ISSN 2515-8260 Volume 9, Issue 06, 2022

Title - Knowledge, attitude, and practices (KAP) of the MBBS interns towards adverse drug reaction (ADR) reporting and pharmacovigilance

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ABSTRACT

Background Physicians, pharmacists, and nurses have a big duty to report a negative drug reaction because they are key healthcare providers (ADR). As a result, the goal of the study was to assess the MBBS interns' knowledge, attitude, and practises (KAP) regarding pharmacovigilance and adverse drug reactions (ADRs).

Aim: To assess the knowledge, attitudes, and the practices of MBBS interns with respect to pharmacovigilance and adverse drug reactions (ADRs).

Materials and Methods- A cross-sectional survey of MBBS interns at a tertiary care hospital in central India was conducted A semi-structured questionnaire was used.

Results: A total of 202 responses were received from MBBS Interns. With the help of a Microsoft Excel spreadsheet, the completed KAP questionnaires were analysed question by question and their percentage value was determined. Average students agreed that reporting ADRs is required, important, and improves patient safety, with an average of 34.83% correct and 64.08% incorrect knowledge about ADRs and pharmacovigilance. Only 7.92% of MBBS interns at the institute reported an adverse drug reaction.

Conclusion: Most MBBS interns agreed that ADR monitoring and reporting are very important, but few had ever reported ADRs due to a lack of pharmacovigilance and ADR sensitization and knowledge.

Introduction- Since the emergence of drugs, the administration of medications has been associated with undesired side effects. A drug is said to have three effects: the one you want, the one you don't want, and the one you don't know about. Adverse drug reactions (ADRs) are described as "a unpleasant and unexpected response to a medicament that occurred at dosages routinely employed for the diagnosis, prevention, treatment, or alteration of a disease or a physiological function" [1]. As a result, ADRs have a significant impact on public health since they impose a significant financial

burden on the healthcare system and society. [3] According to the World Health Organization, pharmacovigilance (PV) is "the pharmacological knowledge and actions connected with the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems" (WHO). In recent years, its focus has broadened to include blood products, medical equipment, and vaccines, in addition to herbal, traditional, and complementary medicines [4]. [5] Global research indicates that ADRs dramatically reduce QoL, contribute to more hospitalizations, longer hospital stays, and higher mortality rates. Because of the move from prescription-only to over-the-counter therapies, the general populace is more vulnerable to ADRs, which are reported seldom. The entire cost of medical care for drug-related illness and death in 2000 was more than $177.4 million, with hospitalisation costs accounting for approximately 70% of that total. This is due to the spectacular discovery of new medications and their excessive commercialization, as well as the inappropriate prescription of existing treatments, incorrect diagnosis, and superficial delivery of evidence-based therapies. [7]. [8] Approximately 4.7 million incidents of ADRs were reported to the international database of ADRs maintained by the Uppsala monitoring centre in Sweden by various national centres from 96 member states. Nonetheless, it is believed that only 6- 10% of ADRs make it to the reporting stage. [9] The key causes of the underreported volume of ADR reporting from countries such as India are a lack of an effective ADR monitoring system and an inadequate reporting culture among healthcare staff. Providing comprehensive PV teaching during undergraduate studies and internships may enhance the frequency with which adverse events are reported. Adverse events (AEs) can be discovered by a variety of methods, including spontaneous reporting, prescription event tracking, and other measurements. [7] Doctors' reporting of adverse events to the ADRs database using these strategies can have a significant impact on the signal detection of rare and unexpected ADRs. The majority of practitioners lack the knowledge and practise necessary to correctly report ADRs. [8,9] Doctors may fail to report AEs for a variety of reasons, including a lack of time, the idea that a single case report is insignificant, the fear of generating additional work, and the fear of legal implications. [7,10] The goal of this study was to assess medical students' knowledge and attitudes about pharmacovigilance in a tertiary care setting.

Materials and Methods- All MBBS Interns who are pursuing internship were registered in the study using a convenient sampling procedure. The KAP questionnaires for pharmacovigilance and ADRs were developed prior to the study. The questionnaires were semi-structured, pretested, and verified as a research tool for data collecting.

Results- Table 1 shows Out of the total (*n* = 202) MBBS Interns , 75.24% were males, and 24.75% were female.

Table 1: Demographic details of MBBS Interns (*n*=202)

Gender	No.	Percent
Male	152	75.24
Female	50	24.75

Table 2 , shows the medical interns have correct knowledge about the pharmacovigilance and ADRs. Every one aware about word pharmacovigilance, but only 3.96 %were having correct knowledge, 19.8% were know meaning of ADRs,73.27 % were knowing that which system affected by ADR. 43.56%,36.63 %,50.5%,25.25% were aware about national ADR monitoring center location , guideline for pharmacovigillance centre , Zonal Pharmacovigilance Center location and important factor necessary to report an ADR respectively.

Table 2: Correct and incorrect knowledge of MBBS Interns about pharmacovigilance and ADRs (*n*=202)

MBBS Interns (*n*=202)		
Questions	**Answer**	**N**
Have you heard the name of pharmacovigilance?	**YES**	**202**
	No	**00**
	Correct knowledge	**Incorrect/partial knowledge**
Questions	**Percent**	**Percent**
Pharmacovigilance means	**3.96**	**96.04**
ADRs mean	**19.8**	**80.20**
Which of the following system reported and commonly affected by ADR is	**73.27**	**26.73**
The national center for ADR monitoring is located at	**43.56**	**56.44**
Who has given a guideline for setting up and running a Pharmacovigilance Center?	**36.63**	**63.37**
As per new Pharmacovigilance Program, the Zonal Pharmacovigilance Center located at	**50.5**	**49.50**
Which important factor necessary to report an ADR is (you may tick multiple options)	**25.25**	**74.75**
Which of following are responsible factors for the occurrence of ADRs? (you may tick multiple options)	**22.76**	**77.23**
ADR is serious, when? (you may tick multiple options)	**19.7**	**70.30**
Which of the following "WHO online data base" available for reporting ADR?	**39.6**	**60.40**
In your opinion, which of these are qualified to report ADRs?	**24.75**	**75.25**
Do you know "Yellow Card" ADR reporting form under pharmacovigilance activity adopted in one of the countries? If yes, which country?	**57.69**	**42.31**
Average % overall correct or incorrect	**34.83**	**64.08**

As shown in Table 3, 93.07%, 87.13%, 92.08% of particpants were agreed that reporting ADRs is necessary, mandatory, increased safety of patient, respectively. About 86.14% of agreed that lack of training of ADR reporting is challenging factor for implementing

Table 3: Attitude Toward Pharmacovigilance And Adrs Reporting

Questions		Agree	Disagree
Do you think reporting ADR is necessary?		**188 (93.07)**	**14 (6.93)**
Do you think reporting ADR should be mandatory?		**176 (87.13)**	**26 (12.87)**
Do you think reporting ADR will increase patient safety?		**186 (92.08)**	**16 (7.92)**
Which of the following are challenges for implementing PvPI?	**Political**	**158 (78.22)**	**44 (21.78)**
	Lack of trained personal	**174 (86.14)**	**30 (13.86)**
	The reporting culture	**162(80.20)**	**36 (19.8)**
	Adequate communication	**164 (81.19)**	**32 (18.71)**

In Table 4, 47.52% of students were find difficulties during reporting ADRs, of them 24.75% of students do not have time to report ADRs. 66.34% of postgraduate students have practices like stop drug immediately when serious ADRs occurred. Only 7.02% student report ADRs and 92.08% do not report ADRs in any way. 40.59% of students were preferred to report ADRs via mail/on web site. 53.47% of postgraduate doctors believed that managing patient more important than reporting ADRs, whereas 44.55% and 47.52% of postgraduate student do not know how to report or where to report, respectively.

Table 4: Practices toward ADRs (*n*=202)

Questions	Options	Percentage
Do you find any difficulty in reporting ADRs?	Yes	47.52
	No	53.47
If yes, what difficulties?	Non availability of ADR form	9.90
	Patient co-operation	7.92
	Do not have time	24.75
	Doctor/patient	4.95
	Communication Any other (please specify)	
Upon occurrence of serious an ADR. What needs to be done with the suspected drug?	Dose reduced	19.80
	Stopped immediately	66.34
	Dose tapered and stopped	13.86
	Depending upon the drug	
	and ADR	
Have you reported an ADR?	Yes	7.92
	No	92.08
If yes, where?	At your institute	3.96
	An ADR reporting center	3.96
	Concerned pharma company	00
	Other (please specify)	00
Which method would you prefer send ADR information to an ADR reporting center?	Direct contact	30.69
	By post	5.94
	Telephone	22.77
	To mail/on web site	40.59
Which are the factors that discourage you to reporting ADRs? (you may tick multiple reasons)	Did not know how to report?	44.55
	Not knowing where to report?	47.52
	Managing the patient was more important than reporting ADR	53.47
	Legal liability issues Other (please specify)	17.82

Discussion- A critical component of any pharmacovigilance programme is ADR reporting. The spontaneous reporting system is a crucial tool for reporting ADRs and new ADRs of new medications. In the current study, we found that Intern doctors had an average of 34.83% incorrect knowledge and 64.08% correct knowledge regarding ADR reporting and pharmacovigilance in each individual year. According to a study by Ramesh and Parthasarathi[11], doctors are not as knowledgeable about pharmacovigilance programmes at the national and international levels. Lack of time and knowledge about ADRs is frequently cited as a contributing factor to underreporting in other studies and the literature.

[12-14] In the current study, 92.08% of Interns agreed that reporting ADRs is mandatory, necessary, and increases patient safety, respectively. Another study[15] discovered that 97.3% of respondents thought ADR reporting was important. The two most frequent justifications for reporting were the need to increase patient safety (28.8%) and the discovery of new ADRs (24.6%). Additionally, 86.14% of Interns concurred that the biggest obstacle to implementing a pharmacovigilance programme in India is a lack of trained medical professionals. Results from a different study[15] had indicated that interns had a positive attitude toward ADR reporting, but in the real world, there were no ADR reporting practises. A study conducted in Mumbai[16] revealed that doctors reported ADRs with high knowledge but poor practises. However, the current study found that in addition to poor practises, there was also little understanding of ADR reporting [Tables 2 and 4]. The current study found that while most PGs had the correct attitude toward ADR reporting, actual ADR reporting was not being done. Another study that was done in Mysore and Muzzafarnagar[17,18] revealed that prescribers had high knowledge of ADR but poor practise. In contrast, our study discovered both inadequate knowledge and poor practise regarding ADR reporting. The average knowledge score was low (34.08%), showing that there is still a need to educate and sensitise doctors who are still in the training phase about the knowledge and significance of ADR reporting and pharmacovigilance (Intern doctors). It was interesting to note that 12.87% of respondents did not believe that reporting ADRs should be required, 7.92% of respondents did not believe that ADR reporting improves patient safety, and 17.82% of respondents were concerned about legal liability. According to a study conducted in Spain[19], the main obstacles to accurately diagnosing and reporting ADRs are a lack of knowledge about the system, the doctors' clinical workload, a concern for patient privacy, and potential legal repercussions. According to the findings of the current study, the biggest barriers to doctors reporting ADRs are a lack of knowledge about where to report them (47.52%), how to report them (44.55%), and the importance of patient management (53.57%) compared to ADR reporting (17.82%). In one study[20], residents' ignorance of where to report ADRs (70%) and how to report them (68%) was found to be the main barrier to reporting. In this study, a higher proportion of residents said they were unsure of how to report it. In the current study, 47.50 percent of intern doctors reported having trouble reporting ADRs due to a lack of forms (9.90 percent), lack of time (24.55 percent), poor doctor-patient communication (4.9 percent), and patient cooperation (7.92 percent). In a different study[16], a major contributing factor to discouraged reporting was difficult access to the ADR reporting form (49.2%). According to the study by Chatterjee et al. [17], clinical negligibility or underreporting of adverse drug reactions (ADRs) by clinicians is caused by a lack of time and a lack of or limited knowledge of the types of reactions that should be reported. Even though a sizable majority of the participants believed that ADR reporting was important, very little ADR reporting was actually done. 7.92% of the respondents to our study said they had previously reported an ADR. Similar findings of under-reporting of ADR to any of the national ADR monitoring centres (2.9%) were also made by the Mumbai study[15], despite the fact that 90% of the respondents thought it was important. According to a study from Northern India,[21] the knowledge scores needed to be raised and the KAP about ADR and pharmacovigilance needed to be updated. A survey of French medical residents[22] revealed that the majority of them knew less about pharmacovigilance. According to a study from Italy,[23] doctors were reported to be poorly informed about ADRs and ADR reporting systems. According to a study from India,[24] doctors had very little knowledge of the pharmacovigilance programme and how to report an adverse drug reaction. Similar findings were found in our study. These results point to the need for interventions to raise healthcare professionals' KAP.

CONCLUSION- We concluded from this study that although the MBBS interns had a generally better attitude toward adverse drug reactions and pharmacovigilance, they lacked knowledge and practises in these areas. Few participants have ever reported an ADR, despite the majority of

participants believing that ADR monitoring and reporting are crucial. They are discouraged from reporting due to a lack of ADR reporting and pharmacovigilance training and incentive. The study's conclusions point to the necessity for ongoing training and awareness-raising about pharmacovigilance and the ADR reporting system for residents, as well as for enhancing current pharmacovigilance operations in our institution.

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