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ORIGINAL ARTICLE

KNOWLEDGE,ATTITUDE, AND PRACTICE OF HEALTH-CARE PROFESSIONALS REGARDING ADVERSE DRUG REACTION REPORTING IN SELECTED PEDIATRIC HOSPITALS IN KURDISTAN/ IRAQ

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ABSTRACT

Background: Adverse drug reactions (ADRs) are one of the major challenges in healthcare settings, especially in pediatric hospitals where children are more vulnerable to drug effects. This study aimed to assess the knowledge, attitude, and practice (KAP) of healthcare professionals regarding ADR reporting and identify factors associated with increased reporting.

Materials & Methods: A cross-sectional study design was conducted on a total of 401 healthcare professionals which were sampled by convenience method and data collected by interview to assess their KAP using a structured questionnaire.

Results: The total knowledge scores were highest among pharmacists (21.0 ±4.3) compared to nurses (15.0 ±4.6) and physicians (17.4 ±4.6) ($p<0.001$). Similar patterns were noted for attitudes and practices. Higher KAP scores were significantly associated with increased ADR reporting.

Conclusion: The finding of this study showed that the KAP of the Healthcare providers towards spontaneous ADR reporting were low. Awareness among Healthcare providers, collaboration among other healthcare professionals and training for healthcare providers were the highly suggested ways to improve ADR reporting.

KEY WORDS: Adverse Drug Reaction reporting; healthcare practioners; Pharmacists; pediatric; Iraq.

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INTRODUCTION

Pharmacovigilance is defined as the "science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems." Pharmacovigilance's main goals are to improve patient care and safety in connection to drug use, assess the medication's advantages, risks, and effectiveness, and effectively inform healthcare professionals and the public about its safety.[1] Once a drug has been marketed, little is known about its safety profile. Information on unidentified Adverse drug reactions (ADRs) is collected over time, due to the fact that the medication is utilized for various purposes or with various populations (e.g., children). This process changes the safety profile of the drug over its lifetime.

The adverse drug reactions collected during the premarketing phase is incomplete, mainly because number of participants in clinical trials are limited and are not representative of the public at large. In addition, information about rare and serious adverse reactions, long term toxicity, use in special groups, or drug interactions is often incomplete. Thus, it's critical to do post-marketing surveillance to find less frequent but occasionally highly serious ADRs. Therefore, health professionals worldwide should report on ADRs as it can save lives of their patients and others.[2]

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An ADR is defined by the world health organization (WHO) as "a noxious, unintended effect of a drug that occurs in doses normally used in humans for the diagnosis, prophylaxis and treatment of disease".[3] ADRs are a significant global issue. They have varied degrees of impact on both children and adults, resulting in morbidity and mortality.[4-6] Different studies have documented that new adverse reactions are discovered efficiently from spontaneous reporting compared to other methods, including large post-marketing studies.[2,6-8] The occurrence of ADRs depends on age, sex, genetics, polypharmacy, dose accuracy, and environmental and other internal factors such as disease conditions.[9-12]

ADRs are more common than before in many nations around the world[13], which has raised patient-related morbidity and mortality in both hospital and community settings. Studies have indicated that healthcare professionals underreport adverse drug reactions, especially in developing countries.[11,14]

ADRs identification and reporting among children and adolescents remains challenging for several reasons. *Kohli et al.* attributed the challenge to the target population, such as young children and babies having limited communication capacity.[15] Substantially low numbers of suspected ADRs reflect the challenge reported in pediatric care facilities such as neonatal care in Iraq and globally. Despite more than 100000 being cared for in neonatal units across Iraq annually, the Iraqi Pharmacovigilance Centre (IqPhvC) received less than 100 reported cases of ADRs in such facilities in 2021.[16] However, even in pediatric care facilities, a vast opportunity exists for improving reporting ADRs through the presence of healthcare providers, including those in highly specialized units like pediatric intensive care.

Therefore, in this study, health care personnel' knowledge, attitudes, and practices regarding spontaneous ADR reporting and the factors influencing the reporting process in a few Iraqi pediatric hospitals were examined.

MATERIALS AND METHODS

Study Setting and Period: Three pediatrics hospitals were selected as a site for this study. The hospitals included Raparin Teaching Hospital for Children in Erbil, Dr. Jamal for pediatric in sulemani and Hevi teaching hospital in dhok. The data collection for this study was conducted between February 2021 to April 2022.

Study Design: Descriptive cross-sectional study design was conducted by using self-administered questionnaires. This questionnaire has 4 sections, the first section is about the demographic information of the participants and the other three sections are about knowledge, attitude and practice (KAP). This study was conducted to answer the question of what factors influence the reporting of adverse drug reactions among healthcare professionals in selected pediatric hospitals in Iraq. It was also investigated what is the level of knowledge of healthcare professionals about the importance of reporting adverse drug reactions. What is the attitude of healthcare professionals about the importance of reporting adverse drug reactions? And what is the performance of health care professionals in reporting adverse drug reactions?

Study Population: The study considered a diverse and broad base of pediatric Healthcare providers using the IqPhvC that suggested Healthcare providers such as pharmacists, nursing, and physicians as the primary and most frequent ADR reporters (Alshammari et al. 2019).[17] Sampling was done by covenience method. The participants included general nurses and specialties like enrolled, public health, nurse prescribers, and emergency care nurses. Pharmacy staff that were considered in this study included; pharmacy technicians and pharmacists, while physicians included medical officers, physicians, and other pediatric-related specialties.

Survey development: The survey instrument was developed by an expert panel consisting of pediatricians, clinical pharmacists, nurses, and faculty members with expertise in pharmacovigilance based on published literature and previous surveys on adverse drug reaction reporting. The survey was designed to collect information on participant demographics, knowledge, attitudes, and practices related to adverse drug reaction monitoring and reporting in pediatric settings.

The draft survey underwent multiple revisions after pilot testing on a sample of 15 healthcare professionals. The final questionnaire consisted of 39 items divided into 4 sections: (1) demographics (7 items), (2) knowledge (6 items), (14) attitudes (7 items), and (4) practices (19 items).

Validity and reliability: Face and content validity of the survey instrument were assessed by having the expert panel review the questions for relevance, clarity, and comprehensiveness in covering the knowledge, attitudes, and practices related to adverse drug reaction (ADR) reporting. The survey was also pilot tested on 15 healthcare professionals to gather feedback, which was incorporated to improve the clarity and understanding of the questions. The reliability of the KAP domains was evaluated by calculating Cronbach's alpha coefficients in the sample of 401 participants. Negative questions were revered for their scores by subtracting their scores from 5 before reliability analysis. For the 6-item knowledge section, Cronbach's alpha was 0.71, indicating acceptable internal consistency. The 14-item attitude and 7-item practice domains had also good reliabilities, with Cronbach's alpha of 0.80 and 0.78, respectively.

Data Collection Process: Data were collected under the direction of the principal investigators, research assistants used structured questionnaires on the sociodemographic status, the KAP of health professional towards ADR reporting, and influencing factors.

Data Analysis and Interpretation: Descriptive statistics including mean ± standard deviation for continuous variables and frequency (percent) for categorical variables were used to summarize participant demographics. Total KAP scores were calculated for each participant. Based on score distributions, the KAP levels were categorized as low/average or high. Participants with a total score of ≥80% of the maximum score of each domain were categorized as high, otherwise, they were categorized as low/average. The maximum scores were 30, 70, and 35 for the KAP domains, respectively.

Differences between provider types (nurses, physicians, pharmacists) were assessed using Kruskal-Wallis tests. Pairwise comparisons between provider types were conducted using nonparametric Wilcoxon tests with Bonferroni correction.

Poisson regression was used to model predictors of self-reported adverse drug reaction reporting rates. Univariate models were first built with each predictor separately. Variables significant at $P<0.05$ were included in a multivariate Poisson model. A P-value <0.05 was considered statistically significant in all analyses. SPSS Statistics version 26.0 (IBM Corporation, Armonk NY, USA) was used for data analysis. R packages were implemented for data visualization.

Ethical Consideration: The Ethical Review Committee of the College of Pharmacy at Hawler Medical University granted approval for the procedure. After outlining the goals and methods of the study, a participant gave written informed consent. Additionally, all of the responses were kept private.

RESULTS

Participants Characteristics: A total of 401 participants completed the survey (response rate 85.3%). The mean age for the participants was 32.6±8.5 years. The sample consisted of 55.4% males and 44.6% females. When it comes to their professional background, 50.4% were nurses, 31.7% were physicians, and 18.0% were pharmacists. In terms of education, most participants had a diploma degree (37.4%), followed by those with a bachelor's degree (33.4%), a master's degree (12%), or a PhD (12.5%). The highest representation comes from the Pediatric Ward (38.9%), followed by NICU (23.7%), Emergency Ward (23.2%), and Hospital Pharmacy (14.2%). On average, participants saw 18.5±6.3 pediatric patients per day and reported a rate of 5.2±2.4 ADRs throughout the year (Table 1).

Table 1: Demographic characteristics of the included participants (N=401)

Characteristic	N = 401[1]
Age (years)	32.6±8.5
Gender	
Male	222 (55.4%)
Female	179 (44.6%)
Health care professional	
Nursing	202 (50.4%)
Physician	127 (31.7%)
Pharmacist	72 (18.0%)
Level of education	
Bachelor	133 (33.2%)
Diploma	150 (37.4%)
Master's degree	48 (12.0%)
PhD	70 (17.5%)
Department	
NICU	95 (23.7%)
Pediatric Ward	156 (38.9%)
Hospital Pharmacy	57 (14.2%)
Emergency Ward	93 (23.2%)
Average Pediatric patients seen per day	18.5±6.3
Rate of ADR	5.2±2.4

[1]Mean±SD; n (%)

Composite scores of KAP: The total knowledge scores were highest among pharmacists (21.0 ± 4.3) compared to nurses (15.0 ± 4.6) and physicians (17.4 ± 4.6) ($p<0.001$). In pairwise comparisons, pharmacists demonstrated higher composite scores of knowledge compared to both nurses and physicians ($p<0.001$ for both comparisons). Only 3.0% of nurses and 10.2% of physicians were categorized as having high knowledge, versus 26.4% of pharmacists ($p<0.001$).

A similar pattern was noted for practice, pharmacists also showed the highest means of composite score of practice (26.6 ±6.0), followed by physicians (23.5 ±5.9) and nurses (20.1 ±5.9) ($p<0.001$). Pharmacists showed significantly higher composite practice scores compared to both nurses and physicians ($p<0.001$ for both comparisons). In professions, 48.6% of pharmacists were classified as having high practice versus only 11.9% of nurses and 27.6% of physicians ($p<0.001$).

Table 2: Comparing the composite scores of KAP among different healthcare professionals (N=401)

Characteristic	Nursing, N = 202[1]	Physician, N = 127[1]	Pharmacist, N = 72[1]	p-value[2]
Total Score of Knowledge	**15.0±4.6**	**17.4±4.6**	**21.0±4.3**	**<0.001**
Low to average	196 (97.0%)	114 (89.8%)	53 (73.6%)	<0.001
High	6 (3.0%)	13 (10.2%)	19 (26.4%)	
Total Score of Practice	**20.1±5.9**	**23.5±5.9**	**26.6±6.0**	**<0.001**
Low to average	178 (88.1%)	92 (72.4%)	37 (51.4%)	<0.001
High	24 (11.9%)	35 (27.6%)	35 (48.6%)	
Total Score of Attitude	**43.8±7.4**	**48.2±7.1**	**54.3±6.6**	**<0.001**
Low to average	201 (99.5%)	127 (100.0%)	70 (97.2%)	0.12
High	1 (0.5%)	0 (0.0%)	2 (2.8%)	
[1]Mean±SD; n (%)				
[2]Kruskal-Wallis rank sum test; Pearson's Chi-squared test; Fisher's exact test				

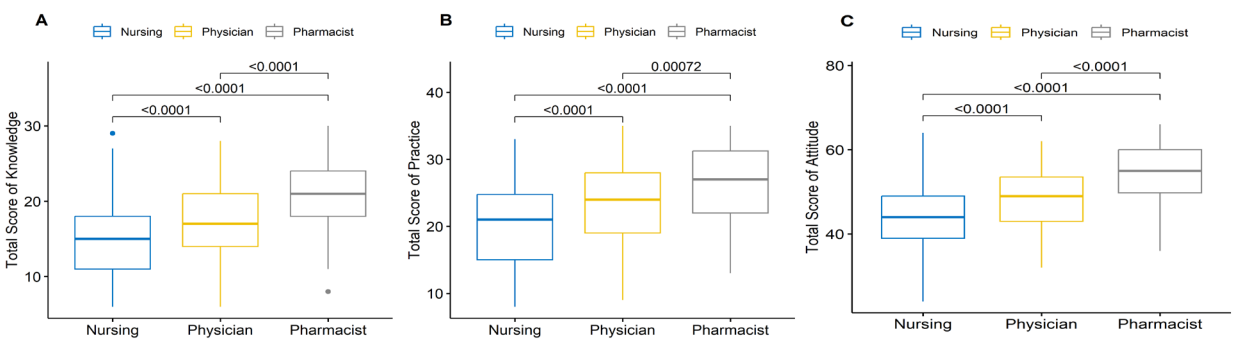

Figure 1: Box-Whisker plots presenting the differences in composite scores of knowledges (A), practice (B), and attitude (C) among different health care providers with pairwise comparisons. The calculated p-value is Bonferroni-adjusted for multiple comparisons.

Though pharmacists had the most favorable attitude scores (54.3 ±6.6), differences between groups were less pronounced. Only 2.8% of pharmacists fell into the high attitude category compared to 0.5% of nurses and 0% of physicians (p=0.12) (Table 2, Figure 1).

Predicting the Factors Associated with ADR Reporting: Poisson regression analysis was conducted to identify factors associated with ADR reporting rates among the 401 healthcare professionals surveyed (Table 3). In univariate models, higher total knowledge scores (IRR per unit 0.23, 95% CI 0.19-0.27), attitude scores (IRR per unit 0.17, 95% CI 0.15-0.19), and practice scores (IRR per unit 0.20, 95% CI 0.17-0.23) were all significantly associated with increased ADR reporting (all p<0.001). Other predictors of higher reporting in univariate analyses included having a master's degree (IRR 0.89, 95% CI 0.11-1.7, p=0.025) or Ph.D. degree (IRR 1.7, 95% CI 1-2.4, p<0.001) versus a bachelor's degree, working in the hospital pharmacy or emergency department versus the NICU (IRR 0.88, 95% CI 0.08-1.7, p=0.031 and IRR 0.78, 95% CI 0.09-1.5, p=0.027, respectively), and seeing more pediatric patients daily (IRR per patient 0.29, 95% CI 0.26-0.31, p<0.001).

Table 3: Poisson regression analysis predicting the factors associated with ADR reporting rates (N=401)

Characteristic	Univariate Poisson Regression				Multivariate Poisson Regression		
	N	IRR1	95% CI1	p-value	IRR1	95% CI1	p-value
Total Score of Knowledge	401	0.23	0.19, 0.27	<0.001	1.01	1.00, 1.02	0.006
Total Score of Attitude	401	0.17	0.15, 0.19	<0.001	1.02	1.01, 1.02	<0.001
Total Score of Practice	401	0.20	0.17, 0.23	<0.001	1.01	1.00, 1.02	0.003
Age (years)	401	0.00	-0.02, 0.03	0.8			
Gender	401						
Male		—	—				
Female		-0.47	-0.95, 0.01	0.053			
Health care professional	401						
Nursing		—	—		—	—	
Physician		0.54	0.02, 1.1	0.043	0.89	0.79, 1.01	0.061
Pharmacist		1.6	0.92, 2.2	<0.001	0.84	0.68, 1.02	0.083
LOE	401						
Bachelor		—	—		—	—	
Diploma		0.44	-0.11, 1.0	0.12	1.06	0.93, 1.21	0.4
Master's degree		0.89	0.11, 1.7	0.025	1.09	0.89, 1.34	0.4
PhD		1.7	1.0, 2.4	<0.001	1.03	0.57, 2.05	>0.9
Department	401						
NICU		—	—				
Pediatric Ward		0.23	-0.38, 0.85	0.5			
Hospital Pharmacy		0.88	0.08, 1.7	0.031			
Emergency Ward		0.78	0.09, 1.5	0.027			
Average Pediatric patients seen per day	401	0.29	0.26, 0.31	<0.001	1.03	1.03, 1.04	<0.001

1CI = Confidence Interval, IRR = Incidence Rate Ratio

In the multivariate model adjusting for all variables, higher knowledge scores (IRR per unit 1.01, 95% CI 1.00-1.02, p=0.006), attitude scores (IRR per unit 1.02, 95% CI 1.01-1.02, p<0.001), and practice scores (IRR per unit 1.01, 95% CI 1.00-1.02, p=0.003) remained independent predictors of increased ADR reporting. Daily pediatric patient volume also persisted as a significant factor (IRR per patient 1.03, 95% CI 1.03-1.04, p<0.001).

DISCUSSION

Adverse drug reactions are the primary cause of patient harm in healthcare. They are preventable and have the potential for re-occurrence. In the present study, we performed a questionnaire survey to investigate the KAP of healthcare professionals on spontaneous ADR reporting and to describe factors affecting the reporting process in three pediatric hospitals in Iraq.

When we compare the knowledge of healthcare providers among themselves, Pharmacists consistently demonstrated greater knowledge of ADR reporting requirements, procedures, and guidelines compared to physicians and nurses; this finding is consistent with studies reported from Saudi Arabia.[11] and Nigeria.[18] However, a study from Nepal[19] reported that physicians and pharmacists are more knowledgeable than nurses. This demonstrates that there are differences in the awareness of spontaneous ADR reporting across the various healthcare providers, which may be due to differing access to information regarding ADR reporting. Furthermore, Addressing the knowledge gaps among nurses and physicians should be a priority.

Concerning the attitude of healthcare providers, the finding of this study showed that pharmacists had the most favorable attitudes, while nurses expressed the least positive attitudes about the importance and effectiveness of ADR reporting across many survey items. This finding is consistent with studies reported from, Nigeria[18], Nepal[19] and Southwest Ethiopia.[20] The difference between healthcare providers in their attitudes towards ADR reporting could be because of lack of training, unawareness regarding the ADR reporting form, and lack of commitments of health-care providers.

Regarding the practice of healthcare providers, this study revealed that pharmacists also had higher mean scores compared to other providers. Pharmacists reported the most optimal practices in terms of frequency of reporting ADRs, recording them in patient charts, and valuing educational programs. This finding is similar to studies reported from Nepal[19], Ethiopia[21] and South India.[22]

This study identified several predictors of adverse drug reaction (ADR) reporting rates. Working as a pharmacist versus a nurse was also associated with higher ADR reporting rates. Additionally, the number of pediatric patients seen per day remained a significant predictor in the model. There may be a variety of reasons why health practitioners underreport ADRs. The personal and professional traits of healthcare professionals, as well as their familiarity with and attitude toward reporting, have been broadly categorized as these elements. In his study[23], Inman summarized these factors as 'seven deadly sins.'. His descriptions of the 'sins' include: attitude relating to professional activities (financial incentives, legal aspects) and problems associated with ADRs related knowledge and attitudes (complacency, diffidence, indifference, ignorance) and excuses made by professionals (lethargy i.e. disinterestedness in reporting or lack of time to find a report card and other excuses).[23] According to our study, nurses indicated the greatest barriers in terms of lack of workplace support, resources, and information provision around ADR reporting. Ensuring adequate systems are in place is vital. Also, significant differences were observed between professional groups on most survey items, this highlights the need for tailored interventions by role. A one-size-fits-all approach may not optimize ADR reporting.

Even pharmacists, who demonstrated the most knowledge and positive attitudes, still showed room for improvement on several measures. Ongoing education and training is important for all groups.

In order to improve the reporting rate, it is important to improve the knowledge, attitude and practice (KAP) of healthcare professionals regarding ADR reporting and pharmacovigilance.[24] The results of this study clearly demonstrate the need for multifaceted interventions to address gaps in knowledge, attitudes, and practices related to pharmacovigilance among healthcare professionals caring for pediatric patients. Regular educational initiatives should provide comprehensive training on ADR reporting protocols and reinforce the professional responsibility to monitor and report all adverse events, regardless of severity. Creating supportive workplace cultures is also imperative, with clear ADR reporting procedures, encouragement and incentives for reporting, and adequate staffing and resources. Furthermore, leveraging pharmacists' expertise through mentorship programs could help improve physicians' and nurses' competencies. Optimizing attitudes through motivational strategies may help overcome detrimental mindsets hampering engagement. Multipronged efforts to strengthen KAP through training, resources, and collaborative policies offer promise for considerably enhancing ADR reporting rates and optimizing medication safety for vulnerable pediatric populations.

CONCLUSION

The finding of this study showed that the KAP of the Healthcare providers towards spontaneous ADR reporting were low. Awareness among Healthcare

providers, collaboration among other healthcare professionals and training for healthcare providers were the highly suggested ways to improve ADR reporting.

Limitations: The use of a cross-sectional survey design provides insights into associations at one point in time but cannot determine causal relationships. The data collected were self-reported by participants and may be subject to recall bias or socially desirable responding. Direct observation of actual practices related to ADR reporting could provide more objective insights.

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CONFLICT OF INTEREST
Authors declare no conflict of interest.
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AUTHORS' CONTRIBUTION

The following authors have made substantial contributions to the manuscript as under:

Conception or Design:	BAS, OA
Acquisition, Analysis or Interpretation of Data:	BAS, OA
Manuscript Writing & Approval:	BAS, OA

All the authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.