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KNOWLEDGE ATTITUDE PRACTICE TOWARDS PHARMACOVIGILANCE AMONG HEALTH CARE PROFESSIONALS AND STUDENTS IN TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Pharmacovigilance (PV) plays a pivotal role in ensuring the safe and effective use of medicines by monitoring and reporting adverse drug reactions (ADRs). This survey-based study aimed to assess the knowledge, attitude, and practice (KAP) of PV among healthcare professionals and students in a tertiary care teaching hospital in developing countries. The study revealed that healthcare professionals, including pharmacists, exhibited poor to moderate knowledge, a positive attitude, and inadequate practice of PV. Continuing education emerged as a crucial factor in improving the KAP of pharmacovigilance, with a focus on enhancing knowledge, which was deemed more amenable to change than attitude and practice. The establishment of robust systems for reporting ADRs was emphasized as essential to alleviate the heavy burden placed on healthcare systems due to increased risks of patient injury, hospitalization, readmission, prolonged hospital stays, elevated healthcare costs, morbidity, and mortality associated with ADRs. Healthcare professionals, being the primary stakeholders in ADR identification and reporting, were identified as key contributors to the success of pharmacovigilance initiatives. The study underscored the importance of instilling confidence in healthcare professionals' ability to diagnose, manage, and prevent ADRs, thereby enhancing their likelihood of identifying and reporting important ADRs. Despite the critical role of healthcare professionals in PV, global under-reporting of ADRs was highlighted in various studies. The primary reasons identified for underreporting included inadequate knowledge, attitude, and practice concerning PV activities and ADR reporting.

KEYWORDS :

INTRODUCTION

The burgeoning pharmaceutical landscape in India, marked by a vast array of drug options and a substantial drug-consuming population, brings to light critical challenges in medication safety practices and regulatory oversight. With an estimated 60,000–80,000 drug brands available in the Indian market, concerns arise regarding irrational prescribing, misuse, and the consequential development of adverse drug reactions (ADRs). Adverse drug reactions represent unintended and noxious responses to medications, occurring at doses used for prophylaxis, diagnosis, therapy, or modification of physiological function. The repercussions of ADRs extend beyond individual health, contributing significantly to mortality, morbidity, unplanned hospitalization, and escalating healthcare costs globally.

Recognizing the imperative to address these issues, the World Health Organization (WHO) introduced pharmacovigilance (PV) in 1961, officially inaugurated after the thalidomide tragedy, where the drug's use during pregnancy led to serious foetal deformities. Pharmacovigilance encompasses the science and activities related to detecting, understanding, and preventing adverse effects or any other medicine-related problems. The "Programme for International Drug Monitoring" initiated by WHO in 1968 aimed to centralize global data on ADRs, emphasizing the identification of early PV signals.

In the mid-70s, the term "pharmacovigilance" was coined by a French group to define activities assessing the risks of side effects associated with drug treatment. Over the years, PV has evolved into a comprehensive science involving the collection, monitoring, research, assessment, and evaluation of information from healthcare providers and patients. It spans various categories of medical products, including medications, biological products, blood products, herbals, vaccines, medical devices, and traditional and complementary medicines. The primary goal is to identify new information about product hazards and prevent harm to patients.

However, the challenge of maximizing drug safety has grown increasingly complex. Pharmaceutical and biotechnology companies are not only required to monitor but also proactively estimate and manage drug risks throughout a product's lifecycle. In India, the national Pharmacovigilance Programme of India (PvPI) was established in 2004 by the Central Drugs Standard Control Organization (CDSCO) to monitor ADRs and provide drug safety reports to the WHO-ADR monitoring centre in Uppsala, Sweden. To coordinate ADR monitoring, peripheral PV centres were established in various hospitals across major Indian cities.

Despite these efforts, under-reporting of suspected ADRs by health professionals is a widespread challenge in India, with the country's contribution to ADR reporting remaining below 1%. Recognizing the existing gaps in the success of the PV program, local and national initiatives have emerged to improve and promote PV activities.

These initiatives aim to raise awareness among health professionals, enhance ADR reporting, and contribute to a better understanding of the challenges faced by national organizations in developing strategies for the improvement of PV activities. In this context, a systematic review and meta-analysis were undertaken to investigate the knowledge, attitude, and practice (KAP) of ADR reporting and pharmacovigilance among health professionals in India, shedding light on crucial aspects that can inform future strategies for drug safety enhancement.

MATERIALS AND METHODS

Study Setting

This study was conducted at a tertiary care teaching hospital in Tamil Nadu, India. The duration of the study was 2 months, from November 2023 to January 2024.

Study Design

It was a cross sectional questionnaire-based study. The Study Participants were the Professors, Pharmacists, Medical Students (UG's and PG's), Nursing Students and Pharmacy Students in a tertiary care teaching hospital.

The participants designation, Age, and Gender were noted. Total 19 questionnaires were made, The questionnaire was prepared taking into consideration the previously conducted studies which include 7 knowledge based, 5 attitude based, 6 practice based questions were prepared and entered into google forms.

The study employed a cross-sectional design with a questionnaire as the primary data collection method. The participants consisted of Professors, Pharmacists, Medical Students (both undergraduate and postgraduate), Nursing Students, and Pharmacy Students affiliated with a tertiary care teaching hospital. Data on participants' roles, ages, and genders were gathered.

A set of 19 questionnaires was developed, comprising 7 focused on knowledge, 5 on attitudes, and 6 on practices. These questions were crafted by considering insights from previous studies and were then input into Google Forms for efficient data collection.

Baseline Characteristics Of The Study

Characteristics	Frequency (number)
Gender	
Male	75
Female	125
Age wise distribution (in years)	
18-25	171
25-45	26
>45	3
Health care professionals	
Professors	6
Pharmacists	16
Medical Students	28
Pharm D students.	119
Nursing Students	31

RESULTS AND DISCUSSION

The survey involved over 300 healthcare professionals and students, with a final enrolment of 200 participants. The majority of those enrolled were pharmacy students, totalling 75 males and 125 females. The participant distribution included 6 professors, 16 pharmacists, 28 medical students, 119 Pharm D students, and 31 nursing students.

Regarding the understanding of Pharmacovigilance, most Pharm D students demonstrated precise knowledge, attributed to a dedicated subject in their academic curriculum. In terms of defining Adverse Drug Reactions (ADRs), 70% of respondents provided accurate responses in line with the World Health Organization's definition.

Thalidomide emerged as the most frequently reported banned drug based on participant responses. Additionally, the study revealed positive perspectives on pharmacovigilance, with 51% of Pharm D students acknowledging the Central Drugs

Standard Control Organization (CDSCO) as the regulatory body responsible for monitoring ADRs in India.

Furthermore, 85% of participants demonstrated a clear understanding of who can report ADRs. Overall, the findings highlight the commendable knowledge among Pharm D students, underscoring the importance of targeted academic subjects in fostering awareness of pharmacovigilance concepts.

Table 1: Response Regarding Knowledge Of Pharmacovigilance

KNOWLEDGE QUESTIONS	Options	n (%)
Define pharmacovigilance	The process of monitoring ADRs in hospital	40(20)
	The detection, assessment, understanding, and prevention of adverse effects	154(77)
	Analysing the safety of drugs	6(3)
	Prevention of adverse effects	-
What is adverse drug reaction?	A response to a drug that is expected and predictable	16(8)
	Any towards medical occurrence in patient administered a pharmaceutical product	42(21)
	Any noxious and unintended effect, at normal dose, used for diagnosis and treatment	140(70)
	Response/effects only seen clinical trials	2(1)
Are you aware of any banned drugs due to ADR?	Yes	118(59)
	No	82(41)
Are you aware of the existence of pharmacovigilance system in India	Yes	162(81)
	No	38(19)
In India which regulatory body is responsible for monitoring the ADR'S	Food safety and standards authority of India (FSSAI)	8(4)
	Central drugs standard control organization (CDSCO)	102(51)
	Medical council of India (MCI)	6(3)
	Indian pharmacopoeia commission (IPC)	84(42)
Who can report ADR?	Health care professionals	16(8)
	Pharmacists	14(7)
	Nurse	-
	Patient	-
	All the above	170(85)

Table 2: Response Regarding Attitude Of Pharmacovigilance

ATTITUDE QUESTIONS	Options	n (%)
Do you feel that ADR reporting can improve patient care?	Yes	198(99)
	No	2(1)
Do you think proper training should be provided for ADR reporting?	Yes	180(90)
	No	20(10)
Do you think there should be ADR monitoring center in every hospital?	Yes	160(80)
	No	40(20)
Is there a need to include pharmacovigilance in the curriculum to create awareness among health care professionals and students?	Yes	194(97)
	No	6(3)
Are you aware about the Indian pharmacopoeia commission's monthly drug safety alert?	Yes	114(57)
	No	86(43)

Do you feel ADR reporting creates additional workload?	Yes	164(82)
	No	36(18)
Do you think ADR reporting is a professional obligation?	Yes	150(75)
	No	50(25)

In terms of attitudes expressed through yes or no questions, it was observed that a significant proportion of medical students lacked sufficient knowledge regarding the reporting of Adverse Drug Reactions (ADRs). Approximately 90% of medical students indicated a clear need for comprehensive training in this area, emphasizing the importance of education and awareness in improving reporting practices.

In rural areas and rural hospitals, there was a notable deficiency in patient knowledge concerning the identification and reporting of ADRs within healthcare facilities. The findings underscore the necessity for establishing dedicated ADR monitoring centres in these regions to facilitate and streamline the reporting process.

Concerns were raised among healthcare professionals regarding the potential increase in workload associated with ADR reporting, with over 82% expressing this sentiment. Addressing this concern requires the implementation of targeted training programs and heightened awareness campaigns to underscore the significance of ADR reporting among healthcare professionals.

Furthermore, an overwhelming majority of healthcare professionals, around 97%, expressed a desire for the inclusion of a dedicated pharmacovigilance subject in their curriculum. This reflects a clear recognition of the need for structured educational initiatives to provide healthcare professionals with precise knowledge and understanding of pharmacovigilance practices.

Table 3: Response Regarding Practice Of Pharmacovigilance

PRACTICE QUESTIONS	Options	n (%)
Have you experienced any ADR reactions in your patients during practice?	Yes	130(65)
	No	70(35)
Have you seen the ADR reporting form?	Yes	162(81)
	No	38(19)
Have you reported any ADR?	Yes	46(23)
	No	154(77)
Have you read any ADR related articles or journal?	Yes	130(65)
	no	70(35)
Would you like to report ADR'S in future?	Yes	200(100)
	No	-

Approximately 65% of healthcare professionals acknowledged encountering Adverse Drug Reactions (ADRs) in the course of their practice. Despite the majority having encountered ADR reporting forms (77%), a significant number, as high as 77%, have not yet reported any ADR incidents. This underscores the necessity for providing healthcare professionals with clear guidance regarding the importance and process of reporting ADRs.

It is imperative to emphasize that reporting adverse reactions plays a crucial role in enabling regulatory agencies to vigilantly monitor the safety of drugs and medical products. Such reporting contributes significantly to the overarching health and safety of the public. Thus, there is an evident need for targeted initiatives aimed at raising awareness among healthcare professionals, ensuring they understand the significance of reporting ADRs and are adequately guided through the reporting process.

Many medical and pharmacy students possess knowledge about pharmacovigilance, yet their engagement in adverse drug reaction (ADR) reporting remains insufficient. Despite recognizing the significance of voluntary reporting among healthcare professionals and students in safeguarding vulnerable populations from morbidity and mortality, there exists a notable gap in actual practice. This underscores the critical need for organizing awareness campaigns and workshops aimed at enhancing doctors' understanding and commitment to ADR reporting. Addressing the root causes of underreporting, such as trivializing reactions, time constraints, waning interest, uncertainty about causality, and the absence of requisite reporting forms, is essential to mitigate the issue of low ADR reporting rates within hospital settings.

Limitations

The potential for sampling bias arises from the over-representation of pharmacy students in the study, potentially restricting the applicability of the results to a more diverse healthcare professional population. Furthermore, the study's reliance on a relatively small sample size may compromise the statistical power and reliability of the findings. Small sample sizes often constrain the capacity to derive robust and universally applicable conclusions from the study data.

CONCLUSIONS

In summary, this study provides valuable insights into the landscape of adverse reactions (ADRs) reporting within the healthcare community. Notably, the findings indicate that pharmacy students exhibit a higher level of knowledge and awareness regarding pharmacovigilance and the significance of reporting ADRs, attributed to their curriculum. On the other hand, medical students demonstrate a notable lack of knowledge in this area.

The study emphasizes the critical necessity for targeted interventions aimed at providing guidance and education to healthcare professionals, particularly in the context of reporting ADRs. It underscores the importance of implementing enhanced training programs and awareness campaigns to address this knowledge gap and motivate healthcare professionals to actively engage in pharmacovigilance efforts.

The conclusion suggests that further research is imperative to strengthen the effectiveness of pharmacovigilance activities. By identifying and addressing the existing gaps in knowledge and reporting practices, future studies can contribute to the development of more robust and comprehensive strategies for promoting ADR reporting within the healthcare community.

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