## RESEARCH PAPER

# Knowledge of Unani and Ayurveda Practitioners Regarding Pharmacovigilance

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#### **Abstract**

**Background:** Pharmacovigilance is concerned with public health and adverse drug reactions. The essence of pharmacovigilance is the reporting of adverse drug reactions (ADRs). All health care professionals should have knowledge about pharmacovigilance.

Objective: To assess knowledge of unani and ayurveda practitioners regarding pharmacovigilance.

**Methods:** A cross sectional study was conducted among 190 selected Unani and Ayurveda practitioners who graduated from Govt-Unani and Ayurvedic medical college. Purposive sampling method was applied for sampling. A semi-structured questionnaire was developed and the respondents were interviewed face to face maintaining confidentiality and privacy. Study places were Govt-Unani and Ayurvedic Medical College of Dhaka and Sylhet and Private medical chambers of Unani and Ayurveda practitioners.

**Results:** This study revealed that out of 190 respondents 60% belonged to age group of 20-34 years and 3.7% were within the age group greater than 54 years and mean age were 34.55±7.42 years. 64.7% of the respondents were Unani practitioners and 35.3% were Ayurvedic practitioners. Regarding concept of pharmacovigilance, 22.6% of the respondents had good knowledge whereas 22.1% of the respondents had good knowledge about ADR and drug safety. Out of total 190 respondents 34.7% had good knowledge regarding pharmacovigilance, 35.8% of respondents had fair knowledge and 29.5% had poor knowledge regarding pharmacovigilance.

**Conclusion:** This study revealed that majority of Unani and Ayurveda practitioners had fair knowledge regarding pharmacovigilance. Education and training programs are necessary to improve knowledge of Unani and Ayurveda practitioners.

 $\textbf{Keyword:} \ \ \textbf{Pharmacovigilance, ADR, Knowledge, Unani and Ayurveda Practitioners.}$ 

#### Introduction

Drugs are blessing to the human society but they also produce unavoidable and undesirable adverse drug reactions (ADR). Adverse Drug Reactions are deliberated among leading causes of morbidity and mortality associated with a high prevalence rate of 3%to 6% and ranked fifth among all causes of death and increase in hospital costs. An adverse drug

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e-mail: zuli01791@gmail.com ORCID: 000-0002-0642-5929 reaction (ADR) has been defined as an unintended and noxious response to a drug that occurs at doses normally used in human beings for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.<sup>2</sup> ADRs account for 0.2%-24% of hospital admissions and 3.7% of patients have fatal ADRs. Admissions due to ADRs in elderly patients were reported to be higher 9%. ADRs contribute to a variety of medical and economic effects, e.g. prolonging hospital stays, raising the cost of care and medication, and almost doubles the risk of death.<sup>3</sup> Now a days the formulation of Unani and Ayurveda medicine have achieved widespread acceptability. Pharmacovigilance plays an important role in detecting

drug errors such that the occurrence of such errors and effects on patients can be minimized. Pharmacovigilance is also called drug safety, Drug safety is a very basic and fundamental principle of medical practice. It is a part of patient care and protection that ensures the effective use of pharmaceutical products for the treatment and prevention of ADR.<sup>4</sup> According to World Health Organization, pharmacovigilance is the pharmacological science relating to the collection, detection, assessment, monitoring and prevention of adverse effect or any other drug related problem mainly long term or short term side effects of pharmaceutical product.<sup>5</sup>

In order to prevent unnecessary suffering and to decrease the financial loss sustained by the patients due to inappropriate or unsafe use of medicines, it is important to assess the knowledge of pharmacovigilance among Unani and Ayurveda doctors. WHO emphasizes the need for consistent monitoring of ADR's related to drugs used in the alternative systems of medicine. The number of ADR's to Unani and Ayurvedic medicines reported to the National Pharmacovigilance Program (NPP) in Bangladesh is negligible which could be due to either the misconception that Ayurvedic drugs are safe or their lack of knowledge about the concept and importance of pharmacovigilance.

In Bangladesh with a large drug consuming population, there is a general misconception that the drugs used in Unani and Ayurvedic medicines are safe and devoid of adverse drug reactions (ADRs). It is important to enhance existing ADR reporting system and database with special emphasis on ADR related to Unani and Ayurvedic medicines. Due to these reasons pharmacovigilance study is required for the safety of people. It is very urgent to strengthen the pharmacovigilance knowledge and practice in our country.<sup>8</sup>

Although WHO supported adverse drug reaction monitoring (ADRM) cell was established in 1996 only 50 ADRs were reported during the next 20 years. Inadequate knowledge and irrelevant attitude of practitioners have been found to be associated factors for not reporting ADR's. To improve the participation of Unani and Ayurveda practitioners spontaneous

reporting and to design strategies for doing soassessment of knowledge regarding pharmacovigilance is important.

#### **Materials and Methods**

This study had been undertaken with the objective to determine the knowledge of unani and Ayurveda practitioners regarding pharmacovigilance. A questionnaire based descriptive type of cross-sectional study was conducted among 190 practitioners who graduated from government unani and ayurvedic medical college. The study period was one year from 1<sup>st</sup> January 2020 to 31<sup>st</sup> December 2020. The study population were practitioners graduated from Government Unani and Ayurvedic Medical College. Study place were Government. Unani and Ayurvedic Medical college and Hospital, Dhaka. Unani and Ayurvedic Medical College & Hospital, Sylhet and Private medical chambers of Unani and Ayurveda practitioners. Purposive sampling technique was applied were estimated Sample size was 190. Data were collected by a pretested semi-structured questionnaire.

Knowledge was assessed by 15 questions. The Fifteen questions on knowledge had possible two responsesyes and no (all yes answer were correct and assigned one point and all no was incorrect and assigned zero score. Total score 15, Within the 15 knowledge related questions those who got 10-15 score were considered to have good knowledge, Within the 15 knowledge related questions those who got 6-9 score were considered to have fair knowledge, Within the 15 knowledge related questions those who got 0-5 score were considered to have poor. 10 knowledge After approval of thesis protocol by the institutional review board (IRB) of National Institute of Preventive and Social Medicine (NIPSOM). Informed written consent was taken from the respondents. The subjects who fulfilled the inclusion criteria were included in the study. The purpose of the study was explained in details to the respondents. Data was collected from the respondent through face to face interview. Descriptive statistics was used for all variables, values were expressed as frequencies and percentage.

#### **Results**

Demographic characteristics of respondents are presented below.

Out of 190 respondents 60% were within the age group of 25-34 years.

Table I: Distribution of respondents by age

Age of the respondents	Percentage	Mean ± SD
(in years)		
25-34	60.0	34.55± 7.42
35-44	27.9	
45-54	8.4	
>54	3.7	

Out of 190 respondents 68% were male and 32% were female, 64.70% of the respondents were Unani and 35.30% Ayurvedic.

**Table II:** Distribution of the respondents by gender and education (n=190)

Gender of the respondents	Percentage
Male	68
Female	32
Educational qualification	
Unani	64.70
Ayurvedic	35.30

Table III shows that 63.6% of respondents knew that the Unani and ayurvedic medicine can cause an adverse drug reaction. About 82.1% of respondents knew that ADR reporting is a professional obligation, 70% of respondents knew about drug ban due to adverse drug reaction but only 22.1% of respondents knew when to report and how to report ADR. 29.0% of the respondents knew causes of under reporting.

Table IV shows that out of 190 respondents 34.7% had good knowledge regarding pharmacovigilance, 35.8% of the respondents had fair knowledge regarding pharmacovigilance and 29.5 % of the respondents had poor knowledge regarding pharmacovigilance.

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Table III: Knowledge of pharmacovigilance among unani and ayurveda practitioners.

Knowledge regarding pharmacovigilance	Correct answers Percentage	Incorrect answers Percentage
Knowledge on concept of pharmacovigilance		3
Knowledge regarding the term pharmacovigilance	66.3	33.7
Knowledge regarding the meaning of pharmacovigilance	56.3	43.7
Knowledge on purpose of pharmacovigilance	54.2	45.8
Knowledge on National pharmacovigilance programme in Bangladesh	30.0	70.0
Location of international center for ADR monitoring	9.4	90.6
Knowledge on ADR and drug safety		
Regulatory body for monitoring ADR in Bangladesh	56.8	43.2
Unani and Ayurvedic medicine can cause ADR	63.6	36.4
ADR reporting isa professional obligation	82.1	17.9
Drug safety is the main concept of pharmacovigilance	45.8	54.2
Drug banned due to ADR	70.0	30.0
Major risk factors for the occurrence of ADR	60.0	40
When to report and how to report ADR	22.1	77.9
Place of obtaining ADR form	34.2	65.8
Prevention of ADR	69.5	30.6
Knowledge regarding causes of under reporting	29.0	71.0

**Table IV:** Distribution of the respondents by level of knowledge regarding pharmacovigilance (n=190)

Level of knowledge	Frequency (f)	Percentage
regarding		
pharmacovigilance		
Good Knowledge	66	34.7
Fair Knowledge	68	35.8
Poor Knowledge	56	29.5

#### **Discussion**

This descriptive type of cross-sectional study conducted on 190 practitionerswere an effort to assess knowledge regarding pharmacovigilance. This study found that majority (60%) of the respondents belonged to age group of 25-34 years and only 3.7% respondents were within the age group greater than 54 years. The respondents mean age were 34.55± 7.42 years.

A similar study in India found that majority of the respondents 41% were between the age group of 26-30 years and only 1.7% of the respondents were between the age group of 46-50 years old. <sup>11</sup> In this study, majority 68% of the respondents were male, which is similar to a study in Chennai, India where 55.65% of the respondents were male. <sup>12</sup>

According to the present study finding, out of 190 respondents 66.3% reported to have heard the term pharmacovigilance and 33.7% of the respondents did not hear the term pharmacovigilance. Regarding meaning of pharmacovigilance 56.3% of the respondents gave correct response that they knew the meaning of pharmacovigilance and 43.7% gave incorrect answer. 54.2% of the respondents correctly answered that they knew the purpose of pharmacovigilance and 45.8% of the respondents gave incorrect answer against this question. A Study in southern India found that28.3% doctors practicing alternative system of medicine had heard the term pharmacovigilance, 3.3% knew the meaning of pharmacovigilance and 66.3% healthcare professional knew the purpose of pharmacovigilance which is not in line with this study finding.<sup>1</sup>

In this study out of 190 respondents, 30% correctly answered about the National pharmacovigilance programme in Bangladesh, 70% gave incorrect answer. 9.4% of the respondents correctly answered about thelocation of international center for adverse drug reaction monitoring and 90.6% gave incorrect answer.

Regarding regulatory body in Bangladesh for ADR monitoring 56.8% gave correct answer and 43.2%gave incorrect answer. A study conducted that 2.5% knew about the National pharmacovigilance programme in that country and another study showed that 32.1% knewabout the location of international center for adverse drug reaction monitoring. Study conducted by showed that 66.3% of the respondents gave correct response regarding regulatory body for ADR monitoring in India. 14

This study showed that 63.7% of respondents knew that Unani and Ayurvedic medicine causes adverse drug reaction, 36.3% of the respondents did not. In a study by conducted in India 20% of the respondents gave correct answer to a question regarding occurrence of ADR in Unani and Ayurvedic medicine and 80% of the respondents gave incorrect answer.<sup>15</sup>

This study demonstrated that 82.1% of respondents gave correct response that ADR reporting is a professional obligation and 17.9% of the respondents gave incorrect response. The response by practitioners to this question reflects that majority are aware about their obligation towards patients. Another study showed that 69.3% health care professional agreed that ADR reporting is a professional obligation which is not in accordance with this study finding.<sup>1</sup>

The present study showed that 45.8% of respondents correctly answered that drug safety isthe main concept of pharmacovigilance, 54.2% of the respondents gave incorrect answer. Another study in India showed 38.2% knew that drug safety isthe main concept of pharmacovigilance, 61.8% of the respondents did not know that drug safety isthe main concept of pharmacovigilance. <sup>15</sup>

The result of this study revealed that 70.0% of respondents knew about drug ban due to adverse drug reaction, 30.0% of the respondents did not know about drug ban. The result of this study showed that 60.0% of the respondents knewabout risk factors for occurrence of ADR and 40.0% of the respondents did not know about major risk factors for the occurrence of ADR. Anothersimilar study conducted in India among health care professionals. showed that 41% of the respondents knew about drug ban due to ADR and 69% of respondents knew major risk factors for occurrence of ADR. 12

The current study showed that 22.1% of respondents knew when to report and how to report ADR and 77.9%

of the respondents replied did not know when to report and how to report ADR. Study conducted in South India among community pharmacist showed that 32.9% knew when to report and how to report ADR and 69.1% did not know when to report and how to report ADR.<sup>11</sup>

The present study showed that 34.2% of respondents knew where to obtain ADR form from, and 65.8% of respondents did not know. Similar study conducted in Goa, India showed that 14.7% of respondents knew where to obtain ADR form from.<sup>14</sup>

This study showed that 34.7% had good level of knowledge, 35.8% had fair level of knowledge and 29.5% of respondents had poor level of knowledge regarding pharmacovigilance. Similar study was conducted in South India among community pharmacists which showed that 27.7% had good knowledge, 10.4% had fair knowledge regarding and 61.9% had poor knowledge regarding pharmacovigilance. 10

#### Conclusion

In conclusion, this study showed that majority of the Unani and Ayurveda practitioners had fair knowledge regarding pharmacovigilance. The reporting rate of ADR in Unani and Ayurveda practitioner's was very low. Hence, there was huge gap between the ADR experienced and ADR reported by healthcare professionals. The absence of training was evident in the answers given to questions about timelines, nature, and duty of reporting, among other things. Majority of respondents agreed that reporting of ADRs was necessary. Although majority of the respondents was well aware about their professional obligation regarding ADR reporting very few had knowledge regarding when and how to report. The study had small sample size, so the findings may not represent the actual scenario of pharmacovigilance in Bangladesh. Therefore education and training program are necessary to improve knowledge and practice of Unani and Ayurveda practitioners.

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