Current Trends in Biotechnology and Pharmacy
Vol. 20 (Supplementary Issue 2A), June 2026, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2026.2s.8

Pharmacovigilance in Community Pharmacy: Evaluating Knowledge, Attitude, and Practice Regarding ADRs in Hyderabad

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Abstract

Adverse drug reactions (ADRs) result in additional illnesses, deaths, and healthcare costs, not to mention the greater public health implications of ADRs. As drug experts, chemists can spearhead the prevention, recognition, and reporting of adverse reactions. As the only healthcare professionals who interact with patients and receive prescriptions, community chemists are best positioned to mitigate the odds of ADRs occurring, though the KAP of chemists certainly pharmacovigilance and reporting ADRs is critical to success in this area. The aim of this research is to evaluate the ADR-related knowledge of community chemists in Hyderabad. A total of 400 chemists from different areas in Hyderabad took part in this cross-sectional survey. A standardized questionnaire that covered demographic and educational information and knowledge, attitudes, and practices concerning ADRs was used to collect data, which was then analyzed both qualitatively and quantitatively. The results indicated that while participants demonstrated ADR and pharmacovigilance knowledge, the engagement in ADR reporting was not integrated into their professional practice. Advanced educational and ADR training disproportionally increased pharmacists' adherence to ADR reporting.

Additionally, these findings indicate the need for ongoing education, improvement of regulations, and consolidated efforts in training aimed at encouraging community pharmacists' participation in community pharmacovigilance. This study's findings will aid regulatory bodies and policymakers in encouraging community pharmacists' participation in ADR reporting aimed at improving ADR surveillance and safeguarding patients' safety.

Keywords: Adverse drug reaction, knowledge, attitude, practice, community pharmacists, pharmacovigilance, Hyderabad.

1. Introduction

Modern healthcare faces considerable challenges when it comes to the pharmacovigilance of newly released medications, as adverse drug reactions and unintended consequences of these medications pose serious public health threats and significant patient morbidity and mortality (1). The severity and cost of health care due to ADRs further increase.

Pharmacovigilance deals with determining and understanding the adverse effects and other drug related issues and encompasses the educational components preventing these issues (2). It remains one of

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the pivotal branches of drug safety and rational drug use. Community pharmacists occupy a distinctive position in the drug use process. For most patients, pharmacists are the initial health-care professional. In Hyderabad, one of the largest metropolitan cities of India, community pharmacists attend to a wide and diverse community with varying health literacy, health awareness, and cultural attributes (3). Their position on the health-care system front line allows pharmacists to continuously gather invaluable real-world evidence on the efficacy and safety of the drugs, thus making them invaluable resources in ADR detection and reporting (4).

Although the contribution of community pharmacists to pharmacovigilance is recognized, reported rates of knowledge deficiencies and suboptimal ADR reporting remain prevalent globally (5, 6). The underreporting of ADRs is a worldwide issue, with estimates suggesting that 94% of ADRs remain unreported (7). The insufficient reporting rates can arise from a lack of time, inadequate training, reporting anxiety, and unclear ADR reporting thresholds (8). These observations necessitate evaluating pharmacists' knowledge, attitude, and practice (KAP) regarding ADR reporting to design targeted, evidence-based ADR reporting initiatives (9, 10).

In India, to improve ADR monitoring and reporting, the country's pharmacovigilance program (PvPI) facilitates the collaboration of various centers with the Central Drugs Standard Control Organization (CDSCO) to coordinate the collection and evaluation of ADR data (11). However, pharmacist involvement, especially in community practice, has been limited (12). Evaluating community chemists' confidence in implementing pharmacovigilance is essential as chemists take on a more pivotal role in the delivery of healthcare services.

In the past, the Indian education system has started integrating pharmacovigilance-related content into pharmacy curriculum (13). Nevertheless, the absence of standardized national requirements has led to inconsistent implementation of CPD programs and practical training regarding the ADR reporting system, which is crucial for developing the required competence and practical skills.

Local organizations and authorities are quite instrumental in filling these gaps (14). For instance, the Pharmacy Council of India (PCI) and the state pharmacy councils could train and equip pharmacists' skills in the identification and reporting of ADRs through implementation of training programs and/or certification courses (15).

This research seeks to complete the assessment of the KAP of community pharmacists in ADR detection, reporting, and management in Hyderabad, India. With the use of qualitative and quantitative data, the research intends to elucidate the key drivers and barriers to community pharmacists' involvement in pharmacovigilance. This work will enable stakeholders to enact the requisite policy changes regarding ADR reporting and management systems, thereby enhancing the safety of patients. Integrating the practical knowledge with the real-life reporting will allow community pharmacists to better fulfill their role in the service of the public. This research, which provides evidence and practical suggestions focused on improving pharmacist-initiated pharmacovigilance in Hyderabad and similar regions, aims to achieve this objective.

Methodology

Study Design

To evaluate the community pharmacists' KAP regarding ADRs in Hyderabad, the author used a cross-sectional survey design method. Cross-sectional designs are best suited for determining the prevalence of specific behaviors and attitudes at a point in time using a validated questionnaire (16). This method enabled broad coverage of pharmacists and allowed for statistical comparison across various demographic and professional groups. For a pilot study of the questionnaire, twenty chemists that did not form part of the study sample took part. Based on their feedback, a

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few minor adjustments were made to improve the clarity of some passages.

Inclusion and Exclusion criteria

The population consisted of community pharmacists practicing in retail settings (independent pharmacies, pharmacy chains, and hospital-associated community pharmacies).Pharmacists who practiced only in hospital inpatient departments or in pharmaceutical industry sectors were excluded to study exclusively community-based practice.

Ethical considerations

Before answering the questionnaire, the online survey form was described, informed consent was given in a clear and concise manner, and they were instructed to move on to the next phase after giving their consent.

Ethical clearance was secured from the Institutional Review Board (IRB), vide IRB number SUCP/IRB/2024/002. Every participant provided their consent after being fully told about the study's goals, methods, risks, and rewards. By anonymising the data and limiting access to the primary investigators, confidentiality was rigorously upheld.

Study Setting

Hyderabad, the capital of Telangana, India, served as the study's site. Its cosmopolitan populace and expanding pharmaceutical industry, Hyderabad provides a suitable location for the investigation of community-based pharmacy practice.

Study Tool

A list of Hyderabad registered community pharmacies was collected from local pharmacy councils and associations (17). By using a systematic random sampling approach, each nth pharmacy was selected from the list to provide geographical and demographic representation. When the chosen pharmacy refused to participate or was unavailable, the subsequent entry on the list was selected.

Data were gathered with the help of a structured questionnaire, prepared in English, as most Hyderabad community pharmacists are English proficient because of the demands of their professional training. There were four main sections to the questionnaire:

1. Demographic and Professional Profile: Age, gender, educational qualification, years of experience, nature of pharmacy, and average prescription load per day.
2. Knowledge Assessment: Multiple-choice items (MCQs) on definitions, ADR classification, reporting methods, and familiarity with national pharmacovigilance programs.
3. Attitude Assessment: Likert-scale questions assessing perceptions regarding the significance of ADR reporting, barriers to reporting, and beliefs regarding outcomes of reporting.
4. Practice Assessment: Items on actual reporting practices, rate reported, particular examples of ADR detection, and reasons for not reporting.
Cronbach's alpha for attitude and practice scales were 0.78 and 0.80, respectively, which was an acceptable level of internal consistency (18).

Sample Size

A sample of 400 pharmacists was calculated using the Cochran formula for cross-sectional studies (19). Using a 5% margin of error, a 95% confidence range, and an estimated.50% prevalence of adequate ADR-related knowledge, this sample size was determined. Additionally, a 10% buffer was included to account for incomplete or non-response surveys.

Data Analysis

The completed questionnaires were coded and entered using Version 26 of the Statistical Package for the Social Sciences (SPSS). For the KAP variables alongside the demographic information, descriptive statistics (frequency, percentage, mean, and standard deviation) were implemented. Each right answer earned one point in the

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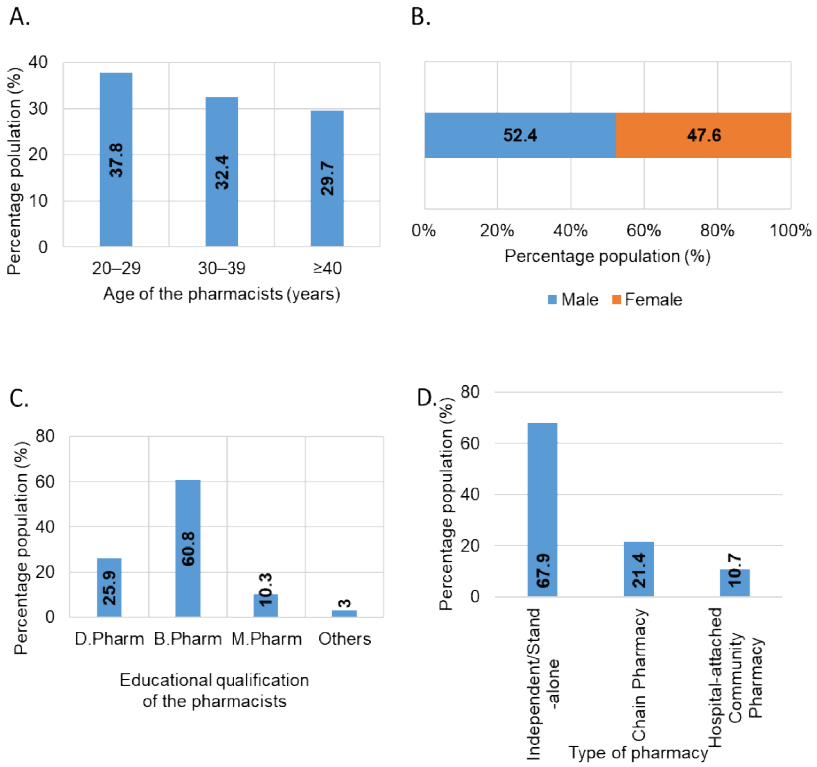

Fig. 1: Demographic Characteristics of Participating Pharmacists in Relation to Adverse Drug Reaction (ADR) Reporting Compliance in Hyderabad. This Figure presents the demographic distribution of pharmacists participating in a study assessing ADR reporting compliance in Hyderabad

knowledge assessment, with a maximum score of 15.

Attitude and practice assessments were also scored on Likert scales with higher scores representing more positive attitudes and stronger practices, respectively.

Inferential statistical methods were utilized to evaluate hypotheses regarding possible differences and associations among groups. One-way ANOVAs and independent-samples t-tests were applied to explore demographic characteristics (years of experience, educational level, etc.) as they relate to knowledge, attitude, or practice scores. Pearson correlation coefficients were used to compute linear relationships among practice, attitude, and knowledge scores. After controlling for potential confounding variables including age and years of experience, multiple regression tests were also performed to identify the most significant predictors of practice scores.

3. Results

Demographic and Professional Characteristics

400 community pharmacists took part in the study. 370 of these were considered complete and valid responses, giving an effective response rate of 92.5% (30 pharmacist responses were excluded due to incomplete, inconsistent, or improperly filled questionnaires, which did not meet the criteria for valid statistical analysis). The respondents' mean age was 33.7 years (SD = 8.4), and the mean years of professional experience was 8.2 years (SD = 5.6) (Fig. 1A). A majority were male (52.4%),

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with the other 47.6% being female as shown in (Fig. 1B). As for educational qualifications, 60.8% possessed a Bachelor of Pharmacy (B.Pharm), 25.9% possessed a Diploma in Pharmacy (D.Pharm), 10.3% possessed a Master of Pharmacy (M.Pharm), and the rest had other or specialized qualifications (Fig. 1C).

Figure 1D shows that most of the respondents (67.9%) were employed in independent or solo pharmacies, 21.4% in chain pharmacies, and 10.7% in hospital-attached community pharmacies. The daily prescription volume varied from 20 to more than 200, with a mean of 98 prescriptions per day (SD = 37).

Knowledge Assessment of ADRs among Community Pharmacists

The scores for knowledge varied between 4 and 15 (out of a maximum of 15), with a mean score of 10.6 (SD = 2.4) and are illustrated in (Fig. 2). Most respondents demonstrated understanding of the fundamental definition of ADRs, with 80.5% correctly identifying the WHO's definition. Yet, fewer than half (45.1%) knew the difference between Type A and Type B ADRs. Awareness of national ADR reporting systems, including the Pharmacovigilance Program of India (PvPI), was fairly high (68.4%), but procedural knowledge in detail (i.e., how to complete and submit ADR forms) was relatively low (39.2%). Additionally, 48.6% were knowledgeable about the procedures for submitting an ADR report. These results highlight gaps in specific areas of pharmacovigilance knowledge, suggesting a need for targeted educational interventions to improve ADR reporting practices among community pharmacists.

Attitude toward ADR Reporting and Pharmacovigilance

Attitudes toward adverse drug reaction (ADR) reporting were evaluated using 10 statements on a Likert scale, scored from 1 (strongly disagree) to 5 (strongly agree). The total attitude scores ranged between 18 and 48 out of a possible 50, with a mean score of 38.2 (SD = 5.6), reflecting an overall positive outlook on ADR reporting among the participants. A large majority (85.1%) acknowledged adverse drug reaction reporting as a professional responsibility of pharmacists, while 78.9% expressed the view that it should be mandatory for all pharmacists (Fig. 3). Additionally, 82.4% reported a greater likelihood of participation if feedback was provided by authorities, and 76.2% indicated they would report more frequently if the process were digital and streamlined (Fig. 3).

The sentiments of community chemists pertaining to various aspects of

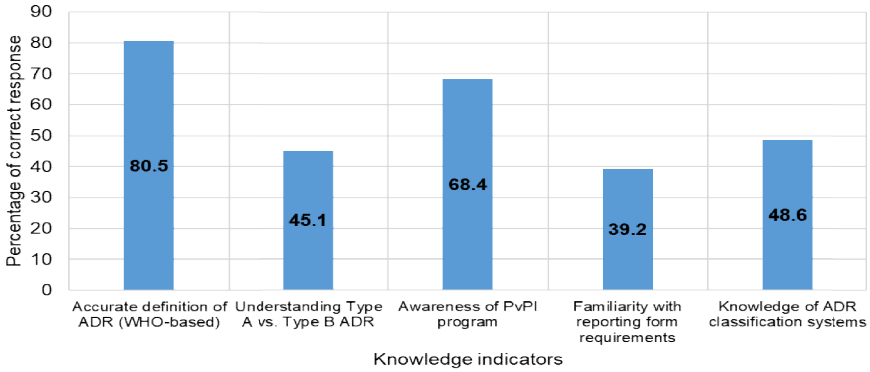

Fig. 2: Knowledge Indicators Related to Pharmacovigilance Among Community Pharmacists. This bar chart illustrates the percentage of community pharmacists who demonstrated awareness of various key pharmacovigilance concepts

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pharmacovigilance and the reporting of adverse drug reactions (ADRs) are illustrated in this figure.The percentage of respondents that indicated agreement, neutrality, or disagreement with particular attitude statements is shown by each bar. The indicators assessed include beliefs about the importance of ADR reporting, willingness to report ADRs, perceived barriers such as fear of legal consequences, confidence in reporting procedures, and the perceived role of pharmacists in ensuring medication safety.

Regarding perceived benefits, 70.8% agreed that ADR reporting improves patient safety and outcomes, while 63.5% expressed confidence in their ability to identify and report ADRs (Fig. 3). Nevertheless, several barriers were highlighted. Over half of the participants (52.4%) cited a lack of time as a limiting factor for reporting, and 41.9% agreed that current reporting procedures are too cumbersome (Fig. 3). A notable 40.8% expressed doubts about the impact of their reports on meaningful change. Legal concerns were also evident, with 22.7% fearing potential legal repercussions associated with ADR reporting, although a larger portion (45.7%) disagreed with this concern (Fig. 3). These findings suggest that while pharmacists generally hold positive attitudes toward ADR reporting and recognize its importance, systemic and procedural barriers may inhibit consistent practice.

Practice of ADR Reporting

According to the practice survey, just 31.8% of participants had ever reportedan ADR to official channels, and only 9.7%

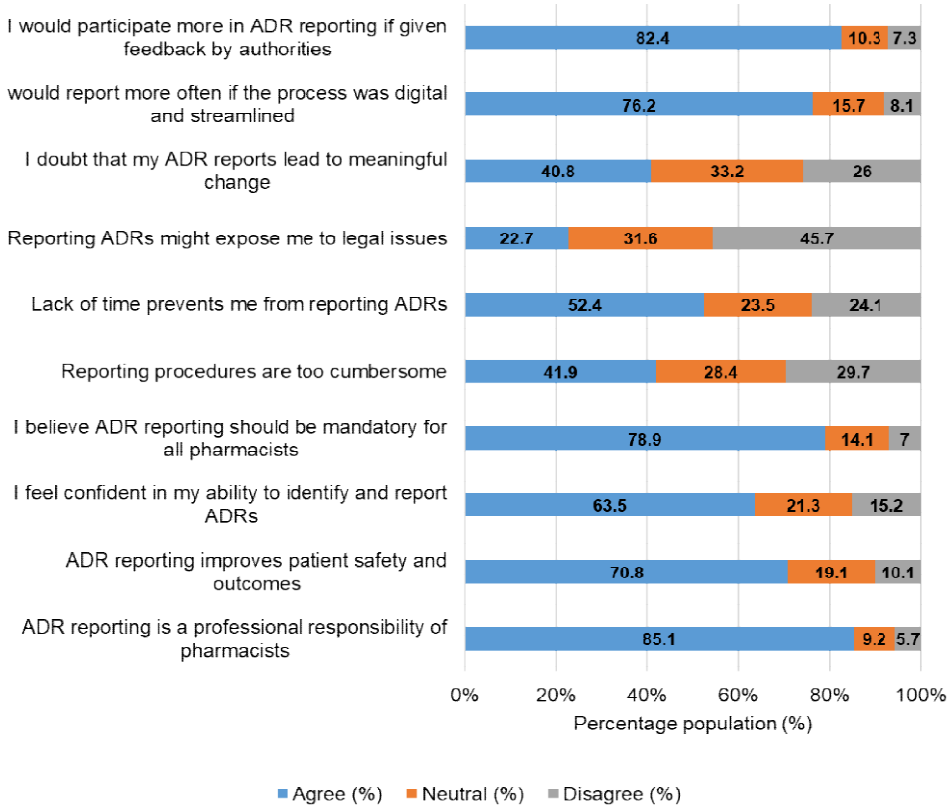

Fig. 3: Attitude Indicators Toward Pharmacovigilance Among Community Pharmacists

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claimed to do so on a regular basis (at least once in every three months) (Fig. 4A). Of those who had reported, manual submission of ADR reporting forms was the most frequently used mode (46.5%), followed by telephone hotlines (28.1%) and email/online platforms (25.4%) (Fig. 4B). The primary reasons to non-reporting of ADRs was frequently attributed to uncertainty about what constitutes a reportable ADR (36.5%), fear of legal repercussions (22.7%), and insufficient perceived feedback by regulatory agencies (40.8%) (Fig. 4C).

Factors Influencing ADR Reporting Behaviour

Multiple logistic regressions were used to determine predictors of frequency of ADR reporting (at least once in three months). These included demographics (age, gender), professional (years of experience, educational qualification, type of pharmacy, number of prescriptions filled daily), and KAP scores. The model depicts a greater knowledge score ($p = 0.019$), attitude scores ($p < 0.001$) and practice scores ($p = 0.001$), suggesting that KAP are strong positive predictors of ADR (Table 1).

Pearson correlation tests revealed a weak but significant positive correlation between knowledge and attitude ($r = 0.07$, $p < 0.001$), attitude and practice ($r = 0.21$, $p < 0.001$), and knowledge and practice ($r = 0.12$, $p < 0.001$) (Fig. 5). These results indicate that enhanced knowledge regarding ADRs will tend to generate more positive attitudes, which can lead to active reporting practices.

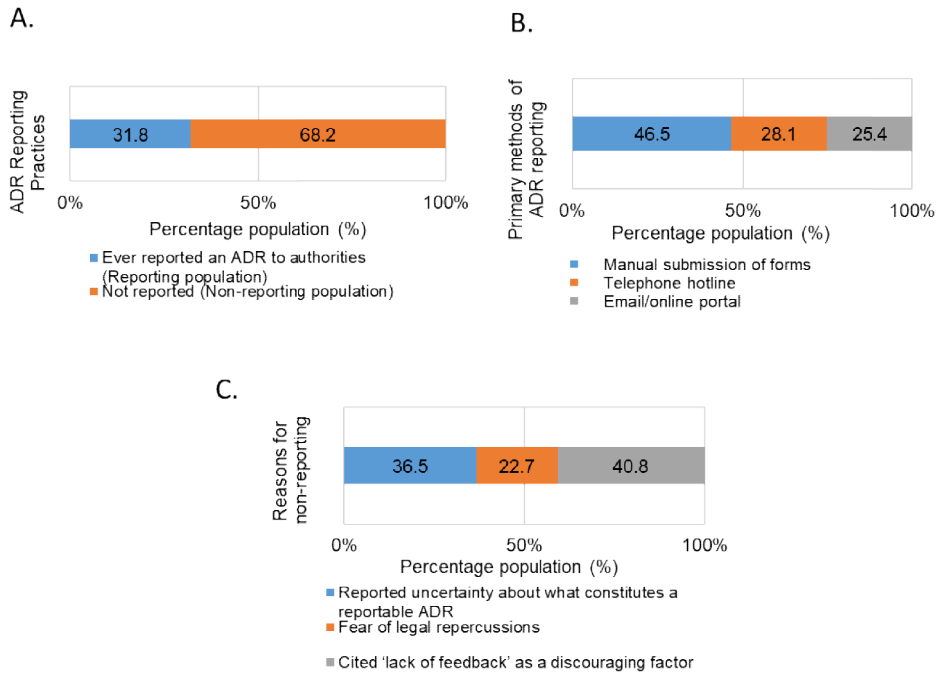

Fig. 4: Practice Indicators of Pharmacovigilance among Community Pharmacists. This Figure presents data on the pharmacovigilance practices of ADR in community pharmacists, (A) whether they have ever reported an ADR (n = 370), (B) mode of ADR reporting amongst the reporting population (n = 118), and (C) reasons for non-reporting amongst the non-reporting population (n = 252)

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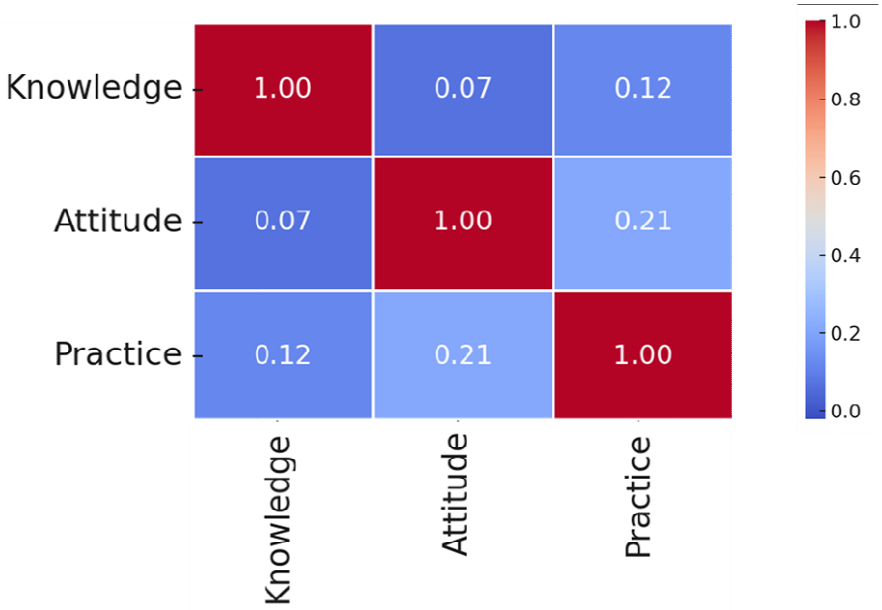

Fig. 5: Pearson's correlation heat map depicting the interrelationship of the Knowledge, Attitude and Practice (KAP) components pertaining to pharmacovigilance among practitioners. The heat map shows the correlation coefficient (r) of each KAP domain with each other. High and perfect correlations positive and negative correlations are described as equal to 1 and -1 respectively, and correlations equal to 0 indicate no correlation. Correlations will always fall on a continuum -1 and +1. The first diagonal of the matrix (value = 1.00) indicates self-correlation as any variable will correlate with itself. The map indicates the KAP dimensions on the behaviours of pharmacovigilance are largely separate. Knowledge and Practice (r = 0.12), Attitude and Practice (r = 0.21) and Knowledge and Attitude (r = 0.07) suggest a marginal degree of association

Table 1: Multiple regression analysis amongst the KAP factors (N = 370)

Variable	Coefficient (β)	p-value	Interpretation
Knowledge	0.0188	0.019	Statistically significant positive effect
Attitude	0.0123	<0.001	Strong positive predictor
Practice	0.0111	0.001	Strong positive predictor
Knowledge, Attitude, and Practice are statistically significant predictors of ADR reporting practices.			
Statistical Correlations amongst the KAP factors			

4. Discussion

This study offers a valuable insight into the current state of KAP factors with respect to ADR reporting among community pharmacists in Hyderabad, India. With an effective response rate of 92.5%, the findings suggest a growing interest and awareness of pharmacovigilance among pharmacists. However, the results also reveal significant gaps between theoretical knowledge and practical application.

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The knowledge assessment revealed a moderately high mean score (10.6 out of 15), suggesting that most pharmacists are familiar with the basic concepts of ADRs and pharmacovigilance. However, procedural understanding, particularly concerning reporting mechanisms and distinguishing between ADR types, was suboptimal. These findings are consistent with earlier literature indicating that there remains a knowledge gap with respect to lack of confidence and clarity in the operational aspects of ADR reporting despite a good theoretical knowledge base of the pharmacists (20, 7).

Attitudes toward pharmacovigilance were generally positive, with over 85% of respondents agreeing that ADR reporting is a professional responsibility, persistent with earlier published studies (5). Most pharmacists also expressed willingness to report if the process was more user-friendly or if meaningful feedback was provided by authorities. Nevertheless, common barriers such as lack of time, cumbersome reporting protocols, and fear of legal consequences, persist and align with global trends in ADR underreporting (21, 22).

When it comes to actual practice, only 31.8% of pharmacists had ever reported an ADR, and just 9.7% did so regularly. These figures confirm a critical disconnect between positive attitude and practical engagement and are in accord with earlier published reports (10). Reasons cited for low reporting rates included uncertainty about what constitutes a reportable ADR and limited regulatory feedback, both of which can be addressed through targeted interventions.

Statistical analysis further supports the interdependence of KAP dimensions. Positive correlations between knowledge, attitude, and practice indicate that improvements in any one domain could positively influence the others. Additionally, individuals in clinical pharmacy roles were more likely to report ADR, indicating that postgraduate degree attainment, participation in interdisciplinary enhancement, and pharmacy practice integration into healthcare systems are pivotal in fostering positive pharmacovigilance outcomes.

The situation calls for systemic responses. Seamless integration of active pharmacovigilance into practice, curriculum development, simplified digital reporting frameworks, and regulatory feedback mechanisms will enhance pharmacist participation. The provision of digital feedback will ensure that pharmacists receive progressive reporting and evaluative outcomes to their ADR submissions. The provision of differential regulatory incentives, and CPD activities addressing procedural competencies will involve pharmacists deeply in ADR reporting. This study, though regionally robust, has its limitations. The cross-sectional design allows no causal inferences to be drawn, and self-reported data are likely to contain bias. In addition, the findings are regionally situated in Hyderabad, thereby limiting their applicability to other areas with different healthcare frameworks.

5. Conclusion

This research highlights the important role that community pharmacists in Hyderabad can play in reporting adverse drug reactions (ADRs) and engaging in other pharmacovigilance activities—however, this role is still underused. While the respondents had a moderately positive understanding of the concept and had a mostly positive attitude towards reporting ADRs, the actual reporting was still very limited. Procedural uncertainties, time constraints, and a lack of regulatory feedback were key barriers that hinder pharmacists from translating their knowledge and intent into consistent reporting behaviour. Notably, pharmacists with higher educational qualifications and those working in hospital-attached community pharmacies were more likely to engage in ADR reporting, highlighting the influence of advanced training and institutional exposure. To bridge the gap between knowledge and practice, there is an urgent need for systemic interventions. These include integrating practical pharmacovigilance training into academic and professional curricula, simplifying digital reporting tools, introducing policy-level incentives or mandates, and ensuring

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timely feedback from regulatory bodies. Strengthening interprofessional collaboration can further enhance ADR detection and management. By addressing these challenges, community pharmacists can be empowered to contribute meaningfully to drug safety surveillance and patient care, ultimately strengthening the pharmacovigilance framework in India.

Acknowledgement

Dr. Naresh Patnaik is acknowledged for his endless support in drafting and proof-reading the research article.

Conflicts of Interest

The authors declare no conflicts of interest.

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