

## Research

# A Cross-Sectional Study on Knowledge, Attitude and Practice Towards Reporting Adverse Drug Reactions among Healthcare Professionals at a Tertiary Care Associated Hospital of Government Medical College, Baramulla, Kashmir

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### Abstract:

**Background:** A study performed on Vigibase (WHO Pharmacovigilance data base) by collecting data from more than 30 countries, revealed that >23 million reports of ADRs were forwarded to the Uppsala Monitoring Centre by national pharmacovigilance systems. This study also reported 1.34% ADRs as fatal and more than 50% of reports included male patients. Several studies have shown that the ADRs reported during hospital stay range from 1.7% to 32.7%. In developed countries, this range from 6.7% to 12.3%. It was also reported that >75 years was the most commonly affected age group in the total population. Several studies have shown that the ADRs reported during hospital stay range from 1.7% to 32.7%. In developed countries, this ranges from 6.7% to 12.3%. In India, the reported incidence of adverse drug reactions ranges from 3.7% to 32.7%. Another study from Srinagar concluded the overall incidence of ADR was found to be 6.23% and the average direct cost for ADR treatment per patient was US\$ 65. The most significant challenge in ADR management is under reporting. An estimated 94% of ADRs going unreported globally. To enhance the reporting rate, it is essential to improve the knowledge, attitude, and practice (KAP) of all healthcare professionals.

**Materials and Methods:** The conducted study was a cross-sectional study, was carried out in the month of August among healthcare professionals by using a pre designed questionnaire developed on the basis of literature review and was divided into 4 parts (sociodemographic characteristics, knowledge, attitude and practice of the study participants). Data were collected and analyzed using descriptive statistics of frequency and percentage.

**Results:** In our study we found that maximum number of the healthcare professionals had good knowledge about the definition of Pharmacovigilance (70%) and its purpose (58%). Most of them had good attitude towards reporting ADR as a professional obligation (90%). However, very less (22.67 %) have reported ADRs and only 10% (n=30) have reported more than 10 ADRs. It was also seen that the reason for not reporting the ADR was difficulty to decide whether ADR has occurred or not, given by maximum number (37 %), lack of time (26.67%) and assuming that one ADR makes no significant contribution.

**Conclusion:** As evident from the findings, our study revealed that even though most of the healthcare professionals had an acceptable knowledge and attitude towards reporting Adverse Drug Reactions but there was lack of reporting Adverse Drug Reactions among the healthcare professionals.

**Keywords:** Adverse Drug Reaction, Practice, Healthcare professionals.

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## **INTRODUCTION**

A drug acts on many tissues / systems to produce favorable responses that may be utilized for therapeutic, diagnostic and prophylactic purposes. However, a drug can also produce unfavourable responses that may be harmful to the patient called as the Adverse Drug Reaction<sup>1</sup>. Adverse drug reactions (ADRs) are “any type of response caused by a drug that is unintentional, noxious, and takes place at the drug doses which are used for diagnosing, prophylaxis, or treatment of a disease or due to the medications for the physiological functions as defined by the World Health Organization (WHO) <sup>2</sup>”. A study performed on Vigibase (WHO Pharmacovigilance data base ) by collecting data from more than 30 countries , revealed that >23 million reports of ADRs were forwarded to the Uppsala Monitoring Centre by national pharmacovigilance systems. This study also reported 1.34% ADRs as fatal and more than 50% of reports included male patients. It was also reported that >75 years was the most commonly affected age group in the total population<sup>3</sup>. Several studies have shown that the ADRs reported during hospital stay range from 1.7% to 32.7%. In developed countries, this ranges from 6.7% to 12.3%. In developing countries the median prevalence of ADRs (with IQR of ADR-related hospitalization) was .5% (1.1–16.9). The reported incidence of adverse drug reactions ranges from 3.7% to 32.7%, shown by a study in India. . ADRs are the 4th to 6th leading cause of death in the U.S. This is contributing to 100,000 deaths annually<sup>4-6</sup>. Another study from Srinagar concluded the overall incidence of ADR was found to be 6.23% and the average direct cost for ADR treatment per patient was US\$ 65.<sup>7</sup> The most significant challenge in ADR management is under reporting. An estimated 94% of ADRs going unreported globally<sup>8</sup>. This creates gaps hindering early identification of drug risks.

In order to improve the patient safety and reduce the financial burden on the healthcare system, timely and spontaneous reporting of the ADRs is very essential. The science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem is called as Pharmacovigilance.<sup>9</sup>

In India ,the PvPI was launched with a broad objective in patient safety for more than one billion people of India. In July 2010, the Central Drug Standard Control organization, New Delhi has initiated a nationwide pharmacovigilance program under aegis of Ministry of health and Family welfare, Government of India<sup>10</sup>.

The success of the PV program in India depends on the active involvement of healthcare professionals. Pharmacovigilance Programme of India (PvPI) contributes to the Uppsala Monitoring Centre database .However , due to the lack of a vibrant ADR monitoring and reporting system among healthcare workers, the reports contributed by India are very few<sup>11</sup>. To enhance the reporting rate, it is essential to improve the knowledge, attitude, and practice (KAP) of all healthcare professionals.

## **AIM AND OBJECTIVES**

To assess the knowledge , attitude and practice towards reporting Adverse drug reactions among various healthcare professionals at GMC ,Baramulla.

## **MATERIAL AND METHODS**

**STUDY DESIGN:** It was a questionnaire based Cross sectional observational study.

**STUDY SETTING:** Department of Pharmacology, Government Medical College , Baramulla.

**STUDY TOOL:** A pre designed questionnaire was developed based on the previous studies. Questionnaire contained a total of 30 questions , divided into 4 parts (sociodemographic characteristics , knowledge , attitude and practice).

**DATA COLLECTION :** Questionnaire was framed in a google form and distributed among the study participants.

**STUDY TIME PERIOD :** The study was conducted during July – August 2024.

## **INCLUSION CRITERIA**

Healthcare professionals willing to take part in the study.

Healthcare professionals working as doctors , nurses , pharmacists including students of medical and paramedical professions of GMC Baramulla.

## **EXCLUSION CRITERIA**

Healthcare professionals working and studying at GMC Baramulla who are not willing to take part in the study.

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**STATISTICAL ANALYSIS**

The data collected was entered in SPSS version 10 and analyzed. The result was obtained in terms of frequency and percentage.

**RESULTS**

A total of 300 healthcare workers including students participated in the present study. Table 1(fig. 1) shows their demographic characteristics. Maximum number of participants were in the age group of 21-30 years. Assessment of knowledge, attitude and practice towards reporting ADRs is shown in table 2 (fig.2) table 3(fig.3) and table 4 (FIG. 4 and 5) respectively.

**Table 1: Socio-demographic characteristics of the study participants**

		NUMBER	PERCENTAGE
AGE(in years )	<20	15	5.00
	21-30	220	73.73
	31-40	40	13.33
	>41	25	8.33
	Total	300	100
GENDER	Male	147	49.00
	Female	153	51.00
	Total	300	100
PROFESSIONAL STATUS	Doctors	60	20.00
	Paramedical staff	52	17.33
	MBBS students	134	44.67
	Paramedical students	54	18.00
	Total	300	100
WORK EXPERIENCE(in Years)	>10	27	9.00
	6-10	41	13.67
	<5	44	14.67
	Not applicable	188	62.67

**Table 2: Knowledge regarding reporting of ADRs among the study participants.**

	RESPONSE	NUMBER	PERCENTAGE
5. What is Pharmacovigilance?	CORRECT	210	70.00
	INCORRECT	90	30.00
	Total	300	100
6. The most important purpose of Pharmacovigilance is?	CORRECT	174	58.00
	INCORRECT	126	42.00
	Total	300	100
7. Which type of ADRs should be reported?	CORRECT	258	86.00
	INCORRECT	42	14.00
	Total	300	100
8. Rare ADRs can be identified in which phase of a clinical trial?	CORRECT	187	62.33
	INCORRECT	113	37.67
	Total	300	100
9. Who are the healthcare professionals responsible for reporting ADRs in a hospital?	CORRECT	260	86.67
	INCORRECT	40	13.33
	Total	300	100
10. To whom ADRs should be reported?	CORRECT	157	52.33

	INCORRECT	143	47.67
	Total	300	100
11. Are you aware of ADR monitoring system in GMC Baramulla?	CORRECT	201	67.00
	INCORRECT	99	33.00
	Total	300	100
12. Are you aware of ADR reporting system in India?	CORRECT	222	74.00
	INCORRECT	78	26.00
	Total	300	100
13. Which regulatory body is responsible for ADR monitoring in India?	CORRECT	249	83.00
	INCORRECT	51	17.00
	Total	300	100
14. Where is national Pharmacovigilance Centre located in India?	CORRECT	169	56.33
	INCORRECT	131	43.67
	Total	300	100
15. Where is the International Centre of ADR reporting system located?	CORRECT	205	68.33
	INCORRECT	95	31.67
	Total	300	100
16. What is the toll free number for reporting ADRs?	CORRECT	190	63.33
	INCORRECT	110	36.67
	Total	300	100
17. Which of the following scales is used to establish the causality of an ADR?	CORRECT	131	43.67
	INCORRECT	169	56.33
	Total	300	100

**Table 3: Attitude regarding reporting of ADRs among the study participants**

	RESPONSE	NUMBER	PERCENTAGE
18. Do you think reporting of ADR is necessary?	Agree	281	93.67
	Disagree	9	06.33
	Total	300	100
19. Do you think Pharmacovigilance should be taught in detail to all health care professionals?	Agree	279	93.00
	Disagree	21	07.00
	Total	300	100
20. Have you anytime read any article on reporting of ADRs?	Agree	165	55.00
	Disagree	135	45.00
	Total	300	100
21. Do you think ADR reporting is professional obligation to all related to healthcare?	Agree	270	90.00
	Disagree	30	10.00
	Total	300	100
22. Do you think ADR reporting benefits both patients and doctors?	Agree	280	93.33
	Disagree	20	06.67
	Total	300	100
23. Do you have any information regarding the Pharmacovigilance programme of India	Agree	193	64.33
	Disagree	107	35.67
	Total	300	100



FIG. 1

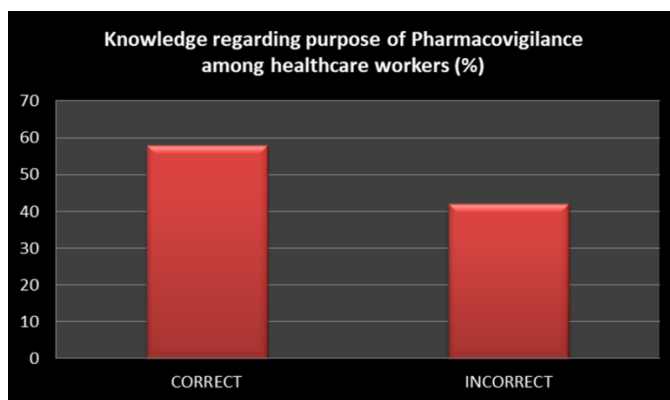


FIG. 2

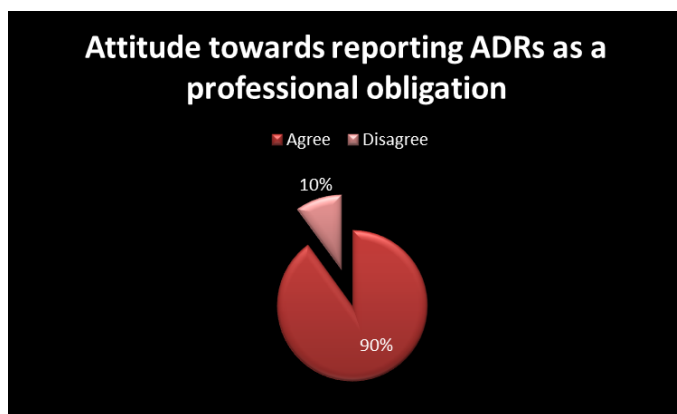


FIG.3

Table 4: Practice towards reporting ADRs regarding among study participants.

	RESPONSE	NUMBER	PERCENTAGE
24. Have you ever seen a case of ADR at your hospital?	Yes	154	51.33
	No	146	48.67
	Total	300	100
25. Have you ever played a role in reporting ADRs to your Centre?	Yes	68	22.67
	NO	232	77.33
	Total	300	100

26. How many ADRs have you reported till now?	0	179	59.67
	<5	57	19.00
	5-10	34	11.33
	>10	30	10.00
	Total	300	100
27. Have you ever visited any ADR monitoring Centre?	Yes	44	14.67
	No	256	85.33
	Total	300	100
28. Have you ever seen ADR reporting form?	Yes	185	61.67
	No	115	38.33
	Total	300	100
29. Have you ever been trained on how to report the ADRs?	Yes	166	55.33
	No	134	44.67
	Total	300	100
30. Factors that discourage you from reporting ADRs?	Lack of time	80	26.67
	Difficult to decide whether ADR has occurred or not	111	37.00
	Fear of legal liability	41	13.67
	Reporting forms are not available	34	11.33
	Assuming that one ADR makes no significant contribution	34	11.33
	Total	300	100

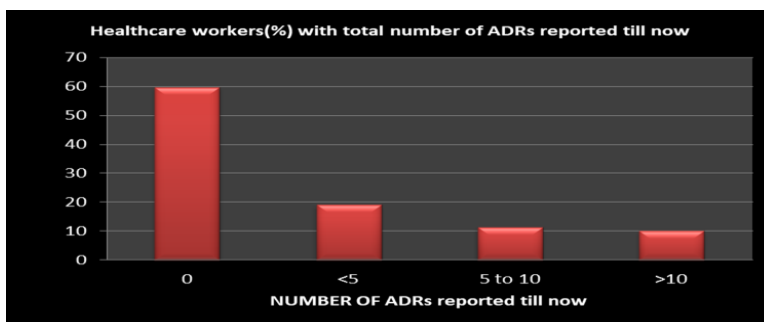


FIG.4

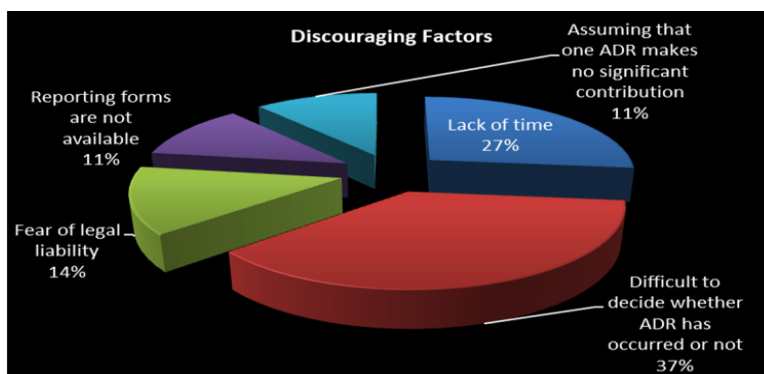


FIG.5



## DISCUSSION

In present study the assessment of knowledge regarding ADR reporting showed that maximum number of participants knew the correct definition of Pharmacovigilance (n=210, 70%). The actual purpose of Pharmacovigilance was known to only 58 % of the study participants. The findings were similar to the studies conducted by Srinivasan et al<sup>12</sup>. One study conducted among doctors and nurses by Subrany et al<sup>13</sup> has shown relatively higher number of healthcare professionals knowing the actual purpose of Pharmacovigilance.

Maximum number of healthcare professionals showed good attitude towards the ADR reporting. Most of them (93.67 %, n=281) mentioned that ADR reporting is very necessary, slightly higher than the studies conducted by Bhat et al<sup>14</sup> and Srinivasan et al<sup>12</sup>. The good attitude towards reporting ADR as a professional obligation was shown by 90 % (n=270) of the healthcare professionals. Studies conducted by Gupta et al<sup>15</sup> and Ashutosh et al<sup>16</sup> showed lesser number of healthcare professionals having good attitude towards reporting ADR as a professional obligation. Regarding the practice towards reporting ADR only 51.33 % (n= 154) have seen a case of ADR, 22.67 % (n= 68) have reported ADRs and only 10% (n=30) have reported more than 10 ADRs so far. Studies conducted by Sideshwara et al<sup>17</sup> and Gupta et al<sup>15</sup> have also shown less number of ADRs reported by the healthcare professionals. The reason for not reporting the ADR was difficulty to decide whether ADR has occurred or not, given by maximum number (37 %, n=111), followed by lack of time (26.67%, n= 80) and assuming that one ADR makes no significant contribution. Similar discouraging factors for not reporting ADRs were also mentioned in studies conducted by Srinivasan et al<sup>12</sup>, Sideshwara et al<sup>17</sup> and Garcia et al<sup>18</sup> among healthcare professionals.

## CONCLUSION

The majority of the Healthcare professionals had good knowledge and positive attitude but poor documentation and practice towards reporting ADRs. This contributes to the under reporting of ADRs from our Institute. The present study strongly recommends creating more awareness, regular sensitization programs and training on ADR reporting among Healthcare professionals of our institute.

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