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Original Research Article

To Evaluate Knowledge, Attitude and Practice of Pharmacovigilance and Adverse Drug Reaction Reporting among the Undergraduate Medical Students and Nursing Staff in a Tertiary Care Teaching Hospital in Assam: A Questionnaire-Based study

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Conflict of interest: Nil

Abstract:

Background: The Pharmacovigilance Program of India relies on spontaneous voluntary adverse drug reaction (ADR) reporting to work effectively. The goal of Pharmacovigilance is to ensure the safe and reasonable use of medicines once they have been approved for general use in society. The key to ensuring that adverse drug reactions (ADRs) are reported in clinical practice is to target younger physicians for Pharmacovigilance sensitization. The objectives of this study are to evaluate knowledge, attitude, and practice (KAP) of Pharmacovigilance and adverse drug reaction reporting among the undergraduate medical students and nursing staff in a tertiary care teaching hospital in Assam: a questionnaire-based study.

Materials & Methods: A cross-sectional study was carried out using a pretested questionnaire. The questionnaire was designed to assess the KAP regarding Pharmacovigilance. The undergraduate medical students and nursing staff were included in the study. Only the participants who gave their consent were included in the study. Results were calculated by proper statistical analysis.

Results: The current study was conducted in Diphu Medical College & Hospital, Diphu, Assam, which included a total of 368 participants of which 328 are medical students (40 from 1st year, 84 from 2nd year, 88 from 3rd year, 116 from 4th year) & 40 are Nursing staff. Most of them accepted that reporting ADR is necessary, and Pharmacovigilance should be taught in detail to health-care professionals & nursing staff.

Conclusions: This study showed that medical student's and nursing staff's understanding of Pharmacovigilance is steadily increasing. Pharmacovigilance and ADR reporting should be made mandatory, and education should be improved and made more engaging so that students can confidently apply it in their clinical practice.

Keywords: Pharmacovigilance, Adverse Drug Reactions, Knowledge, Attitude and Practice.

Introduction

Adverse drug reactions (ADRs) are one of the primary causes of morbidity and impose a significant economic burden on healthcare systems. Pharmacovigilance is "the science and activities relating to detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems," according to the World Health Organization (WHO). [1] Some rare side effects (1:100,000) appear only after drug exposure to a large population. [2] Because of variations in drug response, individual prescribing patterns, drug regulatory systems, and drug availability, it has been recommended that every country build up their own Pharmacovigilance program. [3]

Prescription event monitoring, spontaneous reporting, and other techniques are some of the ways to identify an adverse event (AE). [4] Under-reporting of suspected ADRs by health professionals is clearly a global concern. [5] The knowledge, attitude, and practice (KAP) of healthcare workers on ADR reporting and PV must be improved in order to increase the reporting of ADRs. ADR reporting should be thoroughly taught to medical and nursing students from the start in order to boost the PV program. [6, 7] The existing literature demonstrates gaps in healthcare student's Pharmacovigilance knowledge, attitudes, and practices. According to a cross-sectional study carried out in India, while the majority of medical students were aware of Pharmacovigilance, only a small percentage had thorough understanding of it or took part in ADR reporting. [8] Additionally,

despite the fact that students frequently acknowledge the value of reporting ADRs, this does not always translate into reality because of a lack of training and practical difficulties. [9, 10] Pharmacovigilance education can be improved by focused training sessions and hands-on experiences to close these gaps and encourage proactive engagement. [11]

Regarding healthcare and medical safety, the KAP approach is a proven way to evaluate people's knowledge, attitudes, and behaviors. [12] KAP studies offer important information that can direct the creation of curricula and the application of policies. Educational institutions can pinpoint areas for development and adjust educational interventions by assessing the present level of Pharmacovigilance awareness among MBBS students. [13] Understanding medical student's baseline KAP in terms of Pharmacovigilance also helps to align their training with worldwide standards and practices. [14] The purpose of this study is to assess undergraduate medical students and nursing staff's knowledge, attitudes, and practices regarding Pharmacovigilance.

The study's objectives are to:

1. Evaluate undergraduate medical students and nursing staff's knowledge of Pharmacovigilance, including their awareness of adverse drug reactions, the importance of reporting, and how Pharmacovigilance systems work.
2. Examine how nursing staff and undergraduate medical students feel about Pharmacovigilance; including how important they think it is to report adverse drug reactions and what obstacles they might encounter in doing so.
3. Investigate the ADR reporting procedures of nursing staff and undergraduate medical students, paying particular attention to their experiences and readiness to participate in Pharmacovigilance initiatives.
4. The relationship between age and gender and knowledge, attitude, and practice.

Methodology

Study Design: A cross-sectional Knowledge, Attitude, and Practice (KAP) study was conducted to assess the understanding, perceptions, and behaviors related to Pharmacovigilance among MBBS students & nursing staff.

Study Setting: The study was carried out at Diphu Medical College & Hospital, Diphu, Karbi Anglong, Assam. The duration of the study was three months from 28th September 2024 to 28th December 2024. The target participants were MBBS students from various years of their medical curriculum & nursing staff.

Study Population: The population for this study comprised MBBS students enrolled in 1st to final year & nursing staff. Inclusion criteria were nursing staff & students who were currently attending regular academic sessions and willing to participate. Nursing staff & students who were absent during the data collection period or declined participation were excluded.

Sampling Technique: Convenient Sampling.

Questionnaire Validation: The tool underwent a pilot test with a small sample of 20 MBBS students to assess its clarity, reliability, and validity. Necessary adjustments were made based on their feedback to ensure the final instrument was both comprehensive and user-friendly.

These Questions were designed based on earlier studies for assessing KAP of ADR reporting. [15-18] Total 33 questions were given to the students and they were given one day to fill the answers in the questionnaire. Among 33 questions, 10 were based on knowledge, 10 were based on attitude and 10 were based on practice.

Data Collection Procedure

Data was collected through in-person distribution of the questionnaires. Students & nursing staff were briefed on the purpose of the study, and written informed consent was obtained before participation.

Ethical Considerations: Ethical clearance was obtained from Diphu Medical College & Hospital, Diphu, Karbi Anglong, Assam on 27th September 2024, vide no. DMCH/EC/2022/105/154. Participants were assured of anonymity and confidentiality, with the option to withdraw from the study at any point without any repercussions.

Data Analysis: Data was entered into MS Excel and analyzed using SPSS version 24.0. Descriptive statistics, such as frequencies, means, and standard deviations, were used to summarize demographic data.

Results

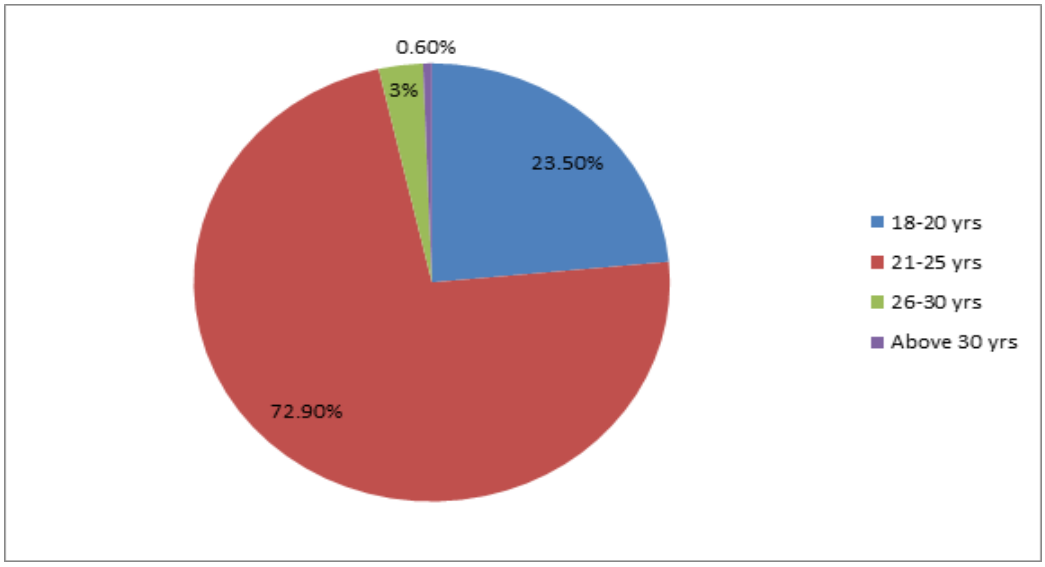

Figure 1: Age

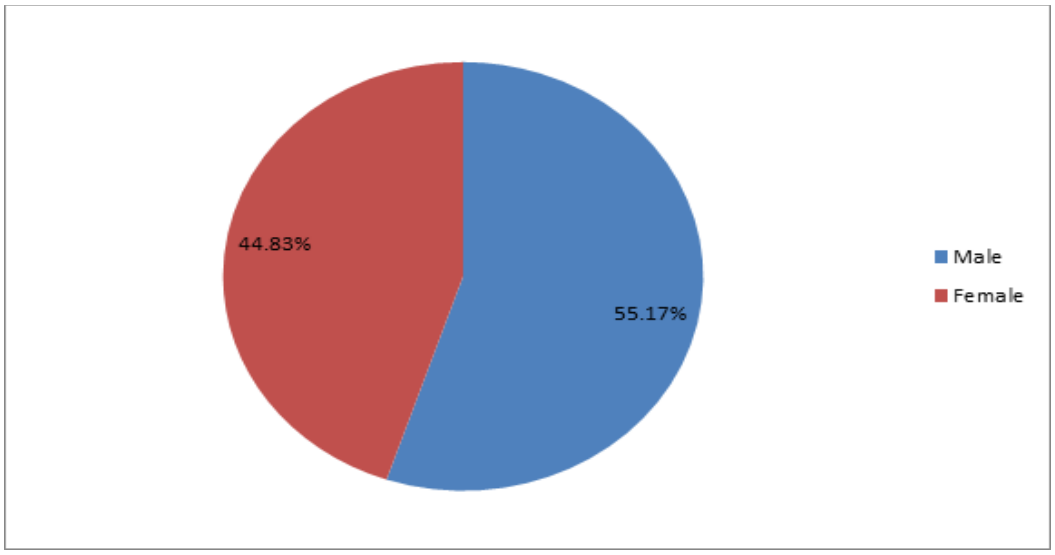

Figure 2: Gender

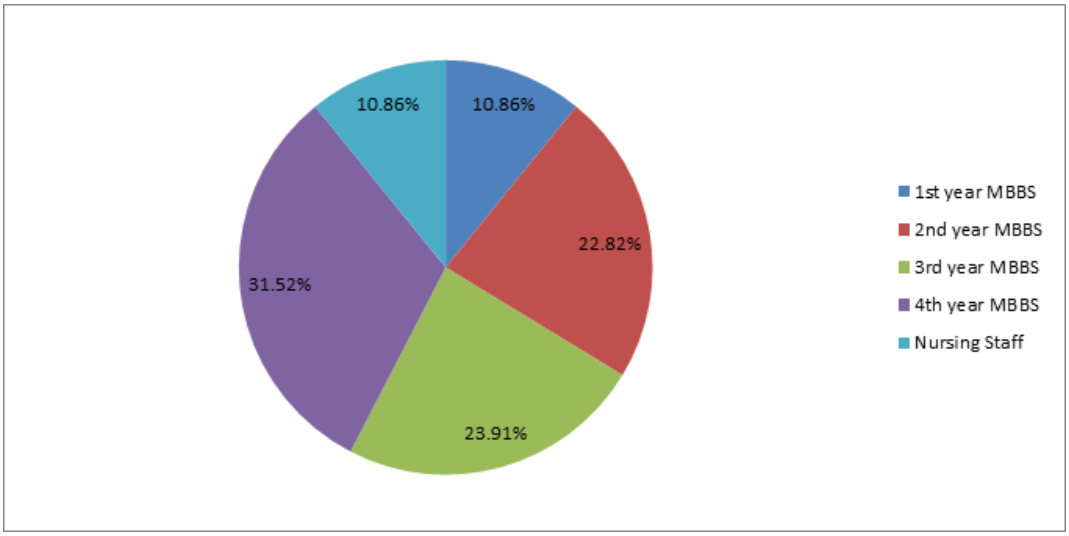

Figure 3: MBBS & Nursing Staff (368 participants)

Table 1: Knowledge about Pharmacovigilance among MBBS Students

		1st year MBBS student (40)	2nd year MBBS student (84)	3rd year MBBS student (88)	4th year MBBS student (116)	Nursing staff (40)
1	What do you understand by Pharmacovigilance?					
	It is the science & activities related to detection, assessment, understanding & prevention of adverse effects or any other drug problems	100%	100%	100%	100%	100%
	It is the study of mechanism of action of drug	-	-	-	-	-
	It is the study of use of drug	-	-	-	-	-
	It is the study of contraindications of drug	-	-	-	-	-
2	Why is Pharmacovigilance needed?					
	To collect ADRs	-	2.4%	1.4%	2.6%	5%
	Knowledge about serious reactions	-	-	-	-	5%
	To prevent future incidents related to drug	-	-	0.9%	-	-
	All of the above	100%	97.6%	97.7%	97.4%	90%
3	What do you understand by ADR?					
	Any noxious, untoward reaction to a drug	50%	88.1%	88.8%	88.8%	75%
	Adherence to drug	25%	2.4%	1.7%	-	10%
	Acute drug reaction	25%	9.5%	8.6%	8.6%	15%
	Alternative dispute resolution	-	-	0.9%	2.6%	-
4	Who are the people that can report ADR?					
	Doctors	-	8.3%	8.2%	8.6%	2.5%
	Nurses	-	1.2%	0.9%	0.9%	2.5%
	Patients	-	-	-	-	-
	All of the above	100%	90.5%	90.9%	90.5%	95%
5	Have you seen an ADR reporting form?					
	Yes	25%	96.4%	96.6%	96.6%	97.5%
	No	75%	3.6%	3.4%	3.4%	2.5%
6	Is there a Pharmacovigilance centre in your institution?					
	Yes	50%	52.4%	52.3%	51.7%	62.5%
	No	50%	47.6%	47.7%	48.3%	37.5%
7	Which of the following is a regional Pharmacovigilance centre in North-East India?					
	Guwahati Medical College & Hospital	-	16.7%	17%	25%	35%
	Jorhat Medical College & Hospital	-	-	-	-	-
	Silchar Medical College & Hospital	-	1.2%	1.2%	2.6%	-
	All of the above	100%	82.1%	81.8%	72.4%	65%
8	What are the types of ADR that have to be reported?					
	Any minor reaction to a drug	-	3.6%	3.4%	2.6%	-
	Any serious reaction to a drug	25%	11.9%	12.5%	17.2%	25%
	All of the above	75%	84.5%	84.1%	80.2%	75%
9	ADRs can be reported for which of the following medicines?					
	IV drug	-	2.4%	2.3%	0.9%	25%
	Oral drug	-	-	-	1.7%	-
	Inhalational drug	-	-	-	-	-
	All of the above	100%	97.6%	97.7%	97.4%	75%
10	Are you aware of any drug banned due to ADR?					
	Yes	50%	71.4%	71.6%	77.6%	20%
	No	50%	28.6%	28.4%	22.4%	80%

Table 2: Attitude about Pharmacovigilance among MBBS Students

1	Do you think Pharmacovigilance should be taught to all healthcare providers in detail?					
	Yes	100%	100%	100%	100%	100%
	No	-	-	-	-	-
2	Do you think the topic of Pharmacovigilance covered in your curriculum is sufficient for reporting ADR in your future practice?					
	Yes	75%	88.2%	86.4%	86.2%	60%
	No	25%	11.8%	13.6%	13.8%	40%
3	Do you think adverse drug reaction reporting is necessary?					
	Yes	100%	100%	100%	100%	100%
	No	-	-	-	-	-
4	Do you think all healthcare providers should consider themselves professionally obliged to report ADRs?					
	Yes	100%	95.3%	95.5%	96.6%	100%
	No	-	4.7%	4.5%	3.4%	-
5	Do you think timely monitoring and reporting of ADR can significantly improve patient safety and reduce morbidity and mortality?					
	Yes	100%	100%	100%	99.1%	100%
	No	-	-	-	0.9%	-
6	Do you think ADR should be discussed during clinical posting/ward rounds?					
	Yes	100%	96.5%	96.6%	97.4%	90%
	No	-	3.5%	3.4%	2.6%	10%
7	Do you think the ADR form is complex to fill?					
	Yes	50%	73.3%	73.9%	72.4%	75%
	No	50%	26.7%	26.1%	27.6%	25%
8	Do you think Pharmacovigilance training/ awareness program should be conducted often?					
	Yes	100%	100%	100%	98.3%	97.5%
	No	-	-	-	1.7%	2.5%
9	Which, according to you, is the preferred method for sending information regarding ADR?					
	Writing in ADR forms	-	46.5%	45.5%	41.4%	55%
	Directly sending online in PVPI website	100%	53.5%	54.5%	58.6%	45%
10	What are the factors you think hinder healthcare providers from reporting ADRs?					
	Lack of knowledge	-	1.1%	1.2%	19.8%	10%
	Time consuming procedure	-	23.3%	22.7%	5.2%	80%
	Both	100%	75.6%	76.1%	75%	10%

Table 3: Practice about Pharmacovigilance among MBBS Students

1	Have you ever seen a case of ADR during your ward?					
	Yes	25%	76.7%	77.3%	72.4%	37.5%
	No	75%	23.3%	22.7%	27.6%	62.5%
2	Have you seen/actively participated in management of an ADR in your ward/clinical posting?					
	Yes	25%	66.3%	65.9%	63.8%	37.5%
	No	75%	33.7%	34.1%	36.2%	62.5%
3	Are you willing to report ADRs?					
	Yes	100%	96.5%	96.6%	96.6%	100%
	No	-	3.5%	3.4%	3.4%	-
4	Have you ever filled up an ADR form?					
	Yes	25%	87.2%	87.5%	87.9%	37.5%
	No	75%	12.8%	12.5%	12.1%	62.5%
5	Have you ever read any articles on prevention of Adverse Drug Reactions?					
	Yes	25%	54%	53.4%	55.2%	80%
	No	75%	46%	46.6%	44.8%	20%
6	Do you usually counsel a patient about possibility of the development of ADRs with drugs and instructed them to communicate the same with you if appears?					
	Yes	50%	64.4%	63.6%	69%	80%
	No	50%	35.6%	36.4%	31%	20%
7	Have you ever attended training/awareness Program on Pharmacovigilance/ADR?					
	Yes	25%	66.7%	65.9%	59.5%	90%
	No	75%	33.3%	34.1%	40.5%	10%
8	Have you seen any patients with serious adverse drug reaction being admitted in ICU?					
	Yes	25%	83.9%	84.1%	81%	7.5%
	No	75%	16.1%	15.9%	19%	92.5%
9	What are the source/sources you prefer for gathering information on ADR?					
	Journals	-	5.7%	5.7%	2.6%	-
	Textbooks	-	-	-	6.9%	12.5%
	Monthly/yearly drug alert report from IPC	25%	-	-	-	-
	All of the above	75%	94.3%	94.3%	90.5%	87.5%
10	What are the measure/measures that can be practiced for improving Pharmacovigilance and ADR reporting?					
	Regular meetings on Pharmacovigilance and ADR reporting	-	-	-	-	-
	Regular visits to wards	-	1.1%	1.1%	2.6%	10%
	Improving knowledge of healthcare professionals regarding Pharmacovigilance and ADR reporting	-	-	-	1.7%	-
	All of the above	100%	98.8%	98.9%	95.7%	90%

Discussion

Adverse drug reactions (ADRs) are one of the leading causes of morbidity and represent a substantial economic burden on health-care resources. It has been reported that 2.4%−6.5% of the total admissions in the hospitals are due to adverse reactions, many of which are preventable. The incidence of serious ADRs is 6.7% in India. [19] Some rare adverse effects (1:100,000)

manifest only after the exposure of drug to a large population. [20, 21] Such rare adverse effects of the drug can only be known through effective Pharmacovigilance.

All the MBBS students & nursing staff know the actual definition of Pharmacovigilance, while 50% of 1st year students, 88.1% of 2nd year students, 88.8% of both 3rd year & 4th year know about the definition of ADR Among all the participants, 100% of 1st year students, 82.1% of 2nd year students, 81.8% of 3rd year, 72.4% of 4th year & 65% of nursing staff know about regional Pharmacovigilance centre in North-East India. In study done by Gupta and Udupa, only 43% are aware of ADR reporting, whereas in this study, more than 60% of students know regarding Pharmacovigilance and ADR reporting. [22]

The overall attitude of the undergraduate students & nursing staff toward Pharmacovigilance and ADR reporting- 100% participants totally agreed that ADR reporting is necessary & timely monitoring & reporting of ADR can significantly improve patient safety & reduce morbidity & mortality.

The practice of ADR reporting is high in 2nd year, 3rd year & 4th year students whereas very less in 1st year students and nursing staff respectively. This was because more emphasis was laid by the department of pharmacology in making them understand the importance of Pharmacovigilance by having extra practical demonstrations, case studies, and group tasks related to adverse drug reactions, which has not yet been implemented for the 1st year students. 25% of 1st year students, 76.7% of 2nd year students, 77.3% of 3rd year, 72.4% of 4th year & 65% of nursing staff had seen an ADR form. 87.9% of 4th year students had filled ADR form, whereas only 25% of 1st year students had filled an ADR form. In a study done by Kutmi et al., more than 40% MBBS students think that ADR reporting is compulsory, whereas in this study, more than 80% students think that ADR reporting is necessary which is similar to the study done by Gupta and Kulmi who identified 89.5% participants, suggesting necessity of ADR reporting. [23, 24] According to another study done by Ponmary et al., 2nd year MBBS students have adequate knowledge and attitude regarding Pharmacovigilance compared to residents, and even though nurses have good knowledge about Pharmacovigilance, they do not have adequate knowledge about reporting ADR. [25] Finding from all the studies including our study implies that there is a significant dearth of ADR reporting practice in spite of a fair attitude toward ADR reporting. Since the doctors are the first tier to come across the patient, they should be motivated to report ADRs. [26]

Out of 40 nursing staff, 37.5% have seen a case of ADR in ward & filled up ADR form, while 90% have attended training/awareness programme in Pharmacovigilance. The study titled "Nursing Professionals' Awareness of Adverse Drug Reactions and Pharmacovigilance in an Institute of National Importance in India: A Cross-Sectional Study" by Bankar et al. (2023) assessed the knowledge, attitude, and practices of 275 nursing professionals regarding adverse drug reaction (ADR) reporting and Pharmacovigilance. Most participants were females (74%) with a Bachelor of Science in Nursing degree (87%), and their mean working experience was two years. While 75% had managed patients with ADRs, a significant majority (96%) had never received formal training on ADR reporting. Knowledge scores varied, with only 4.4% achieving a good score (>80%).

Common barriers included a lack of awareness of ADR monitoring centers and reporting procedures. The study emphasizes the need for targeted educational programs to enhance the role of nursing professionals in Pharmacovigilance systems. [27]

Conclusion

The current study concluded that the overall knowledge and attitude are definitely better among the undergraduate students. Pharmacovigilance and ADR reporting practices need to be improved, and this can be achieved by integrating Pharmacovigilance into the medical curriculum as a whole and by using more effective, engaging, and efficient teaching, sensitization, and practice strategies. The majority of nursing personnel and students in our study correctly answered knowledge-based questions. Thus, Pharmacovigilance knowledge is steadily increasing. The study will bring awareness among students towards Pharmacovigilance and help them in monitoring adverse drug effects.

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