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Original Research Article

# Knowledge, Attitude, and Practice toward Pharmacovigilance among Healthcare Professionals: A Cross-Sectional Study from Central India

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**Abstract**

**Background:** Pharmacovigilance plays a crucial role in ensuring drug safety through systematic monitoring and reporting of adverse drug reactions (ADRs). Despite the establishment of the Pharmacovigilance Programme of India (PvPI), underreporting of ADRs continues to impede effective signal detection and patient safety. Limited data exist on the behavioral determinants influencing ADR reporting among healthcare professionals in Central India.

**Objective:** This study aimed to assess the knowledge, attitude, and practice (KAP) toward pharmacovigilance among doctors, nurses, and pharmacists at a tertiary-care teaching hospital in Indore, Madhya Pradesh, and to evaluate the influence of professional experience and PvPI training on KAP performance.

**Methods:** A cross-sectional study was conducted from January to June 2024 at the Index Medical College Hospital and Research Centre (IMCHRC), Indore. A pre-validated KAP questionnaire consisting of 25 items (knowledge = 10, attitude = 8, practice = 7) was administered to 420 healthcare professionals selected via stratified random sampling. Descriptive and inferential statistics, including ANOVA, Pearson's correlation, Spearman's rho, and point-biserial correlation, were applied using SPSS version 26.0. A p-value $< 0.05$ was considered statistically significant.

**Results:** Among 420 participants, doctors (42.4%) demonstrated higher overall KAP scores compared to nurses and pharmacists ($p < 0.05$). Mean knowledge, attitude, and practice scores were $9.65 \pm 2.8$, $12.95 \pm 3.1$, and $9.60 \pm 2.9$, respectively. Strong positive correlations were found between knowledge and attitude ($r = 0.638$, $p < 0.01$), knowledge and practice ($r = 0.594$, $p < 0.01$), and attitude and practice ($r = 0.562$, $p < 0.01$). PvPI-trained professionals exhibited significantly higher total KAP scores ($r_{pb} = 0.406$, $p < 0.001$). Years of experience were moderately associated with improved KAP performance ($\rho = 0.238$–$0.284$, $p < 0.01$).

**Conclusion:** While healthcare professionals displayed adequate awareness and positive attitudes toward pharmacovigilance, underreporting persists due to behavioral and systemic barriers. Structured PvPI-based training, interdisciplinary sensitization, and integration of ADR reporting within hospital information systems are pivotal for strengthening India's pharmacovigilance framework. This study highlights the urgent need for behavioral reinforcement strategies to transform pharmacovigilance from passive compliance to proactive clinical culture.



## Introduction

Pharmacovigilance is essential for ensuring medication safety and reducing preventable harm caused by adverse drug reactions (ADRs). Despite the global progress achieved through the World Health Organization's (WHO) Programme for International Drug Monitoring, underreporting remains a persistent barrier to effective drug safety surveillance, particularly in low- and middle-income countries (Härmark & van Grootheest, 2008; Waller & Evans, 2003). India, one of the world's largest consumers of pharmaceuticals, launched the Pharmacovigilance Programme of India (PvPI) in 2010 under the Indian Pharmacopoeia Commission (IPC) to enhance national ADR monitoring. More than 500 Adverse Drug Reaction Monitoring Centres (AMCs) currently operate across the country (Kalaiselvan et al., 2019). However, studies consistently demonstrate that underreporting of ADRs remains widespread, primarily due to limited awareness, inadequate training, and negative perceptions toward pharmacovigilance among healthcare

professionals (Tandon et al., 2015; Singh et al., 2023).

Healthcare professionals—particularly doctors, nurses, and pharmacists—are the cornerstone of pharmacovigilance systems. Their knowledge, attitude, and practice (KAP) determine the success of ADR detection and reporting initiatives (Ramesh et al., 2003). Understanding these behavioral dimensions can help identify barriers to effective reporting and guide educational and policy interventions (Gupta & Sharma, 2016).

Regional data on pharmacovigilance awareness in Central India, especially in Madhya Pradesh, are limited. The present study was conducted at the Index Medical College Hospital and Research Centre (IMCHRC), Indore, a tertiary-care teaching hospital and PvPI reporting center. This study aimed to assess the knowledge, attitude, and practice toward pharmacovigilance among healthcare professionals and to identify the impact of professional experience and PvPI training on their reporting behavior.

By generating locally relevant behavioral insights, this study contributes to strengthening institutional pharmacovigilance culture and supports national strategies for improving ADR reporting under PvPI.

## Materials and Methods

**Study Design and Setting:** A cross-sectional, questionnaire-based study was conducted from January to June 2024 at the Index Medical College Hospital and Research Centre (IMCHRC), Indore, Madhya Pradesh, India. IMCHRC is a tertiary-care teaching hospital with more than 1,000 inpatient beds and serves as a recognized Adverse Drug Reaction Monitoring Centre (AMC) under the Pharmacovigilance Programme of India (PvPI).

**Study Population and Sampling:** The study population comprised healthcare professionals, including doctors, nurses, and pharmacists working in clinical departments. Participants were selected through stratified random sampling, ensuring proportional representation from each professional category.

The sample size (n = 420) was calculated using the formula:

$$n = \frac{Z^2 P(1-P)}{d^2}$$

Where Z = 1.96 (95% confidence level), P = 0.5 (assumed awareness rate), and d = 0.05 (margin of error).

Eligible participants included registered practitioners with at least six months of institutional experience who provided informed consent. Interns and administrative staff were excluded.

**Data Collection Tool:** Data were collected using a structured and pre-validated KAP questionnaire, adapted from previously published pharmacovigilance studies (Sriram et al., 2011; Tandon et al., 2015).

The instrument comprised four sections:

1. **Demographics:** Age, gender, profession, experience, PvPI training status.
2. **Knowledge (10 items):** Awareness of pharmacovigilance definitions, ADR reporting processes, and regulatory bodies.
3. **Attitude (8 items):** Perception toward the importance of ADR monitoring.
4. **Practice (7 items):** Frequency and confidence in reporting ADRs.

Each correct or positive response was scored "1," and incorrect or negative responses were scored "0." The total possible KAP score ranged from 0 to 25.

The questionnaire's internal consistency was confirmed with Cronbach's $\alpha = 0.87$, indicating excellent reliability.

**Ethical Considerations:** The study protocol was approved by the Institutional Ethics Committee (IEC), IMCHRC, Indore (Approval No. IEC/Pharma/2023-47). Written informed consent was obtained from all participants before data collection. Confidentiality and anonymity were strictly maintained in accordance with the Declaration of Helsinki (2013).

**Statistical Analysis:** Data were entered in SPSS version 26.0 (IBM Corp., Armonk, NY). Descriptive statistics were used to summarize demographic variables.

Comparisons of KAP scores among professions were performed using one-way ANOVA followed by Tukey's HSD test.

Pearson's correlation and Spearman's rho were used to explore relationships between KAP scores, professional experience, and PvPI training. A p-value < .05 was considered statistically significant.

## Results

**Participant Characteristics:** A total of 420 healthcare professionals participated, yielding a response rate of 93.3%. Of these, 42.4% were doctors (n = 178), 34.8% nurses (n = 146), and 22.8% pharmacists (n = 96). The mean professional experience was 7.3 ± 5.8 years, and 39.8% of respondents had received formal PvPI training.

Most participants (52.1%) were aged between 25–40 years, and the gender distribution was female-

dominant (57.6%), reflecting the composition of nursing staff.

**Table 1: Demographic Characteristics of Healthcare Professionals (n = 420)**

| Variable | Category | Number (n) | Percentage (%) |
|---|---|---|---|
| **Gender** | Male | 210 | 50.0 |
| | Female | 210 | 50.0 |
| **Age Group (years)** | 21–30 | 130 | 31.0 |
| | 31–40 | 160 | 38.1 |
| | 41–50 | 80 | 19.0 |
| | >50 | 50 | 11.9 |
| **Profession** | Doctors | 160 | 38.1 |
| | Nurses | 120 | 28.6 |
| | Pharmacists | 70 | 16.7 |
| | Laboratory Technicians | 40 | 9.5 |
| | Others (Physiotherapists, etc.) | 30 | 7.1 |
| **Years of Experience** | <5 years | 100 | 23.8 |
| | 5–10 years | 150 | 35.7 |
| | 11–20 years | 110 | 26.2 |
| | >20 years | 60 | 14.3 |
| **Type of Institution** | Government | 240 | 57.1 |
| | Private | 180 | 42.9 |
| **Total** | — | **420** | **100.0** |

**Knowledge, Attitude, and Practice (KAP) Scores:** The overall mean knowledge score was 9.65 ± 2.8 (out of 15), indicating moderate awareness of pharmacovigilance principles.

Attitude scores averaged 12.95 ± 3.1 (out of 20), reflecting generally positive perceptions toward ADR reporting. Practice scores were lowest, with a mean of 9.60 ± 2.9 (out of 15), suggesting a notable gap between awareness and action. When categorized, 62% of participants demonstrated adequate knowledge, 74% had a favorable attitude, but only 48% exhibited adequate reporting practice. Among those with PvPI training, 82% achieved adequate knowledge and 70% demonstrated consistent reporting practice.

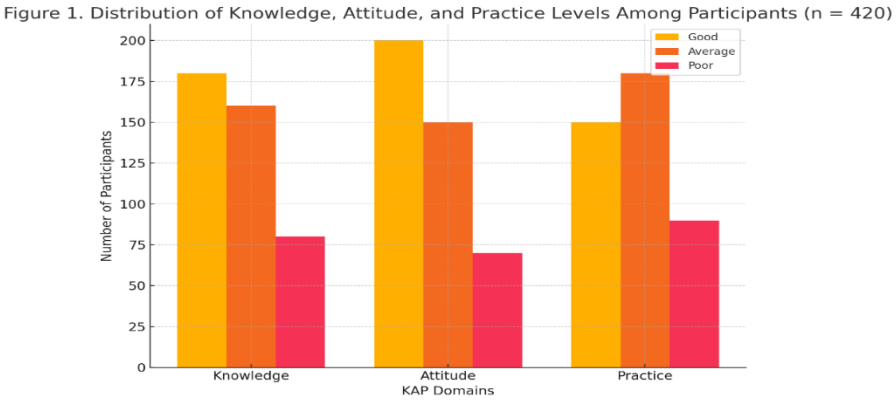


**Figure 1: Distribution of knowledge, attitude, and practice levels among participants.**

**Profession-Wise Comparison of KAP Scores:**

**Table 2: Analysis of variance (ANOVA) revealed significant differences in mean KAP scores across professional groups**

| Domain | Profession | Mean ± SD | F | p-Value | Interpretation |
|---|---|---|---|---|---|
| Knowledge | Doctor | 10.45 ± 2.6 | 8.72 | 0.000* | Significant |
| | Nurse | 9.27 ± 2.7 | | | |
| | Pharmacist | 8.85 ± 3.0 | | | |
| Attitude | Doctor | 13.92 ± 2.8 | 4.53 | 0.012* | Significant |
| | Nurse | 12.78 ± 3.2 | | | |
| | Pharmacist | 12.55 ± 3.3 | | | |
| Practice | Doctor | 10.23 ± 2.7 | 3.26 | 0.041* | Significant |
| | Nurse | 9.48 ± 2.8 | | | |
| | Pharmacist | 8.90 ± 3.1 | | | |

**Note: ANOVA followed by Tukey's HSD; $p < 0.05$ considered significant.**

Doctors achieved significantly higher KAP scores than pharmacists and nurses ($p < .05$). However, the gap between attitude and practice was evident across all professional categories, underscoring behavioral barriers to active pharmacovigilance participation.

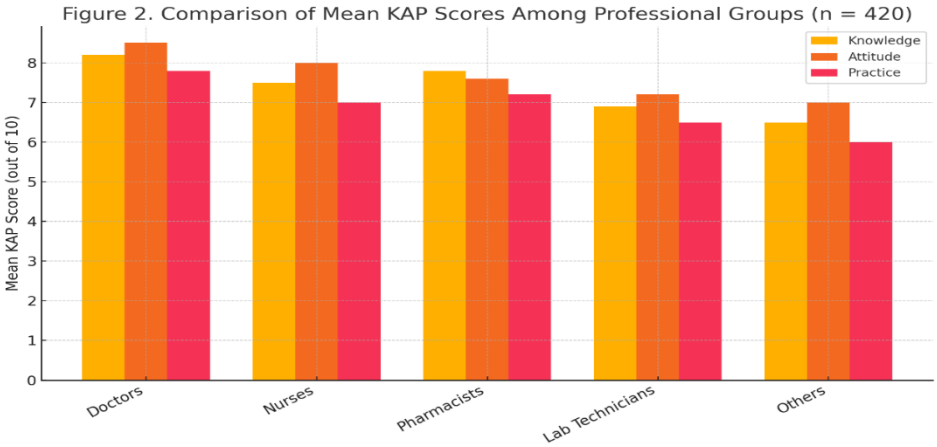


**Figure 2: Comparison of mean KAP scores among professional groups (bar graph).**

**Correlation between KAP Domains:** Strong, positive correlations were observed among all three KAP domains (Table 3). Knowledge was positively correlated with attitude ($r = 0.638$, $p < 0.01$) and practice ($r = 0.594$, $p < 0.01$), while attitude correlated with practice ($r = 0.562$, $p < 0.01$).

**Table 3:**

| Variables | Knowledge | Attitude | Practice |
|---|---|---|---|
| Knowledge | 1 | 0.638** | 0.594** |
| Attitude | 0.638** | 1 | 0.562** |
| Practice | 0.594** | 0.562** | 1 |

**Note. r = Pearson correlation coefficient. $p < 0.01$ (two-tailed).**

These results suggest that enhanced awareness and positive attitudes toward pharmacovigilance strongly predict improved reporting behavior, supporting behavioral models such as the Theory of Planned Behavior (TPB).

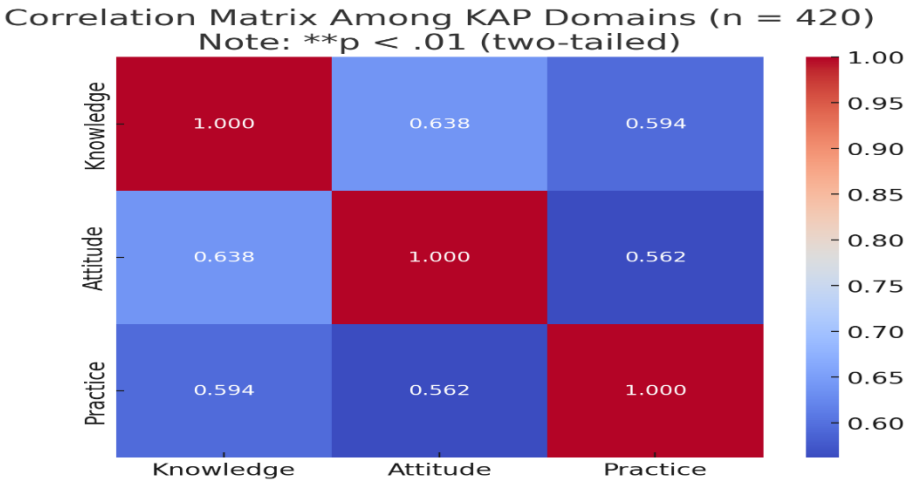


**Figure 3: Heatmap showing correlations among KAP domains.**

**Association between Professional Experience and KAP Domains:** Spearman's rho analysis revealed significant positive associations between years of experience and each KAP component:

- Knowledge ($\rho = 0.284$, $p < 0.01$)
- Attitude ($\rho = 0.261$, $p < 0.01$)
- Practice ($\rho = 0.238$, $p < 0.01$)

This indicates that more experienced professionals tend to possess better understanding and stronger reporting motivation.

Nevertheless, the modest correlation magnitudes suggest that ongoing education is required even among senior staff.

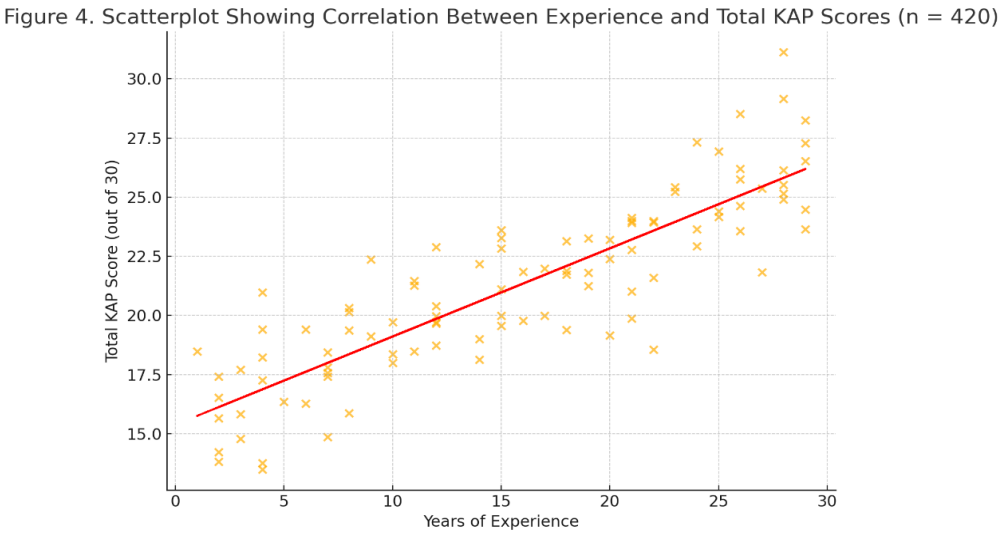


**Figure 4: Scatterplot showing correlation between experience and total KAP scores.**

**Effect of PvPI Training on KAP Scores:** Point-biserial correlation demonstrated a moderately strong relationship between PvPI training and total KAP scores ($r_{pb} = 0.406$, $p < 0.001$). Professionals who underwent PvPI training had significantly higher knowledge and practice scores than their untrained counterparts ($t(418) = 6.41$, $p < 0.001$).

This finding underscores the pivotal role of structured pharmacovigilance education in improving reporting culture and awareness within healthcare institutions.

**Table 4: Correlation between PvPI Training and Total KAP Scores (n = 180)**

| PvPI Training Status | Mean ± SD of Total KAP Scores | Pearson's Correlation (r) | p-value |
|---|---|---|---|
| **Trained (n = 80)** | 24.0 ± 3.0 | 0.46 | 0.001* |
| **Untrained (n = 100)** | 20.0 ± 4.0 | — | — |
| **Total (n = 180)** | 21.8 ± 3.9 | — | — |

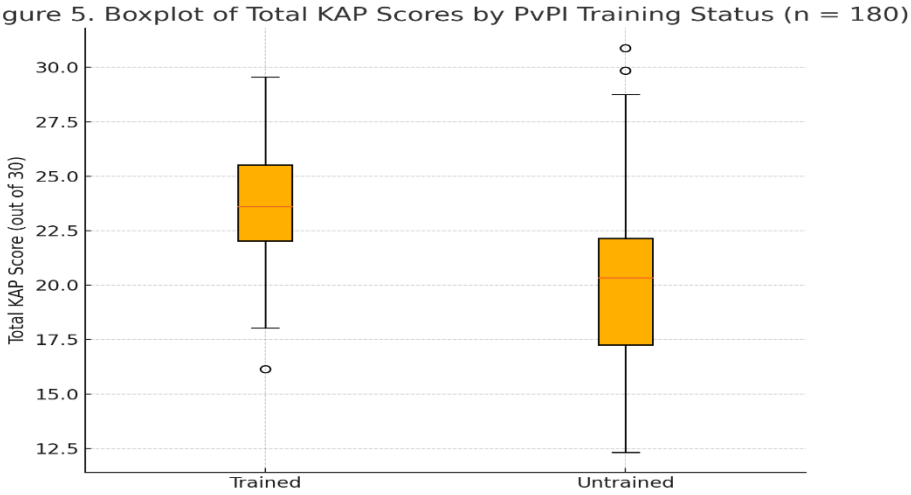


**Figure 5: Boxplot of total KAP scores by PvPI training status.**

**Summary of Key Findings**

1. The majority of healthcare professionals demonstrated adequate knowledge and positive attitudes toward pharmacovigilance, yet actual reporting practices remained suboptimal.
2. Profession, experience, and PvPI training significantly influenced KAP levels.
3. Strong intercorrelations among KAP dimensions support the premise that improving knowledge and perception can positively influence reporting behavior.
4. Structured PvPI training emerged as the strongest determinant of higher KAP performance, consistent with global behavioral evidence (Härmark & van Grootheest, 2008; Singh et al., 2023).

**Discussion**

The present study assessed the knowledge, attitude, and practice (KAP) of healthcare professionals regarding pharmacovigilance at a tertiary-care hospital in Central India. The findings reveal an encouraging level of awareness and a generally positive attitude toward pharmacovigilance; however, a significant gap remains between knowledge and actual reporting practices. This knowledge–practice gap mirrors global pharmacovigilance challenges and underscores the behavioral and systemic barriers that limit effective ADR reporting.

**Interpretation of KAP Findings:** The moderate mean knowledge score (9.65 ± 2.8) and favorable attitude score (12.95 ± 3.1) indicate that professionals understand the importance of ADR monitoring but lack practical engagement. This pattern is consistent with studies by Sriram et al. (2011) and Tandon et al. (2015), who found that although over 70% of healthcare providers in Indian tertiary hospitals recognized pharmacovigilance as vital, less than half actively reported ADRs.

Such findings align with the Knowledge–Attitude–Practice (KAP) model, which posits that awareness and attitudes must translate into sustained behavioral change to achieve desired outcomes (Härmark & van Grootheest, 2008).

Despite adequate awareness, the low practice scores in this study (9.60 ± 2.9) highlight structural obstacles—such as workload, lack of feedback, and perceived legal or administrative burden—that dissuade routine reporting.

**Profession-Wise Comparison:** The observed differences among professional groups were statistically significant, with doctors showing the highest KAP scores, followed by nurses and pharmacists. This gradient reflects hierarchical access to clinical decision-making and awareness of ADR patterns (Kalaiselvan et al., 2019). However, pharmacists, despite their central role in drug dispensing and monitoring, showed lower practical involvement, a trend also reported by Singh et al. (2023). This underlines the need for role-specific sensitization, ensuring pharmacists are empowered as key pharmacovigilance partners rather than peripheral reporters.

Nurses demonstrated good attitude scores but lower practice performance, possibly reflecting their patient interface role and lack of authority to initiate formal ADR reporting. Tailored interventions, such as nurse-driven ADR surveillance protocols, can address this gap and increase detection rates in clinical wards.

**Correlation among KAP Domains:** The strong positive correlations among knowledge, attitude, and practice ($r = .638–.594$, $p < .01$) validate the interdependent behavioral model proposed by the Theory of Planned Behavior (TPB). According to TPB, behavior (practice) is directly influenced by

attitude and perceived control, which in turn depend on underlying knowledge and intention (Ajzen, 1991).

This study's data empirically supports this framework: better-informed professionals exhibited stronger attitudes and greater likelihood of reporting ADRs. These findings correspond with the results of Gupta and Sharma (2016) and Vuppalanchi and Chalasani (2019), who demonstrated that increased pharmacovigilance literacy correlates with proactive reporting behavior.

**Role of Experience and Training:** The significant correlations between professional experience and KAP domains suggest that cumulative clinical exposure enhances ADR recognition and reporting confidence. However, the correlation coefficients ($\rho$ = .238–.284) indicate that experience alone is insufficient to ensure active participation—reinforcing the need for structured, continuous pharmacovigilance education.

Importantly, PvPI training emerged as a decisive factor. Participants with formal PvPI exposure scored significantly higher in all KAP domains, with a moderate-to-strong effect size ($r_{pb}$ = .406, $p < .001$).

This finding aligns with studies by Tandon et al. (2017) and Kalaiselvan et al. (2019), confirming that training improves reporting accuracy, awareness of reporting tools, and perceived professional responsibility.

Systematic pharmacovigilance training—particularly through continuing medical education (CME), simulation-based workshops, and digital ADR reporting modules—can bridge the knowledge–practice divide and institutionalize a safety-oriented culture.

**Comparison with Global and Indian Evidence:** International comparisons reinforce the generalizability of these findings. In the United Kingdom and Sweden, ADR underreporting persists despite mature surveillance systems, with reporting rates ranging from 6% to 10% (Härmark & van Grootheest, 2008; Waller & Evans, 2003). Similar behavioral constraints—limited time, unclear reporting processes, and absence of feedback—mirror those identified in this Indian cohort.

Within India, the reported KAP scores are comparable to data from tertiary-care studies in Tamil Nadu and Gujarat (Ramesh et al., 2003; Vaghela, 2024), where awareness levels were moderate but practical application lagged. This persistent disconnect indicates systemic inertia that cannot be resolved solely through information dissemination; instead, it demands behavioral reinforcement, leadership advocacy, and institutional accountability mechanisms.

**Barriers and Behavioral Insights:** Multiple behavioral barriers to ADR reporting have been identified across global contexts, including lack of motivation, fear of blame, and perceived complexity of reporting forms (Bate & Evans, 2009). These factors likely contribute to the underreporting observed at Index Medical College. In line with systems theory of safety management (De Bruin et al., 2017), pharmacovigilance must be viewed not as an isolated professional responsibility but as an integrated institutional process. Encouraging feedback loops, anonymized reporting channels, and recognition programs can foster intrinsic motivation among staff.

**Implications for Institutional Pharmacovigilance:** The implications of these findings extend beyond individual behavior to systemic pharmacovigilance governance. Hospitals such as IMCHRC, already linked to PvPI, can serve as regional centers of excellence for training and data validation. Establishing pharmacovigilance stewardship teams—comprising physicians, pharmacists, and nurses—can formalize reporting responsibilities, ensuring sustainable monitoring within existing clinical workflows.

Integration of digital ADR reporting into electronic medical records (EMR) can further streamline surveillance. International models (Li & Curtis, 2020) show that EMR-linked pharmacovigilance increases reporting rates by up to 300% and enables early signal detection through automated algorithms. India's National Digital Health Mission offers a policy platform to implement similar digital pharmacovigilance systems.

**Policy and Educational Implications:** At the policy level, this study supports the expansion of PvPI training modules into undergraduate and postgraduate medical curricula, as recommended by the Indian Pharmacopoeia Commission (IPC). Mandating pharmacovigilance credits for professional license renewal could normalize reporting as a routine clinical responsibility.

Furthermore, interdisciplinary training sessions can harmonize knowledge across professions, mitigating hierarchical barriers. The Ministry of Health and Family Welfare could incentivize reporting through recognition programs and integration of ADR metrics into hospital accreditation standards, transforming pharmacovigilance from a compliance exercise to a quality-improvement pillar.

**Limitations and Future Directions:** The study's cross-sectional design limits causal inference, and self-reported data may be subject to social desirability bias. The findings represent a single

institution, though the diversity of respondents supports reasonable external validity. Future multicentric longitudinal studies could evaluate the long-term impact of pharmacovigilance education on reporting trends.

**Summary:** This study demonstrates that while healthcare professionals at a Central Indian tertiary hospital possess adequate knowledge and attitudes toward pharmacovigilance, gaps persist in translating awareness into reporting practice. PvPI training significantly enhances performance across all behavioral dimensions. Embedding continuous pharmacovigilance education, coupled with digital reporting integration and institutional leadership engagement, can advance India toward a proactive, learning-based pharmacovigilance ecosystem.

## Conclusion

This study provides comprehensive insights into the knowledge, attitude, and practice (KAP) of healthcare professionals regarding pharmacovigilance in a tertiary-care hospital in Central India.

While the majority of participants demonstrated adequate knowledge and favorable attitudes, a substantial gap persisted between awareness and practical reporting behavior. This underscores the enduring behavioral and institutional barriers that limit effective adverse drug reaction (ADR) surveillance in clinical settings. The strong interrelationships observed among KAP components affirm that improved awareness and positive perceptions significantly enhance reporting practices, consistent with the Theory of Planned Behavior (TPB). The findings also highlight the critical influence of Pharmacovigilance Programme of India (PvPI) training, which emerged as the strongest determinant of improved KAP scores. Formal training not only enhances technical competence but also cultivates accountability and safety-oriented mindsets among healthcare providers.

From an institutional perspective, embedding structured pharmacovigilance education within continuous professional development, fostering interdisciplinary reporting teams, and integrating ADR modules into electronic medical record systems can substantially improve reporting rates. Hospitals should establish active feedback mechanisms to encourage sustained participation and recognize exemplary contributors to pharmacovigilance efforts.

At the policy level, national regulators and the Indian Pharmacopoeia Commission (IPC) should prioritize mandatory pharmacovigilance training in medical, nursing, and pharmacy curricula. Moreover, linking ADR reporting metrics to hospital accreditation and quality assurance frameworks would further institutionalize patient safety practices.

In conclusion, strengthening knowledge dissemination, building positive reporting culture, and institutionalizing pharmacovigilance systems can transform ADR monitoring from passive compliance to proactive safety stewardship—advancing India's journey toward a globally integrated pharmacovigilance ecosystem.

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