

Assessment of Drug Therapy Interventions by Clinical Pharmacist in a Tertiary Care Hospital.

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ABSTRACT

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The aim of the study was to assess the drug therapy interventions and the feedbacks from the clinicians on interventions. This study was a prospective, observational and interventional study. The drug therapy details of the patients were collected from inpatient case records. Clinical pharmacist reviewed the drug therapy, identified the DRPs and discussed during ward rounds with the physicians concerned and suitable suggestion was provided which had been documented. The clinical pharmacist assessed the contribution made through the above-mentioned parameters through the physician, by feedbacks. A total of 37 DRPs were identified from 31 patients case records. Male predominance was noted over females. DRPs were commonly seen in patients aged between 31-60 years of age. Majority of the DRP resulted from the inappropriate drug selection pattern 35.13%. Majority of the clinical pharmacist recommendations were on drug choice 48.64%. The acceptance rate of recommendation and change in drug therapy was found to be high 78.37%. Most of the pharmacist interventions were seen to have moderate significance in grade. In the feedbacks most of the clinicians commented that this service was helpful and this service to be continued in future. Clinical pharmacy services can produce a high number of interventions, which may benefit patients. This study showed that the Clinical pharmacist interventions in drug therapy helped clinicians in identifying and preventing drug related problems.

Key words: Clinical Pharmacist, Intervention, Drug therapy, Drug related problems.

INTRODUCTION

Drug-related problems (DRPs) can be defined as any event or circumstance involving the drug treatment, which interferes or potentially interferes with the patient, achieving an optimum outcome of medical care. Drug related problems are frequent and may result in reduced quality of life, and even morbidity and mortality¹. Despite excellent benefits and safety profile of most medication drug related problems pose a significant risk to patients, which adversely affect quality of life, increase hospitalization and overall health care cost².

Drug-related problems include medication errors (involving an error in the process of prescribing, dispensing, or administering a drug, whether there are adverse consequences or not) and adverse drug reactions (any response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function). Furthermore, adverse drug events can be defined as an injury whether or not causally related to the use of a drug³.

Drug related problems may arise at all stages of the medication process from prescription to follow-up of treatment. Most problems are centred on administration, dispensing and the patients use of a medicinal product, but lack of follow-up and reassessment of medical treatment is also a major problem. Also problems regarding prescription could entail serious consequences. The health and economic consequences of the medication problem may appear in many ways, for instance in the form of a large extent of drug related hospitalizations. Other consequences for patient and society are unnecessary drug expenses, uncomfortable symptoms, adverse drug reactions and a poorer state of health⁴.

Increased use of medication and availability of new drug therapies potentially increase the risks of patient for iatrogenic adverse drug events in hospitals. Iatrogenic adverse events are important for consideration because it cannot only prolong hospital stay but also increase patient health care expenditure. Therefore, it is important that all drug related problems resulting in serious injury or death are evaluated to assess whether improvement in the healthcare delivery system can be made to reduce the like hood of similar events occurring in the future^{5,6}.

Many studies are carried out in hospitals to assess and

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minimize drug related problems. It is reported that medication errors occur in 3-6.9% of in-patients and the error rate for in-patients medication orders was reported to be 0.03-16.9% with each hospital experienced a medication error every 22.7 hours.⁷ An Indian study reported that the incidence of drug related problems was found to be greater than quoted as an average in developed countries⁸.

Drug therapy has become so difficult that no one professional is expected to optimize the drug therapy and control drug related problems alone⁷. Drug-related morbidity and mortality are often preventable, and pharmaceutical services can reduce the number of ADRs, the length of hospital stays, and the cost of care. Pharmacists must abandon factionalism and adopt patient-centred pharmaceutical care as their philosophy of practice⁹. Many studies have shown that clinical pharmacists can effectively identify and prevent clinically significant drug-related problems and that physicians acknowledge and act on the clinical pharmacists suggestions for intervention to the drug-related problems. A pro-active rather than a reactive approach on the part of the pharmacists seems prudent for obtaining most benefit. This includes participation of pharmacists in the ward rounds at the stage of ordering and prescribing where all types of drug-related problems, including also potential problems, should be discussed. Therefore participation and intervention of clinical pharmacists in health care positively influence clinical practice¹.

Intervention is defined as an action by a clinical pharmacist, which resulted in a change in the patients' therapeutic management. Though pharmacy practice has changed significantly in recent years and continues to evolve towards the provision of better pharmaceutical care, pharmacists represent an under-utilised but potential resource to optimize the usage of drugs. Studies have shown that a clinical pharmacist can reduce health service use and cost while improving the appropriateness of drug prescribing. Medication errors most often occur due to insufficient information and time during prescription¹⁰.

Pharmacists can facilitate improved prescribing and medicines management by working closely with the medical team. This model provides a safer system, improvements in pharmaceutical care and better resource utilization. Analysis of clinical pharmacy interventions has demonstrated that pharmacists have an important role in improving patient care and advice is generally accepted by prescribers. Therefore clinical pharmacists' intervention can have a positive impact on reducing drug related errors in overall patient care¹¹.

Clinical pharmacists are uniquely trained in therapeutics and provide comprehensive drug management to patients and providers (includes physicians and additional members of the care team). Pharmacist intervention outcomes include health-related quality of life, patient satisfaction, medication appropriateness, adverse drug reactions and economics. This type of study is of particular importance because most studies reporting medication errors and ADEs were in hospitalized patients, and with the growth of hospital medicine there is increased focus on interventions to improve the care of hospitalized patients. The role of clinical pharmacist in the care of hospitalized patients has evolved over time, with increased emphasis on collaborative care and patient interaction. The addition of clinical pharmacist services in the care of inpatients generally results in improved care, with no evidence of harm¹².

Safe and effective medicine use is the core business of clinical pharmacists. With the focus on individual patients, comprehensive and accountable clinical pharmacy services are an essential component of contemporary healthcare practice. By working to ensure that medicine therapy is optimum, safe and cost-effective, the provision of clinical pharmacy services serves the interests of individual patients and also the wider community¹³.

India is a country with significant problems with medication use, but until recently Indian pharmacist has not been educated for a patient-care role. The purpose of this study is to assess the drug therapy interventions by clinical pharmacist related to patients in a tertiary care hospital.

METHODS

This study was carried out for a period of 7 months among in-patients who were being treated under the Medicine unit of KLES's Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum which is a 1500 bed hospital. This was a prospective, observational, interventional study. In-patients of either sex of any age undergoing treatment in medicine wards were included. The exclusion criterion was patients receiving treatment on outpatient basis and patients with severely ill conditions. The intervening pharmacist was a postgraduate pharmacy practice student. All the interventions made by the intervening pharmacist were preceded by consultation with the academic clinical pharmacist. The clinical pharmacist designed a standard format to collect relevant data for each intervention such as brief details of the patient, medications, problem identified, physicians response and follow up, if any. The patient's demographic data, current

medication, past medical and medication history, laboratory investigation was collected from the patient's progress records, treatment charts, laboratory reports and patient's history records. The demographic data collected includes the patient's age and gender. The current medication data includes all the drugs, their dosage, route of administration with frequency, date of drug started and stopped. The past medical and medication history data collected includes the patients previous allergies, co-morbidities and the drugs received previously. The laboratory data collected includes the relevant laboratory investigation done in the hospital.

Clinical pharmacist routinely monitored patient's drug therapy and interviewed with physicians as well as patients when necessary. The identified drug related problems were discussed during ward rounds with the physicians concerned and has been documented. The acceptance level of physician for the particular intervention was also recorded as either accepted or not accepted. Similarly, whether or not there was a change in drug therapy was noted. In addition, the total time taken by the intervening pharmacist in preparing and undertaking the intervention was recorded. The intervening pharmacist assessed the clinical significance of each intervention. The feedbacks of clinician's opinion on clinical pharmacist interventions were documented and analysed.

RESULTS

A total of 105 patients drug therapy were followed during the seven months study period. Out of which 31 patients had drug related problems. Out of 31 patients 37 drugs related problems were identified and assessed. Out of 31 patients 18 (58.06%) were male and 13 (41.93%) were female. The age group of 31- 60 years patients had more DRPs compared to age groups of 10-30 and above 60 years. The demographic details of the patients are summarized in Table 1.

The identified drug related problems are Adverse drug reactions 1 (2.70%), Interactions 4 (10.81%), Drug selection 13 (35.13%), Dosing 7 (18.91%), Drug use 6 (16.21%), Monitoring 1 (2.70%) and Patient/Provider 5 (13.51%). The drug related problems are summarized in Table 2.

Out of 37 DRPs identified, 37 recommendations were made by the clinical pharmacist and they are Drug Choice 18 (48.64%), Dosing 7 (18.91%), Optimization of administration 3 (8.10%), Need for drug monitoring 1 (2.70%) and others which is of 8 (21.62%). Various suggestions provided by the intervening pharmacist are summarized in Table 3.

Result of recommendations concerning drug related problems are suggestion accepted and therapy changed 29 (78.37%), suggestion accepted and therapy not changed 5 (13.51%) and neither suggestion accepted nor therapy changed 3 (8.10%). The result of clinical pharmacist recommendations is shown in the Table 4.

The time taken for the intervention by the clinical pharmacist were found to be 5 minutes or less 7 (18.91%), 6-15 minutes 20 (54.05%), 16-29 minutes 8 (21.62%), 30-59 minutes 2 (5.40%).

Out of 37 interventions the Clinical pharmacist contacted doctors for about 25 (67.56%) interventions, PGs 2 (5.40%), nurses 2 (5.40%) and for 8 (21.62%) interventions the personnel contacted are patients.

Out of 37 interventions, the significance grades of interventions were found to be 'moderate' 17 (45.94%), 'minor' 15 (40.54%) and 'major' 5 (13.51%). The significance grade of drug related problems is represented in Table 5.

Out of 10 clinicians 6 (60%) of them gave the opinion that clinical pharmacist interventions were helpful and 4 (40%) of them gave the opinion that clinical pharmacist interventions were very helpful. Out of 10 clinicians 7 (70%) of them gave the opinion that the drug related intervening service provided by the clinical pharmacist was good. Out of 10 clinicians all of them 10 (100%) gave the opinion that this service to be continued in future.

DISCUSSION

Drug-related problems are relatively common in hospitalized patients and can result in patient morbidity and mortality, and increased costs³. The number of drugs used and the number of clinical/pharmacological risk factors significantly and independently influenced the risk for DRPs³³. In India, clinical pharmacy service is an emerging discipline. Clinical pharmacy service is to optimize patient outcomes by working to achieve the best possible equality use of medicines. It has been shown that the clinical pharmacy activities reduce the drug related problems related to hospitalization, probability of readmission and total cost of drug therapy². The aim of the study was to assess the clinical pharmacist interventions pertaining to drug therapy and the feed backs from the clinicians. Medicine department was selected for the study because patients in medicine unit are frequently prescribed a large number of drugs and having variety of diseases.

Among the 105 patients followed during the study period 31

patients were found to need pharmacist intervention in their drug therapy. A total of 37 drug related problems were identified and assessed from 31 patients. Out of 31 patients involved in drug related problems, (58.06%) were males and (41.93%) were females. This study showed a high incidence of drug related problems in males over females. This might be due to increased medication use owing to their multiple comorbidities. This observation is in contrast with the demographic reports of the study conducted by Madhan Ramesh et al², cited a predominant of males over females. The incidence of drug related problems were high (54.83%) in patients aged between 31-60 years, where as age group of 10-30 years was found to be (16.12%) and the patients above 60 years of age were (29.03%) which is similar to the study conducted by Madhan Ramesh et al² which shows more DRPs in patients aged between 41-60 years. This can be attributed to the fact that more number of patients visited the hospital during the study period was ranged between 31-60 years of age group.

Most of the DRP observed in the study resulted from the inappropriate drug selection pattern (35.13%) which constituted more of the 'drug prescribed not needed' 6, followed by 'drug duplication' 4, 'drug needed not prescribed' 1, 'cost of therapy' 1 and 'inappropriate dosage form' 1. This observation is in contrast with the study carried out by Madhan Ramesh et al², in which drug use without indication accounted for highest. The high incidence of inappropriate drug selection may be attributed to lack of standard treatment protocol in the hospital, poor history taking etc. Inappropriate dosing (18.91%) was the second most common DRP observed which included more of 'duration inappropriate' 4, followed by 'dose too high' 2 and 'dose too low' 1. The study carried out by G. Parthasarti et al⁸ showed that inappropriate dosing accounted for highest DRPs but in this study inappropriate dosing is the second most common DRP and this finding is consistent with the study carried out by S. Mangasuli et al¹⁰ which showed that improper dose accounts for the second most common DRP. Drug use was accounted for (16.21%) of the total DRPs which constituted more of 'incorrect storage' 2 and 'incorrect administration' 2, followed by 'Wrong dose taken/ administered' 1 and 'drug not taken' 1. In few cases it was due to lack of patient's awareness on storage and administration. While in few other cases it was due to shift change of nursing staff. Drug related problems due to patients or provider contributed (13.51%) of the total DRPs which integrated more of 'demonstration of devices' 2 and 'non-adherence' 2, followed by 'Patient misuse

(overuse/underuse)' 1. In few cases it may be ascribed to lack of patient's knowledge while in few cases it was due to economic constraints of the patients that lead to non-procurement of prescribed medicines and reluctance of patients to take the medication for unknown reasons. Drug interactions was accounted for (10.81%) of the total DRPs identified which incorporated more of 'drug-drug interaction' 3 followed by 'drug-disease interaction' 1. And both the adverse drug reactions and monitoring were accounted for (2.70%) of the total DRPs.

Recommendations, on drug choice (48.64%) was the most frequently provided recommendations which included more of 'Drug discontinuation' 16, followed by 'addition of a new drug' 1 and 'change of dosage form' 1. This finding is similar like the observation made in an Indian study² where the cessation of drug and addition of drug were the suggestions most frequently provided. Other recommendation made in this study was on dosing 7 (18.91%), Optimization of administration 3 (08.10%), need for drug monitoring 1(02.70%) and others 8 (21.62%) which are adherence, advices to patients, proper storage and cost effectiveness.

In this study the major reason for drug discontinuation were due to drug prescribed not needed and drug duplication. Addition of drug was suggested in case of drug needed not prescribed. This is suggested in a gastric irritation case. In most case recommendation on dosing were sought in dose too high, dose too low and in patients with renal impairment requiring dosage reduction. These finding in this study indicate that there is a scope for clinical pharmacist to suggest issues related to rational drug therapy and emphasis on the importance of involvement of pharmacist in healthcare delivery.

The acceptance rate of intervening clinical pharmacist recommendation and change in drug therapy was found to be high (78.37%). There were (13.51%) other interventions where suggestions were accepted, but therapy was not changed either because the physicians were hesitant to change the prescription immediately, without close monitoring, or because the suggestions were thought to be insignificant. In (08.10%) cases, the suggestions were neither accepted nor therapy changed. One of the reasons for this could be that the pharmacists failed to understand the sophisticated prescribing behaviour i.e., prescribing decisions governed by clinical experience of physicians. These findings in this study correlates with other published studies^{2,10}.

(18.91%) interventions took 5 min or less to complete and

(54.05%) interventions took 6 - 15 min to complete. This reflects the quick turnover of patients and the high number of problems to resolve in a limited amount of time. The philosophy of the clinical pharmacist was to see the maximum number of patients possible, prioritizing their problems to ensure that those in need receive the highest level of care. Consequently, a large number of patients are seen and problems were resolved quickly wherever possible. It should be noted that (21.62%) interventions took 16-29 min to complete and (05.40%) interventions took 30-59 min to complete reflecting the complex nature of some of the problems encountered. This finding in this study is in contrast to R. N. Price et al¹⁷ where in Ninety per cent of interventions took 10 minutes or less to complete. This difference may be attributed to the fact that involvement of experienced clinical pharmacist would have led to the high acceptance rate and also reductions in time spend for each intervention.

The personnel mostly contacted for the interventions were doctors (67.56%) followed by PG's (05.40%). This is because the clinical pharmacist taking rounds in the medical wards along with the doctors and the PG's more over the fact that most of the time postgraduates were involved in writing the medication order. The nurses contacted for the interventions were (05.40%). This may be due to their busy work schedule or inadequate number of nurses in the medicine unit. The patients contacted for the interventions were (21.62%). This may be of lack of patient's knowledge and awareness. This data's consistent with the study carried out by R. N. Price et al¹⁷ showed that 40 per cent of interventions the contact point was a junior doctor.

Of the 37 DRPs, (40.54%) were rated to be 'minor', (45.94%) were 'moderate' and (13.51%) were 'major' significance of interventions. This finding correlates with studies^{2, 8} that reported 60% and 49% of interventions as moderate significance. The moderate significance level is the level of problems requiring adjustments, which are expected to enhance effectiveness of drug therapy producing minor reduction in patient morbidity or treatment cost.

Out of 10 clinicians most of them (60%) gave the opinion that clinical pharmacist interventions was helpful in their practice and (40%) of them gave the opinion that clinical pharmacist interventions was very helpful. Most of the PG's and interns commented that it is very helpful as this helps to improve their attitude towards patient care.

Out of 10 clinicians (70%) of them gave the opinion that the drug related intervening service provided by the clinical

pharmacist was good and (30%) of them gave the opinion that the drug related intervening service provided by the clinical pharmacist was average.

Out of 10 clinicians (50%) of them gave the opinion that the time taken for the Intervention to be shown as per the requirement of the patient was ideal and (20%) of them gave the opinion that the time taken for the intervention by the clinical pharmacist was more and (30%) of them had no opinion. Most of the clinicians commented that the time taken for the intervention was ideal and its helps in patient care and treatment outcome. But in few cases the time taken was more because of lack of knowledge and the complicity of the cases.

All clinicians (100%) of them gave the opinion that this service to be continued in future as they were interested to improve the patient care and treatment outcomes by identifying and resolving the DRPs.

Out of 10 clinicians (50%) of them gave the opinion that all other services like ward round participation, patient counselling, drug information, identifying DRPs are their expectation from the clinical pharmacist, (20%) of them are expecting both the drug information and patient counselling services, another (20%) of them expecting both ward round participation and identifying DRPs and the rest (10%) of the physician expecting both ward round participation and drug information services from the clinical pharmacist.

The overall observation made from this study was that pharmacist has greater responsibility in healthcare team in minimizing and preventing drug related problems and thereby improves the patient care, treatment outcomes and enhances quality of life.

Table No.1 - Demographic details of the study patients

Characteristics	Number (n=31)
Gender	Male 18 (58.06%)
	Female 13 (41.93%)
Age Group (years)	31-60 17 (54.83%)
	Above 60 09 (29.03%)

Table No.2 Types of Drug Related Problems.			
Sl. No.	Types of DRPs	No. of DRPs	Total
1.	Adverse drug reactions a) Allergic reaction b) Side effect	00 01	01 (02.70%)
2.	Interactions a) Drug - Drug interaction b) Drug disease interaction c) Drug food interaction	03 01 00	04 (10.81%)
3.	Drug selection a) Drug needed not prescribed b) Drug prescribed not needed c) Drug Duplication d) Cost of therapy e) Contraindication f) Inappropriate dosage form	01 06 04 01 00 01	13 (35.13%)
4.	Dosing a) Dose too low b) Dose too high c) Duration inappropriate	01 02 04	07 (18.91%)
5.	Drug Use a) Wrong dose taken/ administered b) Wrong drug taken/administered c) Drug not taken d) Incorrect storage e) Incorrect administration	01 00 01 02 02	06 (16.21%)
6.	Untreated Indications a) Condition not adequately treated b) Preventive therapy required	00 00	00 (00%)
7.	Monitoring a) Laboratory monitoring b) Non-laboratory monitoring	01 00	01 (02.70%)
8.	Patient or provider a) Demonstration of device b) Patient didn't understand instruction c) Patient misuse (overuse/underuse) d) Non-Adherence	02 00 01 02	05 (13.51%)

Table No.3 Clinical pharmacist recommendations			
Sl.No.	Types of Recommendations	Number	Total (n=37)
1.	Drug Choice a) Drug discontinuation b) Addition of a new drug c) Change of dosage form	16 01 01	18 (48.64%)
2.	Dosing a) Decrease the dose b) Increase the dose c) Appropriate duration 0	03 01 03	07 (18.91%)
3.	Optimization of administration a) Change of administration route b) Administration modalities	01 02	03 (08.10%)
4.	Need for drug monitoring	01	01 (02.70%)
5.	Others *	08	08 (21.62%)

* Adherence, Advice to patients, Proper storage and Cost effectiveness

Table No 4 - Result of Clinical pharmacist recommendations.

Recommendations	Result (n=37)
Suggestion accepted and therapy changed	29 (78.37%)
Suggestion accepted but therapy not changed	05 (13.51%)
Neither Suggestion accepted nor therapy changed	03 (08.10%)

Table No 5 - Grade of interventions.

Grade *	Result (n=37)
Minor	15 (40.54%)
Moderate	17 (45.94%)
Major	05 (13.51%)

* **Minor:** Problems requiring small adjustments and optimization to therapy, which are not expected to significantly alter hospital stay, resource utilization or clinical outcome.

Moderate: Problems requiring adjustments, which are expected to enhance effectiveness of drug therapy producing minor reductions in patient morbidity or treatment costs.

Major: Problems requiring intervention, expected to prevent or address very serious drug related problems, with a minimum estimated effect on reducing hospital stay by no less than 24 hrs.

CONCLUSION

As the patients in medicine units have a range of diseases and are frequently prescribed with large number of drugs. Clinical pharmacy services helps in monitoring of drug therapy in this area which may benefit patients. This study had presented a pattern of findings of drug related problems identified by the clinical pharmacist, which suggests that a few types of drugs and errors constitute a substantial proportion of clinical pharmacist interventions. Knowledge of the most frequent DRPs could significantly increase the efficiency of clinical pharmacist interventions. This study demonstrates that the physician's acceptance rate of pharmacist intervention is high. This suggests that a joint effort between physicians and pharmacist is possible that provides a safer system, improved pharmaceutical care and better resource utilization. This study showed that the Clinical pharmacist interventions in drug therapy helped clinicians in identifying and preventing drug related problems.

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