



RESEARCH ARTICLE

Knowledge, attitude, and practice among Ayurvedic scholars and trainees towards pharmacovigilance: a questionnaire-based survey in Gujarat, India

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ARTICLE INFO ABSTRACT



Received 07 December 2021; Revised 26 January 2022; Accepted 17 February 2022.	Aim: The study was carried out to assess the knowledge, attitude, and practice of scholars and trainees studying in Ayurveda colleges of Gujarat state regarding pharmacovigilance and ADR reporting.
Keywords: ADR, Ayush, awareness, knowledge, pharmacovigilance, practice	Methods: The questionnaire-based study was carried out during December 2020 and January 2021. Total 29 questions covering points like participants' knowledge, attitude, and practice towards pharmacovigilance, adverse drug reaction reporting, and misleading advertisements related to Ayurveda drugs were made available to participants in Google forms through their Emails. The result was presented using simple frequencies with percentages in appropriate tables. Results: A total of 1790 scholars and trainees from 17 different colleges of Gujarat state participated in the survey. The majority of participants were BAMS students (97.15%) and from private colleges (81.79%). Analysis of survey data reveals that the majority of the respondents have better knowledge and attitude, but limited practice regarding pharmacovigilance and ADR reporting. Among the respondents, 86.74% had correctly defined the Pharmacovigilance and 69.32% knew about the specific ADR reporting form for ASU&H drugs. Even though ADR reporting was considered to be important by a large majority of the participants (87.95%), the actual practices of ADR reporting were very low. A large number of respondents were also not familiar with reporting misleading advertisements. Conclusion: Findings of the present study reflect a good knowledge of the participants about the concept of Pharmacovigilance but lack of skill in practicing the same. The positive attitude towards the practice of Pharmacovigilance and ADR reporting may help in improving ADR monitoring and reporting. Further, it can be suggested that integration of this subject in the curriculum is pivotal in improving the ongoing pharmacovigilance activities.

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Introduction

Pharmacovigilance is an important discipline worldwide to ensure patient safety and the appropriate use of medicines (Kumar *et al.*, 2017). Moreover, it has a vital role in therapeutic decision-making, either for an individual or national or in a global perspective (Arora *et al.*, 2008). Pharmacovigilance and adverse drug reactions reporting education are important competencies all healthcare school students need to obtain before they graduate and be involved in clinical practice as healthcare professionals (Reumerman *et al.*, 2018). Some of the studies demonstrated that knowledge of pharmacovigilance is improving gradually, but unfortunately, the actual practice of ADR reporting is still deficient among medical students and pharmacy students (Patchva *et al.*, 2018; Sharmind *et al.*, 2020). Therefore, educating healthcare students in different systems of medicine including Ayurveda, and involving them early in clinical practice to prescribe, administer and/or monitor medications is essential to ensure the safe use of medications (Van eekeren *et al.*, 2018). As future Ayurveda practitioners, undergraduate students, postgraduate scholars, and trainees need to be well trained on how to recognize, prevent, and report ADR.

Govt. of India established the monitoring of the safety of Ayurveda, Siddha, and Unani (ASU) drugs under a national level program in the year 2008, at Institute for Post Graduate Teaching and Research in Ayurveda (IPGT&RA), Jamnagar, a constituent institute of Gujarat Ayurved University, Jamnagar which is first of its kind institute dedicated to Ayurveda education and research. In the year 2018, the Ministry of AYUSH, Govt. of India reintroduced the program under the Central Sector scheme for promoting "Pharmacovigilance of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs" (PIB 2021). However, the pharmacovigilance program, like most others around the world, suffers from underreporting of ADRs by healthcare professionals. There is a lack of information about the reasons behind this underreporting by healthcare professionals in general and Ayurveda healthcare students in particular, and no studies have explored this issue to date.

Ayurveda Healthcare students could play a major role in the successful implementation of the program if adequate knowledge and skill are imparted to them during their UG/PG training career. But, at present, no significant statistics are available to understand the knowledge, attitude, and perception of pharmacovigilance among them. Therefore, the present study is intended to evaluate the level of knowledge, attitude, and perception of pharmacovigilance and ADRs reporting among Ayurveda healthcare students which will facilitate in identifying the need for education/training on pharmacovigilance.

Material and methods

Type of study

This is a cross-sectional, questionnaire-based study aimed to assess knowledge, attitude, and practice towards pharmacovigilance and adverse drug reaction reporting among Ayurveda scholars and trainees of Gujarat state, which has 24 Ayurveda colleges.

Sampling method and source of data

A convenience sampling method was used in which Ayurveda scholars and trainees studying and working in different Ayurveda Colleges of Gujarat state were requested to provide their responses.

Inclusion and exclusion criteria

Scholars and trainees presently studying and working at Ayurveda colleges, the state of Gujarat, from both government, private and autonomous sectors, who are willing to participate and give their consent for participation irrespective of age, sex and experience were included in the study. Participants who were not willing to participate were excluded from the study.

Ethical considerations

This study was undertaken after getting ethical clearance from institutional ethics committee (IEC) vide its meeting held on 8th January 2021 vide agenda no.4.1

Validity and reliability of the study tool

The survey questionnaire was constructed after an extensive review of literature on KAP studies related to Ayurveda (Prakash *et al.*, 2016; Rajesh *et al.*, 2017) Pharmacovigilance (Toklu *et al.*, 2008; Upadhyaya *et al.*, 2015; Adheed *et al.*, 2017) and healthcare workers (Rathod *et al.*, 2014; Agarwal *et al.*, 2017). An initial draft was made by referring to these available data collection instruments with suitable customization for the present study. A questionnaire covering points like participants' knowledge, attitude, and practice towards pharmacovigilance, adverse drug reaction reporting, and misleading advertisement linked to the objectives of the study was developed. A group of pharmacovigilance experts (n=5) reviewed the questionnaire and checked for the question's consistencies, clarity and relevance then modified accordingly. A pilot study was conducted with the final format among the post-graduate scholars of the institute (n=10), to evaluate the appropriateness of the questions to the target sample and to assess whether data collection procedures are feasible or not. Data obtained during the pilot study were excluded from the reported study results.

Data collection procedure

Total 29 pretested questions; 13 related to knowledge covering concept, the present structure, and reporting of ADR, 10 on attitude and 6 on practice, in Google form, were made available to all the targeted participants through email, as part of a series of awareness program being conducted by intermediary pharmacovigilance centre for

Ayurveda (IPvC), institute of teaching and research in Ayurveda (ITRA), Jamnagar during December 2020 and January 2021. Each eligible participant was asked to complete the consent form that explained the purpose of the study before proceeding to complete an online survey.

Data management and analysis

The survey questionnaire was analyzed question-wise and their percentage value was calculated with the help of a microsoft excel spreadsheet in MS office 2010. The result is presented using simple frequencies with percentages in appropriate tables.

Results

Total 1790 scholars and trainees registered for participating in the survey for 17 different colleges of Gujarat state. Among them, 97.15 % (n=1739) were BAMS students, 2.68 % (n=48) were MD scholars and 0.17 % (n=3) were PhD scholars. The majority of the participants i.e 81.79 % (n=1464) were from private colleges having experience between 0-1 years. Details of participants with regards to their gender, qualification, service sector, and experience are provided in Table 1.

Table 1: Demographics

S No	Indicators	BAMS scholar (n=1270)	PG scholar (n=278)	Ph. D scholar (n=45)	Trainee (n=197)	Total (n=1790)
1	Gender					
	Male	519(40.87 %)	86(30.94%)	26(57.78%)	71(36.04%)	702(39.22%)
	Female	751(59.13%)	192(69.06%)	19(42.22%)	126(63.96%)	1088(60.78%)
2	Qualification					
	BAMS	1270(100%)	278(100%)	--	191(96.95%)	1739(97.15%)
	MD	--	--	45(100%)	3(1.52%)	48(2.68%)
	PhD	--	--	--	3(1.52%)	3(0.17%)
3	Sector					
	Govt.	210(16.54%)	19(6.83%)	--	97(49.24%)	326(18.21%)
	Private	1060(83.46%)	259(93.17%)	45(100%)	100(50.76%)	1464(81.79%)
4	Experience					
	>15 years	--	4(1.44%)	--	--	4(0.22%)
	11 – 15 years	--	2(0.72%)	12(26.67%)	1(0.51%)	15(0.84%)
	6-10 years	--	20(7.19%)	7(15.56%)	4(2.03%)	31(1.73%)
	1 – 5 years	--	34(12.23%)	21(46.67%)	17(8.63%)	72(4.02%)
	0 – 1 year	1270(100%)	218(78.42%)	5(11.11%)	175(88.83%)	1668(93.18%)

Before starting the awareness program total of 3 questions were asked to all the eligible participants. About 68.49 % (n=1226) participants were aware of the pharmacovigilance program for ASU&H drugs in India. The majority of them were interested in the awareness/training program to know the basics of pharmacovigilance (48.60 %) and to update

themselves about pharmacovigilance (33.41 %). A large proportion among the participants i.e. 81.51 % (n=1459) has not attended any lecture series/ training programme in pharmacovigilance previously. Details of the responses are provided in Table 2.

Table 2: Responses of registered participants about awareness/ training programme on pharmacovigilance:

S No	Questions/Responses	BAMS scholar (n=1270)	PG scholar (n=278)	Ph. D scholar (n=45)	Trainee (n=197)	Total (n=1790)
1	Are you aware of pharmacovigilance programme for ASU& H drugs in India?					
	Yes	812(63.94%)	245(88.13%)	42(93.33%)	127(64.47%)	1226(68.49%)

No	458(36.06%)	33(11.87%)	3(6.67%)	70(35.53%)	564(31.51%)
2 Why you are interested in pharmacovigilance awareness/ training programme?					
Unknown about Pharmacovigilance	233(1.83%)	15(5.40%)	0(0%)	26(13.20%)	274(15.31%)
Want to know the basics of Pharmacovigilance	676(53.23%)	78(28.06%)	1(2.22%)	115(58.38%)	870(48.60%)
Want to update about Pharmacovigilance	341(26.85%)	165(59.35%)	39(86.67%)	53(26.90%)	598(33.41%)
Want to how and where to report ADR	20(1.57%)	20(7.19%)	5(11.11%)	3(1.52%)	48(2.68%)
3 Have you attended any lecture series/ training programmes in pharmacovigilance previously?					
Yes	205(11.45%)	89(32.01%)	11(24.44%)	26(13.20%)	331(18.49%)
No	1065(88.55%)	189(67.99%)	34(75.56%)	171(86.80%)	1459(81.51%)

Out of 1790 registered participants, 1286 participated in the survey yielding a participation rate of 73.39 %. Comparatively the participation rate is better among PG scholars and trainees. BAMS scholars and Ph. D scholars showed a moderate participation rate of those who participated in the study, 1154 participants consented to the survey and offered their responses yielding a response rate

of 91.14 %. The majority of the respondents were PG scholars followed by Ph. D scholars, BAMS scholars, and Trainees. The response rate was almost equal in all the responded stakeholders. The details of registered participants, participation, and response rate are provided in **Figure 1**.

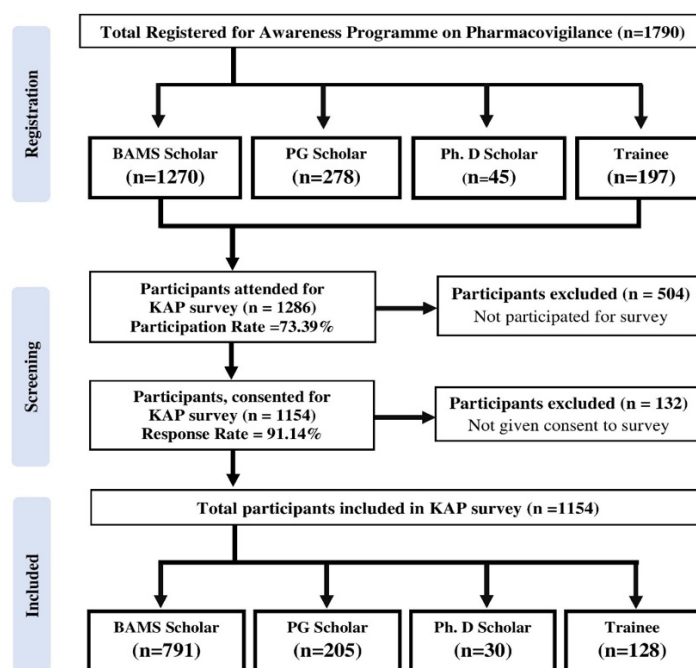


Figure 1: Registration and Participation in KAP Survey

Knowledge

The observation related to participants' knowledge on pharmacovigilance is presented in Tables 3 to 5. Total thirteen questions were designed to evaluate participants'

knowledge regarding pharmacovigilance and ADRs reporting.

The study found that 86.74 % of participants had correctly defined pharmacovigilance as it deals with monitoring of

drug safety and other drug-related problems. A relatively less number of the participants (27.04 %) were aware of the information that, advertising regulation of ASU&H products comes under the domain of the Drug and Magic Remedies Act 1954. Further, more than 30 % of the respondents think that misleading advertisements are regulated by the Drugs and Cosmetics Rules 1945. Though the majority of the participants (49.83 %) consider many Ayush medicines-related advertisements in TV, social media, news papers, and roadside posters claiming a cure for various diseases as misleading advertisements, a considerable proportion of respondents (24.70 %) are not sure about that. About 59.79 % of participants were aware of the inclusion of blood products, nutraceuticals, cosmetics, medical devices, and vaccines under the purview of pharmacovigilance. But, 10.83 % were not aware that they fall under the purview of pharmacovigilance. Rest 11.18 % were not sure about the answer.

More than one-third of the respondents (38.13 %) answered CDSCO as the monitoring authority of pharmacovigilance for ASU & H Drugs, nearly half of the participants (41.51 %) do not know that the international center for Adverse Drug Reaction monitoring is located in Sweden. About 48.53 % of participants think that ADRs related to ASU & H Drugs can be reported to anyone among the national pharmacovigilance centre, intermediary pharmacovigilance centre, and peripheral pharmacovigilance centre or online on the official website of pharmacovigilance program for ASU&H drugs. About 6.07 % think that they can be

reported on the official website of the pharmacovigilance program only. When asked about the misleading advertisements related to ASU & H Drugs, participants provided diverse opinions. Only 42.12 % were knowing that misleading advertisements related to ASU & H Drugs can be reported to the state licensing authority or GAMA portal of the department of consumer affairs. The remaining 66.04 % of the participants opted for a single option between two. The location of the present national pharmacovigilance centre for ASU&H drugs was known by more than half (61.79 %) of the respondents. Almost one-third believe that (28.86 %) national pharmacovigilance center is located at ITRA, Jamnagar. The official website of the pharmacovigilance program for ASU & H Drugs in India was familiar to only 44.11 % of the participants. A major proportion of the respondents (48.44 %) opined that ayushpharmacovigilance.com is the official website designated for the pharmacovigilance program.

Regarding the reporting of ADR, the majority (73.40 %) of the respondents were aware of reporting of ADR by different stakeholders like doctors, pharmacists, nurses, etc. can report. However, there are about 13.52 % of participants believed that only doctors can report ADR. Further, the majority of the participants are aware that, adverse drug reactions (ADR) and side effects (SE) are not the same. It is observed that more than half of the participants (69.32 %) knew about the specific ADR reporting form for ASU&H drugs while the rest of the participants didn't know about the availability of separate ADR reporting forms.

Table 3: Knowledge of participants regarding the concept of pharmacovigilance

S No	Questions/Responses	BAMS scholar (n=791)	PG scholar (n=205)	Ph. D scholar (n=30)	Trainee (n=128)	Total (n=1154)
1	Pharmacovigilance deals with					
	Monitoring of pharmacy	34 (4.30%)	3 (1.46%)	0 (0%)	1 (0.78%)	38 (3.29%)
	Monitoring of quality of traded drugs	56 (7.08%)	4 (1.95%)	1 (3.33%)	13 (10.16%)	74 (6.41%)
	Monitoring of drug efficacy	31 (3.92%)	3 (1.46%)	1 (3.33%)	6 (4.69%)	41 (3.55%)
	Monitoring of drug safety and other drug-related problems	670 (84.70%)	195 (95.12%)	28 (93.33%)	108 (84.38%)	1001 (86.74%)
2	In India, which Rule/Act is applicable for misleading advertisement?					
	Drug and Magic Remedies Act 1954	245 (30.97%)	42 (20.5%)	8 (26.67%)	17 (13.28%)	312 (27.04%)
	Drugs And Cosmetics Rules 1945	293 (37.04%)	90 (43.9%)	13 (43.33%)	62 (48.44%)	458 (39.69%)
	Both of the Above	143 (25%)	54 (26.3%)	8 (26.67%)	25 (19.53%)	230 (19.93%)
	Can't say	110 (25%)	19 (9.3%)	1 (3.33%)	24 (18.75%)	154 (13.34%)

3	Many AYUSH medicines-related advertisements in TV, social media, news papers, roadside posters, etc. are claiming a cure for various diseases. Do you consider them misleading advertisements?				
Yes	359 (45.39%)	127 (61.95%)	21 (70.00%)	68 (53.13%)	575 (49.83%)
No	143 (18.08%)	16 (7.80%)	2 (6.67%)	13 (10.16%)	174 (15.08%)
Maybe	213 (26.93%)	44 (21.46%)	6 (20.00%)	22 (17.19%)	285 (24.70%)
Can't say	76 (9.61%)	18 (8.78%)	1 (3.33%)	25 (19.53%)	120 (10.40%)
4	Does blood products, nutraceuticals, cosmetics, medical device, and vaccines come under the preview of pharmacovigilance?				
Yes	438 (55.37%)	147 (71.71%)	25 (83.33%)	80 (62.50%)	690 (59.79%)
No	94 (11.88%)	19 (9.27%)	4 (13.33%)	8 (6.25%)	125 (10.83%)
May be	172 (21.74%)	29 (14.15%)	1 (3.3%)	8 (6.25%)	210 (18.20%)
Can't say	87 (11.00%)	10 (4.88%)	0 (0.00%)	32 (25.00%)	129 (11.18%)

Table 4: Knowledge of participants regarding the structure of the national and international pharmacovigilance programme.

S No	Questions/Responses	BAMS Scholar (n=791)	PG Scholar (n=205)	Ph. D Scholar (n=30)	Trainee (n=128)	Total (n=1154)
1	In India, who is monitoring pharmacovigilance for ASU & H Drugs?					
	CDSO, New Delhi	234 (30%)	144 (70.2%)	17 (56.67%)	45 (35.16%)	440 (38.13%)
	CCRAS New Delhi	92 (12%)	29 (14.1%)	9 (30.0%)	38 (29.69%)	168 (14.56%)
	Ministry of AYUSH, New Delhi	332 (41.97%)	28 (13.7%)	4 (13.33%)	23 (17.97%)	387 (33.54%)
	CCIM, New Delhi	133 (16.81%)	4 (2.0%)	0 (0%)	22 (17.19%)	159 (13.78%)
2	The International center for adverse drug reaction monitoring is located at					
	United States of America	179 (22.63%)	44 (21.46%)	8 (26.67%)	51 (39.84%)	282 (24.44%)
	United Kingdom	87 (11%)	34 (16.59%)	5 (16.67%)	25 (19.53%)	151 (13.08%)
	France	33 (4.17%)	6 (2.93%)	1 (3.33%)	6 (4.69%)	46 (3.99%)
	Sweden	492 (62.20%)	121 (59.02%)	16 (53.33%)	46 (35.94%)	675 (58.49%)
3	Where to report an ADR related to ASU&H drugs?					
	National pharmacovigilance centre for ASU&H drugs	244 (30.85%)	46 (22.44%)	5 (16.67%)	46 (35.94%)	341 (29.55%)
	Intermediary pharmacovigilance centre for ASU&H drugs	22 (2.78%)	2 (0.98%)	0 (0.00%)	4 (3.13%)	28 (2.43%)

	Peripheral pharmacovigilance centre for ASU&H drugs	121(15.30%)	22 (10.73%)	4 (13.33%)	8(6.25%)	155 (13.43%)
	Online in the official website of pharmacovigilance program for ASU&H drugs	45(5.69%)	17 (8.29%)	3(10.00%)	5 (3.91%)	70 (6.07%)
	Any one of the above	359(45.39%)	118(57.56%)	18 (60.00%)	65 (50.78%)	560 (48.53%)
4	Do you know how to and to whom misleading advertisements related to ASU & H Drugs should be reported?					
	State licensing authority	90 (11.38%)	56 (27.32%)	7(23.33%)	9 (7.03%)	162 (14.04%)
	GAMA portal of Department of consumer affairs	225 (28.45%)	56 (27.32%)	7(23.33%)	36 (28.13%)	324 (28.08%)
	Any one of the above	180 (22.76%)	54 (26.34%)	11 (36.67%)	31 (24.22%)	276 (23.92%)
	Can't say	296 (37.42%)	39 (19.02%)	5(16.67%)	52 (40.63%)	392 (33.97%)
5	In India, the present National coordination center for pharmacovigilance program for ASU & H drugs is situated at?					
	AIIA, New Delhi	541 (68.39%)	97 (47.32%)	15 (50.00%)	60 (46.88%)	713 (61.79%)
	ITRA, Jamnagar	179 (22.36%)	98 (47.80%)	11 (36.67%)	45 (35.16%)	333 (28.86%)
	BHU, Varanasi	36 (4.55%)	5 (2.44%)	2 (6.67%)	15 (11.7%)	58 (5.03%)
	NIA, Jaipur	35 (4.42%)	5 (2.44%)	2 (6.67%)	8 (6.25%)	50 (4.33%)
6	The official website of the pharmacovigilance program for ASU & H Drugs in India is?					
	Ayushpharma.com	47 (5.94%)	5 (2.44%)	1(3.33%)	8 (6.25%)	61 (5.29%)
	Ayushsuraksha.com	401 (50.70%)	65(31.71%)	15(50.00%)	28 (21.88%)	509 (44.11%)
	Ayushpharmacy.com	19 (2.40%)	0 (0.00%)	0 (0.00%)	6 (4.69%)	25 (2.17%)
	Ayushpharmacovigilance.com	324 (40.96%)	135(65.85%)	14 (46.67%)	86 (67.19%)	559 (48.44%)

Table 5: Knowledge of participants regarding reporting of ADR and its format.

S No	Questions/ Responses	BAMS scholar (n=791)	PG scholar (n=205)	Ph. D scholar (n=30)	Trainee (n=128)	Total (n=1154)
1	Who among the following can report ADR					
	Doctor	57 (7.21%)	76 (37.07%)	5 (16.67%)	18(14.06%)	156 (13.52%)
	Nurse	2 (0.25%)	0 (0%)	0 (0%)	0(0%)	2 (0.17%)
	Pharmacist	114 (14.41%)	4 (1.95%)	1 (3.33%)	8(6.25%)	127 (11.01%)
	Patient	16 (2.02%)	4(1.95%)	0(0%)	2(1.56%)	22 (1.91%)
	All of the above	602(76.11%)	121(59.02%)	24(80%)	100(78.13%)	847 (73.40%)

2	Are adverse drug reactions (ADR) and side effects (SE) are same?					
	Yes	92 (11.63%)	19 (9.27%)	3 (10.00%)	6 (4.69%)	120 (10.40%)
	No	505 (63.84%)	176(85.85%)	26 (86.87%)	93 (72.66%)	800 (69.32%)
	Can't say	66 (8.34%)	3 (1.46%)	0 (0.00%)	11 (8.59%)	80 (6.93%)
	May be	128 (16.18%)	7 (3.41%)	1 (3.33%)	14 (14.06%)	150 (13.0%)
3	Is there any specific ADR reporting form for ASU&H drugs available?					
	Yes	369 (46.65%)	118(57.56%)	20 (66.67%)	34 (26.56%)	541 (46.88%)
	No	81 (10.24%)	29 (14.15%)	2(6.67%)	15 (11.72%)	127 (11.00%)
	Can't say	237 (29.96%)	38 (18.54%)	3 (10.00%)	55 (42.97%)	333 (28.86%)
	May be	104 (13.15%)	20 (9.76%)	5 (16.67%)	24 (18.75%)	153 (13.26%)

Attitude

The data observed about the attitude of the participants towards pharmacovigilance is presented in Table 6. There were ten questions related to the attitudes of the participants towards ADR reporting and pharmacovigilance. Among the 1154 participants, 39.08 % believe that mixopathy (A combination of more than one drug therapy) can cause ADR. An equal number of participants (34.06 %) think that this may be a cause for ADR. About 52.60 % of respondents feel that a pharmacovigilance center should be established in every hospital whereas as per 25.48 % of respondents, one center in a city is sufficient. Though a major part of

respondents (72.10 %) opine that poor quality of the drug, medication errors, prescription errors, dispensing errors are part of pharmacovigilance under drug-related problems, 11.44 % are not sure about the answer. About 82.84 % of participants are having the opinion that ADRs may result due to any negligence from the side of physician, nursing staff, pharmacist, attendant or Patients while a considerable number of participants (17.16 %) think that, only physicians are responsible for ADR. 70.02 % of respondents supported the inclusion of drugs of exclusive herbal drug origin under the preview of pharmacovigilance whereas 13.60 % believe that it is not necessary.

Table 6: Attitude of participants regarding pharmacovigilance and ADR reporting

S No	Questions/ Responses	BAMS scholar (n=791)	PG scholar (n=205)	Ph. D scholar (n=30)	Trainee (n=128)	Total (n=1154)
1	Do you think mixopathy (A combination of more than one drug therapy) can cause ADRs?					
	Yes	312 (39.44%)	86 (41.95%)	13 (43.33%)	40 (31.25%)	451 (39.08%)
	No	114 (14.41%)	22 (10.73%)	3 (10.00%)	28 (21.88%)	167 (14.47%)
	May be	263 (33.25%)	84 (4.98%)	11 (36.67%)	35 (27.34%)	393 (34.06%)
	Can't say	102 (12.90%)	13 (6.34%)	3 (10.00%)	25 (19.53%)	143 (12.39%)
2	Do you think ADR reporting is a professional obligation for you?					
	Yes	310 (39.19%)	92 (44.88%)	12 (40.00%)	52 (40.63%)	466 (40.38%)
	No	249 (31.48%)	79 (38.54%)	14 (46.67%)	28 (21.88%)	370 (32.06%)
	Can't say	158 (19.97%)	26 (12.68%)	1 (3.33%)	38 (29.69%)	223 (19.32%)
	May be	74 (9.36%)	8 (3.90%)	3 (10.00%)	10 (7.81%)	95 (8.23%)
3	Do you think reporting of adverse drug reactions of ASU&H drugs is necessary?					
	Yes	687 (86.85%)	200(97.56%)	29(96.67%)	99(77.34%)	1015(87.95%)
	No	25 (3.16%)	2 (0.98%)	1 (3.33%)	1 (0.78%)	29 (2.51%)
	Can't say	43 (5.44%)	1 (0.49%)	0 (0.00%)	17 (13.28%)	61 (5.29%)

	May be	36 (4.55%)	2 (0.98%)	0 (0.00%)	11 (8.59%)	49 (4.25%)
4	Do you think pharmacovigilance should be taught in detail to all healthcare professionals?					
	Yes	693 (87.61%)	190(92.68%)	29 (96.67%)	92 (71.88%)	1004 (87.0%)
	No	22 (2.78%)	6 (2.93%)	0 (0.00%)	7 (5.47%)	35 (3.03%)
	Can't say	51 (6.45%)	3 (1.46%)	1 (3.33%)	18 (14.06%)	73 (6.33%)
	May be	25 (3.16%)	6 (2.93%)	0 (0.00%)	11 (8.59%)	42 (3.64%)
5	What is your opinion about establishing a pharmacovigilance center / ADR monitoring center in every hospital?					
	Should be in every hospital	431 (54.49%)	107(52.20%)	20 (66.67%)	49 (32.28%)	607 (52.60%)
	Not necessary in every hospital	48 (6.07%)	11 (5.37%)	1 (3.33%)	4 (3.13%)	64 (5.55%)
	One in a city is sufficient	202 (25.54%)	47 (22.93%)	4 (13.33%)	41 (32.03%)	294 (25.48%)
	Depending on the number of bed sizes in the hospitals	110 (13.91%)	40 (19.51%)	5 (16.67%)	34 (26.56%)	189 (16.38%)
6	Do you think poor quality of the drug, medication errors, prescription errors, dispensing errors are part of pharmacovigilance, under drug-related problems					
	Yes	577 (72.95%)	150 (73.17%)	25 (83.33%)	80 (62.50%)	832 (72.10%)
	No	51 (6.45%)	21 (10.24%)	2 (6.67%)	8 (6.5%)	82 (7.11%)
	May be	92 (11.63%)	25 (12.20%)	3 (10.00%)	12 (9.38%)	132 (11.44%)
	Can't say	71 (8.98%)	9 (4.39%)	0 (0.00%)	28 (21.88%)	108 (9.36%)
7	Do you think ADRs result only due to any negligence from the side of					
	Physician	131 (16.56%)	41(20.00%)	2 (6.67%)	24 (18.75%)	198 (17.16%)
	Nursing Staff	3 (0.38%)	4 (1.95%)	0 (0.00%)	0 (0.00%)	7 (0.61%)
	Pharmacist	170 (21.49%)	21 (10.24%)	2 (6.67%)	21 (16.41%)	214 (18.54%)
	Attendant	12 (1.52%)	2 (0.98%)	0 (0.00%)	3 (2.34%)	17 (1.47%)
	Patients	97 (12.26%)	30 (14.63%)	3 (10.00%)	9 (7.03%)	139 (12.05%)
	None	378 (47.79%)	107(52.20%)	23 (76.67%)	71 (55.47%)	579 (50.17%)
8	Is it correct to keep the drugs of exclusive herbal drug origin under the preview of pharmacovigilance?					
	Yes	546 (69.03%)	164(80.00%)	24 (80.00%)	74 (57.81%)	808 (70.02%)
	No	42 (5.31%)	9 (4.39%)	2 (6.67%)	6 (4.69%)	59 (5.11%)
	May be	86 (10.87%)	19 (9.27%)	4 (13.33%)	13 (10.16%)	122 (10.57%)
	Can't say	109 (14.79%)	13 (6.34%)	0 (0.00%)	35 (27.34%)	157 (13.60%)
9	Do you think ADRs reporting should be made mandatory to physicians, pharmacists, and nursing staff?					
	Yes	600 (75.85%)	177(86.34%)	28 (93.33%)	78 (60.94%)	883 (76.51%)
	No	51 (6.45%)	5 (2.44%)	0 (0.00%)	4 (3.13%)	60 (5.20%)

May be	64 (8.09%)	15 (7.32%)	1 (3.33%)	13 (10.16%)	93 (8.06%)
Can't say	76 (9.61%)	8 (3.90%)	1 (3.33%)	33 (25.78%)	118 (10.23%)

10 Which of the following ADR to be reported?

Serious	64 (8.09%)	25 (12.20%)	2 (6.67%)	17 (13.28%)	108 (9.36%)
Moderate	44 (5.56%)	4 (1.95%)	0 (0.00%)	11 (8.59%)	59 (5.11%)
Mild	26 (3.29%)	12 (5.85%)	2 (6.67%)	6 (4.69%)	46 (3.99%)
All	657 (83.06%)	164 (80.00%)	26 (86.67%)	94 (73.44%)	941 (81.54%)

Practice

The data observed related to the present practice of pharmacovigilance among the participants is presented in Table 7. The practice of PV is crucial for generating a

national safety database of ASU&H drugs. In the present study, six questions were designed to investigate participants' practice toward pharmacovigilance and ADRs reporting.

Table 7: Practice of participants regarding pharmacovigilance and ADR reporting

S No	Questions/ Responses	BAMS scholar (n=791)	PG scholar (n=205)	Ph. D scholar (n=30)	Trainee (n=128)	Total (n=1154)
1	Is there any pharmacovigilance committee in your institute?					
	Yes	359 (45.39%)	107 (52.20%)	10 (33.33%)	34 (26.56%)	510 (44.19%)
	No	143 (18.08%)	53 (25.85%)	7 (23.33%)	29 (22.66%)	232 (20.10%)
	Not yet formed	213 (26.93%)	10 (4.88%)	6 (20.0%)	15 (11.72%)	244 (21.14%)
	Don't know	76 (9.61%)	35 (17.07%)	7 (23.33%)	50 (39.06%)	168 (14.56%)
2	Have you anytime read an article on the prevention of adverse drug reactions?					
	Yes	286 (36.16%)	117 (57.07%)	20 (66.67%)	59 (46.09%)	482 (41.77%)
	No	391 (49.43%)	62 (30.24%)	7 (23.33%)	37 (28.91%)	497 (43.07%)
	Can't say	47 (5.94%)	8 (3.90%)	1 (3.33%)	21 (16.41%)	77 (6.67%)
	May be	67 (8.47%)	18 (8.78%)	2 (6.67%)	11 (8.59%)	98 (8.49%)
3	Which of the following factor discourage you from reporting ADRs?					
	No remuneration	85 (10.75%)	22 (10.73%)	3 (10.00%)	8 (6.25%)	118 (10.23%)
	Lack of time to report ADR	128 (16.18%)	38 (18.54%)	2 (6.67%)	18 (14.06%)	186 (16.12%)
	A single unreported case may not affect the ADR database	163 (20.61%)	31 (15.12%)	7 (23.33%)	33 (25.78%)	234 (20.28%)
	Difficult to decide whether ADR has occurred or not	415 (52.47%)	114 (55.61%)	18 (60.00%)	69 (53.91%)	616 (53.38%)
4	Have you ever experienced adverse drug reactions in your patient during your professional practice?					
	Yes	100 (12.64%)	49 (23.90%)	10 (33.33%)	23 (17.97%)	182 (15.77%)

No	425 (53.73%)	137 (66.83%)	17 (56.67%)	66 (51.56%)	645 (55.89%)
Can't say	220 (27.81%)	13 (6.34%)	2 (6.67%)	30 (23.44%)	285 (24.70%)
May be	46 (5.82%)	6 (2.93%)	1 (3.33%)	9 (7.03%)	62 (5.37%)
5 Have you ever reported adverse drug reaction					
Yes	64 (8.09%)	15 (7.32%)	3 (10.00%)	13 (10.16%)	95 (8.23%)
No	642(81.16%)	178 (86.83%)	24 (80.00%)	97 (75.78%)	941(81.54%)
Don't know where to submit the ADR reporting form	41 (5.18%)	8 (3.90%)	2 (6.67%)	12 (9.38%)	63 (5.46%)
Don't know how to fill up the ADR reporting form	44 (5.56%)	4 (1.95%)	1 (3.33%)	6 (4.69%)	55 (4.77%)
6 Did you ever report misleading advertisements?					
Yes	114 (14.41%)	27 (13.17%)	3 (10.00%)	21 (16.41%)	165 (14.30%)
No	677 (85.59%)	178(86.83%)	27 (90.00%)	107(83.59%)	989 (85.70%)

Discussion

To the best of our knowledge, this is the first study in India that evaluates the knowledge attitude, and practice of Ayurveda students toward pharmacovigilance and ADR reporting. In the present study, an overall response rate of more than 90 % was recorded. This figure can be regarded as exceptionally high, especially when compared with those of other studies on the same topic carried out among pharmacy, dental, and medical students from different parts of India (Limaye *et al.*, 2018; Chhabra *et al.*, 2017; Gaude *et al.*, 2018).

Along with the early detection of ADRs pharmacovigilance facilitates the identification of both, risk factors and the mechanism underlying the ADR. Although there is an established national pharmacovigilance programme for Ayurveda, Siddha, Unani, and Homoeopathy (ASU&H) drugs, the reported number of ADRs is very little. To improve the reporting rate, it is essential to improve the knowledge of healthcare professionals regarding ADR reporting and PV. The right time to do it is probably during undergraduate and postgraduate education. Because students could play a major role in the successful implementation of the program if adequate knowledge and skill are imparted to them during their training career.

The present study demonstrates that the majority of the respondents were having a good knowledge regarding the concept of pharmacovigilance and ADRs in terms of their definitions and purposes (Table 3). But, a complete knowledge regarding the structure of the National and International pharmacovigilance program (Table 4),

reporting the ADR and its format was still lacking (Table 5). The study found that only 46.88 % of the participants knew about the availability of specific ADR reporting forms for ASU&H drugs. The limited information regarding the location of the present national pharmacovigilance co-ordinating centre, the official website of the pharmacovigilance program can be attributed to restricted information regarding recent advances and updates of pharmacovigilance in the present curriculum. This lacuna can be improved by educational interventions as reports from the published study also reveals a significant improvement in reporting ADR by healthcare professionals after educational intervention (Bagewadi *et al.*, 2018). Available literature also shows that interactive educational intervention on PV among undergraduate medical students and healthcare professionals (Bagewadi *et al.*, 2018; Rajesh *et al.*, 2011) were found to be effective in increasing awareness. However, some studies conclude that only knowledge does not help in increased ADR reporting. The educational intervention like power point presentation and also hands on training in filling up the ADR forms and causality assessment will overcome the practical issues when compared to the studies done by having lectures alone as an intervention (Kalikar *et al.*, 2020).

As per the results obtained in the study, 40.38 % of participants think that ADR reporting is a professional obligation for them. It is noteworthy to mention that, the majority of the participants (87.95 %) think reporting of adverse drug reaction of ASU&H drugs is necessary and Pharmacovigilance should be taught in detail to all the

healthcare professionals (87.0 %) which coincide with the study done on resident doctors by Gupta et al. who identified 89.5 % of resident doctors suggest the necessity of ADR reporting (Gupta et al., 2011). Similarly, another study also finds 82 % of medical students and prescribing doctors felt the need for ADR reporting (Rehan et al., 2002). ADR reporting should be made mandatory to physicians, pharmacists, and nursing staff as per 76.51 % respondents. In contrast to this, in a questionnaire-based study to evaluate the knowledge, attitude, and practice of pharmacovigilance among doctors practicing alternative systems of medicine in Southern India, only 12.5 % thought that reporting an ADR with ASU& H drugs is necessary (Rajesh et al., 2017).

Even though the ADR reporting was considered to be important by a large majority of the participants (87.95 %), the actual practices of ADR reporting were very low. Only 8.23 % of the respondents stated that they had reported an ADR previously. Some of the previous studies also cited similar findings of under-reporting of ADR despite considering it as important (Desai et al., 2011). The major problem associated with reporting ADRs is identified to be difficulty in deciding whether ADR has occurred or not which is following the previous reports (Vallano et al., 2005). An interesting observation was that 20.28 % feel that, a single unreported case may not affect the ADR database. This attitude shows the passive perception and ignores the importance of reporting ADRs.

Nonexposure of a substantial proportion of participants (43.07 %) to any articles related to the topic drags the individual away from the current updates of the program. A major proportion of the respondents have not experienced adverse drug reactions during their professional practice and 81.54 % have not reported any ADRs. This may be due to a lack of training or lack of proper follow-up in identifying the ADR. Even a large number of respondents were also not familiar with reporting misleading advertisements which shows the importance and need of continuous awareness generation which can certainly help in improving the reporting rates. Studies had also shown that enhancing the knowledge and attitude of the medical graduates helps in the practice of increasing ADR reporting to the concerned authorities (Wallace et al., 1995; Suveges et al., 1995).

Conclusion

Results of the study showed better knowledge and attitude, but limited practice toward pharmacovigilance and ADR reporting. The findings of the study suggest the scope for improving the awareness among the students who will be the mainstay of health care delivery in the future. For this, there is a need for incorporating educational intervention as they are proven to be an effective tool in improving knowledge, attitude, and practice. Revision and inclusion of updates related to the pharmacovigilance programme in

the curriculum would also help them to detect adverse effects and report to the concerned authorities.

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Conflict of interest

The authors declare no conflict of interest.

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References

- Adheed, K. S., Haydar, F. A., & Ghassan, S. A. (2017). Knowledge, Attitude and Practice towards Pharmacovigilance and Adverse Drug Reaction Reporting among Pharmacy Students in Basra University, Iraq. *International Journal of Pharmaceutical Sciences and Research*, 46(2), 83-87.
- Agarwal, M. (2017). Knowledge, Attitude, and Practice About Pharmacovigilance Among Healthcare Providers of a Tertiary Care Teaching Hospital in New Delhi (India). *MAMC J Med Science*, 3(3), 146-151.
- Arora, D. (2008). Pharmacovigilance obligations of the pharmaceuticals companies. *Indian Journal of Pharmacology*, 40(5), 13-16.
- Bagewadi, H. G., Deodurg, P. M., Patil, B. V., Dass, A. P. (2018). Knowledge, attitude, perceptions and assessment of effectiveness of educational intervention on pharmacovigilance among undergraduate medical students at Gulbarga Institute of Medical Sciences, Kalaburagi. *International Journal of Basic & Clinical Pharmacology*, 7(1), 103-108.
- Chhabra, K. G., Sharma, A., Chhabra, C., Reddy, J. J., Deolia, S. G., & Mittal, Y. (2017). Knowledge, Attitude, and Practices regarding Pharmacovigilance and Adverse Drug Reaction reporting among Dental Students in a Teaching Hospital, Jodhpur, India: A Cross-sectional Study. *The journal of contemporary dental practice*, 18(10), 964-969.
- Desai, C. K., Iyer, G., Panchal, J., Shah, S., & Dikshit, R. K. (2011). An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. *Perspectives in clinical research*, 2(4), 129-136.
- Gaude, O. S., & Desa, S. (2018). Assessment of knowledge, attitude, and practices of pharmacovigilance and adverse drug reaction reporting among final year medical students-A questionnaire-based study in a tertiary care hospital in

- Goa. *National Journal of Physiology, Pharmacy and Pharmacology*, 8(12), 1657–1661.
- Gupta, P., & Udupa, A. (2011). Adverse Drug Reaction Reporting and Pharmacovigilance: Knowledge, Attitudes and Perceptions amongst Resident Doctors. *Journal of Pharmaceutical Sciences and Research*, 3(2), 1064–1069.
- Kalikar, M. V., Dakhale, G. N., & Shrirao, M. (2020). Effect of educational intervention on awareness of pharmacovigilance among medical undergraduates in a tertiary care teaching hospital. *Perspectives in clinical research*, 11(2), 92–96.
- Kumar A. (2017). Pharmacovigilance: Importance, concepts, and processes. *American journal of health-system pharmacy: AJHP : official journal of the American Society of Health-System Pharmacists*, 74(8), 606–612.
- Limaye, D., Shah, P., Shah, A., Pillay, R., Modak, V., Chaudhari, A., Sydmanov, A., Limaye, V., Pitani, R. S., Sathe, S., Fortwengel, G. (2018). A study to determine the knowledge of pharmacovigilance among pharmacy students from Mumbai university. *International Journal of Research in Medical Sciences*, 6(8), 2621–2625.
- Patchva, L. D. (2018). Study on the knowledge of pharmacovigilance among medical students. *International Journal of Basic & Clinical Pharmacology*, 7(6), 1105–1108.
- PIB. (2004). Press Information Bureau Government of India. Retrieved 15 June 2021, from <https://pib.gov.in/PressReleasePage.aspx?PRID=1542977>
- Prakash, B. G., Subash, K. R., Reddy, V. C. K., Sujith, K. D. S., Jyothi, P. K., Rao, U. K. (2016). Knowledge, attitude and practice of pharmacovigilance among Ayurvedic practitioners: A questionnaire survey in Andhra Pradesh, India. *National Journal of Physiology, Pharmacy and Pharmacology*, 6(5), 475–479.
- Rajesh, B., Dharani, D. R., & Waseem, A. (2017). Assessment of knowledge, attitude and practice of pharmacovigilance among doctors practicing alternative systems of medicine in Southern India: A questionnaire based study. *National Journal of Physiology, Pharmacy and Pharmacology*, 7(1), 119–122.
- Rajesh, R., Vidyasagar, S., & Verma, D. M. (2011). An educational intervention to assess knowledge attitude practice of pharmacovigilance among health care professionals in an Indian tertiary care teaching hospital. *International Journal of PharmTech Research*, 3(2), 678–692.
- Rathod, K. & Panchal, A. (2014). Knowledge, attitude and practice of community pharmacists of Gujarat towards adverse drug reactions. *International Archives of Integrated Medicine*, 1(1), 18–25.
- Rehan, H. S., Vasudev, K., & Tripathi, C. D. (2002). Adverse drug reaction monitoring: knowledge, attitude and practices of medical students and prescribers. *The National medical journal of India*, 15(1), 24–26.
- Reumerman, M., Tichelaar, J., Piersma, B., Richir, M. C., & van Agtmael, M. A. (2018). Urgent need to modernize pharmacovigilance education in healthcare curricula: review of the literature. *European journal of clinical pharmacology*, 74(10), 1235–1248.
- Sharmind, N., Marzia, A., Syeda, F. H. M., & Hamza, A., M. (2020). Knowledge and Attitude about Pharmacovigilance: A Cross-sectional Study Involving Pharmacy Students of Selected Universities in Bangladesh. *Journal of Pharmacovigilance*, 8(5), 28–29.
- Suveges, L.G., Gesy, K., Wallace, S., Blackburn, J.L., & Appel, W.C. (1995). Adverse Drug Reaction Reporting Part II: Evaluation of the Saskatchewan Pilot Project for a Regional Reporting Program in Canada. *Therapeutic Innovation & Regulatory Science*, 29, 581 - 589.
- Toklu, H. Z., & Uysal, M. K. (2008). The knowledge and attitude of the Turkish community pharmacists toward pharmacovigilance in the Kadikoy district of Istanbul. *Pharmacy world & science: PWS*, 30(5), 556–562.
- Upadhyaya, H. B., Vora, M. B., Nagar, J. G., & Patel, P. B. (2015). Knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students of Tertiary Care Hospital in Gujarat. *Journal of advanced pharmaceutical technology & research*, 6(1), 29–34.
- Vallano, A., Cereza, G., Pedròs, C., Agustí, A., Danés, I., Aguilera, C., & Arnau, J. M. (2005). Obstacles and solutions for spontaneous reporting of adverse drug reactions in the hospital. *British journal of clinical pharmacology*, 60(6), 653–658.
- van Eekeren, R., Rolfes, L., Koster, A. S., Magro, L., Parthasarathi, G., Al Ramimmy, H., Schutte, T., Tanaka, D., van Puijenbroek, E., & Härmak, L. (2018). What Future Healthcare Professionals Need to Know About Pharmacovigilance: Introduction of the WHO PV Core Curriculum for University Teaching with Focus on Clinical Aspects. *Drug safety*, 41(11), 1003–1011.
- Wallace, S. M., Suveges, L. G., & Gesy, K. F. (1995). Adverse drug reaction reporting part I: A survey of pharmacists and physicians in Saskatchewan. *Drug Information Journal*, 29, 571–579.