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KNOWLEDGE, ATTITUDE, PRACTICE, AND CHALLENGES TOWARDS REPORTING OF ADVERSE DRUG REACTIONS AMONG HEALTH CARE PROFESSIONALS IN THE NEPHROLOGY DEPARTMENT

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ABSTRACT

Background: Given the potential gaps or obstacles in under-reporting of Adverse Drug Reactions (ADRs), especially among healthcare professionals, it is essential to address this issue in patients of Nephrology, as they have unique pharmacotherapeutic needs and an increased risk of adverse reactions due to renal impairment. Therefore, this study aimed to assess the knowledge, attitude, and practice (KAP) among healthcare professionals regarding ADR reporting. **Method:** A cross-sectional survey study using convenience sampling was conducted in the Nephrology department of a tertiary care hospital in India, after approval by the ethics committee. Participants who provided consent completed a reliable, self-validated questionnaire (using a 3-point Likert scale and Cronbach's alpha score) via Google Forms. Descriptive statistics were applied for continuous and categorical variables; the software used included Microsoft Excel and SPSS (version 20). **Results:** Of the 52 participants, profession-wise, doctors numbered 6 (6,11.53%), nurses 9 (17.3%), pharmacists 6 (11.53%), students 30 (57.69%), and other healthcare professionals 1 (1.92%). In the knowledge domain, 21.20% of healthcare professionals experienced difficulties in understanding ADR reporting; in the attitude, 46.15% felt that patient confidentiality was affected; in the practice, 50.00% reported a lack of training; and 63.41% faced numerous challenges related to under-reporting of ADRs. **Conclusion:** Participants demonstrated good knowledge and attitude but lacked reporting practices due to insufficient training, concerns about patient confidentiality, and skill gaps. Training and awareness programs to improve ADR reporting are needed, coordinated by the Pharmacovigilance Reporting Centre in collaboration with all healthcare professionals.

KEYWORDS: Adverse drug reactions, Health care Professionals, Knowledge, Attitude and Practice.

INTRODUCTION

Adverse drug reactions (ADRs) pose a significant public health issue due to their impact on mortality, morbidity, socio-economic consequences, and management.[1] The Pharmacovigilance Program of India (PvPI) is tasked with monitoring reported ADRs in India and educating healthcare professionals about the importance of reporting. This is essential for effective monitoring, detection, and prevention of ADRs. Several factors, such as lack of awareness, uncertainty about reporting responsibilities, issues with reporting protocols, and limited feedback on submitted reports, all affect ADR reporting.[2] Healthcare stakeholders—including doctors, pharmacists, nurses, students, and other health professionals—play a crucial role in reporting ADRs if they possess good knowledge, positive attitudes, and proper practice (KAP) skills to enhance patient safety and well-being. Previous studies have identified main barriers to ADR reporting, including low levels of awareness, attitudes, and practices regarding under-reporting, challenges in establishing hospital reporting systems, and insufficient training in identifying ADRs. Multiple studies also associate poor adherence to ADR reporting methods with various factors. Some research indicates that healthcare professionals working in tertiary care hospitals often have limited knowledge, are unaware

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of reporting deadlines, and lack familiarity with locations and procedures for reporting ADRs.[3] Strategies to improve ADR reporting include adopting electronic methods to streamline the process, implementing training and educational programs for healthcare providers, and increasing awareness of the reporting system among caregivers. Given the importance of pharmacovigilance, a robust reporting system is crucial but challenging to develop. Careful planning, practical solutions, and focused efforts can foster necessary changes that ensure patient safety—the primary goal of pharmacovigilance. Studies have also been conducted using developed questionnaires to gather relevant data.[4]

The kidney is a major organ for the elimination of many drugs and their metabolites, but in impaired kidney function, accumulation of drugs leads to adverse drug events. This may cause mild, moderate, or severe adverse drug reactions, and severe ones lead to complications that threaten the lives of patients. Hence, renal inefficiency and polypharmacy can significantly contribute to adverse drug reactions.[5] Therefore, HCPs play an important role in identifying, analyzing, reporting, and monitoring ADRs to minimize the early morbidity/mortality associated with them. The present study aims to evaluate the knowledge, attitude, and practice (KAP) and factors challenging in reporting ADRs in the nephrology unit using self-developed and validated questionnaires. Healthcare professionals, like interns, doctors, nurses, undergraduates, and post-graduates, were assessed for their knowledge, attitude, and practice towards reporting adverse drug reactions (ADRs), to help develop the strategies for better ADR reporting.

MATERIALS AND METHODS

The proposed cross-sectional survey study was conducted among 52 health care professionals in the Nephrology unit of a tertiary care hospital, using Google Forms. The KAP questionnaire for ADR reporting was developed in a standardized manner using an acknowledged measure-development technique.

Ethical Clearance

The study was conducted in accordance with the ethical principles of "The Declaration of Helsinki" from March to May 2024, with prior permission from the human ethical committee (KLECOPBGMEC/D001-2024), and all participants provided informed consent.

There were two key steps in the process

A. Development, validation, and reliability of the questionnaires.

Questionnaires regarding Knowledge, Attitude, and Practice on ADR reporting were developed by reviewing the articles and were validated using a 3-Likert scale. The Reliability of the validated questionnaires was calculated using Cronbach's alpha in Excel using data analysis.

B. Administration of a validated and reliable questionnaire to health care professionals in the Nephrology unit

The validated questionnaires from Phase 1 were administered to healthcare professionals through Google Forms with consent. The Questionnaires consisted of demographic details, assessing KAP, and determining the challenges faced by healthcare professionals in reporting ADRs to develop strategies. Data from Google Forms were extracted and analysed using appropriate statistical methods, and the outcomes were assessed for KAP levels.

RESULTS

Table 1: Reliability of the questionnaires on KAP and factors/challenges in reporting ADRs, using Cronbach's Alpha value.

Sl.no.	Domains	Cronbach's Alpha value	Reliability
1	Knowledge	0.88	Good
2	Attitude	0.86	Good
3	Practice	0.91	Excellent
4	Factors/ Challenges	0.74	Acceptable

A KAP study was conducted focusing on various stakeholders among healthcare professionals in the nephrology unit. First, the set of questionnaires was validated using a 3-Likert scale and checked for reliability regarding Knowledge, Attitude, and Practice, as well as factors or challenges in reporting ADRs, with values of 0.88, 0.86, 0.91, and 0.74, respectively (Table 1).

Table 2: Socio-demographic characteristics of the participants.

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Socio-Demographic factors	Frequency	Percentage %
1. Gender		
Female	34	65.38
Male	18	34.62
2. Age (in years)		
18-28	44	84.62
29-38	6	11.53
39-48	2	3.85
3. Educational qualification		
Under graduation	5	9.62
Graduation (Internship)	25	48.08
Post-graduation	16	30.77
Super-specialisation	6	11.53
4. Profession		
Doctors	6	11.53
Nurses	9	17.32
Pharmacists	6	11.53
Students	30	57.70
Other health care professionals	1	1.92
5. Designation		
Senior consultants	3	5.77
Junior consultants	3	5.77
Staff Nurse	9	17.32
Clinical Pharmacists	2	3.84
Hospital Pharmacists	4	7.68
Students (UG, PG, and Interns)	30	57.70
Dialysis Unit Technician	1	1.92

Of the total 52 respondents (Table 2), the majority were female (34, 65.40%), while the others were male (18, 34.60%). Age-wise, the maximum participants were in the age group of 18-28 years with a frequency of 44 (84.6%), and others were 29-38 years with 6 (11.53%), and 39-48 years with 2 (3.8%). Based on the profession, participants were doctors (6, 11.53%), nurses (9, 17.3%), pharmacists (6, 11.53%), students (30, 57.69%), and other healthcare professionals (1, 1.92%).

Table 3: Knowledge of health care professionals on ADR reporting.

SI No.	Knowledge Domain Questionnaires	Yes	%	No	%
1	Do you know what an adverse drug reaction (ADR) is?	52	100%	0	0%
2	Are you aware of the significance of ADR reporting for patient care?	51	98.08%	1	1.92%
3	Are you acquainted with the nephrology unit ADR reporting procedure?	41	78.85%	11	21.15%
4	Do you know that regulations and policies are available to track adverse drug reactions in patients?	48	92.31%	4	7.69%
5	Are you aware of the procedure for recording medication reactions?	46	88.46%	6	11.54%
6	Are you aware of the resources that you used to stay informed about ADR reporting for medications?	50	96.15%	2	3.85%
7	Do you know that National /International agencies provide training on the reporting of ADRs?	41	78.85%	11	21.15%
8	Are you aware of ADR reporting centres?	47	90.38%	5	9.62%
9	Do you think ADR's can be reported for drugs after they are available in the market (During post-marketing surveillance)?	47	90.38%	5	9.62%
10	Are you aware that NSAIDs (E.g., Paracetamol) may cause ADRs?	49	94.23%	3	5.77%

Knowledge of health care professionals on ADR reporting

The knowledge domain had 10 questions, focusing on the definition, significance, regulations, and policies, procedures of entering details of ADRs, resources available to stay updated about ADRs, training by national and international agencies, ADR reporting centres, reporting ADRs in post-marketing surveillance phases, and knowledge about drugs such as NSAIDs causing ADRs in Nephrology patients. The core Knowledge on reporting ADRs in the present study was 90.77%, whereas, in two of the components, 21.20% of health care professionals felt a lack of acquaintance with

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ADR reporting, and 21.15% had less knowledge about national/international agencies for reporting of ADRs.

Table 4: Attitude of health care professionals towards ADR reporting.

Sl. No.	Attitude Domain Questionnaires	Yes	%	No	%
1	It is important to monitor and report Adverse Medication Reactions in the Nephrology unit.	51	98.07%	1	1.93%
2	Personal experience of reporting adverse drug reactions from the unit was sometimes not pleasant.	24	46.15%	28	53.85%
3	Adverse Drug reactions are to be reported through the proper channel	48	92.31%	4	7.69%
4	Increasing the overall safety of medications can be improved by reporting ADR's	50	96.15%	2	3.75%
5	In my opinion, it is very crucial to keep an eye on the occurrence of ADRs in patients with kidney problems	52	100%	0	0%
6	Special methods or recommendations are required for monitoring ADRs in the nephrology unit	42	80.80%	10	19.20%
7	ADR reporting in the nephrology unit is adequately prioritized by healthcare professionals	43	82.69%	8	17.31%
8	Patients and society benefit from ADR monitoring and reporting	48	92.30%	4	7.70%
9	Patient's confidentiality is impacted by ADR reporting	24	46.15%	28	53.85%
10	It is crucial to establish an ADR reporting centre in every unit of the hospital	45	86.54%	7	13.46%

Attitude of health care professionals towards ADR reporting

In the present study, the attitude domain had 10 questions, focusing on whether it was important to monitor and report ADR, personal experience of reporting, and requirements of proper channels, methods, and recommendations to report an ADR. Participants' attitude scores were 82.12%. Many participants expressed that it is very crucial to be vigilant about the occurrence of ADRs in patients with kidney problems. 98.07% of the participants expressed that it was important to monitor and report adverse medication reactions, and 46.15% felt that patients' confidentiality was impacted by ADR reporting.

Table 5: Practice of health care professionals on ADR reporting.

SI No.	Practice domain Questionnaires	Yes	%	No	%
1	Do you frequently come across ADRs in the nephrology unit?	42	80.80%	10	19.20%
2	Have you ever documented and reported any adverse drug reactions in the nephrology unit?	35	67.31%	17	32.69%
3	How often are the ADR reporting practices reviewed and evaluated in the Nephrology unit?	37	71.15%	15	28.85%
4	Do you use any types of reporting forms to report ADRs in the nephrology unit?	36	69.23%	16	30.77%
5	Have you ever observed and reported any instances of ADR's related to Nephrology medications?	38	73.07%	14	26.93%
6	Have you received any training on how to use the software for reporting adverse drug reactions specific to the Nephrology unit?	26	50.00%	26	50.00%
7	How often do you refer to clinical guidelines and protocols for reporting ADRs?	41	78.85%	11	21.15%
8	Do you stay updated with the latest advancements and best practices related to reporting ADRs?	42	80.80%	10	19.20%
9	Are you reviewing the accuracy and completeness of ADR reports?	34	65.38%	18	34.62%
10	Is the feedback process followed upon reporting of an ADR?	45	86.54%	7	13.46%

Practice of health care professionals towards ADR reporting

In the present study, the Practice domain also had 10 questions, focusing on, whether participants in the nephrology unit, frequently come across with ADRs, any time they documented and reported any adverse drug reactions, how often ADR reporting practices were reviewed and evaluated, which type of ADR reporting form were used, observed any instances of ADR's related to nephrology medications, received any training on how to use the software for reporting adverse drug reactions specific to the nephrology unit, how often they refer to clinical guidelines and protocols for reporting ADRs, stay updated with latest advancements and best

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practices related to reporting of ADRs, and feedback process followed after reporting ADR of the patient. The domain of practice in the present study was 72.3%. Almost 50% of the participants lacked practice/training on how to use the software to report adverse drug reactions specific to the nephrotoxicity, and 34.62% on reviewing the accuracy and completeness of ADR reports.

Table 6: ***Challenges in reporting of ADRs by health care professionals.***

Sl. No.	Questionnaires on Factors/Challenges in reporting ADR	Yes	%	No	%
1	Have you ever experienced any difficulty in identifying ADRs related to nephrology patients?	12	23.08%	40	76.92%
2	Did you encounter any barriers while attempting to report ADRs in the Nephrology unit?	14	26.92%	38	73.08%
3	Are there any technological issues within the unit that hinder you from reporting ADR?	10	19.23%	42	80.77%
4	Are there any organizational or administrative obstacles hindering the reporting of ADRs in the Nephrology unit?	12	23.08%	40	76.92%
5	Are there any barriers you face in communicating with patients with respect to collecting information on ADRs?	23	44.23%	29	55.77%
6	Are there any limitations in the current ADR reporting system within the Nephrology unit?	12	23.08%	40	76.92%
7	Do you think inadequate trainings contribute to the underreporting of ADRs in the Nephrology unit?	28	53.85%	24	46.15%
8	Do you think inadequate support is one of the challenges in underreporting ADRs in the Nephrology unit?	28	53.85%	24	46.15%
9	Does ADR reporting regularly have more challenges in collecting patient safety data?	43	82.69%	8	17.31%
10	Does your workload hinder your ability to report ADRs promptly and accurately?	33	63.46%	19	36.54%

Challenges in reporting of ADRs by health care professionals

In the present study, participants had good knowledge and attitude, as many of them were Pharm D interns with background knowledge of pharmacotherapeutics and with better awareness about ADRs due to the pharmacovigilance set-up in the department. The practice domain was not as strong as the other two domains; more efforts should be made to encourage reporting of ADRs with the help of the Pharmacovigilance Reporting Centre. This shows that participants had good knowledge and attitude, but lacked in reporting practice. In addition, regular ADR reporting had many challenges with the collection of patient safety data in the nephrology unit, as there is a requirement for additional resources to focus on the conduct of training and awareness programs, and for effective reporting of ADRs by coordinating with all HCPs for accuracy and completeness of ADR reports.

DISCUSSION

The present study assessed the knowledge, attitude, and practice (KAP) regarding adverse drug reaction (ADR) reporting among healthcare professionals in a nephrology unit. The results revealed an encouraging level of awareness and a positive attitude towards ADR monitoring, similar to findings reported by Shanko et al., Desai et al., Z.U. Nisa et al., and Hu W et al., where attitude scores ranged between 73.9% and 95.1%.[1,12,17,19]

The predominance of female participants (65.4%) and younger professionals (18–28 years), and participants' overall age ranged between 18-60 years, which is consistent with previous KAP studies in hospital settings.[2,10,13-15] The high knowledge and attitude scores could be attributed to the inclusion of PharmD internship students and professionals already exposed to pharmacovigilance concepts.

However, the practice domain lagged, reflecting barriers such as insufficient hands-on training, a lack of familiarity with ADR reporting software, and limited coordination between healthcare professionals and pharmacovigilance centres. These findings align with reports from Hu et al., Gupta et al., and Datta et al., who observed practice scores ranging from 64% to 90%, indicating that knowledge alone does not ensure regular reporting.[18-20]

Improving ADR reporting in nephrology units requires structured training programs, regular sensitization sessions, and interdisciplinary collaboration led by clinical pharmacists. Integrating ADR reporting into routine unit activities and encouraging feedback from pharmacovigilance centres could enhance reporting accuracy and compliance.[21,22]

The strength of this study was the development and validation of the KAP questionnaire to uncover potential gaps or obstacles in ADR reporting standards, particularly for nephrology patients, who typically have

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distinct pharmaceutical demands and sensitivity towards adverse reactions due to renal impairment.

There are some limitations to the study, such as, the present study is a cross-sectional survey study; a qualitative design would have been more imperative in providing a transparent opinion with many explicit responses. In addition, gathering information in a shorter duration of study may lead to recall bias and a smaller sample size. The results obtained from the single centre cannot be generalized to the responses from healthcare professionals from multi-centre sites.

CONCLUSION

This study highlights the need for the practice domain, even though the knowledge and attitude domains were good. Poor ADR reporting practices are linked to inadequate training, patient data confidentiality, and training skills. Therefore, strategies have been suggested to overcome the challenges faced by healthcare professionals, to implement methods to improve the practice of ADR reporting, and to provide training, especially for healthcare professionals working for patient safety. Some strategies proposed are comprehensive education and increased frequency of training to be provided to health care professionals, and encouraging them to report ADRs. Electronic health record (EHR) systems can facilitate easier access to patient charts, enabling healthcare professionals to review patient data more efficiently and communicate with patients in a convenient language in which they are comfortable, to overcome language barriers, fear of losing confidentiality, and retrieve data related to ADRs.

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