

A need of the hour: pharmacovigilance in healthcare setting - nothing less than safety

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Introduction: Pharmacovigilance (PV) is crucial to identify, managing, and reporting adverse drug reactions (ADRs) in the healthcare sector. Young healthcare professionals (HCPs) play an essential role in the PV system. **Objective:** This study aimed to assess awareness, understand the causes of underreporting, and find solutions to encourage ADR reporting among young HCPs. **Methods:** This prevalidated, questionnaire-based, cross-sectional study aimed to evaluate the knowledge, attitude, perception, and strategies to improve PV reporting among 152 young HCP interns at a teaching hospital in India. The study was conducted in January 2023 and approved by the ethics committee. The responses were analysed using a Microsoft Excel worksheet. **Results** In a study of 152 interns, 97.3% agreed that pharmacovigilance (PV) may assist patients, but only 56% had experienced adverse drug reactions (ADRs) in practise. Only 40.5% chose email reporting, and 65.8% did not have a nearby ADR Monitoring Centre (AMC). More over half (53%) thought ADRs should only be reported to an AMC. Training sessions were underutilised, with only 28.6% attending PVPI training. The difficulty in identifying the causal substance, as well as a lack of incentives, were important reasons for underreporting. Continuing medical education/workshops were mentioned by 96% of young HCPs as a way to encourage reporting. **Conclusion:** According to the study, while young HCPs are aware of PV, there is a need for more training and incentives to enhance ADR reporting. Encouragement of National Pharmacovigilance Week and the availability of neighbouring AMCs could further aid raise PV awareness.

Keywords: Adverse drug reactions (ADR), PVPI, AMC, CME

INTRODUCTION

ADRs can cause personal injury and raise healthcare expenses, putting a strain on national healthcare systems [1]. According to studies conducted across the world, adverse drug reactions (ADRs) account for 3-7% of all hospitalisations, and 10-20% of inpatients experience medication-related adverse responses [2]. Serious adverse events were discovered to be the fourth to sixth leading causes of death in hospitalised patients [3]. As a result, both healthcare providers and patients share the goal of detecting and preventing ADRs as early as possible. PVPI was founded in New Delhi in 2010 [4]. In October 2021, VigiBase received almost 28 million reports of adverse reactions [5]. According to studies from a variety of settings, healthcare staff are sufficiently knowledgeable of pharmacovigilance. After having sufficient information, the young HCPs are not

reporting ADRs daily. Its success rate depends on young HCPs attending the programs [6].

Need for the study:

For a PV programme to be effective, adverse drug reactions (ADRs) must be identified and reported in a systematic and required manner [7]. Throughout the history of PV, healthcare professionals (HCPs) have been the primary source of case reports of suspected ADRs [7]. As a result, focusing on these changeable characteristics through education and training may assist improve ADR reporting practices [8].

According to preliminary findings from a review of studies, knowledge and attitude ratings increased following an educational intervention. They also suggested that PV and ADR training has a positive impact on nurses' and pharmacists' knowledge and attitudes [9].

Adverse medication responses are an essential component of drug therapy [10]. These reactions can result in personal harm, hospitalisation overload, and a rise in health costs, putting a strain on national healthcare systems [10]. According to studies conducted across the world, adverse drug reactions (ADRs) account for 3-7% of all hospitalisations, and 10-20% of inpatients experience medication-related adverse responses [2]. Serious ADRs were discovered to be the fourth to sixth main causes of death in hospitalised patients in the United States, resulting in protracted hospitalisation and double the expense of treatment [11]. As a result, both healthcare providers and patients share the goal of detecting and preventing ADRs as early as possible [12].

HCPs play an important role in the health care system; even though HCPs are aware of PV, reporting of ADR can be improved. In this effort, the current study aims to uncover the causes and solutions for under-reporting.

Objectives:

1. To assess awareness about PV among young HCPs
2. To understand the causes of possible Under Reporting which are necessary to facilitate targeted
3. To find out the possible solution to encourage ADR reporting.

Inclusion criteria: The study comprised all Pharm D/MBBS/Nursing Paramedical interns who were willing to participate.

Exclusion criteria: Those who did not return the questionnaire within the specified time frame are not willing to participate in the study, and non-HCPs are disqualified.

Methods: A cross-sectional questionnaire-based survey of young healthcare professionals in a tertiary care hospital in Mangalore was conducted.

Study Procedure: Within 30 minutes, participants were needed to complete a predesigned and verified questionnaire on KAP on pharmacovigilance. The clinical pharmacy department's professors face-validated 20 questions for feasibility, readability, formatting, and clarity. At their respective work sites, all interns distributed hard copies of the questionnaire. When participants agreed to fill out the questionnaire, their agreement was assumed. Only 152 of the 152 participants were considered. For each question, just one response was expected to be marked.

Statistical analysis:

The questionnaire responses were statistically evaluated using a Microsoft Excel spreadsheet (2013). The names of the participants were not revealed.

Results

The questionnaire was completed by all 152 interns within the time frame specified. 95.5% of interns have an understanding of Pharmacovigilance (Fig. 1), 97.4% of HCPs believe PV can help patients (Fig. 2), and 65.4% of intern HCPs consistently inform patients about ADR (Fig. 3), demonstrating awareness of PV. However, only 53.9 per cent of them answered that email was their favourite way of reporting (Fig. 4). Pharmacovigilance reporting will rise as HCs and the general public have a better understanding of Pharmacovigilance. When analysing under-reporting only, 30.2% attended the training of PVPI (Fig. 5), in spite of 81.8% (Fig. 6) being satisfactory towards ADRs training in their health settings, showing underutilization of training sessions.

Knowledge questions	Options	%
Pharmacovigilance is concerned with "The detection assessment and prevention of Adverse reaction to drugs"?	Yes	95.5%
	No	4.5%
Pharmacovigilance's main aim is · Mainly Safety · Mainly efficacy	Yes	97.4%
	No	2.2%
Are you familiar with ADR?	Yes	90.2%
	No	9.8%
Preferred method of reporting for ADR	E-mail	29.9%
	Dropbox	3.2%
	Monitoring centre	53.9%
	Others	13%
Have you heard about the Pharmacovigilance Program of India?	Yes	67.8%
	No	33.3%
Do you know any nearby AMC (ADR monitoring centre)?	Yes	34.6%
	No	65.4%
Both ADR and adverse events are synonyms?	Yes	50.7%
	No	49.3%
What kinds of Adverse events are to be reported?	Death	4%
	Life-threatening	14.4%
	Hospitalization	3.9%
	All of the above	77.8%
Do you instruct regularly about ADRs to patients?	Yes	68.4%
	No	29.5%
Have you ever attended CME/ workshop on PV?	Yes	30.2%
	No	69.8%
In your healthcare setting training on ADR, reporting was satisfactory?	Yes	81.8%
	No	18.2%

Table 1. Awareness about PV among young HCPs

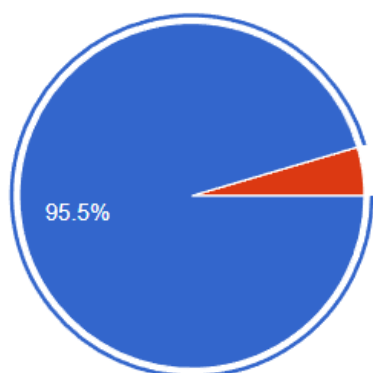


Figure 1

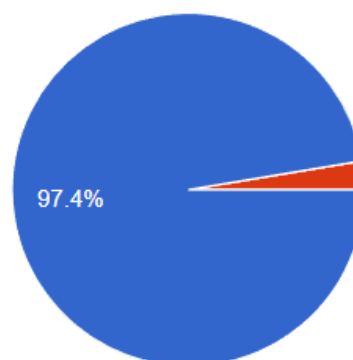


Figure 2

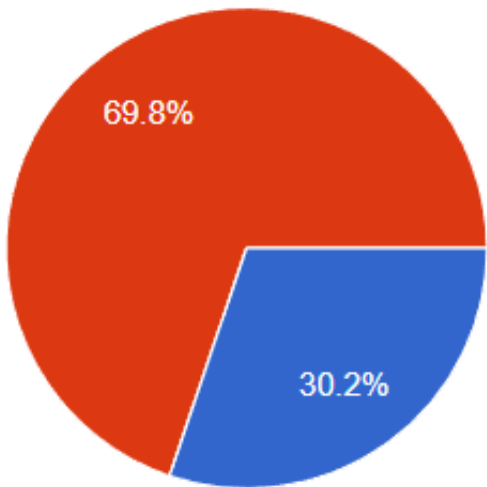


Figure 3

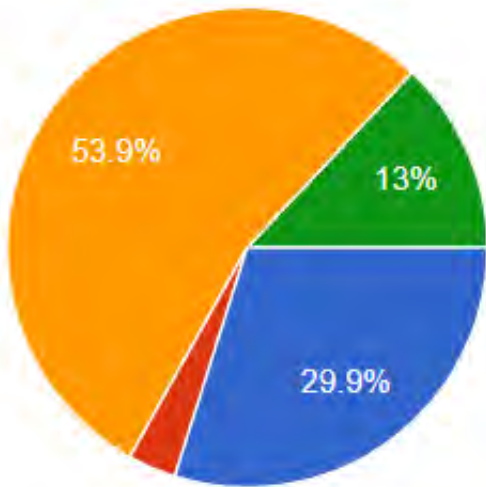


Figure 4

Reasons behind Non-reporting?	%
Only safe medicine exists in the market	35.3%
Unable to confirm the cause, whether disease or drug	27.7%
There is fewer nearby AMC	37.7%
No reporter is awarded any incentives	54.2%

Table 2. Cause of possible under-reporting which is necessary to facilitate targeted

Can workshops/CME improve ADR reporting?	Yes	96.3%
	No	3.7%

Table 3. Possible solution to encourage ADR reporting according to young HCPs

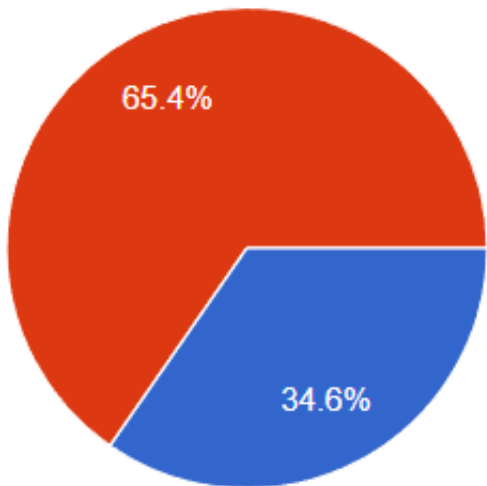


Figure 5

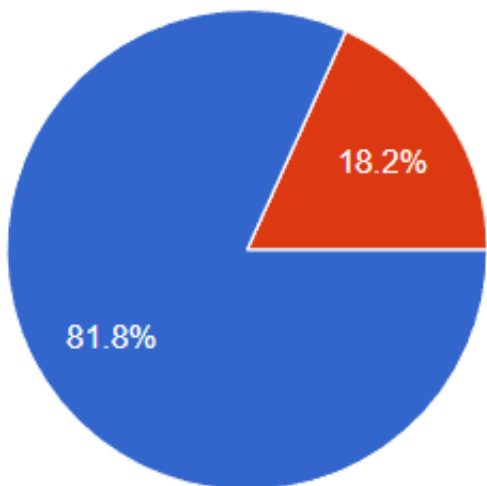


Figure 6

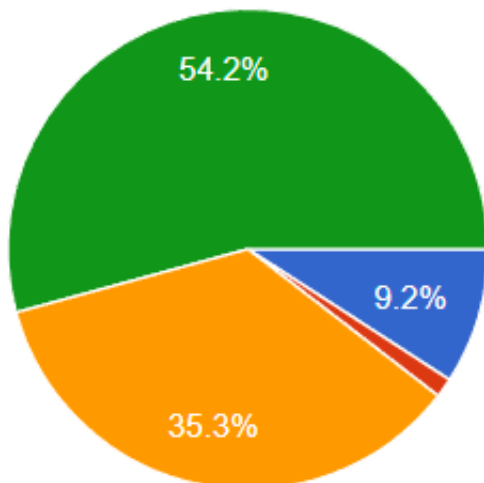


Figure 7

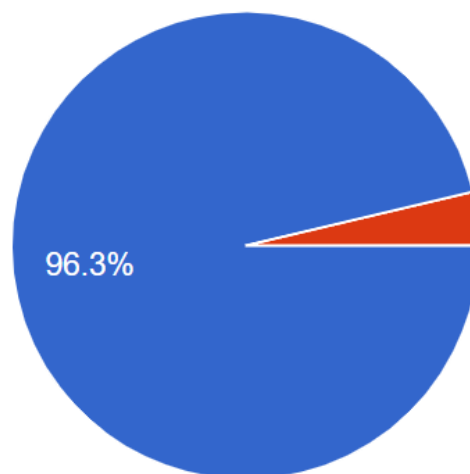


Figure 8

The inability to confirm the cause was the discouraging aspect of ADR reporting and the absence of incentives was also mentioned by the young HCPs (Fig. 7). More than 96.3 % of young HCPs believed that attending continuing medical education/workshops could boost reporting (Fig. 8).

Discussion

With current drugs, ADRs are an unavoidable risk element. ADRs were found to be the leading cause of morbidity and mortality in studies conducted in the United States and France [13]. Clinicians must stay up with the latest ADR data as it becomes available [14]. A questionnaire-based study was conducted in a tertiary care teaching hospital to assess interns' knowledge, attitude, and impression of pharmacovigilance.

Financial incentives, according to Bhagavathula et al.,[15], Kamtane and Jayawardhani[16], and Amedome and Dadson[17], may induce ADR reporting. As a result, actions should be done to make ADR reporting easier and more realistic. Policies to provide non-monetary incentives, such as academic appreciation certificates/awards and medical council points equivalent to CME and CPE points, may be developed. One probable explanation for this disparity is the rigorous schedule of young doctors, namely residents.

Conclusion

The current study found that, despite young HCPs' understanding of ADR complaints, there was no reporting. The current study found that the culprit was a lack of interest in participating in CME/ CPE, despite the fact that a satisfactory training system was in place in hospitals. Young HCPs should not take this lightly, and action should be taken by making CME/CPE a mandatory requirement for continuing in the profession. According to the current study, offering incentives will improve ADR reporting.

Authors contribution

Preeti Shanbhag analysed the data and wrote the final manuscript. Satish S proposed the idea, reviewed the literature, and aided in the data analysis. Ramdas Bhat reviewed the literature and aided in writing the manuscript. A R Shabaraya aided in the data analysis, literature review, and revision of the final manuscript. All authors read the manuscript and agree to its publication.

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