and categorization of DRPs would help in better understanding of the ways in minimizing the errors. Analyzing DRPs helps in increased quality of life and reduced risk of misuse of medications.

Among various ways of understanding DRPs, Pharmaceutical Care Network Europe Classification (PCNE) classification is most reliable in Identifying, categorizing, and analyzing the DRPs.³

According to the latest reports of Ministry of Health, the ratio of doctor to patient is 1:834 which signifies that the physicians are facing heavy patient load which may lead to further increase of DRPs.⁵ These statistics are alarming and shows the importance of revamp in new healthcare strategies involving healthcare professionals who are suitably trained to carryout these duties.

Drug Therapy Management is a “*collaborative approach among a physician and pharmacist wherein a qualified pharmacist is permitted to assume professional responsibility to perform patient assessment, ordering drug therapy related laboratory tests, administer drugs, and selecting, initiating, monitoring, continuing, and adjusting drug regimens*”.^{6,7}

The American College of Clinical Pharmacy (ACCP) advocates the role of qualified pharmacists in CDTM in all practice settings. Pharmacists, practices in an interdisciplinary approach with physician and other health care professionals in order to improve pharmacotherapeutic outcomes and improve value and efficiency to the health care system.⁶ Clinical Pharmacists were observed to have improved pharmacotherapeutic outcomes, provide increased value and efficiency when participated in a collaborative approach with a physician and other healthcare professionals.

Clinical Pharmacist are proficient enough in dealing with complex drug related problems through their knowledge of pharmacodynamics and pharmacokinetics. This makes them more qualified in providing high quality and low-cost care.^{2,16} Few studies in USA found that there is 66% reduction of adverse events related to preventable errors when a pharmacist is involved in daily ward rounds.⁸

Drug Therapy Management is yet to be implemented in developing countries like India. This kind of healthcare setting helps in reducing potential economic burden by reducing unwanted drug use and minimizing of DRPs which accounts to one of the top reasons for mortality and morbidity.

There is an increasing need of further studies involving practical evaluation of clinical pharmacist in India after being included in a healthcare team. Our study shows identification, categorization, classification, analyzation, and comparison of DRPs among various departments. We also included possible ways in minimization of DRPs which would represent the actual role of clinical pharmacist.

MATERIALS AND METHODS

Study Site

This study was conducted in inpatient departments of 300 bed multispecialty Tertiary Care Teaching Hospital in Bhimavaram. A total of 8 Departments (Cardiology, Nephrology, General Medicine, Neurology, Orthopedics, Pulmonology, Gastroenterology, Gynecology) were included in the study.

Study Design

This is a Prospective Observational Study.

Study Material

Patient case profile including laboratory data, Drug Treatment / Medication Chart, PCNE guidelines, NCC MERP classification.

Inclusion Criteria

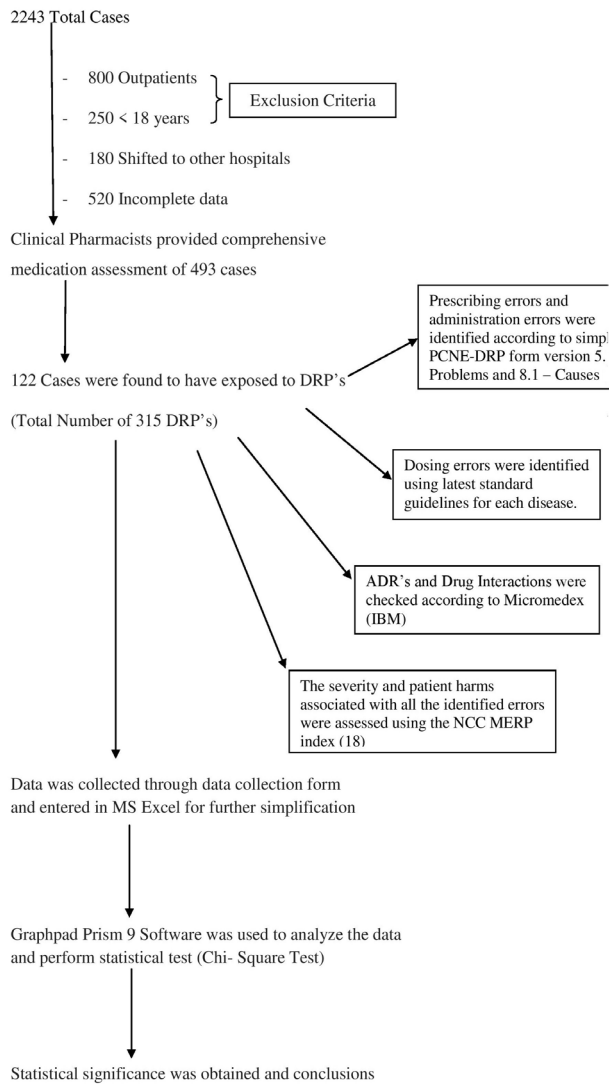
- Patients above the age of 18 years.
- All Inpatients of 8 departments.

Exclusion Criteria

- Out- patients
- Patients who are unwilling to participate in the study.

Study Procedure

Student Pharmacists on their hospital rounds identified the subjects satisfying the inclusion criteria. Detailed explanation regarding the study is done. Informed Consent is obtained. Required data (age, sex, past medical and medication history, laboratory values, treatment



Schematic Representation of the Process of Identification of DRP.

charts) have been collected using a data collection form. The data of subject have been followed up till the patient is discharged. Daily updates and alterations of the medication chart were keenly recorded and compared with standard treatment guidelines as and when required.

Ethics and Consent: The study was approved by the Institutional Human Ethical Committee of Shri Vishnu College of Pharmacy filed under 004/2021/SVCP/IEC. Permission to conduct the study was obtained from the Chairperson of the Institutional Human Ethics Committee.

RESULTS

In the present study, inpatients of 8 departments (Cardiology, Nephrology, General Medicine, Neurology, Orthopedics, Pulmonology, Gastroenterology, and

Gynecology) were randomly included after considering the inclusion criteria.

A total of 493 cases were collected. 122 patients have been exposed to various DRP's. A Sum of 315 DRP's were observed. The mean of DRP's was found to be 2.58 per patient. There was a significant relation between Age (*p* value = 0.0245*), length of hospital stays (*p* value = 0.0011**), Number of drugs prescribed (*p* value = 0.0052**) and Number of diseases (*p* value = 0.0012**) with the Number of Drug Related Problems being observed.

Age Group

The Age Group of 41-60 (51.63%) had experienced a majority of DRP's followed by

>60 years (31.96%) and 20 – 40 (20.40%). This result may be because of the polypharmacy and comorbidities in the age group. Patients above 60 years were shifted to other hospitals for further care which may have caused variations in the results obtained. (Table 1) (*p* Value = 0.0245*).

Length of Hospital Stay

DRP's occurred majorly among people who stayed from 3-7 days (63.93%) which may be due to corrections by physician during the time of prescribing. (Table 1) (*p* value = 0.0011**).

Number of Drugs Prescribed

Patients exposed to polypharmacy were observed to have experienced a greater number of DRP's. Most of the percentage of DRP's were observed in patients who consumed 5 to 10 medication (49.18%) followed by consumption of more than 10 medications (35.24%) as shown in the (Table 1) (*p* value = 0.0052**).

Number of Diseases

Increased comorbidities show increase frequency of Drug Related Problems as shown in the Table 1. Our study observed that patients suffering with more than 3 comorbidities contributed to the majority (37.70%) (*p* value = 0.0012**).

Classes of Drugs Involved in Drug Related Problems

Antimicrobials were the class of drugs which mostly contributed to the Drug Related Problems (27.54%) as shown in the Figure 1. Cardiovascular agents (25.72%) were the second most contributing class of drugs followed by NSAID's (17.70%) and then electrolyte

Table 1: Association between patients' characteristics and drug related problems (n=493).

Characteristics	Category	DRP Present (%)	DRP Absent (%)	Total	p value
Gender	Male	69 (56.56%)	181 (48.79%)	250 (50.7%)	0.2104
	Female	53 (43.44%)	190 (51.21%)	243 (49.29%)	
Age Group	20-40	25 (20.40%)	64 (17.25%)	83 (16.83%)	0.0245*
	41-60	58 (51.63%)	234 (63.07%)	298 (60.44%)	
	>60	39 (31.96%)	73 (19.67%)	112 (22.71%)	
Length of Hospital Stay	<3	20 (16.39%)	115 (30.99%)	135 (27.83%)	0.0011**
	3-7	78 (63.93%)	233 (74.91%)	311 (63.08%)	
	>7	24 (19.67%)	23 (6.19%)	47 (9.53%)	
Number of Disease	1	35 (28.68%)	143 (38.54%)	178 (36.10%)	0.0052**
	2	41 (33.60%)	156 (42.04%)	197 (39.95%)	
	>3	46 (37.70%)	72 (19.40%)	118 (23.93%)	
Number of drugs prescribed	<5	19 (15.57%)	43 (11.59%)	62 (12.57%)	0.0012**
	5-10	60 (49.18%)	243 (65.50%)	303 (61.46%)	
	>10	43 (35.24%)	85 (22.91%)	128 (25.96%)	

Chi-square test (χ²) performed, p value * indicates statistically significant, ** indicates highly significant association.

Table 2: Classes of drugs involved in drug related problems.

Class of Drug	Number of drugs	Percentage
Antimicrobials	260	27.54%
Antacid	198	10%
NSAID's	167	17.70%
Corticosteroids	70	7.41%
Antiemetics	150	5.88%
Cardiovascular agents	139	25.72%
Central Nervous System	89	9.42%
Respiratory	54	11.00%
Gastrointestinal	124	13.13%
Endocrine	76	8.05%
Mineral supplementation	65	6.88%
Electrolyte supplements	145	15.36%

supplements (15.36%) Table 2.

Types of Recommendations

The possible type of recommendation that shall be involved for major DRP's is Drug Discontinuation (26.35%), Need for Antibiotic Susceptibility Test (ABST) (12.38%), Dose Adjustments (11.2%), Drug Change (8.89%) and Therapeutic Drug Monitoring (8%). All other possible types were clearly shown in the Figure 2.

Severity of Drp's

The Severity Rating of DRP's was done using PNCC Medication Error Severity Index (Figure 3). The majority (54.60%) of the DRP's were observed to

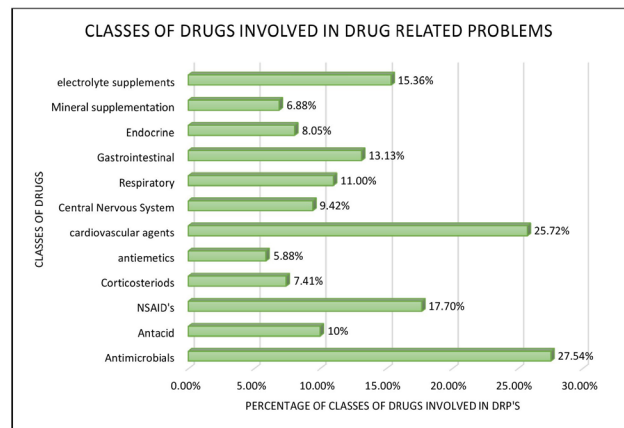


Figure 1: Classes of Drugs Involved in Drug Related Problems.

have no patient harm (Including Subcategories of B, C and D). 39.05% showed temporary harm like prolonged drug activity leading to increased duration of hospital stay (Subcategory E and F). Permanent Damage like development of resistance at various cellular levels is observed to count for 6.35% (Subcategory G and H). There were no deaths observed during our study.

Departments

Top 5 department's data was analyzed as shown in the Figure 4.

Drug Interactions in General Medicine Department (56.86%) contributed the majority which might be due to various kinds of diagnosis in general medicine department which required patients past medical and medication history. Cardiology Department (50.56%) also had a higher occurrence of drug interactions as there were more anticoagulants and antianginal drugs prescribed.

Table 3: Drug or Drug Classes involved in each type of Drug Related Problem.

Drug Interactions	Adverse Drug Reactions	Untreated Indication	Drug without indication	Drugs requiring TDM	Therapeutic Duplication
Tramadol	Diuretics	Vitamin supplements	PPI	Meropenem	Acetaminophen
NTG	Anticoagulants	Statins	NSAIDs	Amikacin	Multivitamin supplements
Clopidogrel	Antipsychotic	Laxatives	Paracetamol	Phenytoin	Antihypertensives
Ondansetron	Anti-tubercular drugs			Digoxin	
Digoxin					

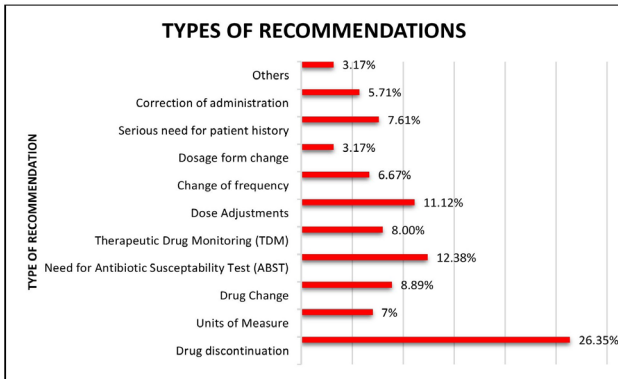


Figure 2: Types of Recommendations.

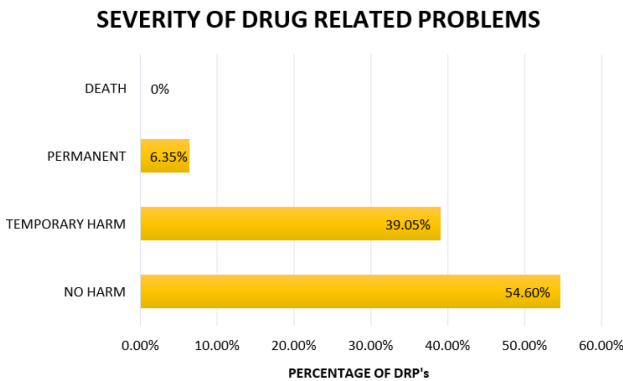


Figure 3: Severity of drug related problems drp among various.

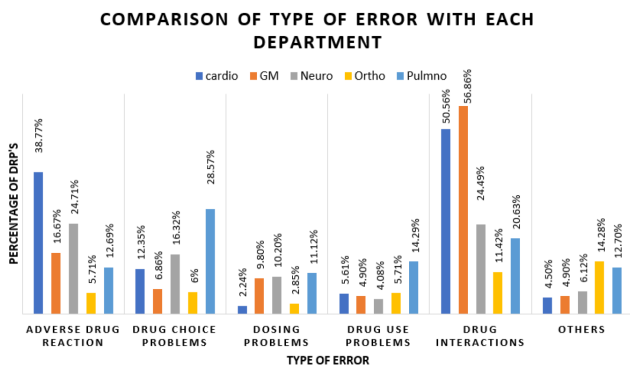


Figure 4: Comparison of Type of Error with Each Department.

Adverse Drug Reactions were the next most common DRP in Cardiology Department (38.77%) might be due to diuretics as they accounted for high electrolyte imbalance.

PCNE domain classification

Problems

A systematic classification of problems of DRP's was shown in Table 4. The most common problem was Drug interactions (40.6%) were highest followed by ADR's (18.73%), Drug Choice Problems (17.14%), Dosing Problems (9.84%).

Causes

A Total of 322 causes were identified as shown in the Table 5. Inappropriate Combination of drugs or food (39.75%) followed by New Indication for drug treatment (18.32%), No or Inappropriate Outcome Monitoring (6.83%), Prescribing Error (Necessary Information Missing) (6.21%) and Inappropriate Duplication of Therapeutic (4.65%).

DISCUSSION

Drug Therapy Management is a practice which helps to manage various gaps in the healthcare system. Assessment of Role of Clinical Pharmacist would be more reliable by determining and understanding the Drug Related Problems.

This study showed that there was a mean of 2.58 DRP's per patient. These results were in line with the studies carried out by Bertrand Guignard *et al.*,⁹ on Drug Related Problems in General Internal Medicine.

The incidence of DRP's were found to be high in patients aged between 41- 60 years (51.63%) followed by patients above 60 years (31.96%) and 20-40 years (20.40%). This may be due to polypharmacy and higher incidence of diseases among this age group. This result was in accordance with few other studies carried out by Javedh

Table 4: Domain Classification of Drp's.

Problems	No. of DRP's	Percentage
P.1 Adverse Drug Reaction		
Side-effects (non-allergic).	49	15.56%
Side-effects(allergic).	2	0.63%
Toxic effects suffered.	8	2.54%
P.2 Drug Choice Problems		
In-appropriate drug.	1	0.31%
In-appropriate drug form.	10	3.17%
In-appropriate duplication of active ingredient.	15	4.76%
Contra-indication for drug.	12	3.80%
No clear indication for drug use.	7	2.22%
P.3 Dosing Problems		
Drug dose too low.	2	0.63%
Drug dose too high.	9	2.85%
Duration of treatment too short.	0	0%
Duration of treatment too long.	3	0.95%
Dose adjustments.	17	5.39%
P.4 Drug Use Problems		
Drug not taken/ administered.	2	0.63%
Wrong drug taken/ administered.	10	3.17%
P.5 Manifested Interactions	128	40.6%
P.6 Others	31	9.84%

Table 5: Domain Classification of Causes of Drp's.

Cause domain (8 categories) total= 322	No. OF DRP's	PERCENTAGE
C1: Drug selection causes		
New indication for drug treatment.	59	18.32%
No indication for drug.	9	2.8%
Inappropriate drug according to guidelines.	7	2.17%
Contra-indicated.	12	3.72%
Inappropriate duplication of therapeutic.	15	4.65%
Inappropriate combination of drugs, or drugs and food.	128	39.75%
C2: Drug form causes		
Inappropriate drug form.	10	3.10%
C3: Dose selection causes		
Drug dose too high.	9	2.79%
Drug dose too low.	2	0.62%
C4: Treatment duration causes		
Duration of treatment too long.	3	0.93%
Duration of treatment too short.	0	0%
C5: Dispensing causes		
Prescribed drug not available.	11	3.41%
Prescribing error (necessary information missing).	20	6.21%
C6: Drug use process causes		
Drug not administered at all.	2	0.62%
Drug under administered.	5	1.55%
Drug over administered at all.	3	0.93%
C7: Patient related causes		
Patient uses unnecessary drug.	0	0%
Patient administered /uses drug in a wrong way.	0	0%
Patient cannot afford drug.	0	0%
Patient unable to use drug/form as directed.	5	1.55%
C8: Other causes		
No or inappropriate outcome monitoring.	22	6.83%

shareef *et al.*,¹⁰ and Rashmi Adhikari *et al.*,¹¹

Drug interactions (40.6%) were highest followed by ADR's (18.73%), Drug Choice Problems (17.14%), Dosing Problems (9.84%). This may be because of drugs which interact high with large number of drugs including Tramadol, Nitroglycerin and anticoagulants and other reasons like lack of availability of patient past medical and medication history. Majority of drug interactions identified in this study were from established literature and well documented. Many studies in different settings were in accordance with these results.^{9,12,17}

Antimicrobials were the class of drugs which mostly contributed to the Drug Related Problems (27.54%).^{11,12} This result might be due to inclusion of antibiotic in maximum number of medication chart and irrationality while prescribing them. The unavailability of Therapeutic Drug Monitoring and Antibiotic Susceptibility Test might also be an associated reason for antibiotics causing drug related problems.

There is a significant correlation between number of drugs prescribed, number of diseases and age distribution of patients with the frequency of DRP's occurring. This might be because of the polypharmacy in geriatric patients having more diseases or comorbidities.^{11,12,15}

The Length of hospital stay showed a different interpretation of DRP's. Our study showed more DRP's in people who stayed for 3- 7 days.^{9,12,17} This might be due to shifting of patients to better hospital setting (rural to urban setting) due to complex comorbidities. The other fact may be that the more patients have been discharged

during our study period.

The majority of DRPs were identified as no or mild harm causing to patient (54.6%). Few DRPs were implicated to cause permanent harm (6.35%). These results were similar to the studies done by Mostafa A. Sayed Ali *et al.*,¹³ on DRPs in hospitalized patients with neurological diseases.

A comparison among the top 5 departments (Cardiology, General Medicine, Neurology, Orthopedic, and Pulmonology) with the most frequent DRPs was also assessed to analyze the occurrence of DRPs according to the departmental variation.

The majority of Drug – drug Interactions were found to occur in General Medicine Department (56.86%) followed by Cardiology department (50.56%).

Comparison among various departments showed down the following sequence of DRPs. Adverse reactions in Cardiology Department (38.77%) followed by Drug Choice Problems in Pulmonology department (28.57%) and then adverse reactions in Neurology department (24.71%). This might be due to various kinds of diagnosis in general medicine department which required patients past medical and medication history.

Cardiology department had high interactions as there were more anticoagulants and antianginal drugs. Cardiology department had higher number of adverse reactions which might be due to diuretics as they accounted for high electrolyte imbalance.

According to the domain classification of PCNE, Drug Interactions (40.6%) was the major problem causing DRPs and choosing Inappropriate drug combinations and food (39.75%) is the major cause of various preventable errors. These results were in line with a study on DRPs in admitted geriatric patients researched by Hailu *et al.*,¹⁶ and different from the study done by Neo Garin *et al.*,¹⁴ which may be due to the setting difference.

The possible type of recommendation that shall be involved for major DRPs is Drug Discontinuation (26.35%), Need for Antibiotic Susceptibility Test (ABST) (12.38%), Dose Adjustments (11.2%), Drug Change (8.89%) and Therapeutic Drug Monitoring (8%).

Drug Discontinuation (26.35%) accounted for the majority of type of recommendation which was similar with the study done by Rashmi Adhikari *et al.*, (2021)¹¹ on assessment of Drug Related Problems among inpatients in Eastern Nepal Table 3.

CONCLUSION

The most frequently detected DRPs were drug interactions (23%). The main cause of DRPs was inappropriate combination of drugs (39.75%), inappropriate outcome monitoring (6.83%), missing necessary information (6.21%). The most possible type of recommendation included Drug Discontinuation (26.35%) and dose adjustments (11.12%). Our study shows significant numbers of DRPs which were obtained during general hospital rounds. These signify that inclusion of a Clinical Pharmacist in ward round participation will reduce the frequency of DRPs. Most of the medication errors can be prevented with the interventions of Clinical Pharmacist as he/ she has a broad knowledge of clinical pharmacokinetics, drug elimination, drug use and safety. Hence, Implementation of Drug Therapy Management in hospitals would help improve patient quality of life.

Therapeutic Intervention Documentation by Clinical Pharmacist would be more appropriate as documentation would help in better understanding of the problems and to acquire relevant interventions. Implementation of new methods would help improve patient Quality of Life by improving quality of healthcare provided.

There is a need of further studies to be conducted regarding impact of Therapeutic Intervention Documentation and COPE (Computerized Prescription Order Entry).

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DTM: Drug Therapy Management; **DRP:** Drug Related Problem; **PCNE:** Pharmaceutical Care Network of Europe; **COPE:** Computerized Prescription Order Entry; **DDI:** Drug-Drug Interactions; **ADR:** Adverse Drug Reaction.

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