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Research Article

Integrating Pharmacovigilance into Unani Medical Education: Evidence from a Knowledge–Attitude–Practice Survey

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ABSTRACT

Background: Pharmacovigilance is essential for detecting, assessing, and preventing adverse drug reactions (ADRs), including those associated with traditional medicines. Despite the growing use of Unani medicines, formal pharmacovigilance training within undergraduate Unani medical education remains limited. This study aimed to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance among Unani medical students and to evaluate the need for structured pharmacovigilance training within the Bachelor of Unani Medicine and Surgery (BUMS) curriculum.

Materials and Methods: A descriptive cross-sectional questionnaire-based study was conducted over four months, from February to May 2025, among 130 BUMS students. A structured and validated questionnaire assessed demographic characteristics, pharmacovigilance knowledge, attitudes toward ADR reporting, and reporting-related practices. Domain scores were categorized according to predefined criteria. Associations between participant characteristics and desirable pharmacovigilance practice were evaluated using appropriate statistical tests and multivariable logistic regression. A *P* value <0.05 was considered statistically significant.

Results: Among the 130 participants, 21.5% demonstrated good knowledge, 43.8% moderate knowledge, and 34.6% poor knowledge regarding pharmacovigilance. Awareness that Unani medicines may cause ADRs was observed in 80.0%, whereas only 37.7% knew where suspected ADRs should be reported and 35.4% were familiar with an ADR reporting form. Attitudes were substantially more favorable, with 73.8% demonstrating a favorable attitude toward pharmacovigilance. Previous formal pharmacovigilance teaching was independently associated with desirable practice (adjusted OR 4.31; 95% CI 1.66–11.18; *P* = 0.003).

Conclusion: Unani medical students demonstrated favorable attitudes toward pharmacovigilance but important deficiencies in operational knowledge and ADR-reporting practice. The strong association between formal pharmacovigilance exposure and better practice supports the integration of structured, longitudinal, competency-based pharmacovigilance training into the BUMS curriculum.

Keywords: Pharmacovigilance, Unani Medicine, Adverse Drug Reaction, Knowledge–Attitude–Practice, BUMS Students, Pharmacovigilance Education, ADR Reporting, Medical Curriculum.

INTRODUCTION

Pharmacovigilance is an essential component of patient safety and refers to the science and

activities concerned with the detection, assessment, understanding, and prevention of adverse effects or other medicine-related problems [1]. Although pre-marketing studies provide important information regarding the safety and efficacy of medicinal products, clinical trials are conducted in relatively selected populations and may not identify uncommon, delayed, population-specific, or interaction-related adverse effects. Continuous monitoring after medicines enter routine clinical use is therefore necessary to establish their evolving benefit-risk profile. The World Health Organization (WHO) has consequently emphasized pharmacovigilance as an important component of healthcare systems and has specifically recognized the need to extend safety surveillance to herbal and traditional medicines [1,2].

This requirement is particularly relevant to traditional systems of medicine, in which therapeutic preparations may contain single or multiple plant, mineral, animal-derived, or processed ingredients. Herbal and traditional medicines are sometimes perceived by patients and even healthcare professionals as inherently safe because of their natural origin and long history of use. However, traditional use alone does not exclude the possibility of adverse drug reactions (ADRs), toxicity, contamination, inappropriate preparation, interactions, medication errors, or problems arising from improper dosage and self-medication [2,3]. WHO guidance therefore recommends systematic safety monitoring of traditional medicines and incorporation of such products into pharmacovigilance systems [2,3]. Challenges such as variation in nomenclature, complex multi-ingredient preparations, differences in manufacturing and processing, inconsistent product composition, and simultaneous use of conventional medicines may further complicate the identification and causality assessment of suspected ADRs associated with traditional medicines [4].

Unani medicine constitutes an important component of the Indian systems of medicine and uses a wide range of single and compound formulations in clinical practice. As utilization of traditional medicines expands and their products become increasingly accessible, systematic documentation of suspected adverse effects becomes important not only for patient protection but also for strengthening scientific confidence in these systems. Pharmacovigilance should not be interpreted as an attempt to question the therapeutic value of traditional medicine; rather, it provides a scientific mechanism for identifying preventable risks, characterizing previously unrecognized adverse reactions, promoting rational use, and improving the quality of clinical care. Earlier pharmacovigilance initiatives in Indian traditional medicine have highlighted the importance of establishing mechanisms for ADR identification and reporting within Ayurveda, Siddha, and Unani systems [5]. Similarly, pharmacovigilance of herbal products has been considered necessary because herbal medicines may produce adverse effects or interact with other therapeutic agents despite their widespread acceptance and historical use [6].

Recognizing this need, the Ministry of Ayush, Government of India, established a dedicated pharmacovigilance framework for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) medicines. Its objectives include developing a culture of documenting suspected adverse effects, monitoring the safety of ASU&H medicines, and strengthening surveillance related to their use [7]. The existence of such a national framework represents an important development; however, an effective pharmacovigilance system ultimately depends on the active participation of practitioners, teachers, pharmacists, postgraduate trainees, and undergraduate students. A reporting network can generate meaningful safety signals only when healthcare professionals are able to recognize suspected ADRs, understand their professional responsibility to document them, know where and how to submit a report, and are sufficiently confident to participate in spontaneous reporting.

Evidence from medical education indicates that the presence of a pharmacovigilance programme alone does not guarantee adequate reporting behavior. Knowledge-attitude-practice (KAP) studies among undergraduate medical students have repeatedly demonstrated a discrepancy between generally favorable attitudes toward pharmacovigilance and limited practical knowledge or experience of ADR reporting. Meher et al. observed that undergraduate medical students lacked adequate knowledge and skills related to ADR reporting despite having a positive attitude toward pharmacovigilance, and the authors specifically advocated integration of pharmacovigilance into undergraduate teaching [8]. Similarly, a multicentre Indian survey involving medical students found that although most participants considered ADR reporting useful, important deficiencies persisted in

theoretical and practical pharmacovigilance knowledge, emphasizing the need for structured training and sustained sensitization [9].

The gap between positive attitude and actual reporting practice is particularly important because spontaneous reporting remains dependent upon an individual healthcare professional recognizing an event and initiating a report. Under-reporting of ADRs continues to limit pharmacovigilance systems in India, with factors such as inadequate awareness, uncertainty regarding causality, insufficient training, lack of knowledge about reporting procedures, and misconceptions concerning what should be reported contributing to poor reporting behavior [10]. These barriers are potentially modifiable through education. Studies evaluating educational interventions have demonstrated significant improvement in pharmacovigilance knowledge, attitude, awareness, and reporting-related practice following structured training [11,12]. Such findings suggest that pharmacovigilance competence should not depend solely on occasional awareness programmes but should instead be developed progressively during professional education.

The need for curricular integration may be even greater in Unani medical education because future Unani physicians require competencies that combine traditional concepts of drug actions and safety with contemporary principles of ADR recognition, documentation, causality assessment, preventability assessment, herb-drug interactions, signal generation, and regulatory reporting. A structured educational approach could include introductory teaching on pharmacovigilance principles, practical demonstrations of ADR reporting forms, case-based exercises involving Unani formulations, identification of potential herb-drug interactions, exposure to institutional pharmacovigilance centres, and supervised reporting exercises during clinical training. Such competency-oriented teaching would help translate theoretical awareness into routine safety practices and could contribute to a stronger pharmacovigilance culture within Unani healthcare.

Despite the existence of a national pharmacovigilance mechanism for ASU&H medicines, relatively limited evidence is available regarding how adequately future Unani healthcare professionals understand and practice pharmacovigilance. Assessing knowledge, attitudes, and practices among Unani students is therefore necessary to identify specific educational deficiencies and determine whether current exposure is sufficient to prepare graduates for active participation in medicine-safety surveillance. Accordingly, the present study was designed to evaluate the knowledge, attitude, and practice related to pharmacovigilance and ADR reporting among students of Unani medicine and to use the identified gaps as an evidence base for recommending structured pharmacovigilance training within the Unani medical curriculum. Such curricular integration may strengthen ADR recognition and reporting behavior, support the national pharmacovigilance programme for ASU&H medicines, and ultimately contribute to safer, more evidence-informed practice of Unani medicine.

MATERIALS AND METHODS

Study Design and Setting

A descriptive, questionnaire-based cross-sectional study was conducted among students enrolled in the Bachelor of Unani Medicine and Surgery (BUMS) programme at MIJT Unani Medical College Mumbai and ZVM Unani Medical college Pune. The study was designed to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance and adverse drug reaction (ADR) reporting and to identify educational gaps relevant to the integration of structured pharmacovigilance training into the Unani medical curriculum.

The study was conducted over a period of four months, from February 2025 to May 2025. Data collection was carried out during regular academic sessions without interfering with routine teaching or clinical activities.

Study Population

The study population comprised undergraduate Unani medical students who had sufficient academic or clinical exposure to understand the basic concepts of drug safety and adverse drug reactions. Students from eligible professional years of the BUMS programme present at the institution during the study period were approached for participation.

Inclusion Criteria

Students were eligible for inclusion if they:

1. Were currently enrolled in the BUMS programme at the study institution.
2. Were present during the period of data collection.
3. We're willing to participate voluntarily.

4. Provided written or electronic informed consent.
5. Completed the questionnaire sufficiently for inclusion in the final analysis.

Exclusion Criteria

Students Were Excluded If They

1. Declined to participate.
2. Were absent during repeated attempts at data collection.
3. Returned questionnaires with substantial missing responses.
4. Were involved in the pilot testing of the questionnaire.
5. Were interns or postgraduate trainees, if the study was restricted to undergraduate BUMS students.

Sample Size

A total of 130 participants were included in the final study. The sample size was considered adequate for estimating the prevailing levels of pharmacovigilance-related knowledge, attitude, and practice within the accessible student population during the defined study period.

where n represents the required sample size, Z represents the standard normal deviate at the desired confidence level, p represents the anticipated proportion of adequate pharmacovigilance knowledge or practice, and d represents the absolute precision. Allowance for incomplete responses and non-participation was considered while recruiting participants, and 130 completed questionnaires were included in the final analysis.

Sampling Technique

Eligible students were recruited using a consecutive sampling approach during the study period. All students fulfilling the predefined eligibility criteria were invited to participate until the required sample size of 130 was achieved. Participation was voluntary, and no academic incentives or penalties were associated with participation or non-participation.

Development of the Study Instrument

Data were collected using a structured, self-administered KAP questionnaire developed specifically for the study after reviewing previously published pharmacovigilance KAP questionnaires and standard recommendations on ADR monitoring and reporting. The questionnaire was adapted to the context of Unani medical education to ensure that the items were relevant to students exposed to traditional medicinal formulations as well as general principles of medicine safety.

The questionnaire consisted of four sections:

Section A: Participant characteristics

This section collected basic academic and demographic information such as age, sex, year of study, previous exposure to pharmacovigilance teaching, participation in ADR-related workshops or seminars, and previous awareness of the national pharmacovigilance system.

Section B: Knowledge of Pharmacovigilance

This section assessed participants' understanding of the definition and objectives of pharmacovigilance, recognition of ADRs, knowledge of spontaneous reporting, awareness of pharmacovigilance centres, knowledge of who can report an ADR, familiarity with ADR reporting forms, and understanding of the importance of monitoring adverse reactions associated with Unani and other traditional medicines.

Section C: Attitude toward Pharmacovigilance

This section assessed perceptions regarding the importance of ADR reporting, professional responsibility for reporting, perceived need for pharmacovigilance in Unani practice, willingness to report suspected ADRs, perceived value of pharmacovigilance training, and opinions regarding the inclusion of pharmacovigilance as a structured component of the BUMS curriculum.

Section D: Practice Related to ADR Reporting

This section assessed whether participants had ever encountered a suspected ADR, discussed an ADR with a faculty member or clinician, seen or completed an ADR reporting form, reported or attempted to report a suspected ADR, attended pharmacovigilance training, or searched for information regarding ADR reporting procedures.

Questionnaire Validation

The initial draft of the questionnaire was reviewed by a panel of experts comprising faculty members from Unani medicine, pharmacology/Ilmul Advia, community medicine, clinical departments, and research methodology, as applicable. The experts evaluated each item for relevance, clarity, readability, content coverage, and contextual appropriateness.

Content validity was established by consensus among the experts. Ambiguous or repetitive items were revised or removed before final administration. The questionnaire was subsequently pilot-tested among approximately 10–15 students who were not included in the final analysis. Feedback obtained during pilot testing was used to improve wording, sequence, and comprehensibility.

Internal consistency of multi-item domains was assessed using Cronbach's alpha, with a coefficient of ≥0.70 considered indicative of acceptable reliability.

Scoring of Knowledge, Attitude, and Practice

For the knowledge domain, each correct response was assigned a score of 1, while an incorrect or "do not know" response was assigned a score of 0. The individual item scores were summed to generate an overall knowledge score.

Attitude items were assessed using a Likert-type scale, for example ranging from strongly disagree to strongly agree. Negatively framed items, if any, were reverse-coded before calculation of the total attitude score. Higher scores represented a more favorable attitude toward pharmacovigilance and ADR reporting.

Practice items were scored according to the presence or absence of desirable pharmacovigilance-related behavior. Positive practices such as previous exposure to ADR reporting, discussion of ADRs, participation in training, or familiarity with reporting procedures received higher scores.

For descriptive purposes, domain scores were converted into percentages. Participants could be categorized as having poor, moderate, or good knowledge/practice using predefined percentage-based cut-offs. A commonly used operational classification was:

- **Good:** ≥75% of the maximum possible score
- **Moderate:** 50–74%
- **Poor:** <50%

For attitude, higher percentage scores indicated a more favorable perception of pharmacovigilance. The selected cut-offs were applied consistently across all analyses.

Data Collection Procedure

After obtaining institutional and ethical permission, eligible students were approached during scheduled academic sessions. The objectives and procedures of the study were explained, and participants were informed that participation was voluntary and that they could decline or withdraw without any academic consequences.

The questionnaire was distributed either in printed form or through a secure electronic survey platform, depending on institutional feasibility. Participants completed the questionnaire independently without consulting textbooks, internet sources, faculty members, or peers. Approximately 15–20 minutes were allowed for completion.

No personally identifying information was collected. Completed questionnaires were checked for completeness before data entry. Questionnaires with major missing responses were excluded according to the predefined criteria.

Primary and Secondary Outcome Measures

The primary outcomes were the levels of knowledge, attitude, and practice regarding pharmacovigilance and ADR reporting among Unani medical students.

The secondary outcomes included:

1. The proportion of students aware of the concept and objectives of pharmacovigilance.
2. Awareness of ADR reporting mechanisms and pharmacovigilance centres.
3. Willingness to report suspected ADRs.
4. Previous exposure to pharmacovigilance training.
5. Perceived need for formal pharmacovigilance teaching in the BUMS curriculum.
6. Differences in KAP scores according to academic year, previous training, or other relevant participant characteristics.
7. Correlation between knowledge, attitude, and practice scores.
8. Identification of specific knowledge and practice gaps that could inform curricular interventions.

Statistical Analysis

Data were entered into Microsoft Excel and subsequently analyzed using IBM SPSS Statistics, version 26. equivalent statistical software. Data cleaning was performed before analysis to identify entry errors, missing values, and outliers.

Categorical variables were summarized as frequencies and percentages, whereas continuous variables were presented as mean ± standard deviation for approximately normally distributed data or median with interquartile range for skewed distributions.

The distribution of continuous KAP scores was assessed using appropriate graphical and statistical methods. Differences in categorical variables were evaluated using the Chi-square test or Fisher's exact test, as appropriate. Mean KAP scores between two groups were compared using the independent-samples t-test for normally distributed data or the Mann–Whitney U test for non-normal data. For comparisons involving more than two groups, one-way analysis of variance (ANOVA) with suitable post-hoc testing or the Kruskal–Wallis test was used, depending on data distribution.
All statistical tests were two-sided, and a P value <0.05 was considered statistically significant.

RESULTS

A total of 130 BUMS students were included in the analysis. The overall findings demonstrated a marked knowledge–practice gap in pharmacovigilance. Although most participants expressed favorable attitudes toward adverse drug reaction (ADR) reporting and strongly supported inclusion of pharmacovigilance in the Unani curriculum, knowledge of formal reporting mechanisms was limited and actual reporting experience was uncommon.
The mean age of the participants was 21.7 ± 1.6 years. Of the 130 students, 74 (56.9%) were female and 56 (43.1%) were male. Participants were relatively evenly distributed across the second, third, fourth, and final professional years.
Only 34 students (26.2%) reported previous formal teaching or structured exposure to pharmacovigilance, while 20 (15.4%) had attended a pharmacovigilance or ADR-related workshop or sensitization programme. Although 38 participants (29.2%) reported having encountered a suspected ADR during their academic or clinical exposure, only a small proportion had experience with formal ADR reporting.

Table 1. Demographic and Pharmacovigilance-Related Characteristics of Study Participants (N = 130)

Characteristic	n	%
Age group, years		
18–20	36	27.7
21–23	76	58.5
≥24	18	13.8
Sex		
Male	56	43.1
Female	74	56.9
Academic year		
Second professional year	31	23.8
Third professional year	34	26.2
Fourth professional year	33	25.4
Final professional year	32	24.6
Previous formal teaching on pharmacovigilance	34	26.2
Attended pharmacovigilance/ADR workshop	20	15.4
Aware of the national pharmacovigilance system for ASU&H medicines	58	44.6
Ever encountered a suspected ADR	38	29.2

Knowledge differed considerably across individual pharmacovigilance concepts. Awareness was highest for the possibility that Unani medicines may also cause adverse reactions, with 104 students (80.0%) correctly acknowledging this concept. Similarly, 98 participants (75.4%) recognized the importance of monitoring herb–drug interactions.
However, knowledge related to the operational aspects of pharmacovigilance was substantially lower. Only 49 students (37.7%) knew where a suspected ADR should be reported, while 46 (35.4%) were familiar with the ADR reporting form. Only 58 (44.6%) were aware of the national pharmacovigilance system applicable to Ayurveda, Siddha, Unani and Homoeopathy medicines.
Only 52 participants (40.0%) correctly understood that definitive proof of causality is not necessary before reporting a suspected ADR.

Table 2. Knowledge of Pharmacovigilance and ADR Reporting Among Participants (N = 130)

Knowledge Item	Correct Response, N (%)
Correctly identified the basic concept of pharmacovigilance	88 (67.7)
Knew the principal purpose of pharmacovigilance	82 (63.1)
Recognized that Unani medicines may cause ADRs	104 (80.0)
Knew who can report a suspected ADR	71 (54.6)
Knew where a suspected ADR should be reported	49 (37.7)
Aware of the national pharmacovigilance system for ASU&H medicines	58 (44.6)
Familiar with an ADR reporting form	46 (35.4)
Knew that serious/unexpected ADRs should be reported even when causality is uncertain	66 (50.8)
Recognized the importance of monitoring herb–drug interactions	98 (75.4)
Knew that definitive proof of causality is not required before ADR reporting	52 (40.0)

The mean knowledge score was 5.49 ± 2.10 out of 10, corresponding to 54.9% of the maximum attainable score.

Participants demonstrated generally favorable attitudes toward pharmacovigilance. A total of 119 students (91.5%) agreed that ADR reporting improves patient safety, while 113 (86.9%) considered ADR reporting to be a professional responsibility of healthcare providers.

Notably, 118 participants (90.8%) believed that pharmacovigilance should be formally included in the BUMS curriculum, and 121 (93.1%) expressed the need for practical or hands-on pharmacovigilance training. Furthermore, 109 participants (83.8%) indicated that they would be willing to report a suspected ADR in future clinical practice.

Although attitudes were generally positive, only 85 students (65.4%) agreed that uncertainty regarding causal association should not prevent the reporting of a suspected ADR.

Table 3. Attitude of Participants toward Pharmacovigilance and ADR Reporting (N = 130)

Attitude Statement	Positive Response, n (%)
ADR reporting is an important professional responsibility	113 (86.9)
Pharmacovigilance should be included in the BUMS curriculum	118 (90.8)
Unani medicines require systematic safety monitoring	111 (85.4)
Would be willing to report a suspected ADR in future	109 (83.8)
Practical/hands-on pharmacovigilance training is necessary	121 (93.1)
ADR reporting contributes to improved patient safety	119 (91.5)
Uncertain causality should not prevent reporting of a suspected ADR	85 (65.4)
Pharmacovigilance should be included in clinical competency assessment	101 (77.7)

The mean attitude score was 32.7 ± 4.9 out of 40, indicating an overall favorable attitude toward pharmacovigilance.

Practical exposure to pharmacovigilance was considerably weaker than knowledge or attitude. Although 38 participants (29.2%) had encountered a suspected ADR, only 31 students (23.8%) had discussed such an event with a faculty member or clinician.

Only 28 participants (21.5%) had previously seen a formal ADR reporting form, while 15 (11.5%) had ever completed one. Most importantly, only 8 students (6.2%) reported having actually submitted or participated in submitting a suspected ADR report.

Similarly, only 20 participants (15.4%) had attended formal pharmacovigilance training, and 22 (16.9%) had accessed or knew how to access a formal ADR reporting contact point or reporting portal.

Table 4. Pharmacovigilance and ADR-Reporting Practices Among Participants (N = 130)

Practice Item	Yes, n (%)
Ever encountered a suspected ADR	38 (29.2)

Ever discussed a suspected ADR with a faculty member/clinician	31 (23.8)
Ever seen a formal ADR reporting form	28 (21.5)
Ever completed an ADR reporting form	15 (11.5)
Ever submitted/participated in submission of an ADR report	8 (6.2)
Attended formal pharmacovigilance or ADR training	20 (15.4)
Independently searched for ADR or medicine-safety information	42 (32.3)
Knew or had accessed a formal ADR reporting contact/portal	22 (16.9)

The mean practice score was 1.57 ± 1.60 out of 8, demonstrating substantially lower practical engagement compared with knowledge and attitude.

Based on the predefined scoring criteria, 28 participants (21.5%) demonstrated good pharmacovigilance knowledge, while 57 (43.8%) had moderate knowledge and 45 (34.6%) had poor knowledge. Thus, 65.4% of participants demonstrated at least moderate knowledge.

In contrast, attitudes were considerably more favorable, with 96 students (73.8%) classified as having a favorable attitude toward pharmacovigilance.

Practice represented the weakest KAP domain. Only 9 students (6.9%) demonstrated good pharmacovigilance practice and 30 (23.1%) demonstrated moderate practice, while 91 participants (70.0%) were categorized as having poor practice.

Table 5. Overall Distribution of Knowledge, Attitude, and Practice Levels (N = 130)

Domain	Category	n	%
Knowledge	Good	28	21.5
	Moderate	57	43.8
	Poor	45	34.6
Attitude	Favorable	96	73.8
	Intermediate/neutral	27	20.8
	Unfavorable	7	5.4
Practice	Good	9	6.9
	Moderate	30	23.1
	Poor	91	70.0

The contrast between the three domains demonstrated a clear knowledge–attitude–practice gap: favorable attitudes were common, whereas practical engagement with formal ADR reporting remained limited.

Knowledge score demonstrated a moderate positive correlation with practice score (Spearman's $\rho = 0.48$, $P < 0.001$), indicating that students with better pharmacovigilance knowledge tended to demonstrate better reporting-related practices.

A weaker but statistically significant positive correlation was observed between attitude and practice scores ($\rho = 0.34$, $P < 0.001$). Knowledge and attitude were also positively correlated ($\rho = 0.29$, $P = 0.001$).

For inferential analysis, moderate and good practice were combined as desirable practice, while poor practice was classified as inadequate practice. Overall, 39 participants (30.0%) demonstrated desirable practice.

Students with previous formal pharmacovigilance teaching showed substantially better practice. Among students with prior formal teaching, 21 of 34 (61.8%) demonstrated desirable practice compared with only 18 of 96 (18.8%) without previous formal exposure ($P < 0.001$).

Similarly, students with at least moderate pharmacovigilance knowledge were more likely to demonstrate desirable practice than those with poor knowledge (40.0% vs 11.1%; $P < 0.001$).

Students in the fourth and final professional years also demonstrated a higher proportion of desirable practice than students in the second and third professional years (41.5% vs 18.5%; $P = 0.007$).

Table 6. Factors Associated with Desirable Pharmacovigilance Practice among Participants

Predictor	Desirable practice n/N (%)	Crude OR (95% CI)	Adjusted OR (95% CI)	P value*
Previous formal pharmacovigilance teaching	21/34 (61.8)	7.00 (2.96–16.56)	4.31 (1.66–11.18)	0.003
Moderate/good pharmacovigilance knowledge	34/85 (40.0)	5.33 (1.91–14.88)	3.02 (1.00–9.10)	0.049
Fourth/final professional year	27/65 (41.5)	3.14 (1.41–6.97)	1.86 (0.75–4.61)	0.181
Favorable attitude toward pharmacovigilance	35/96 (36.5)	4.30 (1.40–13.23)	3.18 (1.02–9.93)	0.046

In the multivariable model, previous formal pharmacovigilance teaching remained the strongest independent predictor of desirable practice (adjusted OR 4.31; 95% CI 1.66–11.18; P = 0.003). Moderate/good pharmacovigilance knowledge and a favorable attitude were also independently associated with better practice. After adjustment, academic year alone was no longer statistically significant.

These findings indicated that while students generally recognized the importance of medicine safety and supported pharmacovigilance education, deficiencies were particularly evident in knowledge of reporting mechanisms and in practical ADR reporting experience.

Figure 1. Distribution of overall knowledge, attitude, and practice levels related to pharmacovigilance among Unani medical students

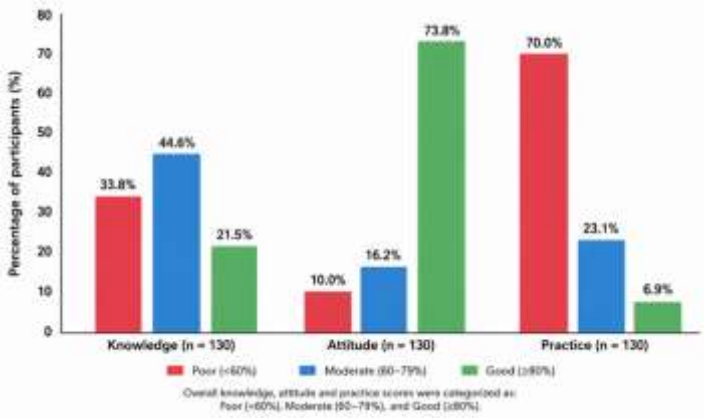

Figure 1 demonstrating that favorable attitude was observed in 73.8% of participants, whereas only 21.5% demonstrated good knowledge and 6.9% demonstrated good pharmacovigilance practice. Poor practice was observed in 70.0% of participants, highlighting the prominent knowledge-to-practice gap.

Figure 2. Knowledge of key pharmacovigilance concepts and ADR-reporting procedures among Unani medical students

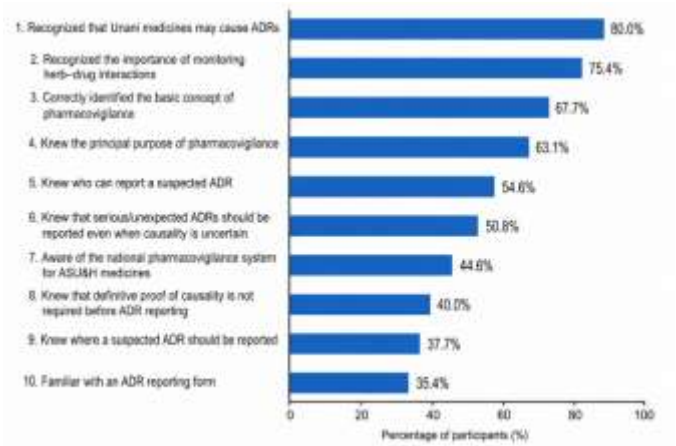

Figure 2 showing relatively high awareness that Unani medicines can cause ADRs (80.0%) and that herb–drug interactions require monitoring (75.4%), compared with substantially lower awareness of where ADRs should be reported (37.7%), familiarity with ADR reporting forms (35.4%), and awareness that definitive causality is not required before reporting (40.0%).

DISCUSSION

The present study provides important insight into the knowledge, attitude, and practice of pharmacovigilance among Unani medical students and highlights a substantial gap between recognition of the importance of medicine safety and actual competence in adverse drug reaction (ADR) reporting. The principal finding was the coexistence of moderate pharmacovigilance knowledge and strongly favorable attitudes with markedly inadequate practical reporting experience. Although 73.8% of participants demonstrated a favorable attitude toward pharmacovigilance, only 21.5% had good knowledge and just 6.9% demonstrated good practice. Furthermore, 70.0% of students were classified as having poor pharmacovigilance practice. These findings indicate that willingness to participate in medicine-safety activities does not necessarily translate into the ability or experience required to report suspected ADRs effectively.

The observed knowledge profile is broadly consistent with previous studies among healthcare students and professionals. Upadhyaya et al. reported that postgraduate medical students demonstrated a relatively favorable attitude toward ADR monitoring but had important deficiencies in knowledge and actual reporting practice [13]. Similarly, Bepari et al., in their comparative evaluation of healthcare professionals in India, identified inadequate pharmacovigilance knowledge and practice despite recognition of the importance of ADR reporting [14]. These observations support the present finding that knowledge of broad pharmacovigilance concepts may be substantially better than understanding of the operational processes required for spontaneous reporting.

In the present study, 67.7% of participants correctly understood the basic concept of pharmacovigilance and 63.1% knew its principal purpose. However, knowledge declined considerably when students were questioned about practical reporting mechanisms. Only 37.7% knew where a suspected ADR should be reported, 35.4% were familiar with an ADR reporting form, and 40.0% understood that definitive proof of causality was not required before submitting a suspected ADR report. This distinction is educationally important. A student may understand what pharmacovigilance means while remaining unable to perform the actual steps required for ADR reporting. Alwhaibi et al., in a study of 710 healthcare students, similarly identified important deficiencies in pharmacovigilance knowledge despite generally positive attitudes toward ADR reporting and found better pharmacovigilance-related knowledge among students receiving greater curricular exposure [15].

The finding that 80.0% of participants recognized that Unani medicines can cause ADRs is encouraging. Furthermore, 75.4% appreciated the need to monitor herb–drug interactions. These findings suggest that most students did not subscribe to an absolute assumption that traditional or herbal medicines are inherently free of adverse effects. Nevertheless, knowledge of formal pharmacovigilance systems for such medicines remained limited, with only 44.6% reporting awareness of the national pharmacovigilance

mechanism applicable to ASU&H medicines. This represents an important educational gap because pharmacovigilance of herbal and traditional medicines presents additional challenges related to variation in botanical composition, nomenclature, product quality, multi-ingredient formulations, contamination, adulteration, and concomitant use with conventional medicines. Shaw et al. emphasized that conventional pharmacovigilance systems require adaptation to address the particular complexities associated with herbal medicines [21]. For future Unani physicians, therefore, pharmacovigilance training should extend beyond general definitions and explicitly address safety surveillance of single and compound Unani formulations.

Attitude was the strongest domain in the present study. More than 90% of students believed that ADR reporting contributes to patient safety and supported practical pharmacovigilance training, while 90.8% specifically supported inclusion of pharmacovigilance in the BUMS curriculum. In addition, 86.9% regarded ADR reporting as a professional responsibility and 83.8% stated that they would be willing to report suspected ADRs in future practice. The predominance of favorable attitudes is consistent with published studies involving medical and other healthcare students. Sidhu et al. reported reasonably favorable awareness and perceptions of ADR-related issues among undergraduate medical students while emphasizing the need for reinforcement and specific training to prepare students for future clinical practice [16].

The positive attitude demonstrated by participants represents an important opportunity for curriculum development. Students appear receptive to pharmacovigilance education; therefore, the principal challenge is not necessarily convincing them of its importance but equipping them with practical skills. A literature review by Reumerman et al. evaluating pharmacovigilance education among healthcare students identified important shortcomings in current educational approaches and concluded that pharmacovigilance education requires modernization, with greater emphasis on clinically relevant competencies rather than passive acquisition of theoretical knowledge [17]. This is particularly applicable to the present findings because favorable attitudes were not accompanied by adequate reporting behavior.

The most striking result was the poor level of pharmacovigilance practice. Although 29.2% of participants had encountered a suspected ADR, only 23.8% had discussed one with a faculty member or clinician. Furthermore, only 21.5% had seen a formal ADR reporting form, 11.5% had completed such a form, and merely 6.2% had ever submitted or participated in the submission of an ADR report. This sequential decline from ADR recognition to actual reporting illustrates a clear knowledge-to-action gap. It suggests that opportunities occurring during clinical exposure are not consistently being converted into structured pharmacovigilance learning experiences.

Similar discrepancies have been observed internationally and among different categories of healthcare professionals. Khan et al. found that healthcare professionals generally demonstrated positive attitudes toward pharmacovigilance but continued to have deficiencies in knowledge and reporting practice, with inadequate training contributing to under-reporting [20]. Such findings reinforce the view that positive perceptions alone are insufficient to establish a sustainable ADR reporting culture. Students must repeatedly encounter the reporting process during their education until identification, documentation, assessment, and submission of suspected ADRs become familiar professional activities.

The statistically significant relationships between the KAP domains further strengthen this interpretation. Knowledge demonstrated a moderate positive correlation with practice ($\rho = 0.48$, $P < 0.001$), while attitude was also positively correlated with practice ($\rho = 0.34$, $P < 0.001$). These findings indicate that increasing knowledge and strengthening positive attitudes may contribute to better reporting behavior, although they also show that practice is a distinct competency requiring direct training and exposure. Educational interventions should therefore move beyond conventional classroom lectures toward experiential learning.

The association between previous pharmacovigilance teaching and improved practice was particularly important. Desirable practice was observed in 61.8% of participants with previous formal pharmacovigilance teaching compared with only 18.8% of those without such exposure. After adjustment for other factors, previous formal teaching remained the strongest independent predictor of desirable practice, with an adjusted odds ratio of 4.31. Although the cross-sectional

nature of the study does not establish causality, this association strongly supports the educational relevance of structured training.

Evidence from intervention studies supports this interpretation. Ganesan et al. demonstrated significant improvement in pharmacovigilance knowledge, attitude, and practice among healthcare professionals following an educational intervention [18]. More importantly, a recent systematic review and meta-analysis by Cervantes-Arellano et al. concluded that educational interventions improve pharmacovigilance knowledge and ADR reporting, with workshops showing particular effectiveness for improving reporting behavior [19]. Collectively, these observations indicate that the association identified in the present study is biologically and educationally plausible and provides a strong rationale for formal curricular intervention.

The results also showed that students in the fourth and final professional years had better unadjusted practice than those in earlier years. This may reflect increased clinical exposure and greater opportunities to encounter medication-related problems. However, academic year was no longer independently significant after multivariable adjustment, suggesting that progression through the course alone may not guarantee adequate pharmacovigilance competence. This distinction has important implications. Simply exposing students to more patients without providing structured ADR-reporting opportunities may be insufficient. Pharmacovigilance competencies should therefore be deliberately taught, practiced, assessed, and reinforced across different stages of BUMS education.

A structured pharmacovigilance curriculum for Unani students could employ a spiral competency-based approach. Early professional years could introduce fundamental concepts such as ADR definitions, preventability, seriousness, causality, and the objectives of pharmacovigilance. Subsequent years could incorporate case-based exercises involving commonly used Unani medicines, suspected herb–drug interactions, medication errors, and adverse effects associated with compound formulations. During clinical training, students could be asked to identify suspected ADRs, complete standardized reporting forms, perform basic causality assessments under supervision, and understand the pathway through which a report reaches the relevant pharmacovigilance centre. Research on pharmacovigilance teaching has emphasized that practical exposure, case-based activities, active reporting exercises, and repeated curricular reinforcement are more likely to develop reporting competence than isolated theoretical instruction [17,22].

The Unani context deserves particular attention. Traditional medicines frequently contain complex preparations, and the identification of an adverse reaction may be complicated by multiple ingredients, variability in composition, concomitant conventional medication, differences in dose or preparation, and uncertainties concerning causality. Pharmacovigilance education for Unani practitioners should therefore integrate contemporary medicine-safety principles with system-specific therapeutic knowledge. Students should be trained to document the exact formulation, ingredients where known, manufacturer, batch details, dosage, treatment duration, concomitant therapies, temporal relationship, dechallenge information, and clinical outcome whenever an adverse event is suspected. Herbal pharmacovigilance literature has emphasized that these product-specific complexities are essential considerations when developing reliable safety evidence for traditional medicines [21].

The strong student demand for training identified in the present study further supports curricular integration. With 93.1% of participants considering practical training necessary and 90.8% favoring formal inclusion in the BUMS curriculum, introducing pharmacovigilance teaching would be consistent not only with patient-safety priorities but also with perceived learner needs. Importantly, curricular integration should not be restricted to a single lecture or workshop. A review of pharmacovigilance education found wide variation in student competencies and highlighted the value of repeated, clinically oriented educational activities [17]. Similarly, Perisin et al. identified gaps and opportunities in the teaching of pharmacovigilance to healthcare students and supported approaches that develop practical competencies applicable to future professional practice [22].

The findings have broader implications for strengthening pharmacovigilance within the Unani healthcare system. Students currently undergoing professional education will become future prescribers and constitute an important potential source of spontaneous ADR reports. Establishing reporting habits during undergraduate training may therefore be more sustainable than attempting to introduce these

practices only after graduation. Formal education could also reduce common psychological barriers to reporting, particularly uncertainty regarding causality. In the present study, only 40.0% knew that definitive causality was unnecessary before reporting, while just 65.4% agreed that uncertain causality should not prevent a report. This misconception can directly contribute to under-reporting because spontaneous pharmacovigilance systems depend upon reporting suspected, rather than definitively proven, associations.

The present study has several limitations that should be considered while interpreting the findings. First, its cross-sectional design allows identification of associations but cannot demonstrate a causal relationship between pharmacovigilance education and improved reporting practice. Second, information was obtained through a self-administered questionnaire and was therefore susceptible to recall and social desirability biases. Participants may have overestimated desirable attitudes or reporting behavior. Third, if conducted at a single institution, the findings may not be fully generalizable to all BUMS students or Unani medical colleges across India. Fourth, practice was assessed predominantly through self-reported previous behavior rather than objective observation of ADR identification and reporting competence. Finally, although previous training showed a strong association with better practice, differences in the content, duration, and quality of such training may not have been captured.

Despite these limitations, the study addresses an important and comparatively underexplored area at the intersection of pharmacovigilance and Unani medical education. The simultaneous assessment of knowledge, attitude, practice, previous educational exposure, and predictors of desirable reporting behavior provides a useful framework for identifying curriculum-related deficiencies. The clear contrast between highly favorable attitudes and limited reporting experience suggests that the principal educational priority should be translation of awareness into practical competence.

Overall, the present findings demonstrate that Unani medical students are receptive to pharmacovigilance and recognize its relevance to patient safety, including the safety monitoring of Unani medicines. However, important deficiencies remain in knowledge of reporting pathways, familiarity with ADR reporting forms, understanding of reporting despite uncertain causality, and actual participation in spontaneous reporting. The strong association between previous formal pharmacovigilance teaching and desirable practice, together with evidence from educational intervention studies, supports the integration of structured, longitudinal, competency-based pharmacovigilance training into the BUMS curriculum. Such training should combine theoretical instruction with case-based learning, ADR-form completion, causality assessment, herb–drug interaction evaluation, supervised reporting, and exposure to functioning pharmacovigilance centres. Embedding these competencies during undergraduate education could help transform favorable student attitudes into sustained ADR-reporting behavior and strengthen the safety surveillance of Unani medicines in routine clinical practice.

CONCLUSION

The present study demonstrates a substantial gap between the favorable attitude of Unani medical students toward pharmacovigilance and their actual knowledge and practical experience of adverse drug reaction reporting. Although most participants recognized the importance of pharmacovigilance, supported its inclusion in the BUMS curriculum, and expressed willingness to report suspected adverse drug reactions, knowledge of formal reporting procedures and direct reporting experience remained limited. The particularly low proportion of students who had completed or submitted an ADR report highlights the need to move beyond theoretical awareness toward practical competency development.

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REFERENCES

1. World Health Organization. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: World Health Organization; 2002.
2. World Health Organization. WHO guidelines on safety monitoring of herbal

medicines in pharmacovigilance systems. Geneva: World Health Organization; 2004.

3. World Health Organization Regional Office for South-East Asia. Pharmacovigilance for traditional medicine products: why and how? New Delhi: WHO Regional Office for South-East Asia; 2018.
4. Choudhury A, Singh PA, Bajwa N, Dash SS, Bisht P. Pharmacovigilance of herbal medicines: concerns and future prospects. J Ethnopharmacol. 2023;309:116383. doi:10.1016/j.jep.2023.116383.
5. Chaudhary A, Singh N, Kumar N. Pharmacovigilance: boon for the safety and efficacy of Ayurvedic formulations. J Ayurveda Integr Med. 2010;1(4):251-256. doi:10.4103/0975-9476.74427.
6. Wal P, Wal A, Gupta S, Sharma G, Rai AK. Pharmacovigilance of herbal products in India. J Young Pharm. 2011;3(3):256-258. doi:10.4103/0975-1483.83780.
7. Ministry of Ayush, Government of India. Ayush Suraksha: Pharmacovigilance of Ayurveda, Siddha, Unani and Homoeopathy drugs. New Delhi: Ministry of Ayush.
8. Meher BR, Joshua N, Asha B, Mukherji D. A questionnaire based study to assess knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a tertiary care teaching hospital of South India. Perspect Clin Res. 2015;6(4):217-221. doi:10.4103/2229-3485.167102.
9. Katyal J, Arora E, Gupta YK. Impact of increased focus on pharmacovigilance on knowledge and attitude towards adverse drug reaction reporting among medical students in India. Int J Risk Saf Med. 2020;31(1):15-24. doi:10.3233/JRS-195012.
10. Tandon VR, Mahajan V, Khajuria V, Gillani Z. Under-reporting of adverse drug reactions: a challenge for pharmacovigilance in India. Indian J Pharmacol. 2015;47(1):65-71. doi:10.4103/0253-7613.150344.
11. Panneerselvam N, Kathirvelu P, Manoharan R. Impact of educational intervention on the knowledge, attitude, and practice of pharmacovigilance among postgraduates of a tertiary care center, Kanchipuram, Tamil Nadu, India. Perspect Clin Res. 2022;13(4):199-204. doi:10.4103/picr.PICR_239_20.
12. Kalikar MV, Dakhale GN, Shrirao M. Effect of educational intervention on awareness of pharmacovigilance among medical undergraduates in a tertiary care teaching hospital. Perspect Clin Res. 2020;11(2):92-96. doi:10.4103/picr.PICR_16_19.
13. Upadhyaya HB, Vora MB, Nagar JG, Patel PB. Knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students of tertiary care hospital in Gujarat. J Adv Pharm Technol Res. 2015;6(1):29-34. doi:10.4103/2231-4040.150369.
14. Bepari A, Niazi SK, Rahman I, Dervesh AM. The comparative evaluation of knowledge, attitude, and practice of different health-care professionals about the pharmacovigilance system of India. J Adv Pharm Technol Res. 2019;10(2):68-74. doi:10.4103/japtr.JAPTR_4_19.
15. Alwhaibi M, Alhindi G, Alshamrani M, Bin Essa M, Al Aloola NA, Alhawassi TM. Pharmacovigilance in healthcare education: students' knowledge, attitude and perception: a cross-sectional study in Saudi Arabia. BMC Med Educ. 2020;20:210. doi:10.1186/s12909-020-02116-2.
16. Sidhu GS, Kumar J, Kumar D, Dey N, Ranjan G, Sinha T, et al. Knowledge and perception regarding adverse drug reactions among undergraduate medical students of Bihar, Eastern India. J Family Med Prim Care. 2023;12(9):2082-2089. doi:10.4103/jfmpc.jfmpc_679_23.
17. Reumerman M, Tichelaar J, Piersma B, Richir MC, van Agtmael MA. Urgent need to modernize pharmacovigilance education in healthcare curricula: review of the literature. Eur J Clin Pharmacol. 2018;74(10):1235-1248. doi:10.1007/s00228-018-2500-y.
18. Ganesan S, Sandhiya S, Reddy KC, Subrahmanyam DK, Adithan C. The impact of the educational intervention on knowledge, attitude, and practice of pharmacovigilance toward adverse drug reactions reporting among health-care professionals in a tertiary care hospital in South India. J Nat Sci Biol Med. 2017;8(2):203-209. doi:10.4103/0976-9668.210014.
19. Cervantes-Arellano MJ, Castelán-Martínez OD, Marín-Campos Y, Chávez-Pacheco JL, Morales-Ríos O, Ubaldo-Reyes LM. Educational interventions in pharmacovigilance to improve the

knowledge, attitude and the report of adverse drug reactions in healthcare professionals: systematic review and meta-analysis. Daru. 2024;32(1):421-434. doi:10.1007/s40199-024-00508-z.

20. Khan Z, Karatas Y, Hamid SM. Evaluation of health care professionals' knowledge, attitudes, practices and barriers to pharmacovigilance and adverse drug reaction reporting: a cross-sectional multicentral study. PLoS One. 2023;18(5). doi:10.1371/journal.pone.0285811.
21. Shaw D, Ladds G, Duez P, Williamson E, Chan K. Pharmacovigilance of herbal medicine. J Ethnopharmacol. 2012;140(3):513-518. doi:10.1016/j.jep.2012.01.051.
22. Seselja Perisin A, Bukic J, Rusic D, Leskur D, Bozic J, Mihanovic A, et al. Teaching pharmacovigilance to healthcare students: identifying gaps and opportunities for improvement. Pharmacy (Basel). 2021;9(3):147. doi:10.3390/pharmacy9030147.