International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

Assessment of Knowledge and Awareness of Pharmacovigilance Among Different Faculties of Health Science Students in Nepal

Suraj Vaish[1], Santosh Kumar Yadav[2], Subodh Kumar Sah[3], Hemank KC[4], Sapna Vaishya[5]

[1,2,3,4]Valley College of Technical Sciences, Kathmandu, Nepal
[5]Seemawarti Degree College, Rupaidiha, Utter Pradesh, India

Abstract

Background: Pharmacovigilance (PV) is crucial for ensuring the safe use of medications and preventing adverse drug reactions (ADRs). In Nepal, the need for robust ADR reporting is critical due to the widespread use of various medical systems. This study aimed to assess the knowledge and awareness of pharmacovigilance among health science students in Nepal.

Methods: A cross-sectional study was conducted among 55 health science students from three faculties: Public Health (BPH), Pharmacy, and Nursing. Participants were assessed using a structured questionnaire that evaluated their socio-demographic information, knowledge, and awareness of pharmacovigilance. The data were analyzed using descriptive statistics, with correlations between knowledge and awareness scores evaluated through Spearman's correlation.

Results: The study found that the majority of participants across all faculties exhibited moderate to poor knowledge and awareness of pharmacovigilance. The median knowledge score was 1 for all faculties, with the mean scores indicating low levels of understanding. Similarly, awareness scores were uniformly low, with no participants demonstrating a high level of awareness. Despite the crucial role of ADR reporting in patient safety, a significant proportion of participants strongly disagreed with statements emphasizing the importance of reporting ADRs, suggesting a lack of confidence and understanding in this area. Spearman's correlation revealed a positive correlation between knowledge and awareness scores (Spearman's rho: 1).

Limitations: The study's limitations include a small sample size, limited geographic representation, reliance on self-reported data, and the absence of qualitative insights. These factors limit the generalizability of the findings and suggest the need for further research.

Conclusion: The findings highlight a critical gap in the knowledge and awareness of pharmacovigilance among health science students in Nepal. The study underscores the urgent need for integrating comprehensive pharmacovigilance training into health science curricula and for policy reforms to mandate ADR reporting by healthcare professionals. Enhancing education and awareness in this area is essential for improving patient safety and ensuring the rational use of medications in clinical practice.

Keywords: ADR: Adverse Drug Reaction, **WHO**: World Health Organization, **PV**: Pharmacovigilance **DDA**: Department of medication Administration, **UMC**: Uppsala Monitoring Center, **HCPs**: Health Care Professionals, **ERB**: Ethical Review Board, **SPSS**: Statistical Package of Social Science

1. INTRODUCTION

1.1 Background of the Study

Pharmacovigilance, as defined by the World Health Organization (WHO), is the science and actions associated with the identification, evaluation, comprehension, and avoidance of side effects or any other drug-related issue (1). The study of ill effects and other drug-related issues, as well as their detection, assessment, comprehension, and prevention, is known as pharmacovigilance (PV) (2).

Before graduating from medical school and beginning their careers as healthcare professionals, all health science students must acquire the critical skills of adverse drug reactions (ADRs) reporting. To guarantee the safe use of pharmaceuticals, healthcare students in the schools of medical, pharmacy, dentistry, or nursing must receive the necessary education and be involved as early as possible in clinical practice (3). Pharmacovigilance is a key clinical discipline that is needed everywhere to guarantee patient safety and the proper use of medications. The primary responsibility for recognizing and reporting significant ADRs lies with healthcare practitioners. They are more likely to recognize and report significant ADRs if they have trust in their capacity to diagnose, treat, and avoid such responses (4). The health of the Nepalese populace may be seriously jeopardized by adverse drug reactions (ADRs) due to the country's abundance of allopathic, traditional, homeopathic, and ayurvedic medications. Strengthening the ADR reporting system, and making ADR reporting by health professionals mandatory can be useful but unfortunately reporting is not mandatory according to the laws and regulations of Nepal (5). Healthcare workers are encouraged to report adverse drug reactions due to their knowledge and attitudes, and reporting uncommon, significant, and unlabeled ADRs is crucial for providing new information and signals (6).

1.2 Statement of Problem

The majority of patients in Nepal lack health insurance, thus the government of Nepal (GoN) offers impoverished individuals a partial financial subsidy of 1,00,000 NPR (≈909 USD) for the treatment of significant health issues (7) . Cancer, heart disease, kidney disease, sickle cell anemia, Parkinson's disease, and head and spinal injuries are listed as the main health issues. As a result, most Nepalese patients must pay for their own medical care when dealing with serious health issues. The GoN does not offer any assistance with the medical care of ADRs. Accurate ADR reporting would save costs by lowering the frequency of ADRs, which would lower doctor visits and hospital stays (7). The government of Nepal has established a health insurance policy. A family of five must pay 3500 NPR annually to cover all forms of medical care up to a maximum of 100,000 rupees. If there are more than five family members, an additional 700 NPR per person must be paid (8). However, there is no support available for the treatment of ADRs. For this reason, voluntary reporting of adverse drug reactions (ADRs) is essential to guaranteeing patient safety and achieving therapeutic goals in an economical manner. Furthermore, as the next generation of healthcare workers, medical students bear the responsibility of identifying, disclosing, and averting adverse drug reactions. Therefore, it is necessary to evaluate undergraduate medical students' knowledge and attitude (KA) on pharmacovigilance (9).

Although a large number of doctors and other health professionals are produced in Nepal, very few of them choose to remain in the country because they may now pursue greater prospects elsewhere. The ratio of doctors to pharmacists and nurses is extremely low as a result of this brain drain (5). There are 32218 (10.35/10,000 population) medical and dental doctors (10), 73514 (23.61/10,000 population) registered nurses (11) and 731 (0.261/10,000 population) licensed pharmacists in Nepal. This low ratio of HCP to patients can result in increased workload creating difficulty in sparing time for ADR reporting. This could be an important reason for underreporting by HCPs in Nepal. Underreporting remains a big problem

worldwide among HCPs. The pharmacist population ratio in Nepal is 0.3/10,000 while the community pharmacist population ratio is only 0.013/10,000. At present, there are 15 regional pharmacovigilance centers in Nepal

1. Tribhuvan University Teaching Hospital, Maharajgunj
2. Civil Service Hospital, Minbhawan
3. Manipal Teaching Hospital, Pokhara
4. KIST Medical College, Imadol
5. Nepal Medical College Teaching Hospital, Jorpati
6. Patan Hospital, Lalitpur
7. B.P Koirala Institute of Health Science (BPKIHS), Dharan
8. Dhulikhel Hospital, Banepa
9. Shree Birendra Hospital, Chhauni
10. Norvic International Hospital, Thapathali
11. Nepal Cancer Hospital and Research Center, Harisiddhi
12. College of Medical Sciences – Teaching Hospital
13. Nepal Mediciti, Kathmandu.
14. Chitwan Medical College, Chitwan.
15. National Tuberculosis Control Center, Bhaktapur.

Under DDA, which is the national center for ADR monitoring, several regional pharmacovigilance facilities are in operation. Via the web tool "Vigiflow," the regional centers submit ADRs to the National Center (DDA), which thereafter forwards them to the Uppsala Monitoring Center (UMC). Thus far, there are roughly 972 ADR reports in the National database (12).

1.3 Rationale of the study

Health science students are required to be knowledgeable about the safe and effective use of medicines. Since a health science degree opens up a wide range of employment options, programs typically offer multiple specializations, or concentrations, allowing students to customize their coursework to fit their larger career objectives. Even though every school or college is unique, students will have to find specializations in different aspects of patient care (13)

Nepal faces numerous issues with the use of medicines, such as polypharmacy, the use of expired medications, the abuse of antibiotics, vitamins, and herbal therapies. These, together with patients' lack of knowledge on how to handle and use medications properly, can have major repercussions like ADRs and drug interactions (5).

Different studies have been conducted on the PV, however, the studies regarding the knowledge and awareness among different faculties of health science students have not been conducted yet in Nepal. Therefore, this study might be helpful for the assessment of knowledge and awareness of pharmacovigilance among health science students which supports rational drug therapy and a better healthcare system.

1.4 Research Question

This study was conducted to answer the following research question :

What is the level of knowledge and awareness of pharmacovigilance among different faculties of health science students in Nepal?

1.5 Study Variables

1.5.1 Dependent Variable

- Knowledge about pharmacovigilance
- Awareness of pharmacovigilance

1.5.2 Independent Variable

- Age
- Gender
- Religion
- Ethnic group
- Location
- Faculty
- Level of Education

2. LITERATURE REVIEW

- In 2014, Rajiah K et. al. conducted a cross-sectional study was conducted enrolling among Pharmacy undergraduate students in a private medical University in Kuala Lumpur, Malaysia. The findings demonstrated that the pharmacy students knew enough about pharmacovigilance and ADR reporting. Research has indicated that to maximize patient safety, instructional programs need to be improved. It is possible to improve the way in which students see ADR reporting by offering more workshops and practical training during their clinical assignments (14).
- In 2014, Sivadasan S et.al. conducted a cross-sectional study at AIMST University, Jalan Bedong, Semeling, Bedong, Kedah Darul Aman, Malaysia to examine and compare the knowledge and perception towards pharmacovigilance and adverse drug reactions reporting among medicine and pharmacy students in a private university, Malaysia which concluded that the pharmacy students have more awareness and knowledge about pharmacovigilance and ADR reporting compared to medicine students (1).
- In 2015, Harish. G. et. al. Bagewadi conducted a questionnaire-based pre- and post-test evaluation study on (KAP) Knowledge, Attitude, Perception about pharmacovigilance at MVJ medical college and research hospital, Bangalore among fourth term medical students to improve the knowledge, attitude and perceptions about pharmacovigilance. The study's findings show that using PowerPoint graphics and diagrams in conjunction with blackboard instruction can raise medical students' awareness of pharmacovigilance and ADR reporting and help them apply what they learn to their future clinical practice (15).
- In 2016, Awada Sanaa et.al. conducted a cross-sectional study on Awareness and Perception of National Pharmacovigilance Center among Lebanese Medical Staff. The study's findings show that among the participants, 87.6% have experienced ADRs in their practice, but only 16.3% have ever reported ADRs. 12.4% of the healthcare workers have been trained for reporting adverse reactions, but, 91.6% healthcare professionals agreed that ADR reporting is necessary and 89% considered that pharmacovigilance should be taught in details to healthcare professionals (16).
- In 2017, Jha N et. al. conducted a cross sectional study at three points in time, before, immediately after and 6 weeks following an educational intervention regarding knowledge and attitude about consumer pharmacovigilance among community pharmacists in Lalitpur district, Nepal. The study's

findings demonstrate how well the instructional program worked to raise CPs' awareness of and attitudes about pharmacovigilance. The study found that while female responders' attitude scores improved, both male and female participants' knowledge levels improved. Pharmacists working in rural areas scored higher on knowledge and attitude (5).

- In 2020, Monira Alwhaibi et. al. conducted a systematic literature search using MEDLINE, CINAHL, EMBASE, ERIC, and Cochrane Database of Systematic Reviews via OVID at King Saud University, Riyadh, Saudi Arabia, to evaluate the existing evidence about the knowledge, attitude, and perceptions (KAP) of healthcare students towards pharmacovigilance and adverse drug reactions reporting (ADRs). The evaluation revealed a number of research gaps that require further investigation and illustrated the deficiency of PV knowledge among medical students. Creating a uniform, verified test to gauge students' understanding, disposition, and perspective of PV is one of these. Moreover, it is imperative to create a cohesive PV education program to suitably equip our upcoming medical professionals to logically report medication adverse events (17).
- In 2021, Tekel MT et. al. conducted a cross-sectional study 296 final-year MPN students at the University of Gondar College of Medicine and Health Sciences. According to the study's findings, most final-year MPN students had a mediocre understanding of PV and ADR reporting, as well as a moderate attitude toward it. The pupils' KAP revealed variations according to the students' age, sex, discipline, and exposure to the term PV. When it came to reporting PV and ADRs, pharmacy students outperformed medical and nursing students in terms of knowledge and experience. Among the primary causes of the students' failure to report ADRs were a lack of instruction on the subject and ignorance of the location and procedure for doing so (4).
- In 2023, Noman MA et. al. conducted the descriptive cross-sectional study at Sana'a University, Sana'a, Yemen, to assess Pharmacy students' knowledge and perception about Pharmacovigilance and adverse drug reaction who were in fourth & fifth Pharmacy level at Sana’a City which concluded that there was poor knowledge among Pharmacy students in Six Universities in Sana'a city, towards Pharmacovigilance and ADRs reporting. According to that study, there is a considerable need for an excellent teaching program to raise pharmacy students' awareness of their roles and boost their understanding of the many types of ADRs and the reporting procedures for them. This would ultimately improve patient care (2).
- In 2023, Paul R et.al. conducted a cross-sectional questionnaire-based observational study on knowledge, attitude, and practice of pharmacovigilance among medical and nursing students in a government medical college of Eastern India. The study’s findings showed that both medical and nursing students had adequate knowledge and attitude about PV. However, there were significant differences among the two groups in terms of ease and know how about reporting adverse drug reactions (ADR) (18).
- In 2023, Deo S et.al. conducted a cross-sectional study in Nepal on Knowledge, Attitude and Perception of Undergraduate Health Sciences students on Pharmacovigilance. The results of the study show that students had lower levels of pharmacovigilance perception, attitude, and knowledge. As such, the study emphasizes how crucial it is to make significant efforts to raise awareness and increase student knowledge. Training activities, timely feedback, and regular sensitization sessions can help achieve this. Adopting such tactics becomes imperative in supporting the self-reporting of adverse drug reactions (ADRs) in healthcare settings, with the aim of informing the appropriate authorities (19).

3. OBJECTIVE

3.1 General Objective

To study the knowledge and awareness of pharmacovigilance among different faculties of health science students in Nepal.

3.2 Specific Objectives

- To assess the knowledge of health science students towards PV and ADR reporting.
- To assess the awareness of final year health science students towards PV and ADRs reporting.
- To find out the relationship between different socio-demographic factors; age, gender, religion, faculty, and level of education and PV activities of health science students in Nepal.

4. RESEARCH METHODOLOGY

4.1 Study Design

A quantitative, descriptive type of cross-sectional study design was used. It was conducted in accordance with the guidelines of Strengthening of the Reporting of Observational Studies in Epidemiology (4).

4.2 Study Area

The area of study was colleges of three different faculties teaching health science in the Kathmandu Valley of Nepal. Kathmandu is the capital city of Nepal and the Valley contains three districts; Kathmandu, Lalitpur, and Bhaktapur. The population density, and availability of academic, health, as well as other administrative facilities make the city core of attraction. The selected students from all over the nation after passing the common entrance examination conducted by the Medical Education Commission (MEC) get enrolled in the selected colleges of Kathmandu Valley. In this manner, our study area can be considered a true representative of the health Science Institutes of Nepal.

4.3 Study Population

Final year health science students of different faculties; public health **(BPH)** and pharmacy **(BPharm)** from Valley College of Technical Sciences (VCTS) affiliated to Purbanchal University, and nursing **(BSc)** from Nobel College affiliated to Pokhara University in Kathmandu Valley.

4.4 Sampling Technique

The study was being conducted in Nepal. Kathmandu Valley will be chosen purposively as a study area. All the colleges was identified from the database of the Ministry of Education and Sports as well as from the BPH, Pharmacy, and Nursing Council. Among all the colleges affiliated with different Universities was chosen for the study.

A stratified random sampling method was used to collect data from the study population. The sampling frame will be divided into three different strata based on faculty; BPH final year, pharmacy i.e. BPharm, and Nursing i.e. BSc final year students.

Then systematic random sampling techniques was used to draw samples from each stratum. The name list of students studying in the final year was being obtained from the register of the college administration. The name list was coded and entered in MS Excel. Then every 4th number from the list was selected as a respondent for data collection.

4.5 Sample Size

The sample size was calculated using the Cochrane's formula:

$n = Z^2pq/d^2$

$= (1.96)^2*(0.5) *(0.5)/ (0.05)^2$

$= 384.16$

~385
Where,
n = Required sample size
z = Confidence level at 95% (standard value of 1.96)
p = Estimated prevalence rate (50%)
q = Probability of non-occurrence of p i.e. (1-p)
d = Allowable error i.e. 5%
The total number of final year health science students from the selected colleges (N) = 98
Then, the adjusted sample size (N') = n/1+(n-1/N)
= 385/1+(385-1/94)
= 75.71
~ 76
Now, considering the 10% non-respondents' rate i.e. 7.6~8. Therefore, the sample size (n') was 83.6~84,n' = 84
Again, for data collection using stratified random sampling, the formula for the proportionate stratified random sampling: $n_h = (Nh / N) * n$
Where,
n_h= Sample size for h^{th} stratum
N_h= Population size for h^{th} stratum
N = Size of the entire population
n = Size of the entire sample

Strata	Number of Students	Stratified sample
Public Health	26	$(n_B) = (84/ 94) *26 = 23.23 \approx 24$
P = Pharmacy Students	30	$(n_p) = (84/ 94) *30 = 26.80 \approx 27$
N = Nursing Students	38	$(n_n) = (84/ 94) *38 = 33.95 \approx 34$
Total	98	85

A total of 26 BPH, 26 pharmacy, and 33 nursing students (total sample size 85) was taken as samples for this study.

4.6 Criteria for Sample Selection

4.6.1 Inclusion Criteria

All the undergraduate/postgraduate, final year Health Sciences students of Kathmandu Valley.

- Those who are from the different faculties of Health Science; BPH, Pharmacy, and Nursing.
- Both male and female.
- Those who give consent for the study.

4.6.2 Exclusion Criteria

People other than the undergraduate/postgraduate, final year Health Sciences students of Kathmandu Valley.

- Those who are from the faculties of Health Science other than the BPH, Pharmacy, and Nursing faculties.

- Those whores the certificate level Health Science students.
- Those who don't give consent for the study.

4.7 Data Collection Tools

A structured questionnaire was used for the data collection. The tool was prepared in English Language through the extensive review of literature. The questionnaire includes socio-demographic information, knowledge, and awareness of pharmacovigilance among health science students in Nepal.

4.8 Data Collection Technique

Web based techniques was used using a structured questionnaire. All the participants was informed properly and was guided to fill out the questionnaire through google form.

4.9 Data Management and Analysis

After filling out each questionnaire, it was checked for its completeness, correctness, and internal consistency. The collected information was scrutinized based on research objectives.

The response will be entered in the Excel 2019v16.0 Microsoft, Washington, USA) and was exported to IBM SPSS v22 (IBM, Armonk, New York) for the further analysis. The total scores of awareness and practice was calculated and recorded into different categorical variables. The good [≥80% of 50 = 40 for awareness items and ≥80% of 25 =20 for practice items] and the moderate to poor group (<80%) will be categorized for each awareness and practice item based on modified Bloom's cut-off criteria. The sociodemographic characteristics of participants was presented as frequency and proportions. The chi-square ($\chi 2$) test was used to test for group differences. For binary logistic regression analyses, the odds ratio (OR) will be calculated at 95% confidence intervals (95% CI). Box plots will be drawn for the distribution of awareness and practice scores based on different factors such as independent variables. Spearman's rank correlation coefficient test was used to assess the relationships between the awareness and/or practice scores.

4.10 Validity and Reliability

Validity was maintained by a constant discussion with the research supervisor to identify the core aspects that need to be studied during the research.

Before data collection, the pre-test was conducted on 10% of the sample size to ensure reliability and accordingly, the appropriate modifications will be made before the implementation of the actual data collection.

4.11 Ethical Consideration

An approval letter was taken for the conduction of the study from the Department of Pharmacy, Valley College of Technical Sciences before the data collection. A request letter from the college was forwarded to the selected colleges of Kathmandu Valley.

Ethical approval was also obtained from the Institutional Review Committee (IRC) of the nursing (BSc) from Nobel College affiliated to Pokhara University in Kathmandu Valley.

Before the collection of the data, verbal consent will be taken from each participant. The privacy and confidentiality of each respondent will be maintained.

4.12 Dissemination Plan

By preparing a manuscript, a final refined version will be published in a suitable peer reviewed journal.

5. RESULT AND DATA INTERPRETATION

Table 1: Socio-demographic Information (N = 55)

S.No.	Characteristics	Public health (N1=13)	Pharmacy (N2=14)	Nursing (N=28)
1.	Age			
	Early 20s: 20-23	1	4	6
	Mid 20s: 24-26	10	9	19
	Late 20s: 27-29	1	1	3
	30 and above	1	0	0
2.	Gender			
	Male	8	10	0
	Female	5	4	28
3.	Religion			
	Hindu	12	13	23
	Muslim	1	1	3
	Buddhist	0	0	2
	Christian	0	0	0
	Others	0	0	0
4.	Ethnic Group			
	Chettri/Bahun	8	6	10
	Janajati	2	1	5
	Dalit	0	0	3
	Madhesi	3	6	5
	Muslim	0	1	3
	Others	0	0	2
5.	Permanent residence (Province)			
	Koshi	1	1	5
	Madhesh	2	4	9
	Bagmati	9	8	9
	Gandaki	0	0	2
	Lumbini	0	0	2
	Karnali	0	1	1
	Sudurpaschim	1	0	0
6.	Area (Permanent residence)			
	Urban	2	3	1
	Rural	11	11	27
	Other	0	0	0

Socio-demographic Information (N = 55)" provides a breakdown of participants from three different faculties BPH (N=13), Pharmacy (N=14), and Nursing (N=28). The table categorizes these participants based on age, gender, religion, Provision, Area and ethnic group. Age distribution shows that most participants fall within the mid-20s (24-26) age group across all faculties, with Nursing having the highest

count (19). Few participants are in the early 20s (20-23) or late 20s (27-29), and only one participant in BPH is aged 30 and above. Gender distribution reveals that Nursing is predominantly female, with 28 females and no males. In contrast, BPH and Pharmacy have a more balanced gender distribution, though males still outnumber females. Religion is predominantly Hindu across all faculties, particularly in Nursing. There are a few Muslims in each faculty and a small representation of Buddhists in Nursing. No participants identify as Christian or other religions. Ethnic group representation shows that Chettri/Bahun is the largest ethnic group in all faculties, particularly in Nursing. Other ethnic groups, such as Janajati, Dalit, Madhesi, and Muslim, are represented in smaller numbers, with the Nursing group having the most diversity. There is a minimal presence of participants identifying as "Others" across all faculties. Additionally, there was maximum number of respondents from each faculty as from BPH 9(69.23%), from Pharmacy 8(14.8%), and from Nursing 9(32.14%). Respondents from Madhesh Province in Nursing was also maximum (i.e. 32.14%).

Table 2: Knowledge and Awareness scores of the participants

S.No.	Particular	Characteristics	Scores/Values		
			Public health	**Pharmacy**	**Nursing**
1.	**Knowledge**	Median(min-max) Mean ± SD Q1-Q3 Moderate to Low High	**1(1-2)** **1.3077** ± 0.48038 1-2 9 4	**1(1-2)** **1.2143** ± 0.42582 **1-1.25** 11 3	**1(1-2)** **1.0714** ± 0.26227 **1-1** 26 2
2.	**Awareness**	Median(min-max) Mean ± SD Q1-Q3 Moderate to Low High	17(14-22) 17.4615 ± 2.78733 14-20 13 -	16.5(12-24) 17.4286 ± 3.77674 14-21.25 14 -	19(14-24) 19 ± 2.14303 18-20 28 -

The median knowledge score of BPH faculty was 1, with a range from 1-2 (25^{th}-75^{th} percentiles: 1-2) while the mean score was 1.3077 ± 048038. A small proportion of participants (30.76%) exhibited good knowledge, while the majority (69.23%) had moderate to poor knowledge. The median knowledge score of pharmacy faculty was 1, with a range from 1-2 (25^{th}-75^{th} percentiles: 1-1.25) while the mean score was 1.2143 ± 0.42582. The median knowledge score of nursing faculty was 1, with a range from 1-2 (25^{th}-75^{th} percentiles: 1-1) while the mean score was 1.0714 ± 0.26227. A small proportion of participants (16.36%) exhibited good knowledge, while the majority (83.64%) had moderate to poor knowledge.

The median Awareness score of BPH faculty was 17, with a range from 14-22 (25^{th}-75^{th} percentiles: 14-20) while the mean score was 17.4615 ± 2.78733. No any participants exhibited good Awareness, so that 100% of participants had moderate to poor Awareness. The median Awareness score of pharmacy faculty was 16.5, with a range from 12-24 (25^{th}-75^{th} percentiles: 14-21.25) while the mean score was 17.4286 ± 3.77674. No any participants exhibited good Awareness, so that 100% of participants had moderate to poor Awareness The median Awareness score of nursing faculty was 19, with a range from 14-24 (25^{th}-75^{th} percentiles: 18-20) while the mean score was 19 ± 2.14303. No any participants exhibited good Awareness, so that 100% of participants had moderate to poor Awareness.

Table 3: Faculty-wise response to awareness related questions

S.No.	Particulars	Faculty	SA	A	Ne	D	SD
1.	Do you think ADRs reporting is necessary?	Public health	-	-	-	2	11
		Pharmacy	-	-	-	3	11
		Nursing				9	19
2.	Do you think reporting adverse drug reaction is a professional obligation?	Public health	7	6	-	-	-
		Pharmacy	8	3	2	1	-
		Nursing	9	16	3	-	-
3.	Do you think it is necessary to confirm that an ADR is related to a particular drug before reporting it?	Public health	-	-	1	4	8
		Pharmacy	-	-	2	4	8
		Nursing	-	-	3	11	14
4.	Do you think pharmacovigilance reporting should be compulsory?	Public health	-	1	1	6	5
		Pharmacy	-	-	-	3	11
		Nursing	1	-	2	12	13
5.	Do you think that it is necessary to report only serious and unexpected reactions?	Public health	1	-	-	7	5
		Pharmacy	2	1	1	7	3
		Nursing	3	1	2	18	4
6.	Pharmacovigilance should be taught to all health care students during their curriculum.	Public health	-	-	-	3	10
		Pharmacy	-	-	2	4	8
		Nursing	-	1	1	13	13
7.	I do not have any idea on how to report ADRs to the relevant authorities in Nepal.	Public health	-	1	-	6	6
		Pharmacy	-	2	2	4	6
		Nursing	-	-	7	10	11
8.	Information on reporting ADRs shall be better learnt during the internship /training/clinical posting.	Public health	1	-	1	5	6

		Pharmacy	**-**	**-**	**2**	**3**	**9**
		Nursing	**-**	**-**	**3**	**15**	**10**
9.	Pharmacovigilance will assure the rational drug therapy in clinical practices	**Public health**	**-**	**-**	**-**	**4**	**9**
		Pharmacy	**-**	**-**	**-**	**5**	**9**
		Nursing	**-**	**2**	**3**	**16**	**7**
10.	I am responsible person for ADRs reporting, if noticed, to the Pharmacovigilance center?	**Public health**	**-**	**-**	**-**	**4**	**9**
		Pharmacy	**-**	**1**	**1**	**5**	**7**
		Nursing	**-**	**-**	**2**	**14**	**12**

84.61% of participants from BPH faculty strongly disagreed while participants from pharmacy (78.57%) strongly disagreed whereas nursing stayed 67.85% strongly disagreed about ADRs reporting is necessary. Most participants of all the faculties (BPH: 61.53%, pharmacy: 57.14%, nursing: 50%) strongly disagreed with that reporting adverse drug reaction is a professional obligation while 7.14% of pharmacy respondents was disagreed with that. 61.53% of participants from BPH faculty strongly disagreed while participants from pharmacy (57.14%) strongly disagreed whereas nursing stayed 50% strongly disagreed with that it is necessary to confirm that an ADR is related to a particular drug before reporting it. 38.46% of BPH, 78.57% of Pharmacy, 46.42% of nursing was found to be strongly disagreed with pharmacovigilance reporting should be compulsory while one respondents from nursing stayed strongly agree. 38.46% from BPH. 10.71% from pharmacy, 14.28% from nursing was found to be strongly disagreed with that it is necessary to report only serious and unexpected reactions while 7.69% respondents from BPH, 14.28% from pharmacy and 10.71% from nursing. 76.92% from BPH. 57.14% from pharmacy, 46.42% from nursing was found to be strongly disagreed with that pharmacovigilance should be taught to all health care students during their curriculum. 46.15% from BPH, 42.85% from pharmacy, 39.28% from nursing was found to be strongly disagreed with that any idea on how to report ADRs to the relevant authorities in Nepal. 46.15% from BPH, 64.28% from pharmacy, 35.71% from nursing was found to be strongly disagreed with that Information on reporting ADRs shall be better learnt during the internship /training/clinical posting while one respondents from BPH stayed strongly agree. 69.32% from BPH, 64.28% from pharmacy, 25% from nursing was found to be strongly disagreed with that Pharmacovigilance will assure the rational drug therapy in clinical practices. 69.23% from BPH, 50% from pharmacy, 42.85% from nursing was found to be strongly disagreed with that they were responsible person for ADRs reporting, if noticed, to the pharmacovigilance center.

Table 4: Factors affecting knowledge of participants about the Pharmacovigilance

S.N.	**Characteristics**	**Knowledge**		**Binary logistic regression**		
		Moderate to poor (%)	**High**	**OR**	**95%CI**	***P***
1.	Age Below 30 Above 30	26 26	3 1	1(Ref) -	- -	-
2.	Gender Male Female	26 26	2 2	1(Ref) 0	- -	-

3.	Religion Hindu Others	21 5	2 -	1(Ref) 0.808	0.974 0.670	0.494
4.	Ethnic Group Chettri/Bahun Others	9 17	1 1	1(Ref) 0.529	90433 0.030	0.662
5.	Permanent residence (Province) Bagmati Others	8 18	1 1	1(Ref) 0.444	8.031 0.025	0.575
6.	Area (Permanent residence) Urban Rural	1 24	0 2	1(Ref) 0.960	1.040 0.886	0.773

For both below 30 and above 30 age groups, 26% have moderate to poor knowledge, and no participants have high knowledge. The odds ratio (OR) is 1 for each, meaning no difference in knowledge levels between the two age groups. Both male and female groups have 26% with moderate to poor knowledge, and no participants have high knowledge. The odds ratio is 1, indicating no difference between genders. 21% of Hindus have moderate to poor knowledge, while only 5% of participants in the "Others" category fall into this knowledge group. The odds ratio is close to 1 for both, indicating no significant difference between religious groups. 9% of Chhetri/Brahmin participants have moderate to poor knowledge, while 17% of those in the "Others" category do. The p-value of 0.039 suggests a statistically significant difference between ethnic groups. 18% of participants from Bagmati have moderate to poor knowledge, while 1% of those from other provinces do. The odds ratio suggests those from other provinces are less likely to have high knowledge. 1% of urban residents have moderate to poor knowledge, and 0% have high knowledge, compared to 1% of rural residents. The above table provides insights into how different demographic characteristics relate to the knowledge of pharmacovigilance among health science students. The binary logistic regression analysis suggests that, with the exception of ethnic groups and permanent residence, most characteristics do not show a statistically significant difference in knowledge levels, as indicated by the p-values.

Table 5: Factors affecting awareness of participants about the Pharmacovigilance

S.N.	**Characteristics**	Awareness		**Binary logistic regression**		
		Moderate to poor (%)	High	**OR**	**95%CI**	***P***
1.	Age Below 30 Above 30	25 0	29 1	1(Ref) 1.034	1.106 0.968	0.849
2.	Gender Male Female	9 16	9 21	1(Ref) 0.762	2.358 0.246	0.223
3.	Religion Hindu Others	24 1	24 6	1(Ref) 6.000	53.681 0.671	3.143

4.	Ethnic Group Chettri/Bahun Others	12 13	12 18	1(Ref) 1.385	4.045 0.474	0.355
5.	Permanent residence (Province) Bagmati Others	2 7	7 12	1(Ref) 0.490	3.045 0.079	0.598
6.	Area (Permanent residence) Urban Rural	0 9	1 17	1(Ref) 1.059	0.947 1.184	0.519

The percentage of participants with moderate to poor awareness of pharmacovigilance. The percentage of participants with high awareness of pharmacovigilance. **OR (Odds Ratio)** Indicates how much more likely the awareness is to happen in one group compared to the reference group. An OR greater than 1 indicates a higher likelihood, while an OR less than 1 indicates a lower likelihood. **95% CI Confidence Interval** Provides a range within which the true odds ratio is expected to lie, with 95% confidence. If this interval includes 1, the result is not statistically significant. **P (P-value)** Shows the statistical significance of the results. A P-value less than 0.05 typically indicates statistical significance, meaning the characteristic is likely associated with the outcome. Participants below 30 years are included, but those above 30 seem not to be statistically significant in influencing awareness. Males and females are compared, but neither shows statistical significance in predicting awareness. Hindu participants show a higher likelihood of awareness, with a significant OR and P-value. Chhetri/Brahmin and others are compared, but the results do not seem statistically significant. The comparison between Bagmati and others shows no significant difference in awareness. Urban and rural areas are compared, but neither shows a statistically significant difference in awareness.

5.4 Spearman's correlation

There was positive correlation between the knowledge and awareness scores (Spearman's rho:1)

6. DISCUSSION

Pharmacovigilance is a broad subject in the field of clinical and therapeutic pharmacy for the monitoring of adverse drug reactions. It monitors the safe, cost-effective, rationale as well as the patient-oriented effective treatment therapy for a better outcome (21). Study conducted on 2023 on a comparative study of knowledge, attitude, and practice of pharmacovigilance among medical and nursing students in a government medical college of Eastern India concluded on Regarding knowledge about PV and ADR, 89.13% of medical students and 82.76% of nursing students were aware of the term PV. About 78.26% of medical students and 68.97% of nursing students knew the definition of PV. About 78.80% of medical students and 72.41% of nursing students knew the definition of ADR. These findings showed no significant differences between the two groups. Regarding the location of the International Center for Drug Safety Monitoring, 60.87% of medical students and 51.72% of nursing students gave the correct response, which was also not significant (22).

The work of Thakuria et. al. in 2016 concludes that there should be a teaching programme for the students and constant motivation of doctors by pharmacovigilance team to report about adverse drugs reaction in

Silchar Medical College and Hospital, Silchar. This will improve the practice and knowledge of students about pharmacovigilance (23).

The work by Awada Sanaa et.al. at Lebanese University, Hadath, Beirut, Lebanon in 2016 regarding the ADR reporting center, the percentage of healthcare providers who were aware of the existence of a pharmacovigilance center in Lebanon is similar to findings from studies form Pakistan which elucidated there are several factors that may impact the awareness of pharmacovigilance among Lebanese medical staff (24).

The study by Zakir Khan et.al. Khyber Medical College, Peshawar, Pakistan conclude that most of HCPs had poor knowledge and practice, but they had a positive attitude about PV and ADR reporting. Lack of training and under-reporting of ADRs was observed among HCPs. Barriers to under-reporting of ADR were also highlighted. Periodic training programs, educational interventions, systematic follow-up of HCPs by local healthcare authorities, interprofessional links between all HCPs, and implementation of mandatory reporting policy are crucial for better HCPs' knowledge, practices, patient safety, and improved PV activities (25).

Community pharmacists should be educated about pharmacovigilance in Nepal to improve their knowledge. Lack of knowledge about what is an adverse drug reaction, what is to be reported, who can and should report, when to report, how to report, where to report, whom to report and lack of availability of ADR reporting forms for community pharmacists as well as for consumers can hamper ADR reporting in community settings (5).

Our knowledge findings are consistent with the previously published review, which investigates the pharmacovigilance competencies of all healthcare students. Knowledge about PV is poor, despite the good perception about PV importance and the good attitude toward PV and ADR reporting. Based on Reumerman et al. review many factors could influence PV competencies such as; type of healthcare school, academic level of study and previous training. This review shows that educational interventions such as; short lectures, workshops, training in ADR reporting and assessment have improved healthcare students' knowledge, perception and positive attitude toward PV (3).

The result of Noman MA et.al. shows that there is a great educational program are needed to increase creating awareness among Pharmacy student's role, their knowledge about the type of ADRs and ADRs reporting processes, thus to have a positive impact on patient caring process (2).

The result of Aamir et.al. Medical students have greater percentage of giving correct response in very few characteristics, but pharmacy students have greater percentage in many characteristics when we looked partially and comparatively on each class. It is also seen that overall poor knowledge towards pharmacovigilance and ADRs reporting was noticed but fourth year students and final year students of MBBS have poor knowledge and awareness comparatively to fourth year pharmacy and final year pharmacy students respectively (26).

7. CONCLUSION

In conclusion, the study underscores the critical importance of pharmacovigilance (PV) as an essential component of healthcare education, particularly in the context of adverse drug reactions (ADRs). Despite the global emphasis on the significance of ADR reporting for ensuring patient safety, the findings reveal a concerning gap in the knowledge and awareness of pharmacovigilance among health science students in Nepal. The majority of participants, across all faculties, demonstrated moderate to poor knowledge and

awareness of PV, with no significant differences observed between different demographic groups such as age, gender, and religious affiliation.

The lack of mandatory ADR reporting laws in Nepal, coupled with the low confidence among healthcare students in their ability to identify and report ADRs, poses a significant challenge to patient safety. The study highlights the urgent need for integrating comprehensive pharmacovigilance training into the health sciences curriculum to enhance students' competency in this area. Additionally, there is a clear necessity for policy reforms that make ADR reporting a mandatory practice among healthcare professionals in Nepal.

The positive correlation between knowledge and awareness scores suggests that improving educational interventions can potentially enhance both aspects, leading to better ADR reporting practices. Therefore, targeted efforts to strengthen pharmacovigilance education and awareness are imperative to safeguard public health and ensure the rational use of medications in clinical practice.

8. RECOMMENDATION

- Inclusion of pharmacovigilance in the undergraduate curriculum for healthcare professionals,
- Conducting periodically educational lectures with good emphasis on the concept of pharmacovigilance and the concept of ADRs,
- Sending warning letters or notifications to healthcare professionals regarding serious ADRs associated with drugs, immediately upon obtaining information from drug authorities / Pharmacovigilance centers, facilitating accessibility to ADR reporting forms for example spontaneous reporting of adverse drug reactions through electronic submission and activating the pharmacovigilance center at the Faculty of Pharmacy in the Universities of Nepal,
- To decrease under-reporting of ADRs, reduce the occurrence of ADR, and deliver high-quality care to patients, it is also essential to guarantee that they receive the correct instruction and have sufficient understanding of PV and ADR reporting,
- Similar studies should be conducted among community pharmacists in other districts of Nepal.

9. LIMITATIONS

The study was conducted with a limited number of participants (N=55) from three different faculties. This small sample size may not adequately represent the broader population of health science students in Nepal, limiting the generalizability of the results.

The study used a cross-sectional design, capturing data at a single point in time. This design does not allow for the assessment of changes in knowledge and awareness over time or the establishment of causal relationships.

The study relies on self-reported data from participants, which may be subject to bias. Participants might have overestimated or underestimated their knowledge and awareness, affecting the accuracy of the results.

The study participants were primarily from specific faculties and provinces, which might not reflect the diversity of health science students across Nepal. This limitation could affect the external validity of the findings.

The study mainly focused on knowledge and awareness of pharmacovigilance but did not explore other crucial factors, such as attitudes, motivations, or barriers to ADR reporting. These factors could provide a more comprehensive understanding of the issue.

Participants may have been influenced by recall bias, especially when reporting past experiences or knowledge related to pharmacovigilance, which could have affected the study outcomes.
The absence of a longitudinal follow-up limits the ability to assess whether educational interventions or changes in the curriculum could lead to improvements in knowledge and awareness over time.
The study's statistical analysis may have been limited by the small sample size, potentially leading to reduced power in detecting significant differences or associations.

References

1. Sivadasan S, Yuong NY, Chyi NW, Ching ALS, Ali AN, Veerasamy R, et al. Knowledge And Perception Towards Pharmacovigilance And Adverse Drug Reaction Reporting Among Medicine And Pharmacy Students. World J Pharm Pharm Sci. 3(3).
2. Noman MA, Alburyhi MM, Saif AA. Knowledge And Perception About Pharmacovigilance Among 4th And 5th Levels Pharmacy Students In Some Public And Private Universities, Sana'a Yemen. 9(11).
3. Alwhaibi M, Al Aloola NA. Healthcare students' knowledge, attitude and perception of pharmacovigilance: A systematic review. Wieland LS, editor. PLOS ONE. 2020 May 20;15(5):e0233393.
4. Tekel MT, Bekalu AF, Sema FD. Knowledge, Attitude, and Practice of Medical, Pharmacy, and Nursing Students Towards Pharmacovigilance and Adverse Drug Reaction Reporting at University of Gondar College of Medicine and Health Sciences, Northwest Ethiopia: A Cross-Sectional Study. Adv Med Educ Pract. 2021 Oct;Volume 12:1129–39.
5. Jha N, Rathore DS, Shankar PR, Bhandary S, Pandit RB, Gyawali S, et al. Effect of an educational intervention on knowledge and attitude regarding pharmacovigilance and consumer pharmacovigilance among community pharmacists in Lalitpur district, Nepal. BMC Res Notes. 2017 Dec;10(1):4.
6. Kc S, Tragulpiankit P, Gorsanan S, Edwards IR. Attitudes among healthcare professionals to the reporting of adverse drug reactions in Nepal. BMC Pharmacol Toxicol. 2013 Dec;14(1):16.
7. Danekhu K, Shrestha S, Aryal S, Shankar PR. Health-care Professionals' Knowledge and Perception of Adverse Drug Reaction Reporting and Pharmacovigilance in a Tertiary Care Teaching Hospital of Nepal. Hosp Pharm. 2021 Jun;56(3):178–86.
8. Insured will have to bear some of the treatment cost from January 15 [Internet]. [cited 2024 Mar 20]. Available from: https://kathmandupost.com/health/2023/12/28/insured-will-have-to-bear-some-of-the-treatment-cost-from-january-15
9. Malla B, Malla KP, Shrestha N, Dhakal G, Simangainda DMS, Nepal S, et al. Knowledge and attitude towards pharmacovigilance among healthcare students at a medical college in Nepal. Int J Basic Clin Pharmacol. 2023 Oct 25;12(6):781–7.
10. GorakhaPatra [Internet]. [cited 2024 Mar 10]. Over 10,000 registered specialist doctors in Nepal: NMC. Available from: https://risingnepaldaily.com/news/23327
11. Underpaid Nepali nurses set their sights abroad [Internet]. [cited 2024 Mar 10]. Available from: https://kathmandupost.com/money/2023/02/01/underpaid-nepali-nurses-set-their-sights-abroad
12. Pharmacovigilence activity in Nepal [Internet]. [cited 2023 Dec 22]. Available from: https://www.dda.gov.np/content/pharmacovigilance
13. health science students requirements [Internet]. [cited 2023 Dec 22]. Available from: https://www.coursera.org/articles/bachelor-of-health-science?isNewUser=true

14. Rajiah K, Maharajan MK, Nair S. Pharmacy students' knowledge and perceptions about adverse drug reactions reporting and pharmacovigilance. Saudi Pharm J. 2016 Sep;24(5):600–4.
16. A comparative evaluation of different teaching aids among fourth term medical students to improve the knowledge, attitude and perceptions about pharmacovigilance: An experimental study. Int J Pharmacol Res.
17. Sanaa A, Amal AH. Awareness and Perception of National Pharmacovigilance Center among Lebanese Medical Staff. J Pharmacovigil [Internet]. 2016 [cited 2023 Dec 20];04(01). Available from: http://www.esciencecentral.org/journals/awareness-and-perception-of-national-pharmacovigilance-center-amonglebanese-medical-staff-2329-6887-1000199.php?aid=69023
18. Alwhaibi M, Al Aloola NA. Healthcare students' knowledge, attitude and perception of pharmacovigilance: A systematic review. Wieland LS, editor. PLOS ONE. 2020 May 20;15(5):e0233393.
19. Paul R, Pal A, Datta A, Mukhopadhyay O. A comparative study of knowledge, attitude, and practice of pharmacovigilance among medical and nursing students in a government medical college of Eastern India. Natl J Physiol Pharm Pharmacol. 2023;(0):1.
20. Deo S et.al., Knowledge, Attitude and Perception of Undergraduate Health Sciences students on Pharmacovigilance: A Cross-Sectional Study in Nepal. Journal of Medical Care Research and Review, 06: (10) October (2023).
21. Balamu B. Knowledge, Attitude and Practices of Pharmacovigilance among the health care professionals at Ishakaadventist Hospital.
22. Thapa, Shankar, Assessment of knowledge and attitude on pharmacovigilance among the healthcare professional and pharmacy student at Dharan
23. Paul et. al., A comparative study of knowledge, attitude, and practice of pharmacovigilance among medical and nursing students in a government medical college of Eastern India.
24. Thakuria et. al., A cross sectional study to evaluate the knowledge, attitude and practices of healthcare professionals on pharmacovigilance at Silchar medical college and hospital, Assam, India.
25. Awada Sanaa et.al., Awareness and Perception of National Pharmacovigilance Center among Lebanese Medical Staff at Clinical Pharmacy Department, Faculty of Pharmacy, Lebanese University, Hadath, Beirut, Lebanon.
26. Zakir Khan et.al., Evaluation of health care professionals' Knowledge, attitudes, practices and barriers to pharmacovigilance and adverse drug reaction reporting: A cross-sectional multicentral study, Khyber Medical College, Peshawar, Pakistan.
27. Aamir et.al., 'Knowledge of Pharmacovigilance and Adverse Drug Reaction reporting of Pharmacy and Medical Students', Pakistan Journal of Medical & Health Sciences.