Section: Pharmacology

Original Research Article

TO ASSESS THE KNOWLEDGE, ATTITUDE AND PRACTICE AMONG PEDIATRIC HEALTHCARE PROFESSIONALS PERTAINING TO ADVERSE DRUG REACTION REPORTING IN KANNAUJ CITY

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ABSTRACT

Background: Adverse drug reactions (ADRs) are unwanted reactions caused by a drug when taken at a therapeutic dose. It causes serious impact on patient safety and quality of life. ADRs are sometimes underreported or not reported in pediatric population. Healthcare professionals are the one who are responsible for reporting and evaluating the ADRs. **Objectives:** To assess the knowledge, attitudes, and practices (KAP) of pediatric healthcare professionals regarding ADR reporting in and around the Government Medical College, Kannauj. **Materials and Methods:** A descriptive cross-sectional study was conducted among 307 pediatric healthcare professionals working at the government medical college and its affiliated hospitals in Kannauj City, India from November 2023 to October 2024 using structured self administered questionnaire. **Result:** The mean KAP score was high 0.91 ± 0.11, indicating similar levels of KAP regarding pharmacovigilance programme and ADR reporting among different healthcare professionals. Nearly all the healthcare professionals were aware about pharmacovigilance programme. Around 96% of HCPs agreed that reporting of adverse drug reactions should be made mandatory for physicians, pharmacist and nursing staff. Almost 91% of the HCPs were aware that all (moderate and serious) adverse reactions should be reported. **Conclusion:** The study provides valuable insights that will help the healthcare professionals in future to emphasize on improvement of their understanding related to Pharmacovigilance, ADR classification, management practices and reporting of adverse drug reactions contributing to better patient outcomes, safety and quality.

INTRODUCTION

The World Health Organization (WHO) defines adverse drug reactions (ADRs) as unwanted reactions in humans caused by a drug on a therapeutic dose for the diagnosis, prophylaxis or management of diseases.[1] ADRs frequently occur in the healthcare industry. The median incidence of ADRs that resulted in hospitalization (ADRAd) and those that occurred while a patient was in the hospital (ADRIn) were 2.85% and 6.34% respectively.[2] The global ADR reporting rate is 5%, while in India it is less than 1%.[3] ADR-affected patients have a higher risk of morbidity and mortality. Patients who experience severe or life-threatening ADRs may experience long-lasting physical and psychological effects.[4]

Children are at high risk of developing ADRs as compared to adults due to multiple factors. These include body physiology-absorption rates, protein content, total body water, developmental stage, ability to express changes objectively etc. Unlike adults, it is difficult to suspect and diagnose ADRs in paediatric population, leading to increased morbidity and mortality. The common risk factors in children leading to ADRs are polypharmacy, previous adverse reaction to another drug, female sex, impaired liver or renal function, general anaesthetic use, off-label and unlicensed drug use, genetic polymorphisms. Asthma, infections, allergy, pain, epilepsy, hypo &

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hyperglycaemia, attention deficit hyperactivity disorder are some of the common conditions morbidities reported as ADRs.[5]

The biggest obstacle in detecting paediatric ADRs is its timely recognition. Parents/guardians often found themselves incapable of detecting such clues due to lack of proper guidance and scientific information. Healthcare professionals (HCPs) like doctors, pharmacists, and nurses can play crucial role in educating parents/guardians regarding the same and help to improve its early reporting. Apart from this they are usually responsible for evaluating and reporting ADR cases to Pharmacovigilance authorities in all healthcare settings, from primary to tertiary care. Especially the pharmacists are in better position to do so during dispensing of medication from outpatient or during the routine rounds in the hospital wards.[6] The general community including patient/patients' relatives can also fill out ADR forms and report to health care professionals, such voluntary reporting activities are known as "spontaneous reporting," and they are acknowledged as an economical way to find fresh and important ADR signals.[7] The early reporting of ADRs is crucial in view of improving patient safety, quality of life, and treatment cost-effectiveness and management of ADRs.

In 2010, Govt. of India started the Pharmacovigilance Programme of India (PvPI), being coordinated by the Indian Pharmacopeia Commission (IPC) in Ghaziabad. This program aims to foster a culture of ADR reporting, generate reliable ADR data for the Indian population, and share this information globally through the WHO Monitoring Centre in Uppsala. The generated signals are utilized to recommend regulatory measures, such as label revisions, safety alerts, and effective communication with healthcare providers.[8]

The pharmacovigilance Programme of India reports had shown an upward trend in reporting of serious adverse drug reactions from 23.4% in 2019-2020 to 27% in 2022-2023.[9]

There are a number of guidelines that try to educate HCPs on the effects of ADRs and stress the importance of their professional and ethical duty to report these incidences in order to lessen the mortality and morbidity caused by medication [9]. This study aims assess the knowledge, attitudes, and practices (KAP) of HCPs involved in child care regarding ADR reporting in and around Government Medical College in Uttar Pradesh, India.

MATERIALS AND METHODS

This was a descriptive cross-sectional study conducted among pediatric healthcare professionals in and around the Government Medical College in Kannauj city, India. The study was conducted over a period of 12 months from November 2023 to October 2024.

Pediatric healthcare professionals (HCPs) working at the government medical college and its affiliated hospitals who provided the written informed consent were included in the study. Those working at the private medical college, private clinic or who were unwilling to participate in the study were excluded.

Initially, 380 HCPs were approached to participate in the study. Out of 380, 73 did not participate in the study due to various reasons (Figure 1). Finally, 307 pediatric healthcare professionals were included in the study through convenience sampling.

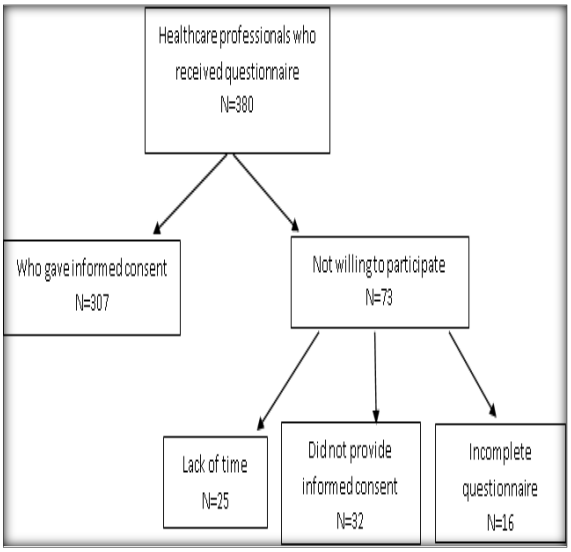

Figure 1: Healthcare professionals recruitment and selection process

The study protocol received approval from the Institutional Ethics Committee (IEC) ensuring that all ethical guidelines and standards would be followed during the research process. Written informed consent was obtained from the pediatric healthcare professionals, ensuring their voluntary participation and understanding of the study's objectives and procedures. The aim of the study was to assess the knowledge, attitude and practices of ADR reporting among healthcare professionals. The pretested structured questionnaire [10] was adapted and modified according to design and aim of the study to obtain information on the knowledge of the ADR reporting, the attitudes towards the reporting and the factors that in practice could hinder the reporting among the healthcare professionals. It was pretested on 30 HCPs who were different from study participants and changes were made as per their responses. The corrected questionnaire was then used to collect data. Healthcare professionals were explained the purpose of study. Questionnaires were distributed both electronically and physically and responses were collected anonymously.

Survey responses were exported to Excel, and pre-coded by a researcher. Data were analyzed by using SPSS software version 21.0. $P < 0.05$ was considered significant. Mean and standard deviation were applied to assess the KAP score of healthcare professionals, while frequency and percentage were

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used for categorical variables. Kruskal Wallis test was performed as the data did not follow normal distribution. This test was done to compare the KAP scores among different healthcare professionals. Fischer's exact test (due to smaller sample size and expected cell counts less than 5) was applied to determine association between healthcare professionals and KAP questions related to adverse drug reaction reporting.

RESULTS

Total 307 HCPs involved in paediatric care were interviewed regarding awareness, attitude and practice related to adverse drug event reporting. Figure 2 represents the distribution of healthcare professionals. The mean KAP score of HCPs was 0.91 ± 0.11 with minimum score of 0.5 and maximum score was 1.

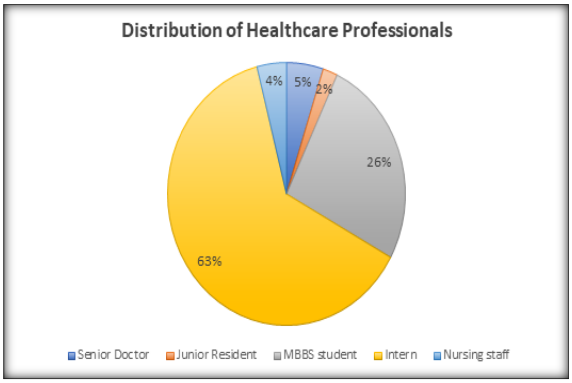

Figure 2: Distribution of Healthcare Professionals (N=307)

Almost all (99%) HCPs were aware of the pharmacovigilance programme. Majority (88%) of healthcare professionals were aware about the Indian Pharmacopoeia Commission (IPC) in Ghaziabad where National Coordination Centre for Pharmacovigilance programme of India is situated. Around 80% of the HCPs mentioned about reporting of adverse drug reaction to all the authorities-including Adverse Drug Reaction Monitoring Centre under Pharmacovigilance Programme of India, National Coordination Centre-Pharmacovigilance Programme of India and fellow healthcare professionals.

Almost 96% of HCPs agreed that reporting of adverse drug reactions should be made mandatory for physicians, pharmacist and nursing staff. Around 91% of the HCPs were aware that all (moderate and serious) adverse reactions should be reported. Most (98%) of the HCPs believed that reporting ADRs would improve patient safety, while 0.65% were uncertain and an equal proportion did not agree.

Around 94% of HCPs believed that training of healthcare professionals would improve the reporting of ADRs. Around 80% of healthcare professionals preferred to send the adverse drug reactions report via ADR monitoring centre to the pharmacovigilance programme of India followed by email (14%), telephone (5%) and speed post (1%).

Nearly 85% healthcare professionals believed that ADR monitoring centre should be established in every hospital while smaller proportion (7%) felt that it should depend on number of bed size in the hospitals. Nearly 90% HCPs agreed that quality defects, lack of efficacy of drugs, medication errors should be part of pharmacovigilance programme.

Kruskal Wallis test was performed as the data did not follow normal distribution. It was done to compare the KAP scores among different HCPs and the p value of 0.1637 showed that there was no statistically significant association among them (Table 1).

Table 1: Comparison of KAP Score Among Healthcare Professionals (N=307)

Healthcare Professionals	Observations	Rank Sum	Chi-square	p* value
Doctor	17	2674.50	6.518	0.1637
Junior Resident	6	1203.50		
MBBS Student	80	13051.00		
Intern	193	28275.50		
Nursing Staff	11	2073.50		

There was no cadre wise significant difference observed among different healthcare professionals indicating their similar levels of knowledge, attitude and practice in terms of pharmacovigilance programme and adverse drug reaction reporting. This may point towards the uniform pattern of training and knowledge sharing among different cadres of participants including undergraduate MBBS students, junior residents, practicing doctors and nursing staff (Table 2).

Table 2: Association between Healthcare Professionals and their Knowledge, Attitude and Practice Regarding Adverse Drug Reaction Reporting (N=307)

	Healthcare Professionals						p* value
	Doctor n (%)	**Junior Resident n (%)**	**MBBS Student n (%)**	**Intern n (%)**	**Nursing Staff n (%)**	**Total n (%)**	
Are You Aware About Pharmacovigilance Programme of India?							
Yes	17 (5.59)	6 (1.97)	79 (25.99)	191 (62.83)	11 (3.62)	304 (100.00)	p*=1.000
No	0	0	1	2 (66.67)	0	3 (100.00)	

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	(0.00)	(0.00)	(33.33)		(0.00)		
Where to Report an Adverse Drug Reaction Related to the Use of Drugs?							
Adverse Drug Reaction Monitoring Centre under Pharmacovigilance Programme of India	2 (4.35)	2 (4.35)	12 (26.09)	30 (65.22)	0 (0.00)	46 (100.00)	p*=0.288
National Coordination Centre-Pharmacovigilance Programme of India	0 (0.00)	0 (0.00)	7 (50.00)	7 (50.00)	0 (0.00)	14 (100.00)	
Physicians/ Healthcare Professionals	1 (50.00)	0 (0.00)	0 (0.00)	1 (50.00)	0 (0.00)	2 (100.00)	
All of the Above	14 (5.71)	4 (1.63)	61 (24.90)	155 (63.27)	11 (4.49)	245 (100.00)	
Which of the Following Adverse Drug Reactions Should Be Reported?							
All	17 (6.05)	5 (1.78)	75 (26.69)	173 (61.57)	11 (3.91)	281 (100.00)	p*=0.729
Moderate	0 (0.00)	0 (0.00)	3 (23.08)	10 (76.92)	0 (0.00)	13 (100.00)	
Serious	0 (0.00)	1 (7.69)	2 (15.38)	10 (76.92)	0 (0.00)	13 (100.00)	
Can Training of Healthcare Professionals Help Improve Adverse Drug Reactions Reporting?							
Yes	16 (5.54)	6 (2.08)	74 (25.61)	183 (63.32)	10 (3.46)	289 (100.00)	p*=0.778
No	0 (0.00)	0 (0.00)	1 (25.00)	3 (75.00)	0 (0.00)	4 (100.00)	
May Be	1 (7.14)	0 (0.00)	5 (35.71)	7 (50.00)	1 (7.14)	14 (100.00)	
How Do You Prefer to Send Adverse Drug Reactions Reports to Pharmacovigilance Programme of India?							
ADR Monitoring Centre	16 (6.50)	6 (2.44)	68 (27.64)	145 (58.94)	11 (4.47)	246 (100.00)	p*=0.169
Email	1 (2.38)	0 (0.00)	10 (23.81)	31 (73.81)	0 (0.00)	42 (100.00)	
Speed Post	0 (0.00)	0 (0.00)	2 (50.00)	2 (50.00)	0 (0.00)	4 (100.00)	
Telephone	0 (0.00)	0 (0.00)	0 (0.00)	15 (100.00)	0 (0.00)	15 (100.00)	
Do You Think Quality Defects, Lack of Efficacy of Drugs, Medication Errors are Part of Pharmacovigilance?							
Yes	14 (5.09)	6 (2.18)	76 (27.64)	170 (61.82)	9 (3.27)	275 (100.00)	p*=0.236
No	0 (0.00)	0 (0.00)	2 (11.76)	14 (82.35)	1 (5.88)	17 (100.00)	
May Be	3 (23.08)	0 (0.00)	2 (15.38)	7 (53.85)	1 (7.69)	13 (100.00)	
Cannot Say	0 (0.00)	0 (0.00)	0 (0.00)	2 (100.00)	0 (0.00)	2 (100.00)	

DISCUSSION

A total 307 pediatric healthcare professionals participated in knowledge, attitude and practice (KAP) assessment regarding adverse drug reaction reporting. The mean KAP score was 0.91 ± 0.11, indicating the high level of awareness among healthcare professionals. Nearly 99% were aware about pharmacovigilance programme of India and knew adverse reporting procedures. A similar level of awareness regarding the programme was reported among paediatricians.[11]

The majority of healthcare professionals (almost 97%) in this study agreed that adverse drug reaction reporting should be mandatory, and nearly as many (94%) thought that training would make reporting better. This was in line with research that demonstrated the importance of raising healthcare professionals' knowledge and training on adverse drug reactions and the necessity of mandatory active reporting of such reactions (Behera MR et al,[11] Dittrich ATM et al,[12] and AlShammari TM et al.[13]).

In present study, 91% healthcare professionals stated that all the adverse drug reactions including moderate and serious should be reported. A study by AlShammari TM et al. (2018),[13] showed similar finding where majority of physicians and pharmacists believed the same. In contrast to the present study, only 11.6% reported all types of ADR in the study by Nisa ZU et al. (2018).[14]

Around 80% healthcare professionals in the present study preferred to report adverse drug reactions directly to ADR monitoring centre followed by email (13.68%). Similarly, 62% participants chose to directly contact the ADR to report adverse drug reactions while 23% used email.[14]

The importance of pharmacovigilance and drug safety, with appropriate classification of adverse drug reactions along with standard approach to manage the cases clinically, depends upon the awareness, knowledge and skills of professionals.[15] Similarly, a study found that 52% had poor knowledge, 71% had positive attitude and 92.5% followed poor practices towards pharmacovigilance and ADR reporting. Thus, systematic training program along with

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interventional programmes will help to improve the awareness and practice level among healthcare professionals and that will in turn enhance the patient safety.[16]

The present study highlighted that there was high level of awareness among all healthcare professionals including undergraduate MBBS students, junior residents, practicing doctors and nursing staff who were found to be familiar with ADR reporting and pharmacovigilance programme. The study has limitations regarding the generalizability due to limited convenient sample which should also be taken into consideration.

CONCLUSION

The findings of the study depicted the positive outlook of healthcare professionals focusing on awareness of pharmacovigilance programme, mandatory reporting of all types of ADR to the concerned authority, establishment of ADR monitoring centre in every hospital, role of training in improving reporting practices. This will help the healthcare professionals in future to emphasize on improvement of their understanding related to Pharmacovigilance, ADR classification, management practices and reporting of adverse drug reactions contributing to better patient outcomes, safety and quality.

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