SHORT COMMUNICATION

PATTERN OF ADVERSE DRUG REACTION RELATED QUERIES RECEIVED BY THE DRUG INFORMATION CENTRE OF A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Accurate information about safety of drugs is very essential for health care professionals in identifying, preventing and managing Adverse Drug Reactions (ADRs), thereby ensuring safe use of medications. The objective of the present study was to assess the pattern of drug information (DI) queries related to ADRs received by the Drug Information Center (DIC) of a tertiary care teaching hospital. Retrospective evaluation of the DI queries received in the DIC over a period of three and a half years (January 2002- July 2005) was done for various parameters such as purpose and type of query, characteristics of the drugs and reactions involved, and references used. Out of 2312 DI queries received, 600 (25.9%) were related to ADRs. Majority of the queries were from the department of medicine (80.5%) and was received during ward rounds (76%). In most of the queries, the information was sought for better patient care (66.3%) and the enquirer wanted the information immediately (59.5%). The category of ADR queries most commonly asked was regarding identification of an ADR (54.3%). Considering the reaction characteristics, the organ system most commonly involved in the queries was nervous system (14.7%) and the reaction was fever and skin rash (14%). Most of the queries were on uncommon reactions. Drug class most commonly involved in the queries were antibacterials for systemic use (18.6%) and the most frequently involved drug was phenytoin (35%). MICROMEDEX system was used as the reference in answering most (57.1%) of the queries.

Information on ADRs is among the most sought information on drugs by the health care professionals. Evaluation of pattern of these queries could reveal opportunities for educational and other interventions in promoting safer drug use in a health care setting. DICs could play a major role in promoting drug safety and it needs to be well equipped to respond to these needs.

Keywords: drug information, adverse drug reaction, drug safety, drug information center.

INTRODUCTION

Adverse drug reactions (ADRs) are a persistent and important problem of health care in terms of morbidity, mortality and cost. (Peyriere 2003) ADRs are of great concern to all health care professionals (Al-Tajir and Kelly 2005) and patients. (Enlund *et al.*, 1997, Antoine *et al.*, 1997)

Drug safety greatly depends on rational prescribing (Leape *et al.*, 1999). Results of a meta-analysis done by Winterstein et al showed that 59% of the ADRs are preventable (Winterstein *et al.*, 2002). Studies have demonstrated that nearly half of preventable ADRs resulted from errors in the prescribing process. A large subset of these errors, such as prescribing the wrong dose or the wrong drug, frequently results from a lack of information about the drug, the patient, or both (Bates *et al.*, 1995, Leape *et al.*, 1995 and Lesar *et al.*, 1997). Health care professionals need to have sound knowledge on drugs. The growing number of newly approved drugs and the vast information on the same makes it humanly impossible to recollect all this information in clinical practice. Hence it is important for health care professionals to have a source for accurate and unbiased information on drugs to ensure safe and effective use of drugs.

Drug information centers (DICs) provide comprehensive, objective and unbiased information to health care professionals for decision-making and problem solving activities. Drug information (DI) is provided on various aspects of drug therapy, which includes information related to administration and dosage, ADR, drug interaction, drug therapy, cost and availability. Information required may be either general information on drugs or patient specific information for a clinical situation. Studies show that queries on ADRs are one of the most often enquired category among the queries received by DICs (Nibu *et al.*, 2001, Rao and Gore, 2004; Maywald *et al.*, 2004). Identifying ADRs is important; managing and preventing them are equally critical

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(Roughead, 2005). DI related to ADRs helps in early detection or identification of an ADR, decision making for further management and considering a preventive action for further occurrence.

Since provision of information on ADRs is one among the major aspects that promotes safe drug use, it is important to know the pattern of such information often enquired by health care professionals. This in turn will contribute in designing education strategies, which caters to the need of health care professionals for safer drug use.

METHODOLOGY

The study was carried out in the DIC of Kasturba Hospital (KH), Manipal; a 1400 bedded tertiary care multi-disciplinary teaching hospital in south India. The DIC is a part of the department of pharmacy practice and was established in 2001. The center is well equipped with trained staff, library consisting of textbooks, national and international journals, computer with internet facility and also with electronic databases such as IDIS and MICROMEDEX. DI services are provided on all days of the week except Sundays and holidays at working hours between 9 am to 5 pm. DI queries are received by telephone, intranet, direct access to the DIC and also by clinical pharmacists during ward rounds.

Evaluation of data
Retrospective evaluation of the DI requests documented in the DIC of KH from January 2002-July 2005 was carried out for the study purpose. All the forms in which the category of query was denoted as 'ADR' was selected for evaluation.

Enquirers details and mode of receipt of the query
Details of the enquirer were evaluated for professional status and department of practice. Further, the queries were evaluated for the mode of receipt of the query as by telephone, intranet, direct access and during ward rounds.

Purpose and urgency of the query
The purpose of the query was classified as to update knowledge, for better patient care, for research, and others. DI queries were classified depending on the urgency of the answer needed by the enquirer as immediately, within 2-4 hours, within a day, within 1-2 days and others.

Category of query
Queries on ADRs were further categorized based on the type of information sought in the query as general adverse drug reaction profile of a drug, queries which seek information on whether drug(s) in question can cause the specified reaction (identification), incidence of the ADR in question, details of ADR in question such as management of the ADR, onset, duration and outcome of the ADR, predisposing factors, monitoring parameters, mechanism, prevention, and clinical manifestations.

Drug characteristics
Specific drugs that were involved in the query were noted and were codified into various drug classes according to anatomical and therapeutic chemical (ATC) classification based on WHO-ATC Index 2006. (WHO drug statistics methodology 2006)

Reaction characteristics
The ADRs involved in the queries were evaluated for their incidence. ADRs that could be assessed (i.e., those reactions for which the frequency is available in the literature) were classified into very common, common, uncommon, rare and very rare depending on its incidence as ≥10%, ≥1-<10%,≥ 0.1- <1%, ≥0.01-<0.1, <0.01%, respectively. The ADRs involved in the queries were categorized as unassessable if the frequency of the reaction under question is not mentioned in the literature or if there are no previous reports which associates the drug in question with the reaction. Further, ADRs involved in the queries on general ADR profile of a drug were not evaluated for this parameter.

System organ class involved
Queries were evaluated to find out the system organ class involved with reactions in question. ADRs involved in the queries on general ADR profile of a drug were not evaluated for this parameter.

References used
Type of references used and number of references used for providing response to the queries were evaluated.

RESULTS

A total of 2312 queries were received by the DIC during the study period, of which 600 queries were related to ADR (25.9%). Majority of the queries were from the department of medicine (80.5%), followed by dermatology (3.8%) and neurology (3.1%). Considering the professional status of the enquirer, clinicians utilized the service to a great extent (76%) followed by post graduate students (20%). A small percentage of queries were from interns (2%) and other health care professionals which included nurses and hospital pharmacists (2%). Majority of the queries were received during ward rounds (76%) through clinical pharmacist, followed by telephone (15%). Few queries were received via direct access to the DIC (7%). Intranet and email was also a source of obtaining queries though to a very small proportion (2%). Most often queries were asked for better patient care (66.3%) and the answer was needed immediately (59.5%), as depicted in table 1.

Table 1: Purpose of enquiry and the urgency of answer needed.

Purpose of	No. of queries	%	Urgency of answer needed	No. of queries	%
Update knowledge	187	31.1	Immediately	357	59.5
Better Patient care	398	66.3	Within 2-4 hours	29	4.8
Research	12	2.0	Within a day	145	24.1
Others	3	0.5	Within 1-2 days	69	11.5

The category of ADR queries most commonly asked was regarding identification of an ADR (54.3%) followed by general adverse reaction profile of a drug and incidence (15.5%), as shown in table 2. While evaluating the frequency of the reactions in question, majority of the queries were unassessable (58.7%). Distribution of the frequency of the reaction in the assessable queries is depicted in table 3, with queries on uncommon reactions (14%) being the most common one. Majority of the queries involved a single drug (70%), followed by 2 drugs (13%).

Table 2: Category of ADR related drug information queries.

Type of query	No. of queries	%
Identification	326	54.3
General reaction profile	93	15.5
Incidence	93	15.5
Management	19	3.1
Onset, duration and outcome	19	3.1
Monitoring parameters	13	2.1
Predisposing factors	12	2.0
Mechanism	10	1.6
Prevention	9	1.5
Manifestations	6	1.0

Table 3: Frequency of the ADRs in the queries

Frequency of reaction	**No. of queries**	**%**
Very common (≥ 10%)	73	8.1
Common (≥1% and < 10%)	100	11.0
Uncommon (≥0.1% and <1%)	127	14.0
Rare (≥0.01% and <0.1%)	54	5.9
Very rare (<0.01%)	18	1.9
Unassessable	529	58.7

Considering the reaction characteristics, the organ system most commonly involved in the reaction in the queries was nervous system (14.7%) followed by endocrine and metabolic system (14.5%); table 4. The reaction most commonly involved in the queries was fever and skin rash (14%); table 4. Drug class most commonly involved in the queries were antibacterials for systemic use (18.6%) followed by antiepileptics (11.7%) and the most frequently involved drug was phenytoin (35%); table 5.

Response to majority of the queries (50.1%) were provided using a single reference and MICROMEDEX system was the most widely used reference (57.1%), followed by Lexi- comps Drug Information Handbook (37.8%) as shown in table 6.

DISCUSSION

Health care is by its nature risky. Hence choosing a safe medicine for a patient is a key task for clinicians. Improving skills and techniques is the way to achieve safer health care (Barach and Moss, 2001). An independent DIC can provide unbiased information about various aspects of drugs ranging from theoretical questions to more practical issues of drug therapy (Joshi, 1998). Results of a study shows that physicians are interested in recognizing problems related to drug therapy and that if they are given appropriate feed back, their prescribing practices do improve (Gilroy *et al.*, 1990). Drug safety is an area where physicians seek additional and patient specific information, which in turn contributes to a rational drug use with regard to drug safety. Pattern of information on drug safety sought by health care professionals are worth to be assessed.

Our evaluation showed that the majority of the queries received by the DIC were related to ADR, similar to the results observed in a study conducted by Nibu et al for a hospital based DIC. Further, ADR related queries was found to be one among the most common category of queries enquired in an evaluation of the services conducted by a community based DIC in India (Lakshmi *et al.*, 2003). Evaluation of the data of a telephone information service which caters to the patient's drug related queries in Netherlands also revealed a predominant number of queries related to ADRs (Antoine *et al.*, 1997).

The factors which influence the higher rate of queries on ADRs in clinical set up might be many. It is estimated that around 6% of hospital admissions are due to ADRs and about 6-15% of hospitalized patients experience a serious ADR (Ditto 2002, Jick 1984, Lazarou *et al.*, 1998). Evaluation of spontaneous reports received in our hospital revealed an incidence of atleast one ADR report in 1.14% of the hospitalized patients. (Jose and Rao 2006) These values influence the probability that the clinicians would often encounter clinical situations of ADRs in patients, which in turn influence the need for seeking information on the same.

Table 4: Organ system and reaction involved in the queries.

Organ System	No. of queries	%	Reaction	No. of queries	%
Nervous	75	14.7	Peripheral-Neuropathy	9	12
			Seizures	8	10.6
			General	7	9.3
			EPS	6	8
			Headache	6	8
			Psychosis	6	8
Endocrine and Metabolic	74	14.5	Fever	14	18.9
			Hypokalemia	12	16.2
			Hyponatremia	9	12.1
			Hyperglycemia	7	9.4
Hematologic	63	12.4	Thrombocytopenia	12	19.0
			Pancytopenia	9	14.2
			Anemia	8	12.6
			Agranulocytosis	7	11.1
Hepatic	61	12.0	General	29	47.5
			Hepatitis	9	14.7
Dermatologic	54	10.6	Skin rash	14	25.9
			General	9	16.6
			Itching	7	12.9
			SJS	6	11.1
Gastrointestinal	54	10.6	Diarrhoea	10	18.5
			Constipation	8	14.8
			Pancreatitis	6	11.1
Cardiovascular	48	9.4	Cardiotoxicity	9	18.7
			Oedema	9	18.7
			Hypertension	6	12.5
			Hypotension	6	12.5
Renal	32	6.3	General	11	34.3
			Increase in Se. Cr.	6	18.7
			Urine retention	6	18.7
Neuromuscular and skeletal	19	3.7	Hyperurecemia	6	31.5
			Myopathy	6	31.5
Respiratory	13	2.5	Cough	6	46.1
Ophthalmologic	7	1.3			
Auditory	7	1.3	Ototoxicity	6	85.7

Clinicians consider drug related effects as a differential diagnosis in many clinical situations were a suitable clinical explanation could not be obtained and hence seek information. Among the various aspects of drug therapy, the detailed information on drug safety is one among the aspects which the practicing clinicians may not be well versed with. This holds true when it is concerned with newer drugs and lesser common. In our study setting, we have a well established ADR reporting unit which functions along with the DIC under the Department of Pharmacy Practice. This may possibly influence the prescribers' willingness to ask for more information pertaining to ADRs.

A great number of queries were received from the department of medicine. Vast number of drugs used in patients, multiple disease state, complex drug decision situations, more number of drug related hospital admissions, greater number of new medications introduced in practice could influence this greater number from the department. Clinical specialty wise distribution of the ADR related queries was comparable with the rate of spontaneous ADR reports received from the specialties in the ADR reporting unit with majority (41.9%) reports from department of general medicine (Jose and Rao, 2006). This shows a possible influence between the safety information seeking nature and spontaneous ADR reporting rate.

Clinicians utilized the service to a great extent (76%), followed by postgraduates. The spontaneous involvement of nurses in our hospital in treatment related aspects is very poor. Hence, the percentage of queries (0.5%) from nursing staff was very less which is comparable to the poor rate of spontaneous ADR reports from this group in our hospital.

Table 5: Drug class and drugs commonly involved in the queries

Drug class	No. of queries	%	Drug	No. of queries
Antibacterials for systemic use (J01)	138	18.6	Ceftriaxone	16
			Ciprofloxacin	12
			Ofloxacin	12
			Amoxicillin	10
			Doxycycline	10
Antiepileptics (N03)	87	11.7	Phenytoin	35
			Carbamazepine	16
			Phenobarbitone	14
			Valproic acid	12
Antimycobacterials (J04)	50	6.7	Isoniazid	16
			Rifampicin	10
			Pyrazinamide	9
			Ethambutol	8
Antivirals for systemic use (J05)	45	6.0	Zidovudine	12
			Lamivudine	10
			Stavudine	8
Antiprotozoals for systemic use (P01)	37	5.0	Chloroquine	14
			Hydroxychloroquine	9
Psycholeptics (N05)	37	5.0	Clobazam	10
			Olanzepine	8
Drugs used in diabetes (A10)	31	4.2	Metformin	10
			Pioglitazone	10
Antiinflammatory and antirheumatic products (M01)	21	2.8	Ibuprofen	8
Analgesics (N02)	21	2.8	Tramadol	15
Agents acting on the renin angiotensin system (C09)	21	2.8	Losartan	10
Immunosuppressive agents (L04)	21	2.8	Methotrexate	8

Presence of a clinical pharmacist, who is in turn a member of the DIC, during ward rounds, influenced the higher number of queries being received during ward rounds (76%). Easy access to a member of DIC and assistance by them can contribute to the amount of utilization of similar services. Intranet and email also served as a media to access information but to a very less population of the enquirers. Delay in getting the response and accessing the same, as well as the lack of a platform to discuss the query and response when the communication is done usually decreases the degree of utilization of this mode of communication. This may hold true for ADR related queries were a proper discussion will facilitate a better response and action.

Information was most commonly sought for better patient care (66%) than for updating knowledge and other purposes. Frequent situations arise for clinicians where the information on ADR is needed at bed side to identify the ADR or in its management. The purpose of the queries in our evaluation were similar to the pattern observed for DI queries in general in our hospital by Gore et al and George *et al.* (Rao and Gore 2004, George 2005).

Information on ADRs is usually required immediately at the patient bedside for identifying the ADR, taking drug safety decisions, changing the therapy and management of situation. This influences the urgency of the response required as observed in the study where in an immediate response was needed in majority of the queries (59.5%).

Identifying whether the drug in question is associated with the clinically unexplained response observed in the patient, or in clinical situations where multiple drug are suspected to be involved in the abnormal response observed in the patient are frequently faced dilemmas by the clinicians. This influence the higher number of category of queries on ADR being related to identification and incidence of ADRs.

Most of the queries were related to ADRs affecting dermatological system and many among them were related to the antibacterials. Individual reaction on which the maximum queries were asked included skin rashes. This pattern was similar to the pattern of reports on ADRs received in our hospital (Jose and Rao, 2006), as well as to those reported in certain other studies (Hartwig *et al.*, 1992, Kanjanarat *et al.*, 2003). Drug class most commonly involved in the queries was antibacterials, while ADRs reported in the hospital included antibacterials as the third most commonly involved drug class (Jose and Rao, 2006). Phenytoin was the individual

Table 6: References used for answering the queries

Reference	No. of queries	%
MICROMEDEX	343	57.1
Lexi-Comp's Drug Information Handbook	227	37.8
Meyler's side effects on drugs	148	24.6
American Hospital Formulay Service Drug information	139	23.1
Martindale's Extra pharmacopoeia	61	10.1
Iowa Drug Information System	41	6.8
Websites	35	5.8
Journals	21	3.5
Medical and pharmacy textbooks	21	3.5
Australian medicine handbook	6	1.0
British national formulary	5	0.8
Brand index book (National)	4	0.6

drug most commonly queried similar to the pattern of ADRs reported in the hospital (Jose and Rao, 2006).

Over all, an observation could be made that the pattern of queries received were similar to the pattern of ADRs reported in our hospital. An association between the pattern of information on drug safety sought by the health care professionals and the pattern of ADRs reported in a health care setting could be considered. On the contrary, there were clear differences regarding the drugs involved in the queries to the telephone service center for patients and ADRs reported to the reporting unit in Netherlands; LAREB (Antoine *et al.*, 1997). The difference in the demographics of the information seekers; one with health care professionals and other with patients should have influenced this difference in pattern.

Proper follow up of the DI queries on ADRs prospectively could possibly help in identifying many of the unreported ADRs in a heath care setting. Evaluation of the pattern of these queries may help in identifying drug safety issues. The extent to which these activities could promote ADR monitoring and reporting activities in a working set up needs to be further studied. This emphasizes the importance of the synergistic functioning of DIC and ADR reporting unit of a hospital.

MICROMEDEX (57.1%) was the most widely used reference as most often the answer was needed immediately and ease of using this computerized database encouraged the same. Further, detailed information on ADRs available in MICROMEDEX, even with inclusion of case reports, and detailed information on many established reactions to drugs, with its incidence, mechanism, predisposing factors, and management makes MICROMEDEX a suitable resource. Drug information handbook was also used widely (37.8%) as it is a comprehensive reference of drugs which also helps easy referencing when the enquirer needed an immediate response. ADR specific resources like Meylers side effect of drugs were used to a lesser extent, as information on identification and incidence of ADRs; which accounted for majority of the queries could usually be provided using MICROMEDEX and drug information handbook.

Evaluation of the pattern of informations sought has revealed areas where educational interventions or other means of interventions could be considered in promoting safer drug use in the hospital set up. The same could be carried out by circulating updated and specific information on drug safety depending on the health care professionals needs. With this purpose the department has started publishing a drug safety bulletin, taking into consideration health care professionals specific information needs on drug safety. More frequent periodic evaluations of pattern of information sought is planned which could be beneficial in better understanding of the needs and responding to the same.

Limitations of our study also need to be mentioned. Since the evaluation was based on the retrospective data documented in the DIC, documentation errors should be considered as a possibility. However, the quality assurance evaluation exercises done regular in the DIC has not revealed significant discrepancies with regard to the documentation of information. Further, even though the data on ADR related DIs was for a period of three and a half years, we could compare its pattern only with the pattern of ADRs reported in the hospital over a period of 1 year. The actual utility of the DIs provided in a particular clinical situation, ie for identification or management of the ADR was not assessed, which is a valuable data that needs to be studied.

CONCLUSION

Information on safety is one amongst the most sought drug related aspect by the health care professionals. Mainly ADR related information is required for better patient care, identifying and clarifying a suspected ADR. Most of the information are sought on lesser common ADRs and an immediate response is most often expected. Similar data evaluations need to be followed by educational interventions depending on the pattern of

information needs of the health care professionals. Our study data revealed an association between the pattern of drug safety information sought by the health care professionals and the pattern of ADRs reported in a health care setting.

DICs could play a major role in promoting drug safety, by virtue of assisting the clinicians in safer use of drugs in clinical situations as well as promoting the reporting of ADRs. DICs should be well equipped with valuable resources, which provides up to date and detailed information on drug safety. The extent to which follow up of these queries helps in the detection and reporting of ADRs needs to be evaluated. DICs and ADR reporting systems should function hand in hand in achieving the common goal of promoting better patient care through rational drug use.

ACKNOWLEDGMENTS

The authors wish to acknowledge the contribution of the staff and students of Department of pharmacy practice and health care professionals of Kasturba Hospital for their support in carrying out the services of the drug information center.

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