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## Assessing Knowledge, Awareness, And Attitude Of Pharmacovigilance Among Interns, Residents, And Faculty Of Tertiary Care Hospital In Mumbai- A Cross-Sectional Observational Study.

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### ABSTRACT

Pharmacovigilance (PV) aims to ensure the safety of drugs and vaccines establishing the drug's efficacy. The study aims to evaluate the level of knowledge, attitude, and perception of adverse drug reporting (ADR) and PV among interns, postgraduate residents, and the faculty in Tertiary Medical Hospital. A questionnaire-based, cross-sectional study was conducted among 150 participants directed to assess knowledge, attitude, and perception. Descriptive statistics were applied to analyze the data using SPSS version 24.0. Based on the pre-specified criteria, just 2% of the participants were well aware of PV. Thirty-one (20.67%) were moderately aware and one hundred sixteen (77.3%) were less aware. 82% of participants had encountered ADR in their practice. While only 44% knew how to report and 62% had known where to report. 81.3% believed ADR reporting is an essential task. However, 48.6% of participants had not reported any ADR form and 39.3% of participants were unaware of the reporting procedure. 58% preferred to report an ADR if encountered in the future. This study documents perceptions of PV among various study participants and the need to report ADR. The study highlights the low awareness and the gap in the knowledge regarding PV necessitating training among healthcare workers.

**Keywords:** Under-reporting, Pharmacovigilance Programme of India (PvPI), adverse drug monitoring centers, vigiflow software.

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## INTRODUCTION

Indian pharmaceutical industry ranks the world's third largest by volume and 14th largest in terms of value [1]. Drugs account for a considerable proportion of healthcare expenditure in every Indian household. An Indian study revealed that outpatient department expenditure accounts for up to 21% of household income [2].

However, the usage of drugs is a mixed blessing. Despite all the benefits on health, adverse reactions are a recognized risk. The terrifying incidence of the Thalidomide tragedy in the 1960s had alarmed physicians regarding the importance of spontaneous reporting of adverse drug reactions (ADR) globally [3]. ADR encumbrances healthcare and patients in terms of morbidity, mortality, and finance. Spontaneous reporting is a main pillar of pharmacovigilance. The World Health Organization (WHO) defines pharmacovigilance (PV) as the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems [4]. PV was established in India in 1986. The National Program of Pharmacovigilance (2005) was renamed as Pharmacovigilance Programme of India (PvPI) in 2010 under the Ministry of Health. PvPI ensures improved health outcomes in the Indian population by systematic risk-benefit analysis of the medicines. To ease the process of reporting, ADRs Monitoring Centers (AMCs) have been established throughout the country at several government hospitals, non-government hospitals, Tuberculosis centers, Anti-Retroviral Therapy centers, corporate hospitals, district hospitals, army hospitals, municipal hospitals, etc. [5]. AMC works round-the-clock in collecting, performing follow-up, ensuring the completeness of the ADR reports, and transcribing the information to the Vigiflow software. It is the duty of the health-care workers to cautiously administer the drugs and a vigil be kept on the event as well as reporting of these ADRs.

Despite, considerable efforts of the Ministry of Health and Family Welfare (MoHFW) and the Government of India, the ADRs remain under-reported. Under-reporting of ADR is a widespread and grievous issue in PV [6]. The lack of knowledge, ignorance, and time constraint contributes to the under-reporting of ADR [7].

This questionnaire-based study was undertaken with the aim to assess the knowledge, awareness, and attitude of PV among the interns, postgraduate residents, and faculty of clinical departments.

## MATERIALS AND METHODS

A cross-sectional, questionnaire-based study was conducted among 150 participants including the interns, postgraduate residents, and the faculty of various clinical departments working at LTMMC & GH Sion, Mumbai. The study was conducted after the Institutional Ethics Committee's permission [IEC/68/22] was sought. Informed consent from the participants was taken prior. The study was conducted according to the principles stated in the Declaration of Helsinki, 2013, ICH-GCP Guidelines, and the ICMR's Ethical Guidelines for Biomedical Research on Healthy Participants, 2006.

The questionnaire comprised of 20 questions in the English language, designed to assess the knowledge, attitude, and perception of PV. Multiple-choice options were given to the participants. The correct answer was scored one point and every incorrect answer was scored zero. The total score of the knowledge domain of the questionnaire was 16. A score of >12 (>75%) was deemed as good awareness, a score of 8-11 (50-75%) was moderately aware and a score of <7 (<50%) was poor awareness. The questionnaire was pre-validated by experts from various departments and only those questions with item level-content validity index (I-CVI) >0.9 were included. The participants were approached via E-mail or WhatsApp, and the information gathered was compiled in Microsoft Excel.

Data was analyzed using SPSS version 24.0. Quantitative data was presented with the help of mean and standard deviation (SD) and frequency (percentage). We have expressed the results in graphs and pictures when deemed necessary.

## EXPERIMENTAL RESULTS

### Demographics

The study included 50 responses from post-graduate students, 50 faculties from various specialties, and 50 interns. 70 (46.7%) of the participants were females while the rest were males. The overall age of the study participants was  $28.5 \pm 5.5$  years with an average age of  $23.9 \pm 1.13$  years among interns,  $27.54 \pm 1.4$  years among the post-graduate residents, and  $34.08 \pm 6.1$  years among the faculty. Figure 1 illustrates the specialty-wise distribution of post-graduate students and faculty included. However, we also noted that 23 (15.3%) participants had not mentioned their specialty in the questionnaire provided.

### Domain A: Questions on knowledge and awareness about Pharmacovigilance

Our study revealed that all the participants had an awareness of what is ADR. While 123 (82%) participants had encountered an ADR in their clinical practice. However, only 66 (44%) of the participants had the knowledge of how to report and 93 (62%) participants knew where to report an ADR. Figure 2 depicts the responses of the 93 participants regarding “where to report an ADR”. The study highlighted that just 8 (5.3%) participants chose the right option of reporting to an AMC.

A multiple-choice question was directed to analyze the knowledge of the participants regarding who can report an ADR. Figure 3 demonstrates the responses of the participants. 25 (16.6%) participants were very aware that all the above-mentioned people could report in case of an ADR. The majority (109) of the participants believed that all the types of ADR (mild, moderate, and severe) must be reported during an event.

The questionnaire aimed in view of assessing the knowledge of PV programs. Just 46 (30.7%) participants had a clear knowledge regarding the types of ADR and stated that Type A was a dose-related and predictable ADR. However, 104 (69.3%) participants provided an incorrect response. 38 (25.3%) participants were ignorant about the ADR monitoring center present in the Institute. More than 90% of the participants were very well informed about the PvPI, an initiative of the Government of India for monitoring ADR. When asked about the objectives of PvPI, the responses given by them has been represented in figure 4. It was observed that just 27 (18%) participants answered right by selecting all four options.

Less than half of the respondents (48.7%) had knowledge of the location of the Indian Pharmacopoeia Commission (IPC) as Ghaziabad. While the rest believed that IPC was located in Delhi/ Mumbai/ Hyderabad. Only 58 (38.7%) participants were acquainted with serious adverse events (SAE). They accurately marked all the options which included Death, Congenital anomaly, Hospitalization, Life-threatening condition, and Disability.

A question was framed to understand the level of awareness regarding ways to report the ADR. Multiple answers were selected by the participants which has been represented in Figure 5. It was noted that 14 (9.3%) participants believed all the mentioned ways of reporting an ADR were legit. Also, only 19 (12.7%) participants were aware of the Vigiflow software.

A series of questions were targeted to evaluate the level of knowledge in WHO-PV. A little above half (56.7%) of the respondents had knowledge about WHO online database- VigiBase. The other responses have been shown in figure 6.

72 (48%) participants replied that the WHO-UMC scale is the commonest scale for assessment of the causality of ADR. The other responses include Schumock and Thornton scale (28%), Hartwig's Severity Assessment Scale (15.3%), and Karch and Lasagna scale (8.7%).

122 (81.3%) respondents believed that ADR reporting was essential to prevent further ADR in other patients who may use the same batch of drugs and to trace the complete lot of medicinal products causing ADR. However, 73 (48.6%) participants had not reported any ADR and 59 (39.3%) participants were unaware of the reporting procedure.

87 (58%) participants acknowledged that they would report an ADR if encountered in their clinical experience and all the participants considered that reporting ADR is very helpful and crucial in public health.

Only 3 (2%) participants had an overall score above 75% indicating good awareness of pharmacovigilance. While 31 (20.67%) were moderately aware and 116 (77.3%) were less aware. On further analysis, we found that 20.67% of faculty, 26% of postgraduate residents, and 30.6% of interns had a level of awareness <50%.

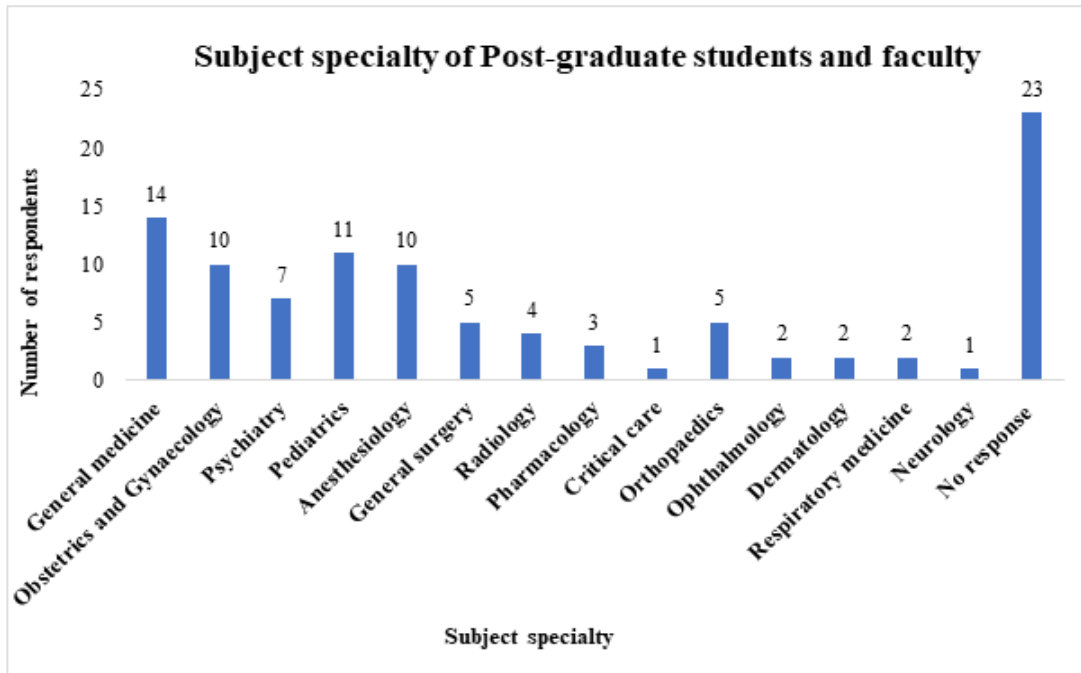


Figure 1: Subject specialty of post-graduate students and faculty

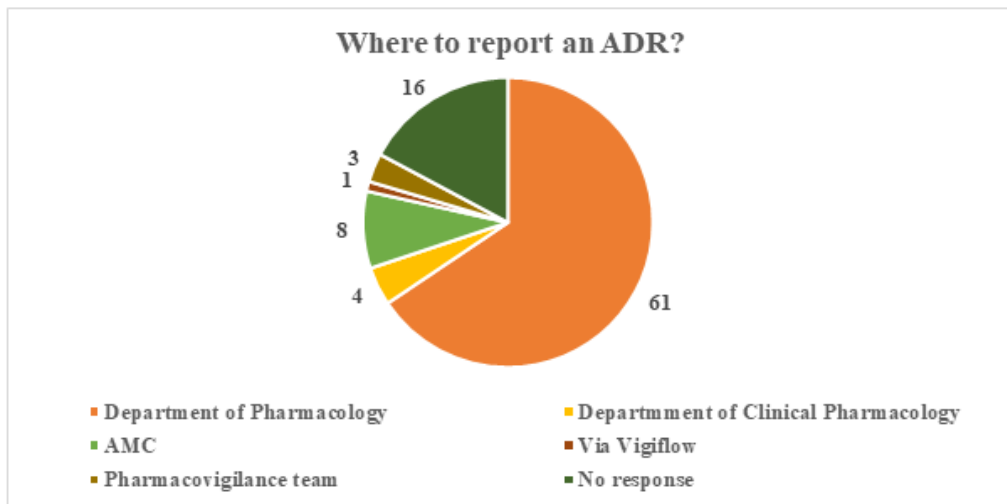


Figure 2: Responses of where to report an ADR.

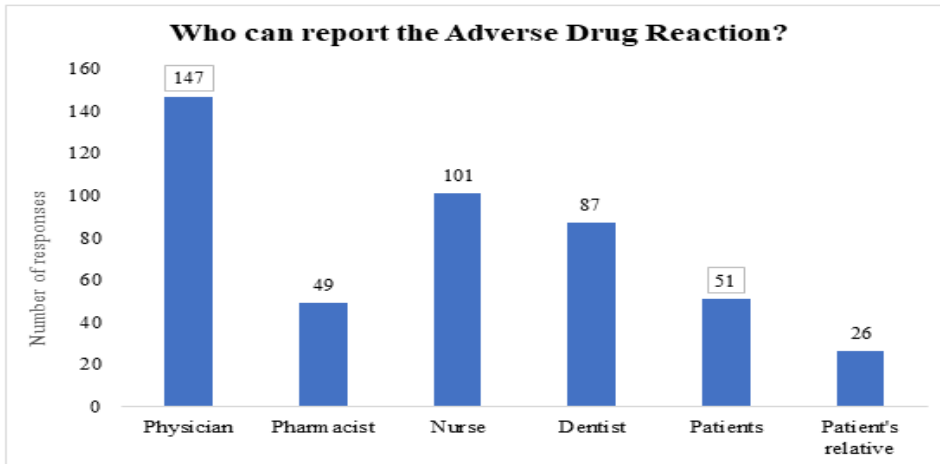


Figure 3: Responses of who can report an ADR.

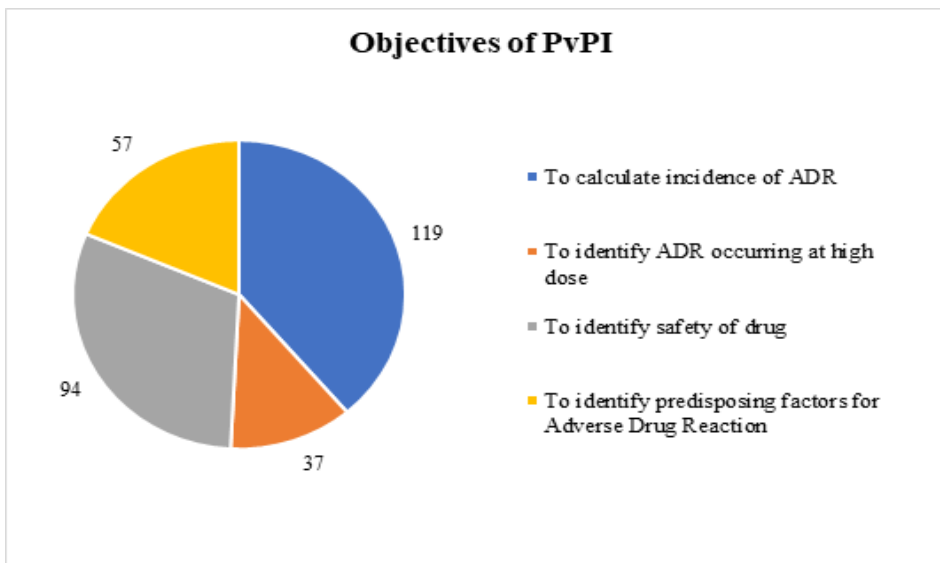


Figure 4: Responses of objectives of PvPI.

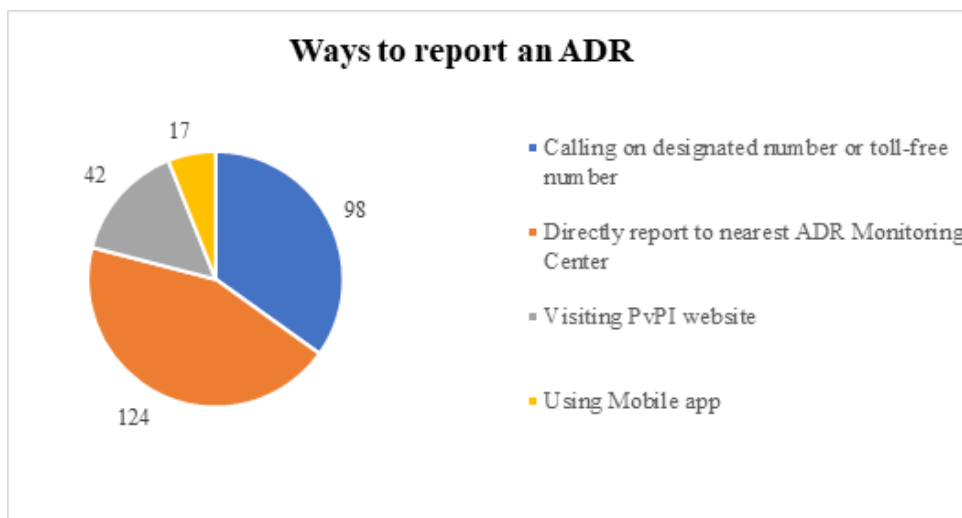
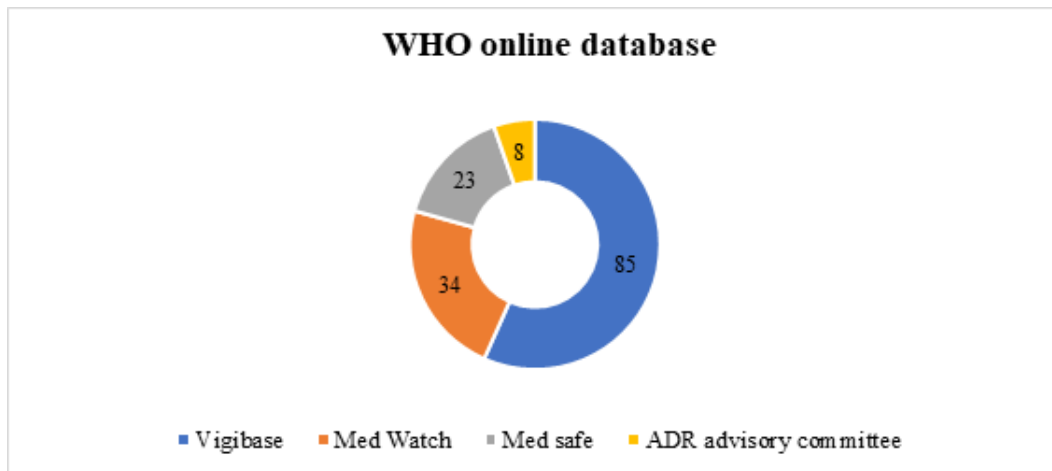


Figure 5: Ways to report an ADR.



**Figure 6: WHO online database**

**DISCUSSION**

The study aimed to assess the knowledge, attitude, and perception of interns, post-graduate students, and faculty toward pharmacovigilance. The study revealed that most of the participants (92%) were moderately or less aware of PV.

The AMC of our institute actively functions throughout the year collecting the ADRs. However, the number of ADRs collected in the year 2022 was a mere 373 visiting our institute. Reporting an ADR is critical for a successful PV program ensuring the safety of medicines and vaccines by consistent and expeditious exchange of information on safety issues [8].

In our study, we observed that 44% of the participants had knowledge of how to report, but 38% of participants were unaware of where to report an ADR. The findings were consistent with the study by Upadhyaya HB et al, where the residents had poor knowledge regarding ADR reporting procedure [9]. Sessions directed to enhance the knowledge and awareness in pharmacovigilance highlighting the importance of ADR reporting like “when to report? What to report? Where to report? how to report? And who can report? are recommended. A study was conducted by Shrestha S et al, with an aim to evaluate the impact of educational intervention on the knowledge and attitude of PV and ADRs. The authors concluded that post the training session, the knowledge and attitude scores were increased emphasizing the positive impact [10]. Frequent workshops/ seminars should be mandated in our institute to sensitize and rebuild the knowledge of PV healthcare professionals. It is also of utmost importance to encourage patients and their relatives to report ADRs by filling out online portals for PV or by contacting their health providers.

The study revealed that just 18% of the study participants rightly mentioned all the objectives of PV. This is lower than the study by Hindolya M et al, where 44% of respondents had a clear idea about the objectives of PV [11].

A major finding of our study was that around 48.6% participants had not reported any ADR so far and 39.3% participants were unaware of the reporting procedure. The observation is in line with the study conducted in pediatricians of Odisha where 50% of the respondents had reported an ADR [12]. This ultimately implies an under-reporting of ADRs. This culture of reluctance in reporting should be addressed by the institution and encourage proactive reporting among the HCPs. Various reasons for under-reporting in Indian hospitals were highlighted by Tandon et al including the lack of knowledge and awareness about PvPI, lethargy, workload, and lack of training [13]. Behera MR et al study also added other explanations owing to under-reporting; apprehension of wrong diagnosis of ADR, absence of reward/ monetary benefits after reporting, a mindset of one report might not influence the organization, and fear of losing out patient’s trust [12]. A slight modification in the institutional protocol can be made to strengthen the reporting of ADR: by keeping ADR registers in all the in-patient wards and out-patient departments, simple to operate ADR reporting, scheduling sessions to brush up the knowledge,



encouraging the HCPs to report irrespective of proof of evidence or absolute certainty on the causality of the drug [14]. These changes in the institutional SOPs can be the future roadmap for a successful PV.

The discrepancy in the number of ADRs encountered and the number of ADRs reported was noted stressing a poor awareness of the protocol of reporting. Similar observations were made by Hindolya M et, where ADR experienced in professional practice was (71%) however only 23% of the residents reported an ADR [11]. This highlights the need for an upbringing easy and simple protocol to streamline ADR reporting.

Interestingly, though the majority of participants were very well informed about PvPI, only about three-quarters of the participants knew about the ADR monitoring center housed in the Institute. This unfamiliarity with one's own institute might be attributed to the lack of time and workload. Suggestions can be made by our institute to carry out an Orientation programme to all the newly appointed HCPs in the respective department with a special mention of the Organization's AMC and the importance of ADR reporting. This not just familiarizes them with the institution but intensifies the ADR reporting rate as well.

It was very encouraging to note that 100% of the participants believed that reporting ADR is very helpful and vital in public health. But only 58% of the respondents had a positive attitude towards ADR reporting in future encounters. The results are in line with the findings of the Adisha et al study, where only 46.2% showed a positive attitude [15]. However, the Pakistani study showed a contrasting result of 78.2% of the participants with a positive attitude toward ADR reporting [16].

The study was limited due to a small sample size. The first 150 filled questionnaires which were submitted within the stipulated time were considered for analysis. Hence, missing out on potential participants was a major limitation. Also, the study was limited to one institution. Hence, the generalizability of the results was not applicable.

## CONCLUSIONS

ADR reporting was deemed important by a large majority of the participants, but the actual practices of ADR reporting were very low. Despite the poor level of knowledge in PV and ADR reporting among Health Care Professionals (HCP), the attitude towards reporting of ADR was uninfluenced. Strengthening the knowledge and beliefs of the HCPs towards PV is critical which can be done by availing regular educational workshops, motivating them to report all the suspected cases, use of simple and easy reporting systems. A collaborative approach involving physicians, pharmacologists, and other healthcare workers is recommended to curb the burden of under-reporting of ADR. Seeking attention to raise public awareness regarding ADRs is pivotal to the success of the programme.

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