



RESEARCH ARTICLE

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Assessment of Knowledge, Attitude, and Practice on Pharmacovigilance among Unani Stakeholders in India: A Cross-Sectional Study

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Aim: To assess the knowledge, attitude, and practice of Pharmacovigilance among Unani stakeholders in India.

Methods: A cross-sectional, non-interventional, questionnaire-based study was conducted among the Unani stakeholders in India. Data was collected online through a Google form-based self-reported questionnaire.

Results: The present study revealed that the average knowledge score of the study participants was 11.36 ± 3.5 (Total score 19). Of the total responders, 47% had a low or very low level of knowledge and 53% had a good or high level of knowledge. There was a positive correlation between KAP scores. Knowledge scores were positively correlated with attitude ($r=0.258$, $p<.001$) and practice ($r=0.056$, $p=0.067$). Attitude scores were also positively correlated with practice scores ($r=0.269$, $p<.001$). These findings suggest that knowledge, attitude, and practice scores showed a weak positive correlation.

Conclusion: This study suggests that the study participants are well-versed in the knowledge of pharmacovigilance, and also have a favorable attitude toward reporting ADRs and misleading advertisements. To implement more effectively the objectives of the pharmacovigilance program of ASU & H Drugs further efforts should be made to increase the practice of pharmacovigilance through awareness programs and on-hand training.

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Introduction

Medicine has transformed the prevention and treatment of diseases. In addition to their benefits, medicinal products may have side effects, some of which may be undesirable and unexpected. Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. The use of herbal medicines continues to expand rapidly across the world, and the safety of herbal medicines has become a major concern to

both national health authorities and the public (WHO, 2004).

The adverse drug reaction (ADR) is defined as any response to a medicinal product that is harmful and unintended and that occurs at doses ordinarily used in men for prophylaxis, diagnosis, or therapy for the disease, or the modification of physiological function (WHO, 2005). ADRs are associated with drug-related patient morbidity by causing a prolonged length of hospital stay, higher economic burden, and sometimes mortality (WHO, 2005).



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The worldwide incidence of ADR driving to emergency hospitalization varies from 0.2% to 41.3%, while 28.9% of these ADRs are preventable (Beijer et al., 2002). Therefore, the detection and monitoring of ADRs are of vital importance for patient safety.

Unani is the ancient Greek system of medicine that evolved throughout the ancient world and which was fostered in the Islamic realms, based on ancient logic and timeless rules encapsulating a cosmological view of human health and the universe. Classical Arab-Islamic medicine was conventionally attributed to the ancient Greeks; thus, it came to be known as Unani (from the Arabic Yūnānī for 'Greek'). Hippocrates (c. 460-375 BCE) was known as the father of this system of medicine and it is he who was the first true medical codified and commentator, building on the theoretical work of his contemporary Democritus (c. 460-370 BCE). Their teachings were propagated by the two sons of Hippocrates, Thessalus and Draco, and a student Polybus. Subsequently, Unani medicine was espoused by several competent Greek scholars who significantly developed the Hippocratic system throughout the Alexandrian world, from Egypt to Bactria. Later, under the benign patronage of Abbasid Caliphs, the Arab and Persian physicians imbibed the Unani system of medicine and elevated it to the highest pinnacle, surpassing the achievements of the ancients and dynamically and persistently developing this medical paradigm for about a millennium (Islam A, 2018).

In Unani, the concept of "Pharmacovigilance" is vibrant. Ibn-i-Sina's pioneering work *Al-Qanoon Fit tib* mentioned the concept of adverse drug reactions and their prevention and management as Muzir was Musleh (Sina I, 2010). Unani pharmacologists had mentioned that drugs having temperaments of third and fourth degree can produce a serious adverse effects (Rahman et al., 2008).

The Ministry of AYUSH, GOI has introduced a Central Sector Scheme for promoting Pharmacovigilance of Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) drugs, with the prime objective to develop the culture of documenting adverse effects of Ayurveda, Siddha, Unani and Homoeopathy drugs and surveillance of misleading advertisements appearing in the print and electronic media. The scheme intends to facilitate the establishment of a three-tier network of National Pharmacovigilance Coordination Centres (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs), and Peripheral Pharmacovigilance Centres (PPvCs). The National Institute of Unani Medicine (NIUM), Bengaluru is designated as an Intermediary Pharmacovigilance Centre for Unani Drugs since 2018 (Ayushsuraksha).

For ages, Ayurveda, Siddha, and Unani systems are being practiced in India. Now in this era of globalization, certain concerns have been raised concerning their safety. There is a widespread misconception that all drugs of "natural" origin are safe. There is also a common belief that long-

term use of traditional medicine is safe and has no adverse effect. Further, when these medicines are used in conjunction with other medicines, there is the potential for serious adverse drug interactions. There are also examples of traditional medicines being adulterated or contaminated with chemicals. Currently, most adverse events related to the use of traditional products that are reported are attributed either due to poor product quality or improper use (AYUSH, 2008).

Knowledge, attitude, and practice (KAP) surveys are representative of a specific population to collect information on what is known, believed, and done on a particular topic and are the most frequently used study tool in health-seeking behavior research. Knowledge is usually assessed to see how far community knowledge corresponds to medical concepts. The attitude has been defined as "a learned predisposition to think, feel and act in a particular way toward a given object or class of objects". Practices in KAP surveys usually aim at the use of preventive measures (Hassali et al., 2013).

Since 2018, the PV Program for ASU & H Drugs is in executed, Pan India, as an objective. Therefore, to understand the knowledge, attitudes, and practices of Pharmacovigilance among Unani Stakeholders in India, awareness cum sensitization programs have been organized. Hence, it is intended to assess the KAP of Pharmacovigilance among Unani Stakeholders to set the tasks for the future as well as to date, the understanding and working behavior of stakeholders.

Methods

To Assess the Knowledge, Attitude, and Practice of Pharmacovigilance, among Unani stakeholders in India

Study design: This was a cross-sectional, non-interventional, questionnaire-based study.

Inclusion criteria: Stakeholders of the Unani system of medicine, who have given their consent were included.

Exclusion criteria: Participants other than Unani stakeholders.

Structure of the questionnaire

A self-reported, 27-item based, structured questionnaire was designed, in which 19 questions were related to the knowledge domain and 4 each, related to attitude and practice of Pharmacovigilance of ASU & H Drugs. The first page of the questionnaire contains the objective of the study and the consent of the respondents, where it is informed that they were free to withdraw at any time, without giving any reason, and that all information and opinions provided would be anonymous and confidential. Data collection was done only after their consent.

Data collection

This cross-sectional study was conducted among the stakeholders of the Unani system of medicine in India, from 13 September 2021 to 30 September 2021. Data were collected online, through a Google form-based self-reported questionnaire, and was circulated through a link to the survey respondents, via WhatsApp to cover a larger sample size for higher external validity and greater generalizability of the study outcomes. A total of 1172 responses were received, of which 1082 participants gave consent and 90 not consented to participate in the study.

Data analysis

The data were coded using Microsoft Excel. Descriptive analysis was conducted, and data were presented as frequencies with percentages (%) for knowledge, attitude, and practice domains. The knowledge scores were categorized as poor, fair, good, and excellent. Similarly, attitude and practice scores were also calculated. The correlation between KAP scores was assessed using Pearson's correlation coefficient. $P < 0.05$ was considered

statistically significant. IBM SPSS Version 28.0.0.0 (190) was used to analyze the data.

Results

Demographic Characteristics

The demographic descriptions of the respondents are summarized in (Table 1). The sample comprised 1082 respondents exclusively of Unani Stakeholders in India, of which 59.3 % were females and 40.7 % were males. According to the occupation, 8.8 % of medical officers, 1.6 % of paramedical staff, 12.2 % of private practitioners, 62.7 % of students, and 14.8 % of teachers at Unani medical colleges participated in the study. The states of domicile were, 14.2 % Andhra Pradesh, 18.5 % Bihar, 14.6 % Karnataka, 5.8 % Madhya Pradesh, 2.4 % Maharashtra, 23.4 % Tamil Nadu, 4.1 % UT - Jammu & Kashmir, 1.3 % UT - The Government of NCT of Delhi, 2.6 % West Bengal and 13.1 % Uttar Pradesh.

Table 1: Demographic characteristics

Variable	Category	Frequency (n=1082)	Percentage (%)
Gender	Male	642	59.3
	Female	440	40.7
Occupation	Medical Officer	95	8.8
	Paramedical Staff	17	1.6
	Private Practitioner	132	12.2
	Teacher	160	14.8
	Student	678	62.7
Region	Andhra Pradesh	154	14.2
	Bihar	200	18.5
	Karnataka	158	14.6
	Madhya Pradesh	63	5.8
	Maharashtra	26	2.4
	Tamil Nadu	253	23.4
	UT – Jammu & Kashmir	44	4.1
	UT - The Government of NCT of Delhi	14	1.3
	West Bengal	28	2.6
	Uttar Pradesh	142	13.1

*Data are presented as count (%).

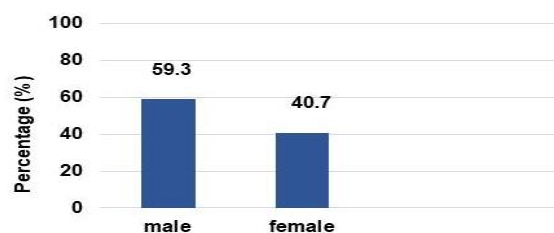


Figure 1: Gender characteristics of the participants

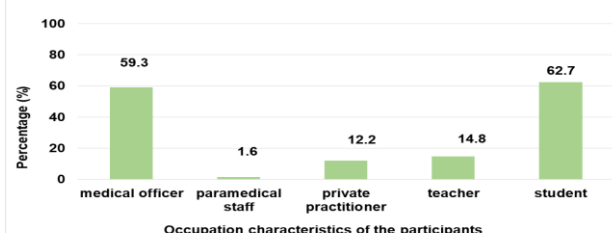


Figure 2: Occupation characteristics of the participants

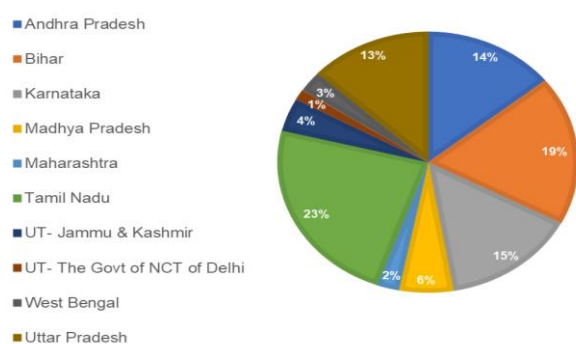


Figure 3: Region characteristics of the participants

Response regarding Knowledge of the pharmacovigilance of ASU & H Drugs

The status of the pharmacovigilance of ASU & H Drugs knowledgeability is summarized in (Table 2). A total of 19 questions were related to the knowledge domain. Out of 19 questions, 15 questions have the correct response compared to the incorrect one. 4 questions that were answered incorrectly are regarding the reporting centers of misleading advertisements, the Intermediary Pharmacovigilance Centre for Unani Drugs, the official website of the pharmacovigilance center of ASU & H Drugs, and one question regarding the mixopathy.

Table 2 Answers to knowledge-related questions

Knowledge Domain Questions	Correct	Incorrect
Pharmacovigilance deals with	891(82.3%)	191(17.6%)
The International Centre for Adverse Drug Reaction Monitoring is located at?	736(68.02%)	346(31.97%)
In India, who is monitoring Pharmacovigilance for ASU & H Drugs?	551(50.92%)	531(49.07%)
In India, the National coordination center for Pharmacovigilance Programme for ASU & H Drugs is situated at?	689(63.67%)	393(36.32%)
The Intermediary Pharmacovigilance Centre for Unani Drugs is at?	518(47.87%)	564(52.12%)
Is it correct to keep the drugs of exclusive Herbal drug origin under the purview of Pharmacovigilance?	845(78.09%)	237(21.9%)
Does blood products, nutraceuticals, cosmetics, medical devices, and vaccines come under the purview of Pharmacovigilance?	693(64.04%)	389(35.95%)
Are Adverse Drug Reactions (ADR) and Side Effects (SE) the same?	658(60.0%)	424(39.18%)
Where to report an ADR related to ASU & H Drugs?	570(52.68%)	512(47.31%)
Who among the following was responsible for reporting ADR?	728(67.28%)	354(32.71%)
Is there any specific ADR reporting form for ASU & H Drugs?	606(56.0%)	476(43.99%)
Do you think mixopathy (a combination of more than one drug therapy) can cause ADRs?	512(47.31%)	570(52.68%)
Do you think reporting Adverse Drug Reactions of ASU & H Drugs is necessary?	907(83.82%)	175(16.17%)
Do you think poor quality of drugs, prescription errors, and dispensing errors can cause ADRs?	829(76.61%)	253(23.38%)
Do you think ADR is due to negligence from the viewpoint of	729(67.37%)	353(32.62%)
Which of the following ADRs should be reported?	751(69.4%)	331(30.59%)
Many AYUSH medicine-related advertisements on TV, social media, newspapers, roadside posters, etc. claim cures for various diseases. Do you consider them misleading advertisements?	588(54.34%)	494(45.65%)

Do you know to whom Misleading Advertisements should be reported?	378(34.93%)	704(65.06%)
The official website of the Pharmacovigilance Programme for ASU & H Drugs is?	412(38.07%)	670(61.92%)

In (Table 3), knowledge scoring of the study participants is obtained from the respondents. 147 (13.6%) responses have poor knowledge with a score of ≤ 40 , 361 (33.4%) responses scored 41–60, 408 (37.7%) scored 61–79 and 166 (15.3%) scored ≥ 80 . They had fair, good, and excellent knowledge levels, respectively. Most respondents agreed that reporting Adverse Drug Reactions of ASU & H Drugs is necessary, however, it was observed that some critical knowledge gaps for the questions like reporting of Misleading Advertisements, the official website of Pharmacovigilance Programme for ASU & H Drugs, and mixopathy (combination of more than one drug therapy) can cause ADRs.

Table 3. Assessment of knowledge-related responses

Knowledge Score	Frequency	%
≤ 40 (poor)	147	13.6
41–60 (fair)	361	33.4
61–79 (Good)	408	37.7
≥ 80 (Excellent)	166	15.3
Total	1082	100.0

*Scores out of 19 were calculated for each response and were converted to a percentage to obtain knowledge levels. The average score was 11.36 ± 3.5 (Mean $\pm$ SD); 12(19–14) [Median (IQR)]. Of the total responders, 47% had a low or very low knowledge level and 53% had a good or high level of knowledge.

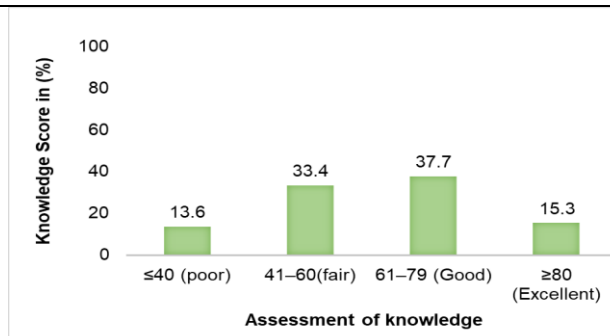


Figure 4: Assessment of knowledge-related responses

Response regarding Attitude of pharmacovigilance of ASU & H Drugs

Out of 27 questions, 4 questions were related to attitude (Table 4). Some positive attitudes were observed, for example, most respondents ($> 80\%$) stated that Pharmacovigilance should be taught in detail to all healthcare professionals and Misleading Advertisements should be reported. However, 1.48 % disagreed that Pharmacovigilance should be taught in detail to all healthcare professionals, and 4.99 % disagreed that Misleading Advertisements should be reported. Regarding the opinion about establishing a Pharmacovigilance center in every hospital, 70.33 % agreed and 15.80 % disagreed. When the respondents were asked, have they experienced Adverse Drug Reactions in their professional practice, 38.54 % agreed and 46.58 % disagreed. Furthermore, $< 20\%$ have a neutral attitude to the four related questions.

Table 4. Answers to Attitude related questions

Attitude Domain Questions	Agree	Neutral	Disagree
What is your opinion about establishing a Pharmacovigilance center in every hospital?	761(70.33%)	150(13.86%)	171(15.80%)
Do you think Pharmacovigilance should be taught in detail to all healthcare professionals?	964(89.09%)	102(9.43%)	16(1.48%)
Do you think Misleading Advertisements should be reported?	887(81.98%)	141(13.03%)	54(4.99%)
Have you ever experienced Adverse Drug Reactions in your patient during your professional practice?	417(38.54%)	161(14.88%)	504(46.58%)

Response regarding Practice of pharmacovigilance of ASU & H Drugs

Out of 27 questions, 4 questions related to Practice (Table 5). Most respondents $> 50\%$ indicated that they had been subjected to the Pharmacovigilance Awareness program

and read articles on the prevention of adverse drug reactions. However, 31.70% never read any article on the prevention of adverse drug reactions, and 45.10% have never been subjected to the Pharmacovigilance Awareness program. Few gaps were noted, 63.40% had never

reported Adverse Drug Reactions, and only 23.30% showed a positive response. When the respondents were asked about, reporting Misleading Advertisements,

24.21% reported and 46.86% never reported misleading advertisements. Further, <30% answered seldom for the four related questions.

Table 5. Answers to Practice related questions

Practice Domain Questions	Always	Seldom	Never
Have you read any articles on the prevention of adverse drug reactions?	598(55.27%)	141(13.03%)	343(31.70%)
Have you ever reported Adverse Drug Reactions?	251(23.20%)	145(13.40%)	686(63.40%)
Have you ever been subjected to the Pharmacovigilance Awareness program/training?	575(53.14%)	19(1.76%)	488(45.10%)
Did you ever report Misleading Advertisements?	262(24.21%)	313(28.93%)	507(46.86%)

Correlation between Knowledge, Attitude, and Practice

This study finding evidences a positive correlation between KAP Scores; However, the magnitude of the correlation is weak. Knowledge scores were positively correlated with attitude ($r=0.258$) and practice ($r=0.056$),

whereas attitude scores were positively correlated with practice scores ($r=0.269$) (Table 6). These findings suggest that knowledge, attitude, and practice scores were correlated with each other, and the direction of the relationship is positive, although the magnitude is a weak correlation.

Table 6. Correlations between KAP

		Knowledge Score	Attitude Score	Practice Score
Knowledge Score	Pearson Correlation	1	.258**	.056
	Sig. (2-tailed)		<.001	.067
	N	1082	1082	1082
Attitude Score	Pearson Correlation	.258**	1	.269**
	Sig. (2-tailed)	<.001		<.001
	N	1082	1082	1082
Practice Score	Pearson Correlation	.056	.269**	1
	Sig. (2-tailed)	.067	<.001	
	N	1082	1082	1082

** . The correlation was significant at the 0.01 level (2-tailed).

Discussion

The current cross-sectional study assessed the levels and determinants of KAP of Pharmacovigilance of ASU & H Drugs, among Unani Stakeholders in India.

In this study, we observed that the average knowledge score of the study participants was 11.36 ± 3.5 (Total score 19), of the total responders, 47 % had a low or very low knowledge level and 53 % had a good or high level of knowledge. This indicates that there is still a need to educate and sensitize the Unani stakeholders about the knowledge and importance of the objectives of Pharmacovigilance of ASU & H Drugs.

In this study, it was observed 82.3 % gave the correct definition of pharmacovigilance. In a study by Gupta et al. 62.5 % and the study by Meher et al. 41 % of participants

responded to the correct answer (Gupta et al., 2015; Meher BR, 2015).

In this study, 83.82 % of participants said that reporting ADR is necessary, which is comparable with the study by Acharya, et al. where 95.48 % of participants said that reporting ADR is necessary, whereas in the study of Meher et al. 59 % answered the correct response (Acharya et al., 2022; Meher BR, 2015).

In this study, 63.67 % provided the correct location of the National coordination center for the Pharmacovigilance Programme of ASU and H Drugs in India, whereas in a study by Acharya, et al. 52.15 % provided correct answers about the location of the pharmacovigilance center (Acharya et al., 2022).

In this study, 45.65 % have the concept of misleading advertisements, whereas in a study by Acharya, et al.

64.89 % replied to the correct answer (Acharya et al., 2022).

In this study, it was shown that 82.3 % of respondents provided an accurate definition of pharmacovigilance. 62.5 % of participants in a study by Gupta et al. and 41 % in a study by Meher et al. answered the correct response (Gupta et al., 2015; Meher BR, 2015).

Regarding the questions: to whom Misleading Advertisements should be reported, the location of the Intermediary Pharmacovigilance Centre for Unani Drugs, the official website of the pharmacovigilance center of ASU & H Drugs, inappropriate knowledge was observed among the participants; this might be because of the lack of awareness of the Pharmacovigilance program of ASU & H Drugs.

The assessment of the questionnaire based on the attitude regarding pharmacovigilance of ASU & H Drugs shows that 89.09 % of respondents stated that Pharmacovigilance should be taught in detail to all healthcare professionals. A similar response was obtained in the study by Gupta et al. where the number was 92.1 % whereas in a study by Acharya, et al. 95.69 % replied the same (Gupta et al., 2015; Acharya et al., 2022).

In this study, it was observed 70.33 % agreed with establishing a Pharmacovigilance center in every hospital, in a study by Acharya, et al. 56.47 % agreed, whereas in the study by Kharadi et al. only 36 % agreed (Acharya et al., 2022; Kharadi et al., 2021).

Even though, ADR reporting is the most important component of the Pharmacovigilance program actual practices of ADR reporting are very low. In this study, 38.54 % of the respondents stated that they experienced Adverse Drug Reactions in their professional practice, in a study by Acharya, et al. 30.59 % experienced them. compared to the Murarai et al. and Desai et al. study, where 85 % and 60% of the participants, respectively, experienced Adverse Drug Reactions in their professional practice, our results are very low. This attitude component is in much need of attention for improving the underreporting of ADRs (Murarai et al., 2011; Desai et al., 2011). 81.98 % of the participants in this study supported the fact that Misleading Advertisements should be reported.

The assessment of the questionnaire based on practice regarding pharmacovigilance of ASU & H Drugs shows that 55.27 % of respondents read articles on the prevention of ADR, which is comparable to the study by Kharadi D et al. and Acharya et al. whereas 41% and 58.93% of the participants, respectively, read articles on the prevention of ADR (Acharya et al., 2022; Kharadi et al., 2021).

In this study 23.20% of respondents reported Adverse Drug Reactions; a similar response was reported by Gupta et al. where the number was 22.8 %, whereas in the study

by Murarai et al. and Acharya et al. it was 15% and 6.57 % respectively. The lack of time and knowledge about ADRs has often been deemed a cause of underreporting. Inappropriate knowledge of drug interactions, food, and drug interactions may mislead healthcare professionals in recognizing the ADR hence, there is less reporting of an ADR, which may ultimately lead to the poor practice of Pharmacovigilance of ASU & H Drugs (Gupta et al., 2015; Murarai et al., 2011; Acharya et al., 2022).

In this study, 53.14 % of the participants stated that they have been subjected to the Pharmacovigilance Awareness program which is comparable to the study by Gupta et al. where 53.5 % of participants were subjected to the Pharmacovigilance Awareness program. lack of Awareness hinders the process of practicing pharmacovigilance of ASU & H Drugs (Gupta et al., 2015).

In this study, 46.86 % of respondents have never reported Misleading Advertisements, whereas in a study by Acharya, et al. 93.84 % unreported Misleading Advertisements, this might be due to a lack of awareness of the Pharmacovigilance program of ASU & H Drugs (Acharya et al., 2022).

In this study, it was observed a positive correlation between KAP Scores. However, the magnitude of this correlation is weak. This is probably because although knowledge is essential in shaping attitudes, promoting knowledge alone is insufficient and effective awareness to improve practice should be needed for both adequate knowledge and positive attitudes.

This study revealed that the Unani stakeholders had knowledge and attitude about pharmacovigilance, but lacked practice. Hence, to improve the practice of Pharmacovigilance of ASU & H drugs, there should be proper implementation of Pharmacovigilance activities, like regular training programs, mandatory provision of ADR reporting forms in every clinical department of the institutions, regular electronic communication updates on the safety of drugs & misleading advertisements to all health care professionals, timely financial funding for programs promotion of patient self-reporting of ADRs, filling the communication gaps regarding Pharmacovigilance of ASU & H drugs among healthcare professionals.

Our study has several limitations including cross-sectional small sample size and larger studies that can be conducted with a greater number of participants from different regions to have a better idea of the pharmacovigilance program of ASU & H Drugs.

Conclusion

The results of this study demonstrate that more than 50% of the study participants are aware of the knowledge of pharmacovigilance, and also have a favorable attitude

toward reporting ADRs and misleading advertisements. Knowledge and attitude alone are insufficient for the success of the pharmacovigilance program of ASU & H Drugs. Efforts should be made on increasing the practice of pharmacovigilance through awareness programs. There is a need for training and educational activities like CMEs for increasing the awareness of reporting ADRs and misleading advertisements, which is essential for the effective implementation of the pharmacovigilance program of ASU & H Drugs.

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Conflict of Interest

The authors declare no conflicts of interest.

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