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Research Article

A STUDY ON KNOWLEDGE, ATTITUDE, AND PRACTICE OF PHARMACOVIGILANCE TOWARD ADR REPORTING AMONG JUNIOR RESIDENT, SENIOR RESIDENT, AND CONSULTANT DOCTORS IN TERTIARY CARE SETTING OF TEACHING MEDICAL INSTITUTION

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ABSTRACT

Objectives: The objective of this study was to improve the adverse drug reaction (ADR) reporting rate. This study was undertaken to evaluate the knowledge, attitudes, and practices of the health-care professionals at a tertiary care teaching hospital, regarding ADR monitoring and pharmacovigilance (PV).

Methods: This cross-sectional study was conducted in a tertiary health-care setting of the State Medical College of Uttar Pradesh, health professionals, such as Junior Residents (JRs), Senior Residents (SRs), and consultants were participated in the study. Knowledge, attitudes, the voluntary reporting system, procedures related and reasons for non-reporting of ADRs, etc., with respect to PV was assessed. Informative data were collected and analyzed by applying appropriate software.

Results: Most of the study participants (62.4%) felt that pharmacovigilance report should be made mandatory. The majority of JR knew the theoretical definition and purpose of PVs comparatively more than SR and consultants. Responses showing the attitude of the study participants toward PVs depict that most of the participants (62.4%) felt that PVs report should be made mandatory. Practical aspects of ADRs by different cadres of participant, namely, consultants (68.0%), SR (50%), and JR (35.7%) were found to be statistically significant; p=0.037. The factors discouraging health professionals from reporting ADRs are mainly 1) non-remuneration, 2) difficulty in taking decision, whether ADR has occurred or not or 3 think that single case will not affect ADR database, or 4) lack of time.

Conclusion: Only few of the health professional (20%) were ever reported an ADR but still there is great need to create awareness among the junior/senior doctors/consultants to improve the reporting of ADRs. An educational intervention and improvement of facilities in coordinating with health-care professionals would definitely bring on a difference in ADRs.

Keywords: Adverse drug reaction, Pharmacovigilance, Health-care professionals.

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INTRODUCTION

Pharmacovigilance (PV) is the science and practice related to detecting, evaluating, understanding, and preventing adverse drug reactions (ADRs) and other drug-related safety concerns. Its primary objective is to mitigate harm caused by adverse effects in humans, whether these arise within or beyond the terms of the marketing authorization throughout the entire lifecycle of medical products. ADRs present a significant global health burden [1]. The World Health Organization defines PV as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems [2]." The important aim of PV is to ensure the safe and effective use of medical products by providing timely safety information to patients, health-care professionals, and the public. This contributes significantly to patient's safety and public health [3]. PV activities encompass various issues, including medication errors, underreporting of drug efficacy, off-label drug use, acute and chronic poisoning, drug-related mortality evaluation, misuse of medical products, and adverse interactions between drugs and chemicals. The advent of pharmacogenomics, fueled by advances in genetics, has opened new pathways in pharmacotherapy, allowing for more personalized treatment approaches [4]. Despite reasonable knowledge and attitudes among some health-care professionals, there is a notable deficiency in effective PV practices. Studies have shown that even well-informed doctors often lack robust practices regarding ADR monitoring and reporting. Similar findings have been reported in various other studies, though with some variations. PV approaches can be clinical, epidemiological, experimental (e.g., reproducing adverse effects in animals to understand mechanisms better), or diagnostic (e.g., using imputable methods). In India, PV has recently gained sensitivity, but there is still a lack of awareness about ADRs and insufficient PV practices [5-7]. There is an absence of an immediate ADR monitoring system and a lack of a culture of voluntary or spontaneous reporting among healthcare workers. To enhance the reporting rate of ADRs, it is crucial to improve the knowledge, attitudes, and practices (KAP) of health-care professionals concerning ADR reporting and PV. This study aims to evaluate the baseline KAP of health-care professionals, including senior and junior doctors, interns, and consultants at a tertiary care teaching hospital regarding ADR monitoring and PV. By addressing these gaps, it is possible to foster a more effective and responsive PV system, ultimately enhancing patient safety and public health outcomes.

METHODS

This cross-sectional study was conducted for a time-period of 3 months (April 2022–June 2022) in a tertiary care setting of State Medical College, Shahjahanpur, Uttar Pradesh. Health professionals such as junior residents (JRs), senior residents (SRs), and consultants were

participated in the study. A total of 110 health professionals present at the time of the visit of the investigator were eligible candidate in the present study while only 85 health-care professionals gave their consent of their participation in the study. Out of them, most of the study participants belong to JR doctors (42), followed by consultants (25) and SRs (15). The study was approved by the Institutional Ethics Committee.

A pre-designed, semi-structured validated set of questionnaire was prepared, consisting of a total of 19 questions (11 questions on knowledge, five on attitude, and three on practices) related to knowledge of adverse drug effects/PV, attitude toward reporting adverse effects, and factors that could hinder reporting practices among health-care professionals. The questionnaire included basic knowledge regarding ADR and PV, attitudes of health service providers/participants toward ADR/PVs and its voluntary reporting system, and related procedures and reasons for non-reporting of ADR under PV. Healthcare workers gave their consent before participating in the present study. They had given a pro forma having a validated set of questionnaire to fill out and returned to their respective ward.

Inclusion criteria

JRs, SRs, and consultants working in the tertiary care teaching hospital were included in the study.

Exclusion criteria

Nurses, pharmacists, undergraduate students, staff, and eligible candidates either not giving consent or not willing to answer the question were excluded from this study.

Study tools

The survey instrument based on pre-designed and semi-structured questionnaires taken from the previous studies were 19 in number, with slight modifications, prepared according to the study environment of a tertiary hospital. The questionnaires were pre-tested with two study participants each from JR, SR, and consultants, and suitable adjustments were done before the start of the study. The study consists of different sets of participants, acknowledging their knowledge (Q. No. 1–9), attitude to report adverse effects (ADR) (Q. No. 10–14), and their practices in reference to PV (Q. No. 15–19). The purpose of the present survey was explained and the prepared final updated version of the questionnaire was distributed to JR and SR doctors and consultants during their routine departmental activities. Participants had 15 min to provide the necessary information related to our study. The format of the responses included multiple-choice questions in which study subjects were asked to select the correct answer. One mark was awarded to each correct answer and the maximum score was considered 19 (viz., knowledge 11, attitude 05, and practice 03).

Statistical analysis

Data information of completed questionnaire was recorded using a Microsoft Excel sheet. Information from the filled questionnaire pro forma was coded and appropriate analysis was done after entering data into the Statistical Package for the Social Sciences version 21.0 software. p-value was considered to be statistically significant at $p<0.05$ with a 95% confidence interval.

RESULTS AND DISCUSSION

A total of 110 health professionals present at the time of the visit of the investigator were considered eligible candidates for our study while only 85 health-care professionals gave their consent to their participation in the present study. The response rate in our study was found to be 77.27%. The questionnaires provided to them were duly filled and received back by the investigator. The set of questionnaire comprising 19 questions were divided and tabulated into three sections, such as knowledge, attitude, and practices with 11, 06, and 02 questions, respectively.

In the knowledge assessment of the study group, a total of 76.5 % of study participants knew that PV deals with the safety of drugs while only 67.1% knew the purpose of PV. The present study depicts that the majority of JRs knew the theoretical definition and purpose of PVs comparatively more than SRs and consultants. Knowledge regarding the method employed by pharmaceutical companies to monitor ADRs after a drug launch among study participants showed in decreasing trend, namely, consultants (100%), SR (88.9%), and JR (52.4%). The Knowledge of the city where zonal/sub-zonal centers situated, was significantly more among JRs(81%) than SRs(61%) & Consultants(40%) (p=0.003. Knowledge of health-care professional responsible for reporting ADR' was in decreasing trend from JR (83.3%), SR (66.7%), and consultant (56%) (Statistically significant p=0.048). A total of 85.9% of study subjects knew the location of the National Coordinating Center of the PV Program. Overall, positive responses for knowledge of PVs like "Department dealing with PVs in medical college?" "Location of international center for Adverse Drug Reaction monitoring?" and "Drug banned due to ADR" were, respectively, 85.9%, 65.9%, and 55.3% of study participants. Participants were aware of its major risk factor for the occurrence of maximum ADRs and the regulatory body responsible for monitoring PV, respectively, 72.9% and 61.2% (Table 1).

Responses showing the attitude of the study participants toward PV depict that most of the participants (62.4%) felt that PVs report should be made mandatory. An average number of study subjects (52.9%) knew their responsibility while ADR was in their hospital. The most common practical difficulty faced by the doctors in reporting of the ADR's was that a majority of them did not know how and where the ADRs had to be reported. About 69.4% of participants felt that ADR reporting is a professional obligation. The majority of the study subjects understood the importance of PVs and thinking the need of frequent teaching of PVs (65.9%) and has given a valuable suggestion for establishing ADR (58.8%), with the majority being consultants(80%) followed by SR (72.2%) and JR (40.5%) (statistically significant p=0.003). Finally, most of the study health professional had given suggestion that PV awareness programs should be organized frequently at regular intervals as seminars or workshops (Table 2).

In our study, only a few of the study health professional (20%) were ever reported an ADR. Only 48.2% of study participants were ever trained of ADR, and among them, the majority being consultants (68.0%), followed by SR (50%) and JR (35.7%) (The positive responses against the questions concerning practical aspects of ADRs by different cadres of the participant were found to be statistically significant; p=0.037). About 41.2% of the health-care professionals knew the factors hindering health professional from reporting an ADR and their priority was given to hospitalized patient management (Table 3).

There are different factors which most of the time discourages health professional from reporting ADRs, namely, non-remuneration, lack of time, single case not affect ADR database, and difficulty in decision whether ADR has occurred or not.

The most common practical difficulty which was faced by the doctors in the reporting of ADRs was that a majority of them (76%) did not know how and where the ADRs had to be reported in a short time. Hence, most of them suggested that PV awareness programs should be organized as seminars or workshops (Table 4).

PV relies heavily on the spontaneous reporting of ADRs by health-care professionals, which is crucial for the early detection of safety signals. However, under-reporting of ADRs poses a significant challenge to this system, delaying signal detection, and increasing the economic burden on the community. In India, PV is still in its developmental stages, necessitating increased awareness among junior doctors, SRs, and consultants. The factors contributing to under-reporting are not well-studied in India, prompting this study to assess the KAP regarding ADR reporting in a tertiary care teaching hospital.

Table 1: Knowledge of PV/ADR reporting among resident doctors and consultants

Questions (Corrected Response)	Participants			Total N=85 (%)	Statistical Test	
	JR n=42 (%)	SR n=18 (%)	Consultant n=25 (%)		χ^2	p-value
Definition of PV?	35 (83.3)	13 (72.2)	17 (68.0)	65 (76.5)	2.277	0.320
Purpose of PV?	30 (71.4)	11 (61.1)	16 (64.0)	57 (67.1)	0.757	0.685
Method used by pharmaceutical companies to monitor ADRs after drug launch?	22 (52.4)	16 (88.9)	25 (100)	63 (74.1)	21.122	0.001
SAE reported within how many days in India?	31 (73.8)	13 (72.2)	15 (60.0)	59 (69.4)	1.493	0.474
Department in the college dealing with the program?	32 (76.2)	16 (88.9)	25 (100.0)	73 (85.9)	7.498	0.024
Location of the international center for ADR monitoring?	29 (69.0)	12 (66.7)	15 (60.0)	56 (65.9)	0.577	0.749
Drug banned due to ADR?	26 (61.9)	9 (50.0)	12 (48.0)	47 (55.3)	1.485	0.476
Major risk factor for the occurrence of maximum ADRs?	32 (76.2)	13 (72.2)	17 (68.0)	62 (72.9)	0.539	0.764
Responsible regulatory body for monitoring ADR?	28 (66.7)	9 (50.0)	15 (60.0)	52 (61.2)	1.494	0.474
City where zonal/sub-zonal center situated?	34 (81.0)	11 (61.1)	10 (40.0)	55 (64.7)	11.638	0.003
Responsible health-care professional for reporting ADR?	35 (83.3)	12 (66.7)	14 (56.0)	61 (71.8)	6.071	0.048

ADR: Adverse drug reaction, SAE: Serious adverse event, PV: Pharmacovigilance, JR: Junior resident, SR: Senior resident

Table 2: Attitude of health-care professionals toward ADR and PV

Questions (Corrected Response)	Participants			Total N=85 (%)	Statistical Test	
	JR n=42 (%)	SR n=18 (%)	Consultant n=25 (%)		χ^2	p-value
PV report should be made mandatory?	19 (45.2)	14 (77.8)	20 (80.0)	53 (62.4)	10.382	0.006
If ADR is in your hospital, what should you do?	16 (38.1)	12 (66.7)	17 (68.0)	21 (52.9)	7.352	0.025
ADR reporting is a professional obligation?	25 (59.5)	12 (66.7)	22 (88.0)	64 (69.4)	6.066	0.048
PV should be taught in detail to health-care professionals?	23 (54.8)	13 (72.2)	21 (84.0)	57 (67.1)	6.34	0.042
Do you think PV be taught?	22 (52.4)	13 (72.2)	21 (84.0)	56 (65.9)	7.379	0.025
Opinion for establishing ADR given?	17 (40.5)	13 (72.2)	20 (80.0)	50 (58.8)	11.80	0.003

ADR: Adverse drug reaction, PV: Pharmacovigilance, JR: Junior resident, SR: Senior resident

Table 3: Practice of health-care professionals toward ADR and PV

Questions (Corrected Response)	Participants			Total N=85 (%)	Statistical test	
	JR n=42 (%)	SR n=18 (%)	Consultant n=25 (%)		χ^2	p-value
Have you ever reported an ADR?	6 (14.3)	5(27.8)	6 (24.0)	30 (20.0)	1.788	0.409
Have you ever trained?	15 (35.7)	9 (50.0)	17 (68.0)	41 (48.2)	6.571	0.037
What are the factors, which hinder you from reporting an ADR?	15 (35.7)	8 (44.4)	12 (48.0)	35 (41.2)	1.077	0.584

ADR: Adverse drug reaction, PV: Pharmacovigilance, JR: Junior resident, SR: Senior resident

Table 4: Distribution of participants according to their responses for factors discouraging from reporting ADR

Which factor discourages you from reporting ADRs? (Corrected Response)	Participants			Total N=85, (%)
	JR n=42 (%)	SR n=18 (%)	Consultant n=25 (%)	
Non-remuneration	19 (45.24)	02 (11.10)	00 (00)	21 (24.70)
Lack of time/or how and where the ADRs had to be reported	05 (11.90)	12 (66.70)	19 (76)	36 (42.35)
Single case does not affect the ADR database	06 (14.28)	02 (11.10)	06 (24)	14 (16.47)
Difficulty in decision whether ADR has occurred or not	12 (28.58)	02 (11.10)	00 (00)	14 (16.47)

ADR: Adverse drug reaction, PV: Pharmacovigilance, JR: Junior resident, SR: Senior resident

The previous studies, such as those by Gupta and Udupa (2011) [8], Hardeep *et al*. (2013) [9], and Mohapatra *et al*. (2019) [10], have explored similar objectives and findings. These studies had given emphasis on the need for awareness programs to enhance ADR reporting under PV. In addition, paramedical staff, who are closely connected with patients from admission to discharge, should be encouraged by health professional, namely, junior, senior doctors, and consultants to understand the importance of ADR reporting to make PV programs more effective.

The present study revealed that a significant proportion of doctors (62.4%) believed that ADR reporting should be mandatory. This finding aligns with the results obtained by Qing *et al*. (2004) [11] and Belton *et al*., [12] but contrasts with those by Bateman *et al*. [13] finding. Several factors discourage spontaneous reporting among doctors, including a lack of knowledge about the reporting procedure (52.3%), practical issues related to patient management (45.7%), and concerns about patient confidentiality (31.4%). Despite these practical challenges at tertiary hospital settings, most doctors agreed that ADR reporting should be a voluntary practice. To enhance spontaneous reporting rates, the doctors had recommended organizing training programs and simplifying the reporting system, including providing quick feedback on the reports submitted. A similar study by Tabali *et al*. (2009) [14] demonstrated that educational interventions could

significantly increase physicians' awareness of ADRs, enabling them to apply this knowledge in their daily clinical practice. This emphasizes the need for regular seminars and workshops to reinforce the importance of ADR reporting and PV.

PV in India requires substantial improvements in the awareness and practices of health-care professionals. Addressing the determinants of under-reporting through targeted educational programs and system simplifications could lead to more effective ADR reporting, ultimately contributing to better patient safety and public health outcomes. Encouraging both medical and paramedical staff to participate in PV activities will be crucial in advancing the medical field and ensuring the safe use of medical products.

CONCLUSION

The health professional particularly junior doctors exhibited better theoretical knowledge of the definition, purpose, and responsibility of ADR reporting in PV compared to senior residents and consultants. Conversely, consultants had a better understanding of the methods used by pharmaceutical companies to monitor ADRs. Overall, the knowledge of PV among health-care professionals was generally high. However, most doctors were unaware of how and where to report ADRs. Only a small percentage (20%) had ever reported an ADR, highlighting the need to raise awareness among both junior and senior doctors and consultants about the importance of ADR reporting in the medical profession. Training sessions at national, state, district, or institutional levels should clearly outline the roles of various health-care professionals in PV. A significant majority (76%) did not know the correct procedures for ADR reporting within a short time frame. To address this, fostering closer relationships between doctors and PV centers is essential. Educational interventions and improved coordination facilities with health-care professionals can significantly enhance ADR reporting under pharmacovigilance and ultimately improve patient safety in tertiary health-care setting.

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AUTHOR'S CONTRIBUTIONS

Prof (Dr.) Deepak Sharma had participated in the research study with a literature search, definition of intellectual content, and manuscript review. Dr. Manjusha Nath had been involved in the concept of the present original research article, collection of data, and also contributed in preparing design, analysis of collected data, statistical analysis, preparing the manuscript, and editing of the manuscript. Prof (Dr) Som Nath had supported in preparing the manuscript and applying appropriate statistical analysis.

CONFLICTS OF INTEREST

Nil.

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