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A questionnaire study to assess the knowledge, attitude and practice of Pharmacovigilance in a paediatric tertiary care centre

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ABSTRACT

Drug safety in children is one of the neglected areas in India. Due to vulnerability of children to experience adverse drug reactions (ADRs) and lack of data from India, it is very essential to identify and report all ADRs in children. In this context, it is important to evaluate the awareness and knowledge about pharmacovigilance among the health care professionals in a paediatric hospital which would indirectly promote reporting of ADRs in children. The study was conducted at Vani Vilas Hospital, Bangalore, India using a pre designed questionnaire which was structured to obtain the designation of the doctors, information about their knowledge, attitude and practice of ADR reporting. A description approach was used to analyse the responses, and the results are expressed as a percentage of the total number of responders to that question. About 115 health care professionals were included in the study. This study showed that majority of the health care professionals have good knowledge about ADR reporting and understand the need for reporting. Lack of facilities and clinical knowledge about ADR discourages them from reporting. More emphasis was given on establishment of a regional paediatric pharmacovigilance centre in our Hospital. Educational interventions and improvement of facilities were also suggested to enhance reporting rate in children.

Key words: Adverse drug reactions, pharmacovigilance, attitude, knowledge, practices of pharmacovigilance.

INTRODUCTION

The World Health Organization (WHO) defines an Adverse drug reaction (ADR) as a response to a drug which is noxious, unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

ADRs not only may result in hospital admission or prolonged hospitalization but also may lead to permanent disability or even death.

In general, drug safety is one of the neglected areas in developing countries like India. Though pharmacovigilance programme was started in India in 1982, the awareness about it is much lower [1]. The primary source of information for pharmacovigilance is from spontaneous reporting by health care professionals. Under-reporting of ADRs is a major problem, affecting pharmacovigilance programme of India. Because of under reporting, Indian drug regulators are very much dependent on data and advice from other countries especially in children. Due to socio-economic and ethnic factors, ADRs in India could be different from other country which makes it necessary to generate our own data. At present Indian clinicians are not aware of their valuable contribution towards drug safety. In this context, it is important to enhance the awareness and knowledge of the health care professionals in India to improve reporting rate.

The safety of medicines, especially in children is a major issue. In a meta-analysis by Lazarou et al, fatal ADRs among both adults and children ranked as the fourth to sixth leading cause of death in the United States [2]. Another study demonstrated that ADRs were associated with an average of 243 reported deaths among young children, from newborn to 2 years of age, each year [3]. On the basis of a meta-analysis of 17 prospective studies conducted in the United States and Europe, the incidence of ADRs among hospitalized children was 9.5%, with severe reactions accounting for 12% of the total [4]. Limited studies from India have reported ADRs in children [5]. Because clinical trials involving neonates, infants, children, and adolescents are limited, the safety and tolerability of many drugs are not well established. Therefore hospitals are required to monitor routinely for ADRs and report all ADRs that may result in a sentinel event. In this setting, the documentation of ADRs relies heavily on spontaneous reporting by health care professionals [6]. This limited information available in children about drug safety leads to medical errors like overdosing and accidental exposure.

Considering the vulnerability of the children to experience ADRs, difficulty in extrapolationg ADR pattern of adults to children and lack of data from India, makes ADR monitoring in children mandatory in our country. Hence, it is very important to evaluate the awareness and knowledge about pharmacovigilance among the health care professionals in paediatric hospitals which would indirectly promote reporting of ADRs. A dedicated study in a paediatric hospital involving health care professionals of various levels is lacking in India, which led to the conduct of this study. The present study will focus on the need for regional paediatric ADR monitoring centre in our hospital. The study will also help in formulating various approaches for the improvement of the current reporting system.

EXPERIMENTAL SECTION

This study was conducted at Vani Vilas Hospital, Bangalore, which is a 300 bedded hospital and a major paediatric referral centre for the state of Karnataka, India. The target sample included teaching faculty of doctors (professors, associate professors and assistant professors), postgraduate students, nurses, and undergraduate medical students posted in the hospital.

The study instrument was a pre designed questionnaire which was structured to obtain the designation of the doctors, information about their knowledge, attitude and practice of ADR reporting. Provision was also made for suggestions on through open questions. Small changes in the order and phrasing of the questions were made after a pilot study. The final questionnaire included; subject demographics, basic knowledge of ADRs, attitudes toward the voluntary ADR

reporting system, practices regarding ADR reporting system, reasons for failures to report, etc. Investigators interviewing healthcare professionals carried out these interviews in person. A description approach was used to analyse the responses, and the results are expressed as a percentage of the total number of responders to that question.

RESULTS

Levels of heath care professionals participated in the study (Table1)

About 115 health care professionals were included in the study, of which 17% were teaching faculty of different cadres, 21.7% were interns, 17% were post graduate students in paediatrics and 21.7% were under graduate medical students and 21.7% were nurses in the Hospital.

Table 1: Levels of health care professionals participated in the study

Professionals	Percentages (n=115)
Teaching faculty of doctors	17%
Postgraduate students	17%
Interns	21.7%
Undergraduate students	21.7%
Nurses	21.7%

Knowledge about ADR (Table 2)
Definition of ADR
About 60% of the teaching faculty, 78% of postgraduate students, 94% of the interns, 84% of the medical students and 45% of the nurses stated the correct definition of the ADR.

Table 2: Knowledge about ADRs

Questions	Teaching faculty of doctors	Postgraduate students	Interns	Undergraduate students	Nurses	Total
Right Definition of ADR						
	60	78	94	84	45	72.20
Every day encounter of ADR						
	0	0	0	0	0	0
Every week encounter of ADR						
	0	0	18	23	0	8.2
Every month encounter of ADR						
	60	35	23.5	48	19	37.1
Rare encounter of ADR						
	40	65	59	29	81	54.8

Frequency of ADR
Majorty of the respondents agreed to encounter ADRs rarely (54.8%), followed by everymonth (37.1%) and every week (8.2%).

Practices regarding ADR reporting (Table3)
About 66.2% of the respondents understood the need for reporting ADRs with majority being Nurses. But only 12.4% them had actually reported a ADR with the majority being Interns.

Only 26% of the participants of the study were aware of the existent Pharmacovigilance centre in our Hospital and only 12% agreed that the facilities were adequate.

About 73% of the paediatric health care professionals stated that no adequate counselling is being given to patients about identifying and reporting ADRs back to the hospital.

Table 3: Practices regarding ADR reporting

Questions	Teaching faculty of doctors	Postgraduate students	Interns	Undergraduate students	Nurses	Total
Awareness about need for reporting ADRs						
	60	64	70	65	72	66.20
Actually reporting ADRs to any centre						
	20	7	23	8	4	12.40
Existance of ADR centre at our hospital						
	60	14	5	25	27	26.20
Facilities at ADR centre in our hospital is adequate						
	0	7	5	10	36	11.60
Adequate counselling given to patients about ADRs						
	40	18	11	25	42	27.20

Attitudes regarding ADR reporting (Table 4)
Majority of the respondents (94.4%) stated the need for regional paediatric pharmacovigilance centre and all of them (100%) felt that it will improve the reporting rate.

About 72% of the paediatric health care professionals felt that only significant ADRs need to be reported in children.

Reasons for not reporting ADRs
Majority of the teaching faculty (80%), interns (59%) and nurses (54%) felt that there are no facilities in the hospital to report ADRs.

But postgraduate students (58%) and the undergraduate students (46%) felt that the ADRs to be reported are well known.

Table 4: Attitudes regarding ADR reporting

Questions	Teaching faculty of doctors	Postgraduate students	Interns	Undergraduate students	Nurses	Total
Need for regional paediatric Pharmacovigilance centre						
	80	100	100	100	92	94.40
Improvement in reporting rate after establishment of paediatric pharmacovigilance centre						
	100	100	100	100	100	100
Only significant ADRs need to be reported						
	60	85	76	84	54	71.80
Lack of facilities to report ADRs in our hospital						
	80	14	59	42	54	49.8
Lack of knowledge about report of ADRs in our hospital						
	0	7	6	12	36	12.2
Lack of time to report ADRs to phrmacovigilance centre in our hospital or elsewhere						
	0	21	6	0	0	5.4
ADR in question is well known which discourages reporting						
	20	58	29	46	10	32.6

Open Questions (Table 5)
Majority of the respondents agreed to reporting ADRs to senior doctors (87%), followed by senior nurses (11%) and state health authority (2%).

Drugs to which ADRs were most commonly seen in our hospital were antiepileptics (46%), penicillins (29%) and sulfonamides (19%).

About 58% of the respondents felt that awareness of the doctors and nurses needs to be improved by educational programmes. About 27% of them felt that their motivation to report would increase if information about ADR reporting is incorporated in theory classes for the medical students. About 11% of them felt that more ADR forms are required in the hospital and 4% of them stated that a dedicated telephone line is required for reporting.

Table 5: Open questions

ADRs reported to	State health authority (2%) Senior Doctors (87%) Senior Nurses (11%)
Drugs to which ADRs seen	Antiepileptics (46%) Penicillins (22%) Sulfonamides (19%) Cephalosporins (11%) Vaccines (2%)
Ways to improve ADR reporting rate in our Hospital	Increase awareness by educational programmes (58%) Incorporate Pharmacovigilance in theory classes for medical students (27%) Provide more ADR forms (11%) Provide telephone line for reporting (4%)

DISCUSSION

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems [7]. Pharmacovigilance depends mainly on spontaneous reporting by health care professionals which leads to signal detection of ADRs. Under-reporting of ADRs is a major problem of spontaneous reporting which would delay signal detection leading to high economic burden on the public. Though pharmacovigilance is still in its infancy in India, this is likely to expand in the time to come which requires more awareness among doctors & nurses. The determinants of under reporting are not well evaluated in India. Therefore this study was conducted to mainly assess the knowledge, practices and attitude regarding reporting of adverse drug reactions in a paediatric hospital. Though few studies from India have evaluated the same objective [8,9], but none of them have involved various levels of health care professionals in a paediatric hospital in India. As many studies have shown the importance of ADR monitoring in children, this study was designed to evaluate our objective in a paediatric hospital.

A total of 72.2% of the paediatric health care professionals in our hospital understood the definition of ADR with majority being interns. In a similar study conducted in China, only 2.7% of the respondents correctly answered the definition of ADR. Hence, the knowledge of the respondents in our hospital is much higher compared to other studies. However, the knowledge of the nurses needs to be improved regarding this aspect in our hospital.

Majority of the respondents (54.8%) expressed that they rarely encounter an ADR. However, most of the teaching faculty of doctors (60%) felt that they encounter ADR at least every month. Therefore, more training needs to be given for students and nurses in identifying the ADR and improve their clinical knowledge about ADR. This would reduce the fear and anxiety among junior doctors and nurses in reporting ADRs as they may be worried about appearing incompetent.

Though 66.2% of the respondents understood the need for reporting ADRs, only 12.4% had actually reported an ADR. In a similar study conducted in northern India, only 2.9% of the resident doctors had reported an ADR. Hence, awareness about importance of reporting ADRs needs to be encoraged in our hospital and more facilities should be given to them for reporting.

In our study only 26% of the respondents were aware of the presence of Pharmacovigilance centre in our hospital, of which only 12% felt that facilities were adequate. This is much lower compared to other studies where 50% of them were aware of pharmacovigilance centre in their hospitals[10]. Lack of knowledge about where ADRs should be reported hinders the reporting rate. The possible reason for lower awareness about the existence of the Pharmacovigilance centre in our hospital could be the location of the centre which is about 2 kilometres away from the paediatric hospital and they are involved in many activities of the pharmacovigilance centre.

About 95% of the respondents felt that a separate paediatric pharmacovigilance centre is required in vicinity of the hospital and all of them (100%) agreed that the reporting of ADRs will improve after the establishment of the same. A study by Amanda Clarkson et al[11] showed that establishment of a proactive scheme like regional paediatric ADR monitoring centre in Trent, UK successfully increased the reporting of suspected ADRs in that region and also improved awareness towards drug surveillance in children. A similar type of focussed approach for drug surveillance for children was also shown to be very successful in North America[12].

Only about 27% of the respondents in our study felt that adequate counselling is being given to the patients about reporting ADRs to the hospital. Whenever a drug is used in a child, a thoughtful monitoring plan should be established so as to appropriately monitor efficacy and adverse events. Because children may not be able to express how they feel, caregivers must play an active role in this monitoring process and must be educated regarding appropriate medication use.

About 72% of the participants felt that only severe adverse drug reactions should be reported. Similar attitude was seen in another study by Williams D & Feely J.[13]. Hence, the awareness about the need for reporting all the adverse drug reactions in children should be improved in our hospital. Because of the paucity of information that may be available regarding the use of a particular drug in children, health care professionals should be encouraged to report whatever information they encounter regarding specific drugs[14].

The reasons for not reporting an ADR were mainly lack of facilities (50%), followed by the belief that ADR in question is well known (33%), lack of knowledge (12%) and lack of time (6%). Though the teaching faculty felt that the facilities for reporting ADRs needs to be improved, the students were in doubt that the ADR to be reported was well known. This indicates that the students may need more training about what needs to be reported to the ADR centre. A study by Li Quing et al[15] reported lack of facilities and knowledge to be the main reasons for not reporting ADR. Another Indian study from Mumbai stated lack of clinical knowledge to identify ADR and its reporting were the main reasons for under reporting (8). Another study in Germany stated that the major reasons for not reporting ADRs were: ADR well known (75.6%), too trivial (71.1%), causality uncertain (66.3%) [16].

The participants of our study stated that reporting of ADRs can be improved by increasing the awareness by educational programmes which was also seen in other studies from Portugal [17] and Nigeria [10]. Our study also suggested that providing more ADR forms would improve reporting rate which is in consistent with another study by Castel JM et al [18]. Providing a

dedicated telephone line and incorporating the importance of reporting ADRs into theory classes for encouraging reporting of ADRs was also shown in many other studies [10]. . In addition these studies have also suggested that the administrators of the hospital should be trained, ADR cards should be provided instead of forms as it is less time consuming for the reporters and feedback should be given after reporting[15].

In conclusion, the present study conducted in a paediatric hospital, shows that majority of the health care professionals have good knowledge about ADR reporting and understand the need for reporting. Lack of facilities and clinical knowledge about ADR discourages them from reporting. More emphasis was given on establishment of a regional paediatric pharmacovigilance centre in our Hospital. Educational interventions and improvement of facilities were also suggested to enhance reporting rate in children.

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