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Original Research Article

Evaluation of Knowledge, Attitude and Practice among Healthcare Professionals to Adverse Drug Event Reporting in a Tertiary Care Teaching Hospital Siddipet, Telangana

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Abstract:

Background: Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem. The adverse drug reaction (ADR) or adverse drug event (ADE) is a health concern that is not rigorously observed and discovered by medical professionals. India has an ADR reporting rate of 1%, which is significantly lower than the global ADR reporting rate of 5%. Since there is poor reporting of ADRs, this study was aimed to assess the knowledge, attitude and practice of Pharmacovigilance among healthcare professionals.

Methods: A cross-sectional survey of 303 healthcare workers was done using a pretested, validated questionnaire to measure their knowledge, attitude, and practice regarding ADR reporting. The questionnaire was divided into three parts: 15 questions assessed knowledge of ADR reporting, 5 questions assessed attitude, and the final 5 questions rated practice of ADR reporting among healthcare staff. All participants were given 30 minutes to complete the questionnaire. The data was collected and processed using SPSS software, with descriptive statistics applied.

Results: 303 healthcare workers completed the questionnaire, including 69 doctors, 34 nurses, 100 medical students, 84 nursing students, and 16 chemists. Most healthcare professionals (91.2%) have a positive attitude towards ADR reporting. Fewer healthcare professionals (52%) had adequate knowledge on ADR reporting. Healthcare providers had inadequate reporting practices (42%). In terms of reporting practices, 34% of respondents were unaware of the reporting form. In our study, nurses reported more adverse drug reactions (47%) than doctors (27.5%).

Conclusion: The current study reveals that there is a knowledge gap that is resulting in poor ADR reporting, despite the fact that healthcare professionals have a positive attitude towards it. As a result, more sensitization activities must be implemented to promote the ADR reporting culture among healthcare workers.

Keywords: Adverse drug reactions, healthcare personnel, and pharmacovigilance.

Introduction

Pharmacovigilance (PV) is the science and practice of detecting, assessing, understanding, and prevention adverse effects or other medical/vaccine-related problems. [1] An ADR is described as "A response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function" . ADRs raise the risk of hospitalisation, readmission, longer hospital stays, higher healthcare expenses, morbidity, and mortality, putting a considerable strain on the healthcare system. The adverse drug reaction (ADR) or adverse drug event (ADE) is a health risk that medical practitioners do not closely monitor and detect [2]. The first organised multinational efforts to address drug safety issues. The first organised international efforts to address drug safety issues began in 1961, following the tragic story of thousands of congenitally deformed newborns born as a result of the usage of the pharmaceutical thalidomide during pregnancy. Furthermore, this experience led to the implementation of tougher drug approval procedures, testing methodologies, and monitoring systems, such as the United States Food and Drug

Administration (FDA) [3]. The most important strategy for post-marketing surveillance of suspected drugs is the spontaneous or voluntary reporting of adverse drug reactions. It is the passive reporting of adverse drug reactions (ADRs) by patients or healthcare providers. The goal of these spontaneous reporting systems is to promptly and affordably identify ADRs, and the quality of reports submitted by HCPs affects their success. It may also be useful for identifying new or suspected ADRs. This data is critical for regulatory authorities, healthcare practitioners, and pharmaceutical corporations to make informed decisions concerning drug safety. It also helps to improve treatment guidelines and promote the responsible use of drugs throughout their lives.

Healthcare personnel are responsible for identifying, recording, and reporting adverse drug reactions (ADRs), and it is critical that they help with early detection and reporting [4]. However, a number of factors, such as ignorance, uncertainty about ADRs and their reporting systems, and difficulties understanding the reporting system, influence whether a healthcare professional reports an ADR [5, 6]. Maintaining and monitoring the safety and efficacy of drugs is critical. As a result, pharmacovigilance is a key discipline that is required everywhere to ensure patient safety and the right administration of pharmaceuticals. India's ADR reporting rate is 1%, much lower than the global ADR reporting rate of 5%[7].

To address this issue, the Ministry of Health and Family Welfare established the Pharmacovigilance Programme of India (PvPI) in July 2010.PvPI's mission is to gather and review ADR data, and then use those findings to educate health-care professionals and the general public about a drug's potential risks [8]. All healthcare students should be fluent in PV and ADR reporting to guarantee pharmaceutical safety. In reality, the PV course is required to be included in the curriculum. To reduce the frequency of ADRs, prevent underreporting, and maintain patient quality of care, it is critical that health care providers obtain proper pharmacovigilance and ADR reporting training. Because of the inadequate reporting of ADRs, the purpose of this study was to assess healthcare professionals' knowledge, attitude, and practice of pharmacovigilance.

Methods:

Study Design and Setting: This was a cross-sectional questionnaire-based study done at Government Medical College in Siddipet. Since 2019, the Department of Pharmacology at Government Medical College in Siddipet has served as one of the PvPi's AMCs.

Ethical permission and sample size: The Scientific Review Committee and the College's Institutional Ethics Committee both approved the conduct of this study. The trial lasted three months, from July to September 2023. Using a 6% margin of error and a 95% confidence interval, the sample size was calculated to be 267.

Sample Selection Criteria:

Inclusion Criteria: The study included a non-probability convenience sample of second, third and fourth year medical students, postgraduate students, nursing students, nurses, chemists and medical officers from Government Medical College, Siddipet, who provided informed consent.

Exclusion criteria: First-year medical students and those unwilling to participate in the study were excluded.

Design of Questionnaire: This study used a questionnaire with 25 questions. It was developed following a thorough evaluation of relevant literature. The questionnaire was pre-tested and validated. It was divided into three parts: the first 15 questions assessed healthcare workers' knowledge of ADR reporting in Pharmacovigilance, the next 5 questions examined attitudes, and the final 5 questions assessed practice of ADR reporting among healthcare professionals.

Data collection involved a questionnaire briefing. The responses of health care providers who did not fully comply with the research were excluded. The participants responded anonymously and voluntarily.

303 healthcare professionals who met the inclusion criteria were included in the study, and each participant had 30 minutes to complete the questionnaire. Data were collected and entered into Microsoft Excel.

Statistical Analysis: The data was coded in Microsoft Excel and analysed with SPSS version 16.0 (Chicago, SPSS Inc.). Descriptive statistics were used to assess the KAP scores of participants.

Results

The study comprised 303 healthcare workers, including 69 doctors, 34 nurses, 100 medical students, 84 nursing students, and 16 pharmacists.

Knowledge about Adverse Drug Reaction Reporting The purpose of this study was to assess HCPs' awareness of reporting adverse medication reactions. Most healthcare practitioners (85%) used the right definition of adverse medication responses. More than 80% of HCPs understood who may report ADRs.

Understanding the many forms of ADRs that need to be reported the majority of doctors, chemists, and nurses feel that adverse medication reactions, including suspected reactions, reactions that require

hospitalisation and reactions that cause lasting disability, should be documented. Knowledge of Pharmacovigilance: Only 20% of healthcare practitioners properly answered the definition of pharmacovigilance. 57% of healthcare providers were aware of a nearby ADR reporting and monitoring centre.

Attitudes about ADR reporting: The majority of participants (98%) believed that reporting adverse drug responses was vital. More than 97% of healthcare professionals agree that pharmacovigilance should be thoroughly taught to them.

Similarly, the majority of HCPs believed that an ADR reporting form should be available in all wards and OPDs for simple access and reporting. The majority of participants (96%) saw ADR reporting as a strategy to improve the safety of medications. The current study also reveals several positive elements of pharmacovigilance, with the majority of participants stating that ADR reporting will be useful and that additional sensitization sessions should be carried out to enhance awareness about ADR reporting.

Practices related to ADR reporting: Among the HCPs, less than one-third have seen an ADR reporting form. In their line of work, less than 39% of healthcare professionals have encountered an adverse drug reaction. Healthcare providers had inadequate reporting practices (42%). In our study, nurses reported more adverse drug reactions (47%) than doctors (27.5%).

The majority of survey participants (63%) stated that they have received instruction on how to report adverse drug reactions.

Table 1: Response of participants towards Questions assessing Knowledge

Knowledge Questions	Option	N (%)
Pharmacovigilance is a study that relates to	Safe, effective, appropriate and economic use of medicines	12
	Therapeutic drug monitoring	1
	Detection, assessment, understanding & prevention of adverse effects.	61
	All of the above	229
The functions of Pharmacovigilance are:	Detection and study of ADRs	28
	Measurement of risk and effectiveness of drug use	19
	Dissemination of ADR information and education	5
	All of the above	251
Definition of Adverse Drug Reaction	A response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.	255
	Adverse outcome associated with drug overdose	13
	Adverse health outcome associated with inappropriate drug use	21
	Harm resulting from use of substandard/counterfeit drugs	14
National Pharmacovigilance programme in India is governed by:	CDSCO under the aegis of Health and Family Welfare	81
	Medical Council of India & ICMR	117
	Pharmacy Council of India	25
	None of the above	80
Pharmacovigilance includes:	Drug related problem	102
	Herbal products	3
	Medical devices	4
	All	194
Is there any Pharmacovigilance committee/ ADR monitoring centre in your institution?	Yes	175
	No	128
The health care professionals responsible for ADR reporting in a hospital is/are:	Doctors	37
	Nurses	13
	Pharmacists	10
	All of the above	243
Do you think reporting an ADR is professional obligation for healthcare workers?	Yes	127
	No	176
Which ADR should be reported?	ADRs to new drugs	9
	ADRs to herbal and non-allopathic drugs	38
	ADRs to vaccine	7

	All of the above	249
Do you know regarding the existence of a National Pharmacovigilance Programme of India	Yes	204
	No	99
According to Wills & Brown, how many types of ADRs are classified:	6	129
	7	87
	8	44
	9	43
Which one of the following is the "WHO online databases" for reporting ADRs	ADR advisory committee	189
	Medsafe	7
	Vigibase	37
	Med watch	70
An adverse event is serious when the patient outcome is	Disability	46
	Life threatening	8
	Prolongs hospitalization	17
	All of the above	232
Augmented drug reaction is	Dose dependent, common in occurrence, rarely fatal	121
	Dose independent, comparatively rare in occurrence, more fatal	53
	Both of the above	105
	None of the above	24
Mandatory elements for making a valid ADR report include	Identifiable patient and reporter	265
	Identifiable reaction	12
	Identifiable drug	11
	All of the above	15

Discussion

This study uses a questionnaire to evaluate clinicians' knowledge, attitudes, and practices regarding pharmacovigilance and ADR reporting at a tertiary care teaching hospital. Spontaneous reporting of ADRs is important for drug safety. However, underreporting is a significant weakness of the spontaneous reporting system. Many studies have been undertaken to assess the knowledge gaps in pharmacovigilance (KAP) among medical professionals; however, relatively few studies have been conducted to analyse the knowledge of aspiring or practicing physicians [9,10,11].

The Indian market is saturated with novel medicines, many of which are over-the-counter (OTC). These medications include allopathic, non-allopathic, and herbal formulations. Current tendencies in globalisation and the consumer sector contribute to this. Consequently, it is highly recommended to submit even a single ADE report [4].

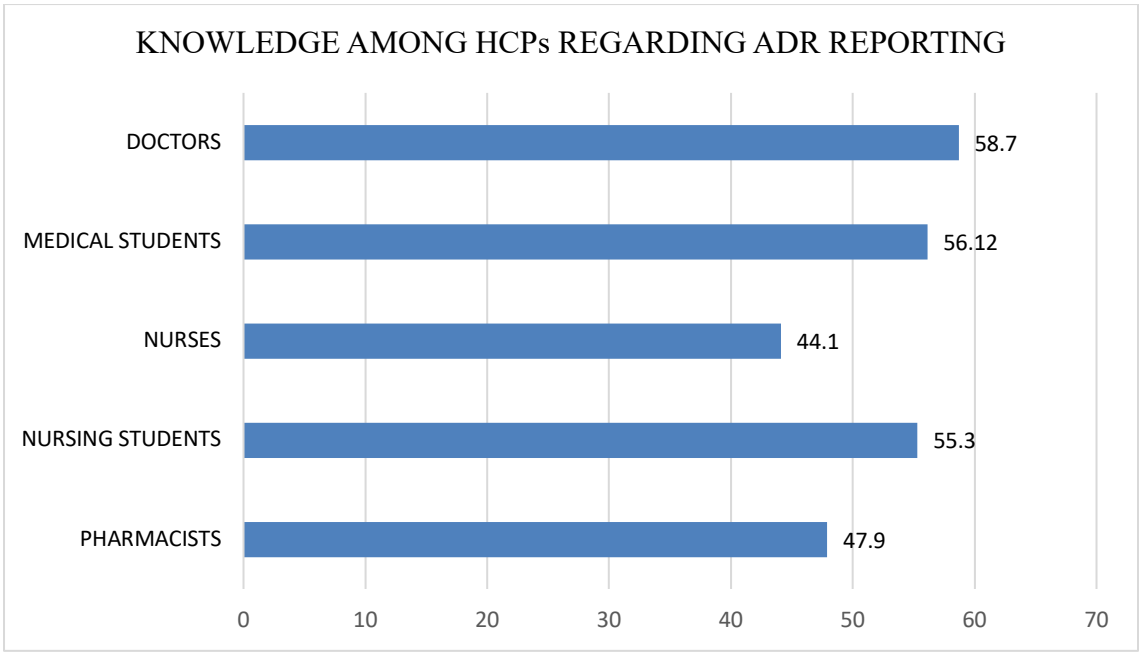

Figure 1: Knowledge Among HCPs Regarding ADR Reporting

In our study, just 20% of healthcare practitioners understood the correct definition of the term Pharmacovigilance. Meher et al. conducted a similar study among undergraduate medical students and found that 33% of final, 41% of prefinal, and 22% of second-year students understand the definition of pharmacovigilance [12]. Parthiban et al. discovered that while 81% of participants understood the meaning of pharmacovigilance, only 53% knew more about it and ADR reporting. [13]. This finding contrasts with another study by Adisha et al. [14], which discovered that 72.5% of respondents were aware of pharmacovigilance. Another study by Nisa et al. found that healthcare staff had a high level of awareness (83.1%) about pharmacovigilance [15]. According to a research by Ramesh and Parthasarathi, physicians were under informed and uninformed of national and worldwide PV efforts [16]. According to a study conducted by Praveen et al, the most common cause for the inability to implement the Indian Pharmacovigilance programme was a lack of information and awareness [17].

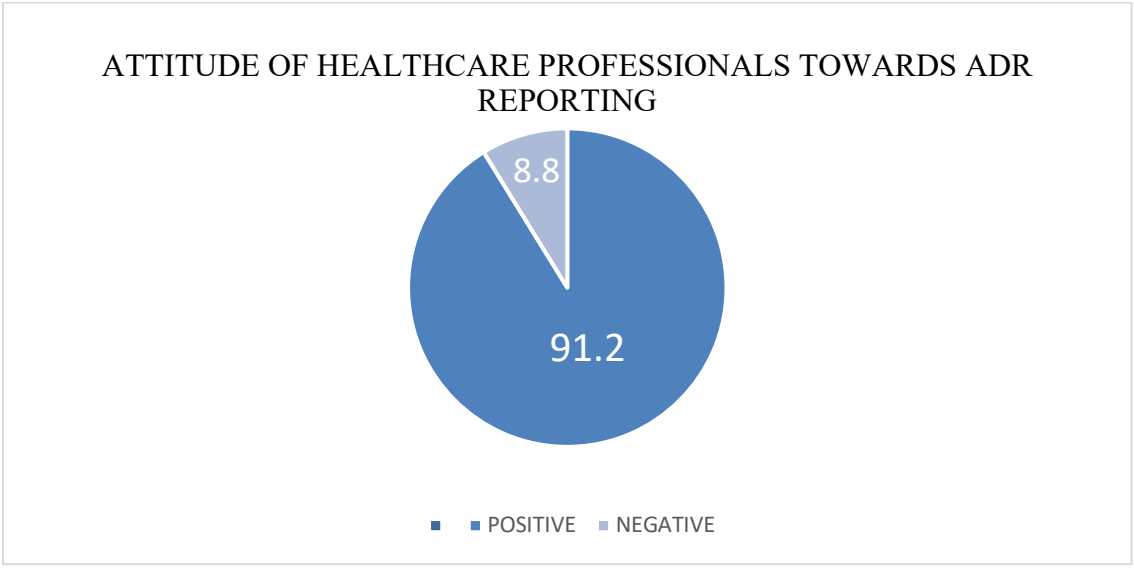

Figure 2: Attitude of Healthcare Professionals Towards ADR Reporting

Our survey found that 57.7% of healthcare professionals were aware of our institute's ADR monitoring and reporting system. The fact that 98.3% of healthcare practitioners were willing to disclose ADRs is very positive. However, Nisa et al. [15] found that healthcare staff had a good attitude towards ADR reporting (78.2%), which is consistent with our findings. In contrast, Adisha et

al. [14] discovered that only 46.2% of participants had a positive attitude. In our study, 38% of individuals stated that they had encountered ADR while at work, although only 16% reported them.

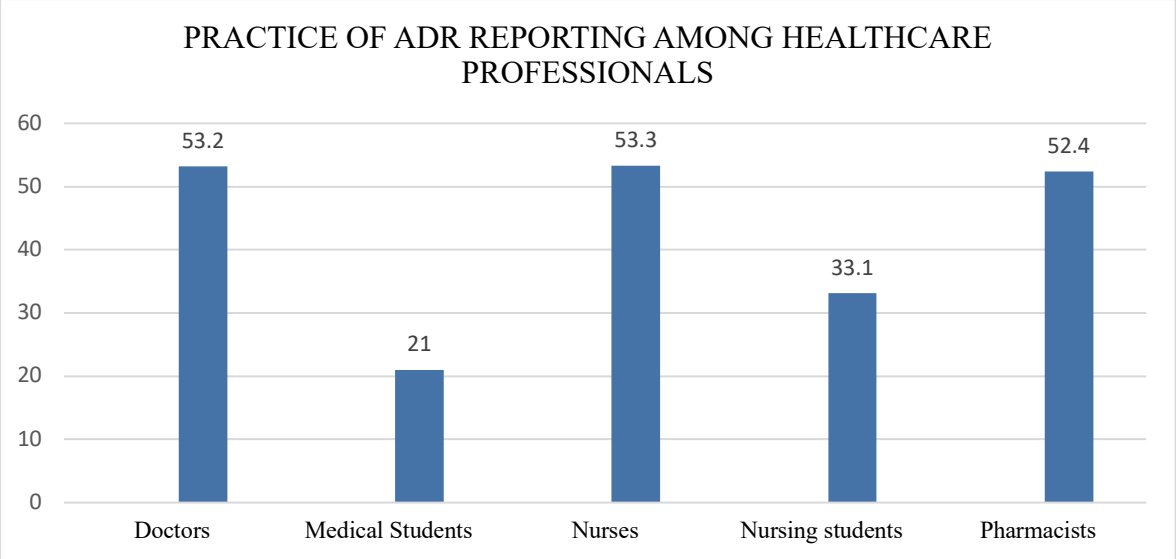

Figure 3: Practice of ADR Reporting Among Healthcare Professionals

Limitations: Respondents may have given socially desired responses, resulting in social desirability bias. This may have resulted in over-reporting of positive behaviours and under-reporting of negative behaviours, resulting in data inaccuracies. To increase data dependability, the poll was conducted anonymously, and respondents were informed that their data would be kept confidential. Because this was a cross-sectional study, it cannot prove a causal association between poor reporting habits among healthcare practitioners. Furthermore, because the study was conducted in a single centre, the findings may not be applicable to all healthcare providers.

Strengths: This study provides useful insights into healthcare professionals' and patients' awareness, attitudes, and reporting behaviours for adverse drug reactions.

Results: The findings of this study will aid in targeted educational initiatives and improve ADR reporting by identifying knowledge gaps and impediments to reporting ADRs. This will eventually lead to improved drug safety monitoring systems, regulatory decision-making, and the promotion of a reporting culture, all of which will benefit patient safety.

Conclusion

Despite healthcare professionals' good attitudes about ADR reporting, there is a knowledge gap leading to unsatisfactory results. ADR reporting databases and monitoring systems are hampered by a variety of difficulties, including inadequate training of healthcare staff, false impressions, attitudes, and other issues. As a result, more sensitization activities must be implemented to promote the ADR reporting culture among healthcare professionals.

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