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Clinical Pharmacy Interventions in a Secondary Care Hospital in South India

LAKHVINDER S. BATOLAR, S. D. RAJENDRAN* AND B. SURESH
Department of Pharmacy Practice, J. S. S. College of Pharmacy, Ootacamund-643 001.

A prospective study of interventions was carried out at Government Head Quarters Hospital, Ootacamund in order to document the nature and frequency of interventions made by clinical pharmacists at the hospital. Approval of the hospital's ethics committee was obtained. Intervention Data Record included information on patient demographics, admission details, past medical and drug history, present diagnosis and treatment and intervention. Data was collected for a period of seven months between September 1998 and April 1999 from selected wards. Reactive interventions occurred in 8.2% of the 1840 patients admitted, of whom 54.3% were males and 45.7% were females. The mean age of the patients was 44.9 years (±15.3). Interventions were accepted on 147 of 151 cases. Frequency of interventions in various wards included female medical ward (38%), male medical ward (36.7%), intensive care unit (21%) and intensive cardiac care unit (4%). Clinical conditions in which interventions occurred included congestive cardiac failure (15.9%), chronic obstructive pulmonary disease (15.9%) and diabetes mellitus (13.2%). Drugs most frequently involved in the interventions were antibiotics (31.8%), insulin (10.6%) digoxin and frusemide (8.6% each). Intervention to discontinue a drug (29.8%) was the most common recommendation made. Majority of recommendations addressed the issue of inappropriate or unnecessary drug or drug regimen (31.1%). Recommendations for appropriate drug therapy were made in 29.8% of interventions. Outcomes could be measured in 37.1% of interventions, of which, 89.2% were beneficial.

The importance of documenting the value of clinical pharmacy services has been widely emphasized[1-5]. This documentation has been useful for developing recognition for the role of clinical pharmacists, establishing adequate staffing levels, documenting economic and health outcomes of clinical pharmacy services, and identifying the nature of drug-related problems within an institution or community. Documentation may also be part of a broader quality assurance program for the pharmacy department or hospital.

One aspect of clinical pharmacy services that has been studied extensively is the nature, frequency and significance of interventions made by pharmacists to improve the efficacy, safety and cost-effectiveness of drug therapy. Published studies in this area have mainly been from USA, United Kingdom and Australia. Clinical pharmacy has been evolving in India since the establishment in 1996 of a joint Indo-Australian program to develop clinical pharmacy practice and education. Over this time interventions have become a routine part of service provision in the two hospitals associated with this program.

Prevalence of irrational prescribing and antimicrobial resistance is a global issue[6]. The problem of antibiotic resistance is low in countries where the accessibility of drug is restricted and high in countries where easy accessibility of antibiotics exists[7]. India is a country with significant drug use problems and irrational prescribing and antibiotic resistance are widespread[8]. While documentation of systematic health, disease and drug use data is good in the developed

*For correspondence
E-mail: sdrajendran@hotmail.com

world, there is a paucity of the same at the institutional, state and national levels in our country. India does not have a government-subsidized universal pharmaceutical benefits scheme and most drug prescribing and dispensing occurs in the private sector. As a result there are few sources for accurate information about the epidemiology of drug use in India. Drug Utilization Studies have recently come up both in government and private hospitals in our country. These may throw more light on the drug use behaviour in the country and assist to improve documentation and use of drugs[9].

Government Head Quarters Hospital, Ootacamund (GHQH) is a 420-bed secondary care hospital and caters to the healthcare needs of economically deprived patients from the surrounding district. Since 1997, clinical pharmacy services have been provided here by staff and postgraduate students of the Department of Pharmacy Practice, J. S. S. College of Pharmacy, Ootacamund through an Indo-Australian program that aims at evolving the concept of clinical pharmacy in India[8]. Daily participation in ward rounds has provided pharmacists with the opportunity to review drug therapy for individual patients, and to provide timely advice on drugs and therapeutics to medical staff. Interventions have been made since the establishment of the service but were not routinely documented. The present study was carried out as a prospective study to document the nature and frequency of interventions made by clinical pharmacists at the hospital. Another outcome has been the characterisation of drug-related problems at the hospital, which may be typical of other secondary care government hospitals in the Indian setting.

MATERIALS AND METHODS

Approval of the hospital's ethics committee was obtained and a clinical meeting was conducted to inform medical staff about the study. An Intervention Data Record sheet was designed to include information on patient demographics, admission details, past medical and drug history, present diagnosis and treatment and intervention details (Appendix 1). Field-testing of the data sheet over a two-week period resulted in some modifications.

Data was collected for a period of seven months between September 1998 and April 1999 from four wards in which clinical pharmacists were providing services, viz., intensive care unit (ICU), intensive cardiac care unit (ICCU), male medical ward (MMW) and female medical ward (FMW). Clinical pharmacists were requested to notify the investigator of their interventions as and when they occurred. Technical deficiencies such as prescribing of non-stock or non-formulary drugs and illegible prescriptions were not included.

Once an intervention occurred, the attending clinical pharmacist and the investigator recorded the relevant details in the documentation. The investigator then regularly monitored the outcome of the interventions made on the lines of expected improvement based on the intervention. Interventions were evaluated upon the following major categories as suggested by Hatoum *et al.*[10]; the recommendation (intervention), basis of the recommendation and the category of the intervention. Recommendations were classified into the following classes; a. recommending a drug, b. recommending a drug change, c. discontinue a drug, d. order a laboratory test, e. decrease dose, f. increase dose and g. change in dosage scheduling. The basis of recommendation was classified into various classes such as, 'patient-not-responding-to-therapy', 'unwanted-signs-and-symptoms-occurring', 'laboratory-findings', 'literature-cited', 'inappropriate/unnecessary-drug-or-drug regimen' and 'avoiding-predictable-complications'.

The category of the intervention was classified into various classes such as 'drug-therapy-indicated-but-not-prescribed', 'drug-prescribed-when-not-clinically-indicated', 'drug-used-not-the-safest-or-the most-efficacious', 'therapeutic-duplication', 'predictable-drug-drug-interaction', 'inappropriate-route-of-administration', 'inappropriate-dosage-form', 'inappropriate-duration', 'lack-of-supportive-laboratory-data', 'suspected-adverse-effect' and 'recommendation-for-appropriate-drug-therapy'. Interventions were also classified based on drug class used and the diagnosis. The results were then calculated and tabulated.

RESULTS

Reactive interventions (interventions made by the clinical pharmacist as part of direct patient care activity) were made in 8.2% of the 1840 patients admitted during the study period, of whom 54.3% were males and 45.7% were females. The mean age of the patients were 44.9 years (±15.3). No patient had more than one intervention. Interventions were accepted on 147 occasions and were not accepted in 4. The majority of interventions occurred in medical wards, (FMW-38%, MMW-36.7%), followed by ICU-21% and ICCU-4%. Clinical conditions in which interventions occurred most frequently included congestive cardiac failure (CCF-15.9%), chronic obstructive pulmonary disease (COPD-15.9%) and diabetes mellitus (DM-13.2%) (Table 1). Drugs most frequently involved in the interventions were antibiotics (31.8%), insulin (10.6%) and digoxin and frusemide (8.6% each). (Table 2).

The recommendation:

Intervention-to-discontinue-a-drug (29.8%) was the most common recommendation made, closely followed by recommending-a-drug-change (23.2%). (Table 3). Antibiotics figured in a majority of the interventions involving a drug change or discontinuation. As a single agent atropine was most frequently involved in drug discontinuation. Change in the dosage schedule was most frequently recommended for insulin.

Basis of recommendation:

The majority of recommendations were based on 'inappropriate/unnecessary-drug-or-drug regimen' (31.1%). Interventions for 'preventing-possible-unwanted-effects' closely followed next (27.8%). In 18.5% of the interventions, the basis was 'patient-not-responding-to-therapy'. Major drugs involved in this intervention included antibiotics and insulin. Interventions to prevent 'unwanted-signs-and symptoms-occurring' were seen in 12.5% of prescriptions, with digoxin being the most frequently involved drug. (Tables 2 and 3).

Categorisation of interventions:

Recommendations for appropriate drug therapy were made in 29.8% of interventions. Inappropriate dose and inappropriate duration were noted in 12.6% of cases each. In

TABLE 1: CLINICAL CONDITIONS IN WHICH INTERVENTIONS WERE MADE.

Clinical condition	Number of cases	Interventions*(n = 151)	Frequency#
Diabetes Mellitus	104	20 (19.2%)	13.2%
Asthmatic bronchitis	41	4 (9.6%)	2.6%
Bronchitis	120	8 (6.7%)	5.3%
Acid peptic disease	95	3 (3.2%)	2%
Congestive Heart Failure	120	24 (20%)	15.9%
Ischaemic Heart Disease	152	7 (4.6%)	4.7%
Rheumatic Heart Disease	15	3 (20%)	2%
Pyrexia of unknown origin	112	6 (5.4%)	4%
Myocardial infarction	77	3 (3.9%)	2%
Chronic Obstructive Pulmonary Disease	187	21 (11.2%)	13.9%
Hypertension	81	3 (3.7%)	2%
Poisoning	349	16 (4.6%)	10.6%
Lower Respiratory Tract Infections	18	2 (11.1%)	1.3%
Anaemia	29	4 (13.8%)	2.6%
Renal Failure	17	5 (29.4%)	3.3%
Alcoholic intoxication	21	3 (14.3%)	2%
Cor Pulmonale	22	3 13.6%)	2%
Pneumonia	16	5 (31.3%)	1.3%
Others	451	11 (2.4%)	7.3%

Clinical conditions (diseases) in which interventions were made during the study period. *Interventions made were calculated as a percentage of the number of cases treated in the wards during the study period. #Frequency of interventions in different clinical conditions (diseases) was calculated as a percentage of total number of interventions made during the study period.

TABLE 2: DRUGS INVOLVED IN INTERVENTIONS.

Clinical activity	Drugs involved (numbers)												
	I	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII	XIII
Recommendation (n=151)													
Recommended a drug	3	5	4	2	1	1	1	4	3	-	3	-	8
Recommended a drug change	-	-	15	-	1	-	2	-	-	-	-	3	1
Discontinue a drug	5	-	14	8	5	4	2	1	-	-	-	-	3
Order a lab test	1	2	2	-	-	1	-	-	1	-	-	-	2
Decrease dose	4	-	1	1	-	1	-	-	-	-	-	-	-
Increase dose	-	4	4	-	-	2	-	-	-	-	-	-	1
Change in route	-	-	2	-	-	4	-	-	-	-	-	-	3
Change in dosage schedule	-	5	6	-	-	-	-	-	-	-	-	-	2
Basis of Recommendation (n=151)													
Not-responding-to-therapy	-	9	13	-	1	1	-	-	-	-	1	-	3
Unwanted-signs-and-symptoms-occurring	1	1	-	1	2	3	1	-	2	-	-	-	6
Laboratory-findings	3	3	-	-	-	1	-	-	1	-	-	-	-
Literature-cited	1	-	1	-	-	-	1	1	-	-	2	-	1
Inappropriate/Unnecessary- drug-regimen	2	2	26	6	4	4	1	-	-	2	-	-	-
Preventing-possible-unwanted-effects	6	1	6	4	-	4	2	4	1	1	-	3	10
Category of Intervention (n=151)													
Drug-given-with-no-clinical indication	1	-	-	8	-	-	-	-	-	-	-	-	2
Drug-not-given-when-clinically-indicated	2	1	3	-	1	-	1	1	1	-	-	-	4
Drug-used-not-the-safest-or the-most-efficacious	-	-	12	-	3	-	-	-	-	-	-	-	4
Predicting-drug-drug- interactions	1	-	-	-	-	-	2	-	-	-	-	2	-
Inappropriate- route- of- administration	-	-	2	-	2	4	-	1	-	-	-	-	1
Inappropriate-dose	3	6	2	-	1	3	1	-	-	-	-	-	3
Inappropriate-duration	-	-	12	1	-	-	-	-	-	3	-	-	3
Lack-of-supportive-lab-data	-	2	2	-	-	3	-	-	-	-	-	-	-
Suspected-adverse-effect	1	-	-	-	-	-	-	-	-	-	-	-	1
Recommendation-for-appropriate-drug-therapy	5	7	15	2	-	3	1	3	3	-	3	1	2

Table 2 describes the involvement of various drugs in which the interventions were made during the study period. The drugs were denoted by numbers in the table. These numbers represent, I- digoxin, II-insulin, III-antibiotics, IV- atropine, V- analgesics, VI- frusemide, VII- deriphylline, VIII- vitamin C, IX- vitamin B, X- domperidone, XI- enalapril, XII- verapamil, XIII- others.

TABLE 3: ANALYSIS OF INTERVENTIONS.

Clinical activity	Wards				
	MMW	FMW	ICU	ICCU	Total
Recommendation (n = 151)					
Recommended a drug	20	9	5	1	35 (23.2%)
Recommended a drug change	12	7	2	1	22 (14.6%)
Discontinue a drug	17	12	14	2	45 (29.8%)
Order a lab test	5	2	2	0	9 (5.9%)
Decrease dose	1	5	1	0	7 (4.6%)
Increase dose	4	6	1	0	11 (7.2%)
Change in route	4	5	0	0	9 (5.8%)
Change in dosage schedule	5	8	0	0	13 (8.6%)
Basis of recommendation (n = 151)					
Not-responding-to-therapy	14	12	2	0	28 (18.5%)
Unwanted-signs-and- symptoms-occurring	9	7	2	1	19 (12.5%)
Laboratory-findings	1	6	1	0	8 (5.3%)
Literature-cited	3	2	2	0	7 (4.6%)
Inappropriate/Unnecessary- drug-regimen	21	18	7	1	47 (31.1%)
Preventing-possible- unwanted-effects	14	15	11	2	42 (27.8%)
Categorisation of Recommendation (n = 151)					
Drug-given-with-no-clinical- indication	1	3	7	0	11 (7.2%)
Drug-not-given-when- clinically-indicated	5	6	2	0	14 (9.2)
Drug-used-not-the-safest-or the-most-efficacious	8	6	4	1	19 (12.6%)
Predicting-drug-drug interactions	1	1	3	0	5 (3.3%)
Inappropriate-route-of-administration	3	7	0	0	10 (6.6%)
Inappropriate-dose	7	11	1	0	19 (12.6%)
Inappropriate-duration	8	6	3	2	19(12.6%)
Lack-of-supportive-lab-data	4	2	1	0	7 (4.6%)
Suspected-adverse-effect	1	1	0	0	2 (1.4%)
Recommendation-for- appropriate-drug-therapy	23	12	8	1	45 (29.8%)

Table 3 describes the analysis of interventions with respect to the type of intervention (clinical activity) and the wards in which these were made. MMW represents Male Medical Ward, FMW represents Female Medical Ward, ICU represents Intensive Care Unit and ICCU represents Intensive Cardiac Care Unit.

12.6% of the interventions drugs used were found not to be the safest or most efficacious. Drugs were not prescribed in 9.2% of the patients even though clinically indicated and were prescribed in 7.2% of the patients when not clinically indicated. Potential drug interactions were detected in 3.3% of prescriptions and inappropriate route in 6.6% of prescriptions. Insulin, digoxin and antibiotics were the major drugs recommended for appropriate drug therapy (Table 3).

Outcomes:

Outcomes could be measured only in 56 (37.1%) interventions. Clinical pharmacists measured the outcome of the intervention based on the expected improvement due to intervention. The opinion of the treating physicians was obtained where necessary to measure outcome. Beneficial outcomes were obtained in 89.2% of these interventions and no effect was seen in the remaining cases (Table 4).

DISCUSSION

Ooty Government Hospital has a limited hospital formulary and access to laboratory and other investigations is also restricted. Drug therapy, which frequently requires pharmacist intervention in developed countries, such as oral anticoagulants and psychotropic drugs, are not prescribed at the hospital. Laboratory investigations are confined to basic tests like blood count, blood sugar and urine sugar levels. Even sensitivity screening of antibiotics is not done routinely due to lack of funds. These conditions mean that the nature of interventions is different from tertiary care hospitals in India and overseas. For example a change in therapy based on laboratory findings was made in only 5.3% of interventions. Despite this the intervention rate in our study

TABLE 4: OUTCOME OF INTERVENTIONS.

Outcomes (n=51)		Frequency
Not recorded		95 (62.8%)
Recorded		56 (37.2%)
	Beneficial*	50 (89.2%)
	Harmful*	0
	No effect*	6 (10.8%)

Table 4 describes the outcome of interventions made during the study period. The frequency of out comes is given both in numbers and percentages. Outcomes were recorded in 56 cases (n=56). These outcomes were further classified as beneficial, harmful and no effect. The percentages for these have been calculated based on n=56.

was significantly higher than those reported by some other authors[11,12]. The shortage of medical staff at the hospital and a high patient load provides pharmacists with a range of different opportunities for improving drug therapy. For example, medication history interviews by clinical pharmacists sometimes revealed co-morbidities that were not documented during short 1-2 min medical consultations. This may be a contributing factor to a higher rate of interventions.

The majority of interventions were made in relation to therapy for CCF, COPD and IHD. This was possibly due to the availability of monitoring facilities that enabled the clinical pharmacists to follow the patient's progress and make timely interventions where possible. A significant percentage of interventions made were in respiratory disease (24.4%). In our practice, we have observed a high incidence of respiratory complaints and infections in our patient population. This may be due to tuberculosis, a cold climate, overcrowding in poorly ventilated dwellings, a high prevalence of smoking, the use of biomass fuels for cooking and exposure to pollen and other allergens as a result of agricultural employment.

Interventions in diabetic patients were largely due to improvements in the testing and monitoring of urine glucose levels initiated by the clinical pharmacists in the absence of sophisticated blood glucose monitoring equipment. In poisoning cases, development of a simple poison identification methods and treatment protocols formed the basis of interventions in this area. This has highlighted a new role for clinical pharmacists in poison treatment[13].

Interventions for drug discontinuation were made in a significant number of cases, most of which involved antibiotics. In this regard our results correlated well with published studies (25.6% by Hatoum *et al.*, 32.6% by Brown *et al.*)[9,14]. The hospital does not use treatment charts and doctors write prescriptions daily during ward rounds. This makes it difficult for medical staff to quickly access the starting date for antibiotic therapy. Based on the patient's clinical progress and the completion of an adequate treatment course, interventions to cease antibiotics were then made where appropriate. However, as a single agent atropine was the most frequently discontinued drug. In deliberate poisoning cases where the poison was not identified, doctors routinely prescribed atropine for assumed organophosphate poisoning. By implementing a method to identify the poison involved, clinical pharmacists dramatically reduced the number of unidentified poisonings and made interventions to institute

appropriate therapy. In two poisoning cases atropine therapy was recommended since it was found to be the appropriate drug but was not prescribed.

Only two interventions (1.37%) were made in relation to a suspected adverse drug reaction (ADR), where the clinical pharmacists identified the cause of ADR in these patients. None of the interventions were assessed to have a harmful effect on patient outcome. All but four of the interventions were accepted, showing that the advice of clinical pharmacists was well accepted by the medical staff of the hospital. A high rate of acceptance of interventions has also been reported by others[10,11,15].

Limitations of our study methodology included non-documentation of outcomes in a significant number of interventions due to insufficient duration during admission, lack of monitoring facilities and lack of assessable endpoints. A more robust assessment of clinical outcomes would also have been obtained if outcomes had been assessed by a panel which included medical staff.

The significant level of clinical pharmacist-initiated interventions and their acceptance by medical staff has confirmed the value of clinical pharmacy in the Indian clinical setting. We believe this study will help to raise awareness amongst our colleagues in the rest of the country about the ways in which a clinical pharmacist can contribute to improving healthcare in the hospital setting. This study also assisted us to identify specific areas where further attention should be focused. The need for drug utilization studies involving antibiotics, cardiovascular agents and antidiabetic agents was highlighted and work has commenced in this area.

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REFERENCES

1. Ahanel, G.G., Gin, A.S., Przybylo, A., Louie, T.J. and Oitten, N.H., **Amer. J. Hosp. Pharm.,** 1989, 46, 2493.
2. Catania, H.F., Yee, W.P. and Catania, P.K., **Amer. J. Hosp. Pharm.,** 1990, 47, 2701.
3. Huntress, J.D., Possidente, C.J. and Harry, D.J., **Amer. J. Hosp. Pharm.,** 1990, 47, 2711.
4. Strong, D.K., Dupuis, L.L. and Domaratzki, J.I., **Amer. J. Hosp. Pharm.,** 1990, 47, 1350.
5. Ross, A.J., **Pharm. J.,** 1985, 234, 683.
6. Vergiere-Dalmacion, G and Delini, R.A., **Pharmacoepidemiol. Drug Saf.,** 1999, 8, 51.
7. Anonymous, In; Disease fighting back-the growing resistance of Tuberculosis and other diseases to treatment. Parliamentary office of Science and Technology, London, 1994,1.
8. Nyfort-Hansen, K. and May, F., **Aust. J. Hosp. Pharm.,** 1998, 28, 343.
9. George, J., Senthil Kumar, A.B., Rajendran, S.D. and Suresh, B., **Indian J. Pharm. Sci.,** 2001, 63, 491.
10. Xavier, D., Mathew, N., Pradeep, J. and Pais, P., **Indian J. Pharmacol.,** 2001, 33, 456
11. Hawkey, C.J., Hodgson, S., Norman, A., Daneshmend, T.K. and Garner, S.T., **Brit. Med. J.,** 1990, 300, 986.
12. Bebee, R., and Freitag, D.W., **Aust. J. Hosp. Pharm.,** 1990, 26, 356.
13. Kaleemuddin, M., Rajendran, S.D. and Suresh, B., **Aust. J. Hosp. Pharm.,** 2001, 31, 16.
14. Brown, G., **Amer. J. Hosp. Pharm.,** 1991, 48, 2644.
15. Huntress, J.D., Possidente, C.J. and Harry, D.J., **Amer. J. Hosp. Pharm.,** 1990, 47, 2711.