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IDENTIFICATION OF DRUG RELATED PROBLEMS IN PATIENTS VISITING GENERAL WARD IN TERTIARY CARE HOSPITAL: A PROSPECTIVE, OBSERVATIONAL STUDY

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ABSTRACT

Background: The Drug Related Problems (DRPs) are the unwanted and undesirable effects caused within any phase of Pharmaceutical care which can actually or potentially interfere with desired health outcome and may cause drug-related morbidity and mortality. Objective: This study aims at assessment of the DRPs in patients admitted to the General Ward of tertiary care hospital in India by using Pharmaceutical Care Network Europe Classification. Materials and Methods: A prospective, observational study was conducted for 200 patients at the general ward of tertiary care hospital in Surat between December 2020 to March 2021. DRPs were assessed and categorized via Pharmaceutical Care Network Europe Classification. Results: Medication charts of 200 patients were analyzed. The patients' median age was 51.3 years and 57% of patients were prescribed with polypharmacy. The average length of stay per patient was 4.8 days. 74% patients had at least one comorbid condition among which hypertension and diabetes mellitus were most common. In 84% of patients, the major reason for admission was cardiovascular diseases. A total number of 2246 medication orders were reviewed and majorly prescribed agents were gastrointestinal agents(20.3%), cardiovascular agents(15.9%) and antimicrobial agents(15.6%). In 16 patients, 21 clinical actual DRPs were detected. The most frequent clinical DRPs were treatment effectiveness (33.7%). Antimicrobial agents(29%) and cardiovascular agents(22%) drug classes were responsible for the majority of DRPs. Prevalent causes of DRPs were found to be selection of drugs(42.8%), dose selection(23.7%) and patient related(4.7%). Conclusion: The DRPs cannot be ceased immediately but can be prevented by active and rationalized pharmaceutical care. The problem arising from pharmacotherapy can be identified, resolved by the upgraded clinical knowledge and patient centric pharmacotherapeutic management.

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INTRODUCTION

Pharmaceutical care is a synchronized way of patient care and has been defined as "the responsible provision of drug therapy for the purpose of achieving certain health outcomes intended to improve health related quality of life". Direct patient care practice requires specific standards along with the help of other healthcare professionals[1]. Pharmaceutical care demands the responsibility by the provider to identify the medication related problems, to provide therapeutic care plans and to ensure that the patient receives appropriate therapy and ultimately desired health outcome[2-6]. According to WHO, patient safety is a preventive measure to avoid or prohibit the harm during the course of therapeutic care and bring them to an acceptable minimum[7]. In the US, medication errors are the third leading cause of mortality and in the UK, on an average one incident of patient harm is reported in every 35 seconds[6]. It has been estimated in several studies that not more than 10% of all medication error results in adverse drug events. Medication errors act as risk factors primarily due to their nature to cause adverse drug events and the fact that they are avoidable. In a literature review, a median of 46.5% of adverse drug reactions were reported to be preventable and concluded as a result of medication error[8,9]. Risk factors like age, geriatric and pediatric population, female sex, poly pharmacy, drugs with narrow therapeutic window, renal elimination of drugs, use of anticoagulants or diuretics, drug- drug interactions ultimately contributes to higher occurrence of DRPs[10-12]. Geriatric patients are particularly vulnerable to DRPs for two major reasons: (1) age related physiological changes may alter the pharmacokinetic and pharmacodynamic properties of the drugs and (2) they often have multiple comorbidities with a lot of medication history[13]. Polypharmacy is a major determinant of multiple aspects of DRPs such as adverse drug events, drug- drug interactions, inappropriate drug choices and poor medication adherence[11].

Medication errors occur throughout the entire medication process from drug administration, drug dispensing and drug use process. There are different methods to assess and evaluate the occurrence of DRPs, but very few have got the clinical application and are reliable as compared to others. DRPs are always combined with increased hospital stay, increased economic burden and increases the risk of death by 2 folds. Assessment of DRPs by clinical pharmacists may help the healthcare professionals to tailor the drug therapy of specific patients and which consequently influence the healthcare cost, improvement in health outcome, decrease in morbidity and mortality and as a by-product provides the increase in HRQOL. There are various classifications to address DRPs like Hepler and Strand, Drug Associated Risk Tool (DART)[15]. Here in this study, we have used Pharmaceutical Care Network Europe classification V8.01 for the evaluation of DRPs. It provides a medium for healthcare professionals to document DRPs at different stages of the pharmaceutical care process[14]. This system attributes five items to each observation: (a) coding for the problem itself, (b) the actual or suspected cause of the problem, (c) the interventions required to resolve DRPs, (d) outcomes, (e) status of DRP.

The scope of this present study was not limited to a specific group of patients, nor to one type of DRP but examined a range of problems among patients in the general ward of a tertiary care hospital. The objectives of the study are, (1) to access and document type and number of DRPs, (2) to determine relationship among the types and number of problems identified and the age, gender, number of prescribed drugs, poly pharmacy, drugs causing DRPs etc.

SUBJECTS AND METHODS

This project was conducted at the inpatient general ward department of a tertiary care hospital in the Southern region of Gujarat, India. This study was conducted in accordance with the ICH-GCP guidelines and was approved by the institutional review board of the hospital. The study enrolled participants with the following inclusion criterias: (1) patients of either gender and any age with any type of disease, (2) patients admitted in general ward for more than 24 hours, (3) patients who are willing to participate in the study. All the transferred patients from intensive care units or emergency departments were excluded due to lack of observation at the time of admission was conducted at tertiary care hospital for inpatients who have been admitted in the general ward during december 2020 to march 2021. The main aim was to identify drug related problems in patients admitted in general ward. All the participants were provided with written informed consent in preferred language and study protocols were also explained verbally. All the relevant data was collected via regular follow ups of patient prescription, interaction with patients and their caretakers, patient medical records and relevant laboratory investigations. Different to transfer. The study documents such as study protocol, data collection form like ICF, CRF were presented to the Ethics committee for approval of the same. The study proceeded after the permission was granted (approval no: SDPC/IHEC/01/2021). This study was designed as a prospective and observational study in which sections of CRF like patient demographics, patient medical history, medication history, current prescription details and laboratory workups were used to document study data. DRPs were identified by comparing it with standard treatment guidelines of relevant disease conditions. The medications given to the patients during the course of study with dose, frequency with actual administration time, route, brand name and generic names were documented. All the dosage, frequencies, side effects, ADRs were evaluated properly and the patient treatment was thoroughly reviewed from the day of the commencement of therapy till the discharge details of the patients to identify DRPs. Identified actual DRPs were re-evaluated by clinical pharmacists and documented appropriately via PCNE classification V8.01. Collected data was analyzed by using MS excel software. PCNE classification was first created in 1999 and has been used in studies in Europe and Australia. The instrument is open for unrestricted access at the PCNE website. During the study period only version 8.01 was available. e. The advantage of this instrument lies in its hierarchical design, with separated codes for six problem domains (P1–P6), eight cause domains (C1–C8), five intervention domains (I0–I4), three intervention acceptance (A1- A3) and four status of DRPs (O0- O3). Several categories are generally available for each domain. One drug may have multiple problems. Each problem is recorded on a separate sheet. For each problem detected, 1 cause can be applied. As the nature of study was observational only, we have not used the intervention domain, intervention acceptance domain and status of DRP domain.

The PCNE classification V8.01 is as follows:

Code	Primary domain	Code	Problem
P1	Treatment effectiveness	P1.1	No effect of drug treatment/ therapy failure
		P1.2	Effect of drug treatment not optimal
		P1.3	Untreated symptoms or indication
P2	Treatment safety	P2.1	Adverse drug event (possibly) occurring
P3	Others	P3.1	Problem with cost-effectiveness of the treatment
		P3.2	Unnecessary drug treatment
		P3.3	Unclear problem/ complaint, further clarification necessary (use as escape only)

Code	Primary domain	Code	Causes
C1	Drug selection	C1.1	Inappropriate drug according to guidelines/ formulary
		C1.2	Inappropriate drug (within guidelines but otherwise contraindicated)
		C1.3	No indication for drug
		C1.4	Inappropriate combination of drugs or drugs and herbals
		C1.5	Inappropriate duplication of therapeutic group or active ingredient
		C1.6	No drug treatment in spite of existing indication
		C1.7	Too many drugs prescribed for indication
C2	Drug form	C1.2	Inappropriate drug form (for this patient)
C3	Dose selection	C3.1	Drug dose too low
		C3.2	Drug dose too high
		C3.3	Dosage regimen not frequent enough
		C3.4C	Dosage regimen too frequent
		3.5	Dose timing instructions wrong, unclear or missing
C4	Treatment duration	C4.1	Duration of treatment too short
		C4.2	Duration of treatment too long
C5	Dispensing	C5.1	Prescribed drug not available
		C5.2	Necessary information not provided
		C5.3	Wrong drug, strength or dosage advised (OTC)
		C5.4	Wrong drug or strength dispensed
C6	Drug use/ process	C6.1	Inappropriate timing of administration and/or dosing intervals
		C6.2	Drug under- administered
		C6.3	Drug over- administered
		C6.4	Drug not administered at all
		C6.5	Wrong drug administered
C7	Patient related	C7.1	Patient uses/ takes less drugs than prescribed or does not take the drug at all
		C7.2	Patient uses/ takes more drug than prescribed
		C7.3	Patient abuses drug (unregulated overuse)
		C7.4	Patient uses unnecessary drug
		C7.5	Patient takes food that interacts
		C7.6	Patient stores drug inappropriately
		C7.7	Inappropriate timing or dosing intervals
		C7.8	Patient administers/ uses the drug in a wrong way
		C7.9	Patient unable to use drug/ form as directed
C8	Others	C8.1	No or inappropriate outcome monitoring (incl. TDM)
		C8.2	Other cause; specify
		C8.3	No obvious cause

RESULTS

Socio- demographics of the study population

Overall, data from 200 hospital admissions were reviewed and registered. Among the 200 patients reviewed, 119 (59.5%) were males and the rest 81 (40.5%) were females. Gender wise distribution is summarized in Table 1.

Table 1: Gender wise distribution of the subjects.

Gender	Frequency (n=200)	Percentage
Male	119	59.5%
Female	81	40.5%

In this study, the majority of patients i.e; 132(66%) belonged to the age group of 18- 65 years, followed by 56(28%) in the age group of >65 and 12(6%) patients in the age group of <18. The mean age of participants was 51.37 years (SD: 18.45). Table 2 outlines the age wise distribution of the subjects.

Table 2: age wise distribution of patients.

Age group	Frequency (n=200)	Percentage
<18	12	6%
18- 65	132	66%
>65	56	28%

Out of 200 patients, a total of 11 (5.5%) patients presented with social history of alcohol intake and 13 (6.5%) presented with social history of tobacco consumption. Table 3 outlines the social history of the subjects.

Table 3: Social history of patients.

Social history	Frequency (n=200)	Percentage
Alcoholic	11	5.5%
Tobacco users	13	6.5%

In this study, maximum length of stay was 20 days and minimum length of stay was 01 day. Maximum no. of patients stayed for 3 days. The average length of stay was 4.8 days (SD: 2.9).

In regards to the presence of comorbidities, 148 (74%) patients among 200 have at least one co-morbid condition. Maximum no. of co-morbid conditions per patient was 06 and minimum was 01. The most common being Hypertension (n=87, 27.9%) followed by Diabetes mellitus (n=64, 20.5%) and Renal disorders (n=41, 13.2%) and others. Out of 148 patients with comorbidities, 123 (83%) were taking medications to treat comorbidities. Table 4 outlines the number of comorbidities per subject.

Table 4: Number of Co- morbidities among subjects.

No. of comorbidities	Frequency (n=148)	Percentage
≤2	100	67.5%
2- 6	46	31%
≥6	02	1.35%

Table 5: Comorbid conditions in study population.

Comorbid conditions	Frequency (n=148)	Percentage
Hypertension	87	27.9%
Diabetes mellitus	64	20.5%
Respiratory disorders	12	3.8%
Renal disorders	41	13.2%
Cardiovascular disorders	38	12.2%
Neoplastic disorders	11	3.5%
Others	58	18.6%

Polypharmacy

Regarding Polypharmacy, out of 200 patients, 114 (57%) patients were prescribed with polypharmacy and the rest 86 (43%) without poly pharmacy. Mean number of drugs was 12.6 (SD: 4.5). Table 6.6 depicts polypharmacy among the study population.

Table 6: Polypharmacy among study population.

Polypharmacy	Frequency (n=200)	Percentage
Patients on polypharmacy	114	57%
Patients without polypharmacy	86	43%

Classification of disease condition in the study population

Most common diseases observed in enrolled patients were cardiovascular disorders (n=168, 84%) followed by renal disorders (73, 36.5%). Diseases like dermatological disorders (n=10, 5%), urological disorders (08, 4%), bone & joint disorders (4, 2%), psychiatric disorders (n=4, 2%) and others (18, 9%) were found to be less frequent. The classification of disease conditions of the study population is presented in Table 7.

Table 7: Classification of disease condition in the study population.

Comorbidities	Frequency (n=200)	Percentage
Cardiovascular disorders	168	84%
Renal disorders	73	36.5%
Gastrointestinal disorders	66	33%
Endocrine disorders	44	22%
Infectious diseases	39	19.5%
Neurological disorders	30	15%
Respiratory disorders	23	11.5%
Neoplastic disorders	15	7.5%
Hematological disorders	11	5.5%
Dermatological disorders	10	5%
Urological disorders	08	4%
Bone & joint disorders	04	2%
Psychiatric disorders	04	2%
Others	18	9%

Prescription analysis of the study population

Total 200 prescriptions were evaluated and a total number of 2246 medication orders were reviewed. Mostly prescribed drug classes were gastrointestinal drugs (n=456, 20.3%) followed by cardiovascular agents (n=358, 15.9%) followed by antimicrobials (n=351, 15.6%). Least prescribed drug classes were drugs acting on respiratory disorders (n=60, 2.67%) and neoplastic agents (n=24, 1.06%). The classification of prescribed drug classes for the study population is presented in Table 8.

Table 8: Classification of prescribed drug classes for study population.

Drug classes	Frequency (n=2246)	Percentage
Gastrointestinal agents	456	20.3%
Cardiovascular agents	358	15.9%
Antimicrobial agents	351	15.6%
Analgesics	250	11.13%
Drugs affecting blood and blood formation	169	7.52%
Drugs acting on kidneys	144	6.4%
Antipsychotics	103	4.5%
Drugs acting on endocrine disorders	91	4%
Drugs acting on respiratory disorders	60	2.67%
Neoplastic agents	24	1.06%
Others	253	11.26%

Drug related problems as per the PCNE classification

Problem domain

A total of 21 Drug Related Problems were identified (males: 10 (62.5%) ; females: 6(37.5%)). All the found DRPs are accounted as actual. On average, each patient in the study experienced 0.12 % DRPs during their hospitalization. DRP profiles with problems as primary domains are presented in Table 9. As depicted in Table 9, unclear problems like the drugs prescribed in high doses contributed to the majority of DRPs.When conducting a further analysis of DRP sub domains, DRPs related to treatment effectiveness was 33.37%, DRPs related to Treatment Safety was 19.04% and DRPs related to other problems contributed to 48 % of the total problem. The most frequent drug classes responsible for DRPs were antimicrobial agents (29%) followed by cardiovascular agents (22%). Total number of drugs implicated in DRPs was 13.

Table 9: The frequency of Drug Related Problem/ DRP with Problem as Primary Domain (n=21).

Primary domain	Code	classification of problems	Frequency(n=21); (%)
P1: Treatment effectiveness (33.3%)	P1.2	Effect of drug treatment not optimal	4; (19.04%)
	P1.3	Untreated symptoms or indication	3; (14.3%)
P2: Treatment safety (19.04%)	P2.1	Adverse drug event (possibly) occurring	4; (19.04%)
P3: Others (48%)	P3.2	Unnecessary treatment	5; (24%)
	P3.3	Unclear problem/ complaint	5; (24%)

Causes domain

Table 10 outlines DRP profiles with Causes as primary domains. The most prevalent cause of DRPs was the selection of drug (42.8%) and selection of dose (23.7 %); this domain constituted the majority of all DRPs. Further other domains were responsible for the rest of DRPs followed by drug use pattern (10 %), patient related (4.7%) and other causes (19%).

Table 10: The frequency of drug related problems / DRPs with causes as primary domains (n=21).

Primary domain	Code	Classification of causes	Frequency(n=21); (%)
C1: Selection of drugs (42.8%)	C1.1	Inappropriate drug according to guideline/ formulary	03;(14.2%)
	C1.3	No indication for drug	01; (4.7%)
	C1.5	Inappropriate duplication of therapeutic group or active ingredient	02; (9.5%)
	C1.6	No drug treatment in spite of existing indication	03;(14.2%)
C3: Dose selection (23.7%)	C3.2	Drug dose too high	04;(19.04%)
	C3.4	Drug regimen too frequent	01;(4.7%)
C6: Drug use process (10%)	C6.1	Inappropriate timing of administration and / dosing intervals	01;(4.7%)
	C6.5	Wrong drug administered	01;(4.7%)
C7: patient related (4.7%)	C7.3	Patient abuses drug (unregulated overuse)	01;(4.7%)
C8: Others (19.04%)	C8.3	No obvious cause	04;(19.04%)

Incidence of DRPs

Out of 200 prescriptions reviewed, 21 DRPs were identified from 16 prescriptions, among these 4 problems are ADRs. The incidence of DRPs was found to be 8%. The average number DRP per prescription was found to be 0.08. The incidence of ADR was found to be 2 % . The average number of ADR per patient was found to be 0.13.

Drug - drug interactions

Out of 200 prescriptions reviewed, 79 DDIs were observed . The Incidence of drug- drug interaction among the study population was found to be 23.5% and the average number of DDIs in a prescription was 0.7. Most of DDIs were serious DDIs (n=71, 90%) and contraindicated DDIs (n=08, 10%) respectively. Out of 79 DDIs, 61 (77%) were pharmacodynamic in nature and 18 (22%) were pharmacokinetic in nature.

DISCUSSION

This study was conducted to evaluate DRP identification and incidence in real clinical practice during hospital admission in the context of a standardized pharmaceutical care program and as this was an observational study, interventions were not included in the study. This study includes the data of 200 patients from the time period of december 2020 to march 2021. In this study, patients directly admitted in the general ward with no restriction of either gender and age with hospital stay of more than 24 hours. The selection criteria was limited for direct admission at the general ward therefore transferred patients from ICU and ER were excluded due to lack of monitoring at the time of admission. Among 200 patients, males were predominant as compared to females. Also, the majority of patients belonged to the age group of 18 to 65 years followed by geriatric population. Hypertension and diabetes mellitus were the most common comorbid conditions in patients. More than half of the population(57%) were prescribed polypharmacy which can be considered as the greatest risk factor for causing DRPs. A total number of 2246 medication orders were reviewed. Among this, highly prescribed agents were gastrointestinal drugs and cardiovascular drugs followed by antimicrobials. Out of 200 patients, 16 patients were identified with at least one actual DRP. From 16 prescriptions, 21 DRPs were identified and documented with 4 ADRs and 79 DDIs. Majority of DDIs were serious and pharmacodynamic in nature. Problem types like unclear problem, unnecessary treatment was identified as a major problem followed by treatment effectiveness and ADRs. selection of drugs and selection of dose types of causes contributed to the majority of problems. Oral levofloxacin, IV octreotide, IV ofloxacin, and paclitaxel were found to be responsible for 4 actual ADRs. Drug classes like antimicrobials and cardiovascular agents caused most DRPs.

CONCLUSION

We cannot cease DRPs immediately but it can be prevented by an active and rationalized clinical care, which is only possible when all healthcare workers work hand in hand. By conducting this study, we came across various important considerations which elaborates the efficient role of a clinical pharmacist in the Indian scenario i.e., medication review, drug use pattern, medication reconciliation, monitoring of lab data and other clinical activities. From our study, we have concluded that a patient's therapeutic outcome can be improved by proper monitoring, identifying and resolving DRPs, monitoring treatment outcome, individualizing medication regimen, decreasing risk of medication errors via medication chart endorsement by help of a clinical pharmacist on a regular basis. The problems arising from drug pharmacotherapy or drugs can be identified, resolved and precluded by the upgraded clinical knowledge and patient centric pharmacotherapeutic management. This study can be further done more at a patient level by taking into consideration the other parameters of PCNE classification which we could not use in our study by providing intervention, by providing more direct assistance to physicians and other healthcare professionals in tailoring the treatment or pharmacotherapy based on each individual patient parameter. Clinical pharmacists can take part in screening of the incidence of DRPs or by doing timely medication review and prevent the occurrence of DRPs in populations prone to it. Thus, clinical pharmacists can be a part of the healthcare team by ensuring an optimal pharmaceutical care.

ABBREVIATIONS

DRP - Drug Related Problem,
ADR - Adverse Drug Reaction,
ADE - Adverse Drug Event,
DDI - Drug Drug Interaction,
PCNE - Pharmaceutical Care Network Europe,
IV - Intravenous,
HRQOL- Health Related Quality Of Life,
WHO - World Health Organization,
US - United States,
UK - United Kingdom,
DART - Drug Assessment Risk Tool,
ICH - International Council of Harmonization,
GCP - Good Clinical Practice,
ICF - Informed Consent Form,
CRF - Case Report Form,
ICU - Intensive Care Unit,
ER - Emergency Room

AUTHOR'S CONTRIBUTION

Dhvani Patel, Ruchi Yadav, Yesha Joshi for designing and conducting study, analyzing data, interpreting results and drafting manuscript. Hardi Patel and Dr. KalpeshChopda was involved in supervision of the study and its critical review. Final approval of the version to be published is given by all the authors.

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CONFLICT OF INTEREST
The authors declare no conflict of interest.

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