



## PHARMACOVIGILANCE IN A TERTIARY CARE HOSPITAL IN KASHMIR: A CALL FOR ACTION

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### ABSTRACT

**Introduction:** In present era safety and efficacy of a drug is of paramount importance. Therefore, pharmacovigilance (PV) is an essential component to detect and prevent adverse drug reaction (ADRs) after marketing of a drug. Nevertheless, underreporting is a global issue creating health and economic burden on health care system. **Aim:** To assess the knowledge, attitude and practices (KAP) of doctor's nurses and pharmacists towards PV and ADRs reporting and to determine the factors limiting ADR reporting rates from the Healthcare Professionals (HCPs) point of view. **Methods:** The purpose and need of the study was explained to all HCPs (doctors, nurses and pharmacist) to whom a standard 30 inventories open-ended validate questionnaire was administered. All the responses were entered to Microsoft Excel sheet and analysed statistically through SPSS software version 27. **Results:** A total of 150 HCPs (98 doctors, 38 nurses and 14 pharmacists) participated in the study. Results reveal that doctors and nurses have equal knowledge and are updated about PV, ADRs and PVPI. All participants are of the opinion that periodic educational intervention and PV and ADR reporting training are necessary. **Conclusion:** The study in a broader perspective reveals that our HCPs have fairly good awareness of PV and ADR monitoring but regular and periodic sensitization and orientation of HCPs on PV would bring paradigm shift and improvement in ADR reporting rate.

**KEYWORDS:** Pharmacovigilance, Adverse drug reactions, Knowledge, Attitude, Practice.

### INTRODUCTION

In the present era of evidence based medicine safety and efficacy of a drug is indeed a matter of concern. This has led to a pressing need of efficient post-marketing surveillance (pharmacovigilance) to optimize and take set of coherent actions to promote the use of drugs responsibly, appropriately and prudently. This will eventually maximize pharmacotherapeutic efficacy while minimizing adverse drug effects. (ADRs). ADRs are an inevitable consequence of modern drug therapy. They are an important cause of iatrogenic illness in terms of morbidity and mortality.<sup>[1]</sup> ADRs are most frequent cause of serious harm to the patients as well as carrying medico legal and economic consequences.<sup>[2]</sup> ADR reporting is the foundation of any pharmacovigilance (PV) system and the timely identification and reporting of ADRs to the regional or national drug regulatory authorities are critical. The world health organization (WHO) has

defined ADR as a "response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis diagnosis or therapy of diseases or for the modification of physiological function".<sup>[3]</sup> ADRs have increasingly drawn worldwide attention accounting for significant morbidity and mortality and associated with increased health costs.<sup>[4,5]</sup> Recent estimates suggest that ADRs are the fourth major cause of death in United States of America (USA).<sup>[6]</sup> They are common and often preventable cause of hospital admissions. The world wide incidence of ADR's leading to emergency hospitalization varies from 0.2% to 41.3% while 28.9% of these ADRs are preventable.<sup>[7]</sup> A meta-analysis conducted in 2012 by Hakkarainen et al suggested that 52% of ADRs related emergency hospitalization and 45% of ADRs in patients were preventable.<sup>[8]</sup> This explicitly implies that there is insufficiency in recognizing and reporting of ADRs.<sup>[9,10]</sup>

Therefore, detection and monitoring of ADRs by health care professionals (HCPs) and patients (in some countries) are of vital importance for patients safety. To ensure patient safety and appropriate use of medicine PV becomes an important discipline which is exponentially used worldwide.<sup>[11]</sup> WHO defines pharmacovigilance (PV) as “the science and activities relating to detection, assessment, understanding and prevention of adverse effects of any other drug related problem”.<sup>[12]</sup> PV has instrumental role in patient care and outcome based treatment protocols.

The objectives of PV are rapid identification of adverse drug events, identification of possible causal relationship between an adverse event and medicine following the introduction of a new drug or drug combination, assessments of these signals to evaluate causality, clinical relevance, frequency and distribution of ADRs in particular population groups. The outcome based PV programme depends upon the active involvement of the HCPs in reporting the ADRs. It is the professional and ethical responsibility of key HCPs, the doctors, nurses and pharmacists in reporting ADRs and strengthening the PV mechanisms that exist in their professional places. Moreover, PV and ADR reporting education are important competencies all health care school students need to obtain before they graduate and be involved in clinical practice as healthcare professionals.<sup>[14,15]</sup> Further, underreporting and the lack of understanding of ADRs can significantly increase the magnitude of burden on health care systems. Under reporting of ADRs is widespread and a daunting challenge in PV.<sup>[16,17]</sup> The WHO promotes PV at the country level. Pharmacovigilance programme of India (PVPI) was found in July 2010. A joint programme initiated by Central Drug Standard Control Organization (CDSCO) New Delhi and Ministry of Health and Family welfare (MOHFW) Government of India. The All India Institute of Medical Sciences (AIIMS) was established as the National Coordinating Centre (NCC) under which 22 ADR monitoring Centre’s (AMC) all over India were formed for monitoring ADRs in India. In order to strengthen the programme and for better implementation the NCC was relocated to Indian Pharmacopoeia Commission (IPC) Ghaziabad (UP) from AIIMS. The Uppsala Monitoring Centre (UMC) in Sweden has the international database of suspected ADRs reports from all over the world.<sup>[18]</sup> The objective of this study was to assess the perception and awareness of PV among HCPs. This is evaluated by studying the knowledge, attitude and practice of PV among the physicians, nurses and pharmacists of a multispecialty Tertiary Care Hospital of Union Territory of Jammu & Kashmir.

## MATERIALS AND METHODS

**Study Design:** It was a cross sectional non interventional questionnaire based study.

**Study Setting:** The study was conducted at Sheri – Kashmir Institute of Medical Sciences a multispecialty tertiary care hospital in the Union territory of J&K.

**Ethical Considerations:** The study was conducted after Institutional Ethics committee (IEC) approval.

**Study Period:** The study was conducted for a period of 6 months from March 2020 - September 2020

**Selection Criteria:** The study participants constituted of all the practicing HCPs (doctors, nurses and pharmacists) who gave their informed consent and who were working at the hospital during the study period.

**Sample size:** A total of 150 HCPs including 98 physicians, 38 nurses and 14 pharmacists participated in the study.

**Study procedure:** Designing of the protocol and standard self-administered questionnaire based on knowledge, attitude and practice/perception of HCPs (KAP) questionnaire. The KAP questionnaire comprised of 30 inventories the details are as follows

1. Knowledge based inventories: The assessment of participant’s knowledge about PV in general and PVPI in particular and ADRs included 11 inventories on definition and objectives of PV and PVPI. Awareness regarding PVPI android application and PVPI toll free numbers.

2. Attitude and Practice based inventories: Assessment of attitude is based on 11 questions and practice on 8 questions regarding importance of ADR monitoring, reporting and part of undergraduate curriculum.

## Cronbach’s alpha value

The internal consistency of the questionnaire based on Cronbach’s alpha coefficient was 0.609 hence the research study with 30 inventory KAP questionnaire was found reliable and valid. Furthermore, the frame work of questionnaire was evaluated by a panel of healthcare practitioners and academicians with subject expertise on PV, clinical pharmacology and clinical pharmacy for the clarity, relevance and conciseness of inventories.

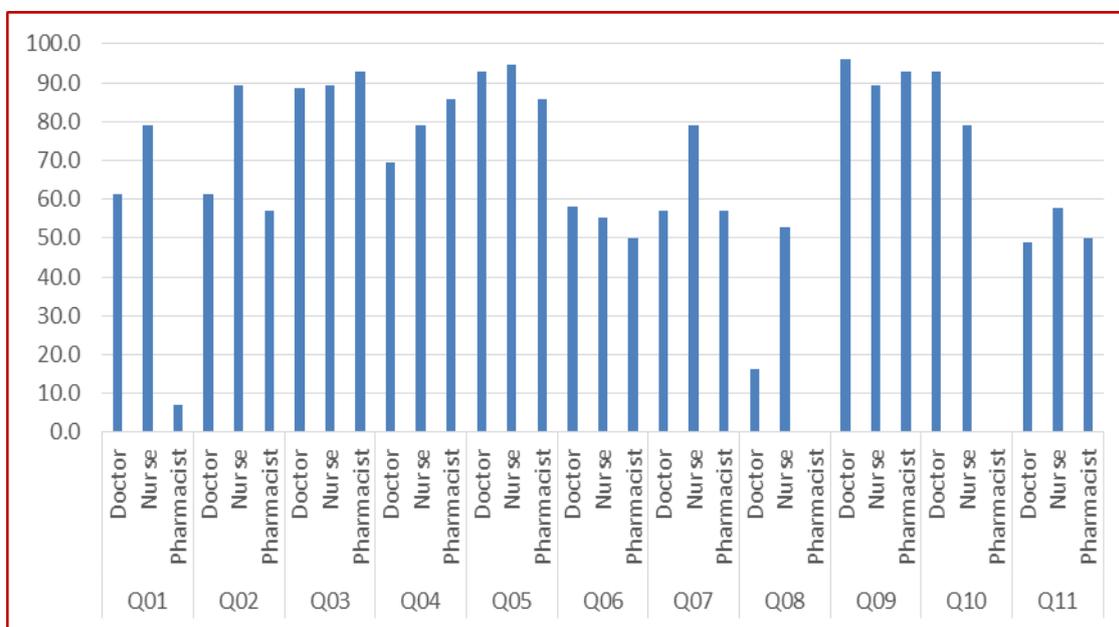
**Statistical analysis:** The data was coded using Microsoft Excel and analysed using SPSS version 27. Descriptive statistics was calculated for overview of correct responses from doctors, nurses and pharmacists.

## RESULTS

The results of the study are tabulated in Tables 1-3 and bar charts Fig 1-3. A total of 150 HCPs (98 doctors, 38 nurses and 14 pharmacists) participated in the study.

**Table 1: Assessment of Knowledge.**

Question	Profession	Frequency (Correct)	Percent % (Correct)
PV refers to	Doctor	60	61.2
	Nurse	30	78.9
	Pharmacist	1	7.1
The most important purpose of PV is	Doctor	60	61.2
	Nurse	34	89.5
	Pharmacist	8	57.1
Healthcare professional responsible for reporting ADRs in a hospital are	Doctor	87	88.8
	Nurse	34	89.5
	Pharmacist	13	92.9
PV includes safety assessment of	Doctor	68	69.4
	Nurse	30	78.9
	Pharmacist	12	85.7
All the drugs available in the market are safe	Doctor	91	92.9
	Nurse	36	94.7
	Pharmacist	12	85.7
Are you aware of the existence of PvPI?	Doctor	57	58.2
	Nurse	21	55.3
	Pharmacist	7	50.0
Is your Institution ADR Monitoring centre under PvPI?	Doctor	56	57.1
	Nurse	30	78.9
	Pharmacist	8	57.1
Are you aware of PvPI android application & toll free number for reporting ADRs?	Doctor	16	16.3
	Nurse	20	52.6
	Pharmacist	0	0.0
Assessing & reporting ADRs even after drug is marketed & widely consumed is important	Doctor	94	95.9
	Nurse	34	89.5
	Pharmacist	13	92.9
Drug related adverse events contribute significantly to the mortality, morbidity & increased health care costs	Doctor	91	92.9
	Nurse	30	78.9
	Pharmacist	0	0.0
Are you aware of any drug that has been banned recently due to ADR?	Doctor	48	49.0
	Nurse	22	57.9
	Pharmacist	7	50.0



**Fig 1: Knowledge related correct response of Doctors, Nurses and Pharmacists.**

Table 2: Assessment of Attitude.

Question	Profession	Frequency (Correct)	Percent % (Correct)
Do you think ADR reporting is professional obligation?	Doctor	84	85.7
	Nurse	33	86.8
	Pharmacist	8	57.1
What is your opinion about establishing ADR monitoring Centre in every hospital ?	Doctor	84	85.7
	Nurse	33	86.8
	Pharmacist	13	92.9
Do you think reporting ADR is necessary?	Doctor	97	99.0
	Nurse	38	100.0
	Pharmacist	14	100.0
Only serious ADRs should be reported	Doctor	86	87.8
	Nurse	35	92.1
	Pharmacist	10	71.4
Spontaneous voluntary reporting by all healthcare professional is most efficient way of reporting ADRs	Doctor	92	93.9
	Nurse	32	84.2
	Pharmacist	13	92.9
PV should be taught in detail to Healthcare professionals	Doctor	95	96.9
	Nurse	37	97.4
	Pharmacist	14	100.0
Is there a need to include PV in UG curriculum to create awareness among future doctors ?	Doctor	95	96.9
	Nurse	37	97.4
	Pharmacist	12	85.7
Which one among the following do you think is most appropriate method to educate healthcare professionals regarding ADR monitoring & reporting?	Doctor	24	24.5
	Nurse	18	47.4
	Pharmacist	6	42.9
Do you think ADR reporting can significantly improve patient safety?	Doctor	98	100.0
	Nurse	37	97.4
	Pharmacist	14	100.0
what encourages you to report ADR	Doctor	17	17.3
	Nurse	16	42.1
	Pharmacist	5	35.7
In your opinion can previous knowledge of an ADR help prevent an ADR from occurring in future?	Doctor	93	94.9
	Nurse	35	92.1
	Pharmacist	13	92.9

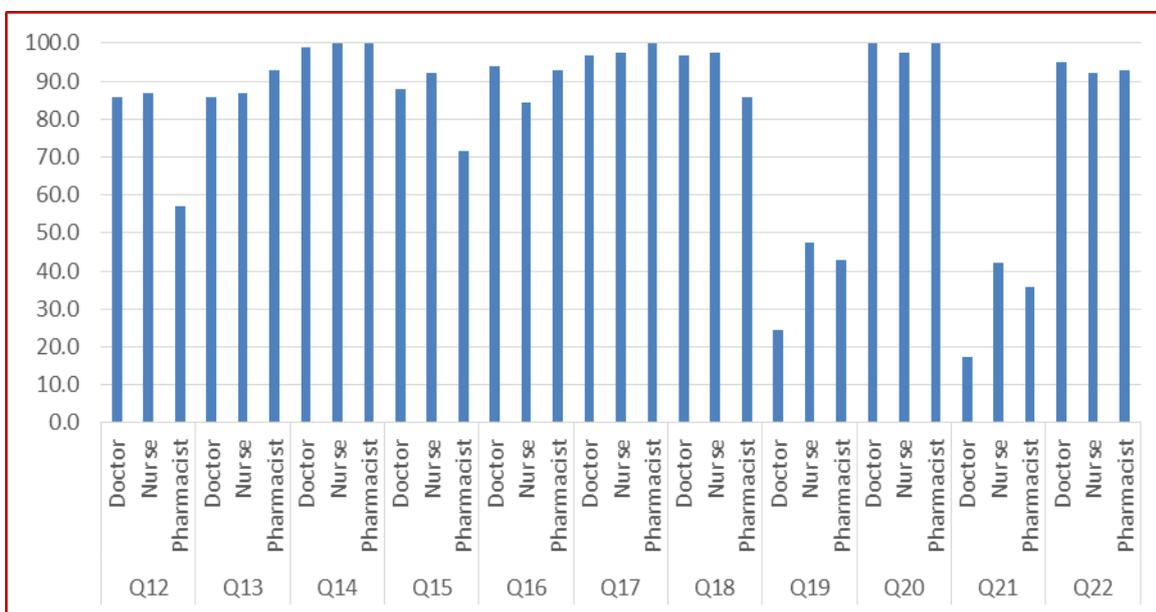
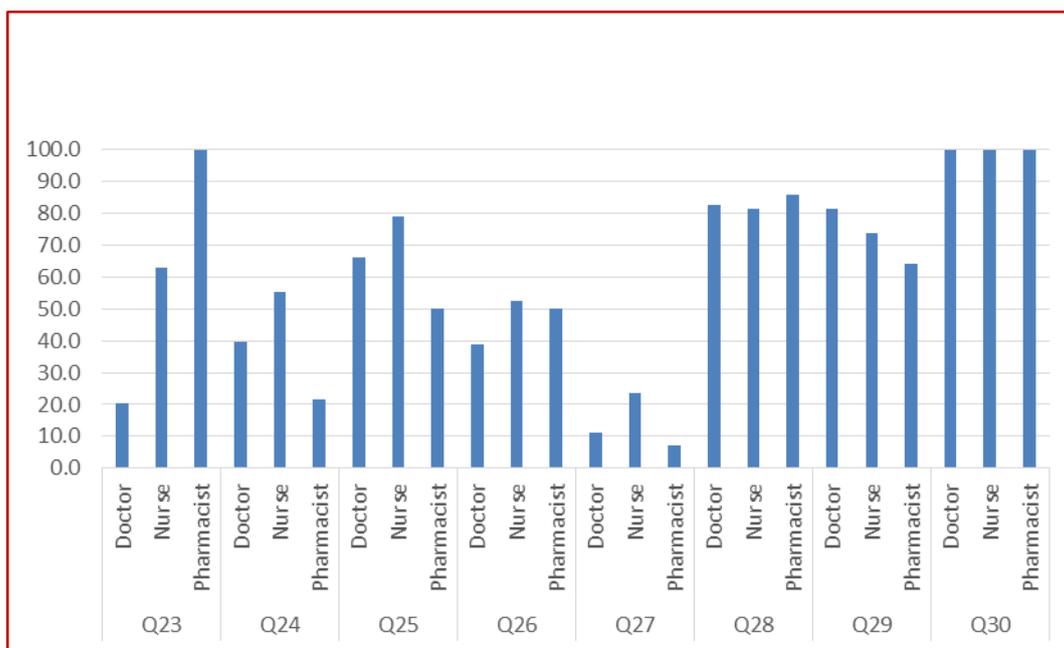


Fig. 2: Attitude related correct response of Doctors, Nurses and Pharmacists.

**Table 3: Assessment of Practice**

Question	Profession	Frequency (yes)	Percent % (Yes)
Have you ever reported an ADR to PV Centre?	Doctor	20	20.4
	Nurse	24	63.2
	Pharmacist	14	100.0
Have you ever read any papers regarding prevention of ADRs?	Doctor	39	39.8
	Nurse	21	55.3
	Pharmacist	3	21.4
Have you ever experienced an ADR in your patients during your professional practice?	Doctor	65	66.3
	Nurse	30	78.9
	Pharmacist	7	50.0
Do you keep a record of ADRs observed in your patients?	Doctor	38	38.8
	Nurse	20	52.6
	Pharmacist	7	50.0
Have you ever been trained for reporting of ADRs or attended any CME regarding PV & ADR reporting?	Doctor	11	11.2
	Nurse	9	23.7
	Pharmacist	1	7.1
Do you counsel your patients regarding possible ADRs of drugs prescribed?	Doctor	81	82.7
	Nurse	31	81.6
	Pharmacist	12	85.7
Have you personally suffered from ADR?	Doctor	80	81.6
	Nurse	28	73.7
	Pharmacist	9	64.3
In your opinion what factors discourage you from reporting an ADR	Doctor	98	100.0
	Nurse	38	100.0
	Pharmacist	14	100.0



**Fig. 3: Practice related correct response of Doctors, Nurses and Pharmacists.**

Response of HCPs towards knowledge, attitude and practice based inventories shows that pharmacists have comparatively less knowledge regarding PV and PVPI and ADRs.(Table-1) (Fig-1). Only 7.1% (n=1) pharmacists are aware about the definition of PV. Table-1 and its respective bar chart (Fig1) depicts that doctors and nurses have relatively same knowledge and are

equally updated and PV, PVPI, ADR's and ADR monitoring centers operating under the aegis of PVPI.

From Table-2 and Fig 2 the results show that the perception regarding the reporting of ADR is 99% for doctors (n=97) and 100% for both nurses (n=38) and pharmacists (n=14). Moreover, all HCPs are of the opinion that ADR reporting can significantly improve

patient safety (doctors 100%, nurses 97.4% and pharmacist 100%).

Table-3 and Fig 3 reveal that only 20.4% (n=20) of doctors have reported ADR to PV centre. Nurses being closely associated with patients in inpatient department have experienced more ADRs in patients in wards 78.9% (n=30) than doctors 66.3% (n=65) and pharmacist 50.5% (n=7). Likewise doctors keep a little record of ADRs observed in their patients 38.8% (n=38). Nurses 52.6% (n=20) and pharmacists 50% (n=7). Counselling of patients about ADRs is equally made by all HCPs, doctors 82.7% (n=81), nurses 81.6% (n=31) and pharmacists 85.7% (n=12).

When asked about factors discouraging from reporting an ADR all participants had one or the other valid reason for non-reporting an ADR. In fact, all options were correct in their own perspective. These were a) not aware where and how to report b) non availability of ADR forms c) failure to recognize as ADR d) lack of time e) no remuneration /financial incentives for reporting f) A single report may not add significantly to the ADR database g) ADR reporting may generate extra work load. h) difficult to decide whether an ADR has occurred or not or pinpoint a particular drug.

All participants were 100% correct, doctors (n=98), nurses (n=38) and pharmacists (n=14) has a valid and logical factor which discouraged them from reporting ADR.

## DISCUSSION

This is the first study which has been conducted in our hospital with regard to PV, PVPI and ADR reporting among HCPs working in our hospital. The aim of this study was to assess the knowledge, attitude and practice with regard to ADR reporting, to determine the major barriers and to identify the factors which discourage HCPs from reporting an ADR. The ADR reporting rate in India is below 1% compared to the worldwide rate of 5%.<sup>[19]</sup> HCPs play an integral role in the success of safety surveillance of drug.<sup>[20]</sup> In our study 61.2% (n=60) of doctors and 78.9% (n=30) of nurses gave correct response about definition of PV. Similar finding were reported by Torwani *et al.*<sup>[21]</sup> Results from this study show that majority of doctors and nurses had good knowledge regarding the concept of PV and ADRs in terms of their definitions and purposes. Results from other published studies from some Middle East countries reveal that they are still in an early stage with regard to knowledge and awareness of PV and ADR monitoring.<sup>[22-25]</sup> Despite the satisfactory results in our study most ADR reporting systems in the Middle East are in their infancy with some countries having more developed systems.<sup>[26]</sup>

In our study 99% of doctors (n=97) and 100% of nurses and pharmacists (n=14) agreed that reporting of ADRs are necessary, findings of which are better than those of

Ramesh *et al.*<sup>[27]</sup>, Khan *et al.*<sup>[28]</sup> and Desai *et al.*<sup>[29]</sup> In our study 24.5% doctors (n=24), 47.4 Nurses (n=18) and 42.9% pharmacists (n = 6 ) believed that most appropriate method to educate HCPs regarding ADR monitoring and reporting is Continuous Medical Education (CME). This educational initiative could improve ADR reporting. This was lower in comparison to findings reported by Ramesh *et al.*<sup>[27]</sup> and Rajesh *et al.*<sup>[30]</sup> It has been shown that educational interventions and other activities to promote ADR reporting increases awareness to ADRs thereby increases its reporting rates.<sup>[31-35]</sup> Our study population showed high willingness to receive training. Inclusion of PV and ADR reporting trainings to continuous education programme curricula, besides being part of undergraduate curricula is highly needed.

According to our results there was a perception that reporting duty rested mainly with doctors. On the contrary, nurses showed their positive attitude towards ADR reporting and were more willing to participate in related activities than physicians. Moreover, role of nurses is instrumental in identifying ADRs particularly in patients that remain outside the reach of physicians and in more vulnerable patients such as children, women and the elderly. In order to get the desirable and outcome based results in terms of ADR reporting especially from nursing side a significant educational intervention is required which is the demand of an hour.<sup>[34,36]</sup>

Underreporting has been as a matter of concern and a global issue even in countries with more organized PV systems. The reasons for not reporting globally are also similar to those in the findings of our study. With the most common reasons being lack of awareness of the reporting system requirements, lack of time, failure to recognize an ADR, where and how to report and difficulty to decide whether an ADR has occurred or not or pinpoint a particular drug.<sup>[37-42]</sup>

A review framed by Reumerman *et al.*<sup>[13]</sup> revealed that many factors could influence PV competencies such as type of healthcare Institute, academic level of study and previous training. This study shows that educational interventions such as short lectures, workshops, hanging posters about ADRs reporting on walls of health institutions or by adding contact information for ADR reporting on patients information sheets of pharmaceutical products and lastly a training in ADR reporting and assessment have improved HCPs knowledge, perception and positive attitude towards PV. In India ADR reporting process has been made more simple and executable by facilitating online reporting of ADRs. NCC-PVPI has developed an advanced version of the Android mobile app. "ADR-PVPI" which will enable all HCPs and consumers to instantly report ADRs to NCC. This will consequently help in enhancing the reporting rate of ADRs.

## CONCLUSION

The current study provides a basis to encourage and implement strategies to improve ADR reporting. It shows that practical knowledge regarding ADR reporting and PV is more important and outcome based than its theoretical aspect. The current academic curriculum should incorporate the application of PV in the medical practice. Further, our study strongly suggests that the development of a unified PV education and training to adequately prepare our future HCPs to rationally report ADR is crucial.

## LIMITATIONS

The sample size in our study was limited but similar to those of other studies conducted in various tertiary care hospitals in India. There is a scope for the study at larger scale involving greater number of HCPs from various District Hospitals and private health care sectors.

## CONFLICTS OF INTEREST

None declared.

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