International Journal of Pharmacy and Pharmaceutical Sciences

Print ISSN: 2656-0097 | Online ISSN: 0975-1491 Vol 17, Issue 1, 2025

Original Article

A CROSS-SECTIONAL SURVEY-BASED INVESTIGATION ON KNOWLEDGE, ATTITUDE, AND PRACTICE OF PHARMACOVIGILANCE AMIDST HEALTHCARE PROVIDERS OF JORHAT CITY, ASSAM

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Received: 06 Jun 2024, Revised and Accepted: 19 Nov 2024

ABSTRACT

Objective: Among the main causes of increasing rates of sickness, death rates, and medical cost expenses is an Adverse Drug Reaction (ADRs). To guarantee improved patient safety, the Pharmacovigilance Programme of India (PvPI) encourages every healthcare worker to report possible ADRs. However, current data indicates that suspected ADRs are not being reported enough. In light of this, the current study was carried out to gauge the healthcare provider's Knowledge, Attitude, and Practice (KAP) on pharmacovigilance and to investigate the causes behind the underreporting of suspected ADRs in Jorhat City, Assam.

Methods: KAP of HCPs, comprising pharmacists, physicians as well as nurses, about pharmacovigilance is the subject of this observational investigation with a cross-section, carried out at Jorhat City, Assam. The pretested and peer-reviewed multiple-choice test consisting of 30 queries was utilized to assess the knowledge (1-16), attitude (17-22), and practice (23-30) between 61 HCPs of the city and the responses were collected after 30 min from each HCP. Utilizing Microsoft Excel software, data were analyzed and expressed as a percentage.

Results: 53 responses-21 pharmacists, 20 nurses, and 20 doctors were obtained from 61 surveys. Although the Healthcare Professionals demonstrated a good attitude (73.38%) and adequate knowledge, they did not perform pharmacovigilance for several reasons, the primary one being training on ADR reporting (34.33%), didn't send any suspected ADR report to the manufacturer (44.17%), haven't seen pharmacist reporting ADR (36.67%) and also due to not available of ADR Reporting form (25.11%).

Conclusion: The HCPs exhibited a good attitude**.** Still, the modification from attitude to knowledge and practice wasn't sufficient. Expertise and training can be significantly raised by making ADR reporting forms more accessible and adopting accessible techniques like instruction and guidance on reporting adverse drug reactions.

Keywords: Adverse drug reaction, Pharmacovigilance, Health care providers' attitudes, Practices, and knowledge

DOI: https://dx.doi.org/10.22159/ijpps.2025v17i1.51703 Journal homepage: https://innovareacademics.in/journals/index.php/ijpps

INTRODUCTION

Any unpleasant and unexpected response to a medication is known as an Adverse Drug Reaction (ADR) [1]. It raises the expense of healthcare and represents one of the biggest factors for death and disability in the globe [2, 3]. The purpose of these systems for spontaneous reporting is to quickly and affordably identify ADRs; the standard of reports that HCPs deliver to such networks impacts their effectiveness. Healthcare workers are in charge of identifying, recording, and disclosing Adverse Drug Reactions (ADRs), and also their involvement is crucial back to the initial identification and notification of an ADR [4]. By the law and the World Health Organization's recommendations, pharmaceutical companies were required to conduct surveys and ADRs associated with newly launched medications as part of Post Marketing Surveillance (PMS). However, long-term impacts and potential adverse drug reactions cannot be identified during the development stage. Therefore, it's crucial to keep an eye out for any possible ADRs for both recently approved and established medications.

The primary technique for keeping an eye on medication safety is the Spontaneous Reporting System (SRS) [5]. The continuous risk, PvPI urges each Health Care Professional (HCP), including physicians, nurses, pharmacists, and medical students, to take part in filing expected adverse drug reactions, or ADRs, to the CDSCO by fulfilling a suspicious ADR notification form [6]. There is underreporting of ADR, which is all over the nation since the PvPI continues to be in its infancy, primarily as a result of HCPs' negative attitudes and insufficient understanding [7]. According to studies, 0.2-24% of hospital admissions are caused by ADR [8, 9]. Furthermore, a wide variety of homeopathic, allopathic, Unani, Siddha, and Ayurveda medications has been obtainable and used in combination in India. Thus, it should be a top priority to disclose ADRs [10]. The estimated global reporting rate for ADRs is only 6–10% [11]. India's ADR reporting rate is less than 1% [12]. Furthermore, because medical personnel may be unable to recognize ADRs or accurately correlate those with pathological, biochemical, or radiological abnormalities, ADRs frequently remain undetected [13]. The necessity of monitoring and reporting can be made more widely known, and a culture of accurate ADR reporting can be promoted, all through educational interventions [14]. Every party involved has a shared responsibility for pharmacovigilance. ADR underreporting is a significant problem. Having a good surveillance system in place will facilitate better reporting of ADRs. The fundamental element driving the dynamism of this initiative is the engagement of healthcare providers. Consequently, to inform trainee physicians who will eventually provide healthcare about the several factors that contribute to inadequate reporting of adverse reactions to drugs, an experiment was designed with this in mind. If given the right training on pharmacovigilance, medical students might significantly contribute to the successful completion of the initiative while bringing about a paradigm shift. However, at the moment, they have no meaningful role, which is because they have not received the necessary training [15, 16]. Thus, the purpose of the research was to evaluate the various justifications for underreporting suspected adverse drug reactions to the ADR Monitoring Center (AMC) and also to examine the knowledge, attitudes, and practices of drug surveillance and reports of adverse drug reactions within the HCP in Jorhat City, Assam. Starting in

2014, JMCH was endorsed by PvPI to serve as Authorized Merchant. Even if the AMC of JMCH frequently reports ADRs, there's always room to improve the reporting culture.

MATERIALS AND METHODS

The research was conducted in Jorhat City, Assam, applying a cross-sectional subjective design and a questionnaire. Between April and May of 2024, two months, the study was carried out. The medical staff of Jorhat City, Assam, include doctors, nurses, and pharmacists.

Inclusion criteria

Medical experts in the city during the study's duration and those who agreed to participate after giving informed permission.

Exclusion criteria

Participants who declined to provide their knowledgeable permission.

The KAP survey was developed with references to earlier research [7-9]. The intention behind the query aimed to assess respondents' knowledge, attitudes, and reporting practices on pharmacovigilance, including notifying the AMC and the appropriate regulatory body of adverse drug reactions.

In total, there were thirty questions. One question concerned the individual's competent details; fifteen questions evaluated knowledge; six questions assessed attitude toward pharmacovigilance; eight questions judged drug safety and ADR reporting practices; and one question examined the various justifications for underreporting. The survey was given to sixty-one of the city's medical experts. Everyone who answered the questionnaire had thirty minutes to do so.

Statistical analysis

Using an MS Excel spreadsheet, data analysis was done. The outcomes were given as a percentage (%).

RESULTS

61 healthcare professionals, comprising 21 pharmacists, 20 nurses, and 20 doctors, were given the questionnaires. Overall, 53 (87%) replies were received (table 1), and 8 respondents did not respond. Analysis of the data was done using n=53.

Table 1: Professional details

Characteristics	Total	Pharmacist	Nurses	Doctors
Sample size	61 (=N)	21 (=N)	20 (=N)	20 (=N)
Responders	53(87%)	16 (76%)	18 (90%)	19 (95%)
Non-responders sex, n (%)	8(13%)	5 (24%)	2 (10%)	1 (5%)
Male	19 (31%)	7 (33%)	0	12 (60%)
Female age, n (%)	34(56%)	9 (43%)	18 (90%)	7 (35%)
Less than 20 y	3(5%)	1 (5%)	2 (10%)	0
21-30 y	39(64%)	15 (71%)	9 (45%)	15 (75%)
31-40 y	7(11%)	0	4 (20%)	3 (15%)
41-50 y	4 (7%)	0	3 (15%)	1 (5%)

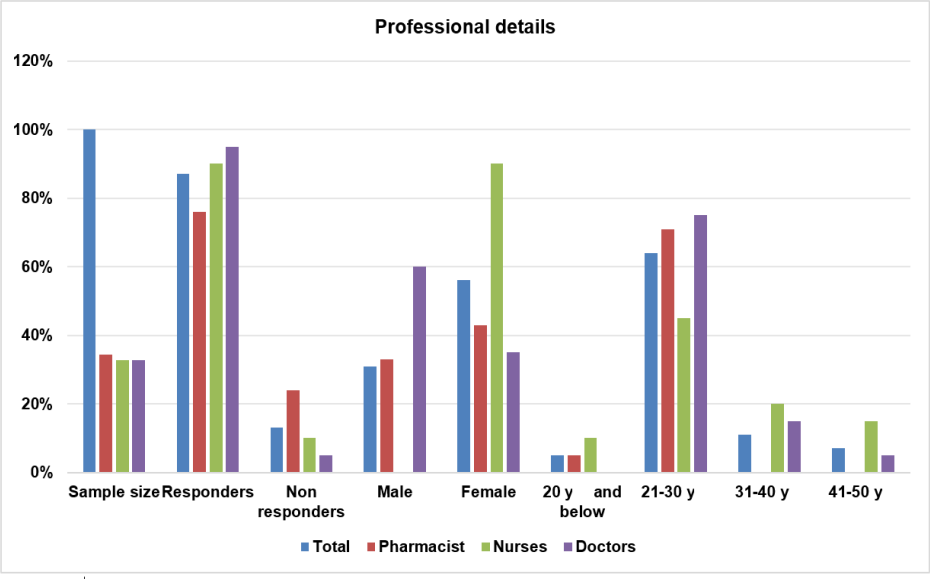

Fig. 1: Professional details

The healthcare providers in the current research knew little to nothing about ADR. Despite their strong knowledge of both pharmacovigilance and PvPI, rarely half the doctors (58.74%) and pharmacists (69.13%) could correctly answer the questions. Regarding what constitutes an ADR versus 50% of nurses, 69% and 95% of physicians and pharmacists, correspondingly, was appropriate (table 2).

The ADR monitoring center was known to the majority of medical practitioners. Concerning the requirement of ADR reporting, the vast majority of medical professionals expressed support and knowledge of mobile software and apps for reporting suspected ADRs. Patients and the healthcare care system itself could both gain from ADR reporting. Nurses observed barely 33 percent of suspicious ADR cases, in contrast to 95 percent of physicians and 87 percent of pharmacists. A majority of nurses (89%) and pharmacists (69%) are unaware of the distinction between ADRs and side effects (table 3).

Table 2: Outcomes demonstrating healthcare workers' knowledge of pharmacovigilance

Questions	Pharmacists N (%)			Nurses N (%)			Doctors N (%)		
	Correct/ Yes	Incorrect /No	No response	Correct /Yes	Incorrect /No	No response	Correct /Yes	Incorrect /No	No response
1. The study and practice of identifying, evaluating, comprehending, and averting side effects or other drug-related issues is referred to as	11 (69)	1 (6)	4 (25)	9 (50)	2 (11)	7 (39)	19 (100)	0	0
2. PVPI stand for?	13 (81)	2 (13)	1 (6)	4 (22)	3 (17)	11 (61)	18 (95)	0	1 (5)
3. Pharmacovigilance continues throughout which of the following?	8 (50)	5 (31)	3 (19)	5 (28)	4 (22)	9 (50)	7 (37)	12 (63)	0
4. What is an adverse drug reaction?	11 (69)	5 (31)	0	9 (50)	3 (17)	6 (33)	18 (95)	1 (5)	0
5. Serious adverse events may lead to?	14 (88)	0	2 (12)	3 (17)	8 (44)	7 (39)	16 (84)	3 (16)	0
6. Pharmacovigilance leads to?	11 (69)	2 (12)	3 (19)	2 (11)	3 (17)	13 (72)	14 (74)	4 (21)	1 (5)
7. UMC stands for?	12 (75)	2 (12)	2 (13)	4 (22)	3 (17)	11 (61)	16 (84)	1 (5)	2 (11)
8. The Pharmacovigilance Programme of India (PvPI), coordinated by the Indian Pharmacopeia Commission, is situated at?	10 (62)	4 (25)	2 (13)	3 (17)	0	15 (83)	14 (74)	1 (5)	4 (21)
9. The Uppasala Monitoring Center is located in which of the following countries?	9 (56)	3 (19)	4 (25)	1 (5)	3 (17)	14 (78)	8 (42)	7 (37)	4 (21)
10. Who can report an ADR?	12 (75)	4 (25)	0	4 (22)	9 (50)	5 (28)	13 (68)	6 (32)	0
11. Have you ever seen any suspected ADR (Adverse Drug reaction)?	14 (87)	0	2 (13)	6 (33)	3 (17)	9 (50)	18 (95)	0	1 (5)
12. Are you aware of the ADR Monitoring Center (AMC)?	12 (75)	3 (19)	1 (6)	3 (17)	4 (22)	11 (61)	17 (89)	2 (11)	0
13. Do you know of any mobile apps or software that may be used to report suspected ADRs?	12 (75)	3 (19)	1 (6)	3 (17)	3 (17)	12 (66)	12 (63)	5 (26)	2 (11)
14. Is there any difference between adverse drug reactions and side effects?	5 (31)	0	11 (69)	0	2 (11)	16 (89)	10 (53)	1 (5)	8 (42)
15. Do you know about "Drug Alerts"?	12 (75)	1 (6)	3 (19)	5 (28)	3 (17)	10 (55)	12 (63)	5 (26)	2 (11)
Correct Responses	69.13%			18.83%			58.74%		
Overall average knowledge	48.9=49%								

ADR reporting paperwork might be easily found at their job, according to the majority of respondents; nevertheless, only 6% of pharmacists had ever reported an adverse drug reaction. ADR Reporting System participation was desired by a sizable portion of responders (table 4). Among the many explanations for underreporting ADRs, 45% of respondents said they did not believe it was necessary to record ADRs, and 36% said their employer had no ADR reporting forms available. 19% of respondents cited fear of repercussions and ignorance as the main causes of underreporting (table 5).

Table 3: Research results indicate the attitudes of healthcare workers toward pharmacovigilance and reporting adverse drug events

Questions	Pharmacists N (%)			Nurses N (%)			Doctors N (%)		
	Yes	No	No response	Yes	No	No response	Yes	No	No response
1. Do you think ADR Reporting will benefit the healthcare delivery system?	14 (88)	0	2 (12)	13 (72)	0	5 (28)	17 (90)	1 (5)	1 (5)
2. Reporting an ADR is a professional obligation. Do you agree?	9 (56)	2 (13)	5 (31)	3 (17)	3 (17)	12 (66)	17 (90)	2 (10)	0
3. Educational intervention may improve the culture of reporting ADR's.	12 (75)	1 (6)	3 (19)	8 (44)	0	10 (56)	18 (95)	0	1 (5)
4. Do you think reactions due to herbal medicinal products should be reported?	11 (69)	1 (6)	4 (25)	12 (67)	0	6 (33)	18 (95)	1 (5)	0
5. Are you interested in participating in the ADR Reporting System?	13 (81)	0	3 (19)	7 (39)	5 (28)	6 (33)	16 (84)	1 (5)	2 (11)
6. Do you think ADR Reporting will increase patient safety?	13 (81)	1 (6)	2 (13)	14 (78)	0	4 (22)	19 (100)	0	0

Table 4: Studies showing how healthcare workers practice pharmacovigilance and report adverse events

Questions	Pharmacists N (%)			Nurses N (%)			Doctors N (%)		
	Correct /Yes	Incorrect /No	No response	Correct /Yes	Incorrect /No	No response	Correct /Yes	Incorrect /No	No response
1. Did you ever report any suspected ADR?	10 (62)	3 (19)	3 (19)	7 (39)	5 (28)	6 (33)	15 (79)	4 (21)	0
2. Did you receive training on reporting of ADRs during matric, intermediate, under graduation, post-graduation, or PhD?	8 (50)	5 (31)	3 (19)	1 (6)	12 (66)	5 (28)	12 (64)	5 (26)	2 (10)
3. Did you report any ADR to the ADR Monitoring Center?	9 (56)	6 (38)	1 (6)	5 (28)	9 (50)	4 (22)	10(53)	9 (47)	0
4. Have you ever reported any ADR in the last 12 mo?	10 (63)	5 (31)	1 (6)	3 (17)	11 (61)	4 (22)	12 (63)	6 (32)	1 (5)
5. Have you ever sent a suspected ADR report to the manufacturer?	2 (13)	13 (81)	1 (6)	1 (6)	13 (72)	4 (22)	3 (16)	14 (74)	2 (10)
6. Have you ever seen the ADR Reporting Form?	10 (63)	6 (37)	0	9 (50)	3 (17)	6 (33)	11 (58)	8 (42)	0
7. Have you seen a pharmacist reporting ADR?	9 (56)	4 (25)	3 (19)	3 (17)	8 (44)	7 (39)	9 (47)	9 (48)	1 (5)
8. Is the ADR Reporting form available at your workplace?	10 (63)	4 (25)	2 (12)	10 (55)	3 (17)	5 (28)	14 (74)	3 (16)	2 (10)

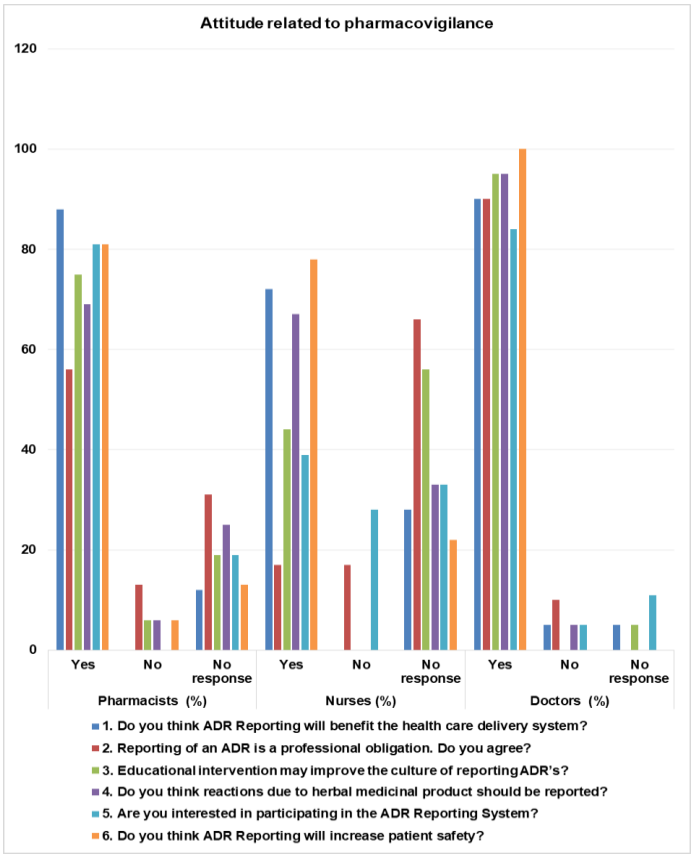

Fig. 2: Attitude related to pharmacovigilance

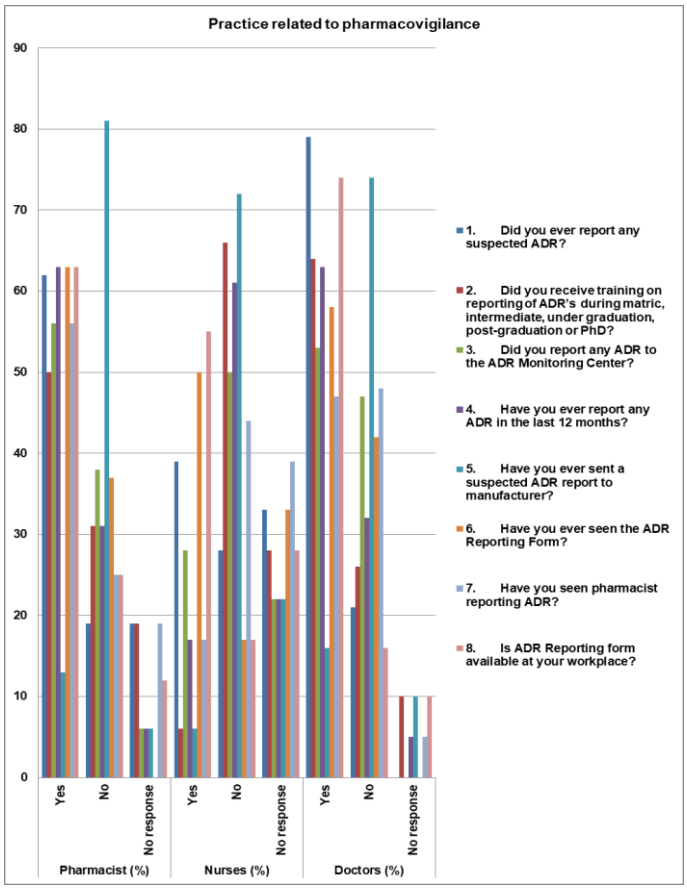

Fig. 3: Practice related to pharmacovigilance

Table 5: Causes of ADR underreporting

Reasons	Frequency N (%)
Consider not necessary	12(22.67)
The Workplace lacks ADR reporting forms	10(19.33)
Absence of awareness	20(19)
Fear of the repercussions	20(19)
Others	12(22.67)

DISCUSSION

Jorhat is an important city in the Upper Assam part of India and it is additionally rapidly changing into a hub for providing primary to tertiary-level healthcare to the population of Jorhat and nearby districts. The city serves as the host of two government medical colleges, several nursing colleges/institutes, pharmacy institutes, nursing homes, private clinics, polyclinics, and pharmacies. Naturally, a huge number of prescriptions are served daily across the city. So, it is expected that with the use of medications, there will be cases of suspected ADRs. Therefore, the goal of the study was to access the knowledge, attitude, and practice of ADR reporting and pharmacovigilance among different HCPs in Jorhat City.

The timely and voluntary ADR reporting is crucial to the effective execution and accomplishment of PvPI, underreporting of ADRs remains a concern [2]. The ability of different healthcare individuals to effectively perform drug surveillance and report ADRs, or adverse drug reactions, are among the key determinants of spontaneous ADR reporting, among other things.

In this study, nurses' understanding of pharmacovigilance and PvPI was low (50% and 78%, respectively), while pharmacists' knowledge was 31% and 19%. 32% of surgeons, 50% of nurses and 25% of pharmacists got it wrong about who might report an ADR. However, the overall respondents' average percentage of accurate answers was 49%, indicating that the HCP's familiarity with drug surveillance and ADR was mediocre. A study by C. R. Anuradha *et al.* discovered that 32% of clinicians lacked pharmacovigilance knowledge [17]. In contrast to our investigation, Z. Khan *et al.*'s previous study revealed that doctors' and pharmacists' average awareness of pharmacovigilance was 77.1% and 68%, respectively [18].

The researchers who conducted the research discovered that medical professionals have varying opinions on the usage of drug surveillance. A majority of respondents knew that AMC even existed. More than 95% of respondents believe that reporting ADRs will improve patient safety; 85% said they would be interested in taking part in the system; and 90% said it will improve the way healthcare is delivered. Similar attitudes were discovered amongst healthcare workers throughout a related study by Monika Agarwal *et al.* [6]. Above and beyond 90% of those who responded to the research study felt that obligatory disclosure of adverse reactions would improve patient safety over time. ADR reporting should be made necessary despite the findings of this study and other studies suggesting otherwise. This is because requiring reports could encourage false reporting, it might diminish the caliber of reports and information received [2, 6]. According to our poll, 20.67% of those assessed seemed unclear of the existence of an ADR notification app or application for smartphones, and 32 percent of them were unfamiliar with an ADR filing form.

This study also showed that HCPs conduct good pharmacovigilance; 56% of pharmacists and 53% of doctors reported suspected ADRs to their AMC, compared to only 28% of nurses, 63% of pharmacists, 50% of nurses, and 58% of doctors who saw the ADR filing form. Only 40% of respondents had received instruction on reporting of ADRs during matric, intermediate, under graduation, post-graduation, or PhD. In their survey, Srinivasan *et al.* noted a positive attitude toward pharmacovigilance, with 83.9% of those surveyed believing that disclosing ADRs was essential and 91.3% believing that comprehensive pharmacovigilance education is crucial for healthcare providers [19]. However, even if the study's participants had positive attitudes, 36.5% reported using inadequate ADR reporting practices. Research by Adithan *et al.*, and Supratim Dutta *et al.* also revealed similar outcomes [20, 21].

The primary reason for worry over the effectiveness of PvPI is the underreporting of ADRs [19]. ADR underreporting has been linked to several conditions, according to several researches. Numerous prior studies have identified several key factors that contribute to a failure to report ADR, including lengthy processes, a perception of more work, a shortage of a period of anxiety about arbitration from different stakeholders, an absence of awareness of who to disclose as well as how to disclose it, significance does not have of medical expertise, a hectic lifestyle, and are lacking incentives, concerns about patient confidentiality, etc [7, 22-25].

Maintaining constant knowledge of drug safety concerns is essential to developing better patient care [26]. One should think of pharmacovigilance programs as a component of the healthcare system. Pharmacovigilance and post-market analysis, in particular, require a fully committed national surveillance infrastructure for practice and knowledge of the spontaneous reporting system to succeed [27].

The main causes of ADR underreporting that we identified in our study included inadequate utilization of submission of ADR forms, assumption that reporting wasn't necessary, anxiety about repercussions, ignorance, etc. Additional significant factors included a large number of patients and little time, insufficient understanding of ADR submitting reports, a shortage of instructions, protracted and complicated reports, etc.

The medical staff in India are optimistic about pharmacovigilance, as this investigation and others from throughout the nation have shown. However, underreporting of ADRs has occurred because of the previously mentioned causes [19-21]. The rate of reporting might be raised if HCPs received the necessary training on pharmacovigilance, conducted sensitization campaigns to raise awareness, completed undergraduate course educational interventions, and were given a positive work environment.

There is a shortage of existing literature on knowledge, attitude, and the application of pharmacovigilance in India. To fill the knowledge gap, we have undertaken this study and to our knowledge, this is the initial research done among different HCPs across Jorhat City. The study not only helped to understand the status of pharmacovigilance practice among the target population but also helped to expand awareness of the same. However, there are some inherent drawbacks of this study as well. The study period was relatively short and could only include a small sample compared to the actual size of the target population.

CONCLUSION

The current study unequivocally demonstrates the healthcare professionals' positive pharmacovigilance attitudes. The attitude's inadequate translation into knowledge and practice, however, can be improved by facilitating easier access to ADR reporting forms. This implies that further work must be carried out to progress in the field of pharmacovigilance. The above-discussed learning assistance and training on reporting adverse reactions will be extremely beneficial in overcoming that changeable barrier in the future.

ACKNOWLEDGEMENT

The paper's authors thank the medical experts who participated in this survey for their assistance.

FUNDING

Nil

AUTHORS CONTRIBUTIONS

Data collection, results calculation, and manuscript writing were done by Nayan Dey. Dr. Sahid Aziz helped with the study's concept,

study design, and manuscript writing. Ms. Nyagi Riba and Dr Rajesh Jesudasan helped in data collection and overall editing of the manuscript.

CONFLICT OF INTERESTS

Declared none

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