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Original Articles

Exploration of Knowledge, Attitude, and Practice of Pharmacovigilance Among HealthCare Professionals: A Cross-Sectional Study

Exploración del conocimiento, la actitud y la práctica de la farmacovigilancia entre profesionales de la salud: un estudio transversal

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Resumen

Introducción: Para garantizar el uso seguro de los productos farmacéuticos y la detección de reacciones adversas a los medicamentos, es fundamental tener conocimientos de farmacovigilancia. Aunque la India ejecuta el Programa de Farmacovigilancia de la India, la tasa de notificación espontánea sigue siendo muy baja. Es necesario concienciar a los profesionales sanitarios sobre la importancia de la farmacovigilancia. Este estudio se realiza para evaluar el conocimiento, la actitud y la práctica de la farmacovigilancia entre los profesionales de la salud en la región norte de Uttar Pradesh.

Material y Métodos: Se conceptualizó un estudio transversal mediante un cuestionario basado en formularios de Google con 16 preguntas (08 de conocimiento, 05 de actitud y 03 de práctica), un medio adecuado para evaluar los conocimientos, actitudes y prácticas esenciales de la farmacovigilancia. . El cuestionario se distribuyó entre los profesionales sanitarios desde marzo de 2024 hasta abril de 2024.

Resultado: Se circularon 390 cuestionarios pretestados entre los profesionales de la salud, de los cuales 332 fueron respondidos por los encuestados, es decir, la tasa de respuesta fue del 85,12 %. Entre todos los encuestados, el 63,25 % eran hombres y el 36,74 % eran mujeres. Se observó en este estudio que los profesionales de la salud tienen conocimientos teóricos limitados sobre farmacovigilancia. A pesar de una actitud positiva hacia el requisito de informar las reacciones adversas a los medicamentos, los profesionales de la salud mostraron menos práctica de notificación.

Conclusión: los profesionales de la salud carecen de conocimientos y habilidades adecuados en la notificación de reacciones adversas a medicamentos, pero tienen una actitud positiva hacia los programas de farmacovigilancia. La incorporación de conceptos de notificación de reacciones adversas a medicamentos en el plan de estudios educativo, la capacitación y la participación voluntaria de los profesionales de la salud en la notificación de reacciones adversas a medicamentos es muy crucial para lograr los objetivos de seguridad y salvaguardar la salud pública.

Palabras clave: Reacciones adversas a medicamentos; Farmacovigilancia; notificación espontánea.

Abstract

Introduction: To ensure the safe use of pharmaceuticals and the detection of adverse drug reactions, it is essential to have an understanding of pharmacovigilance. Although India is running the Pharmacovigilance Program of India, still the spontaneous reporting rate is very low. There is a requirement to be aware healthcare professionals about the importance of pharmacovigilance. This study is conducted to assess the knowledge, attitude, and practice of pharmacovigilance among healthcare professionals in the Northern region of Uttar Pradesh.

Material and Methods: A cross-sectional study was conceptualized by a Google forms-based questionnaire with 16 questions (08 of knowledge, 05 of attitude, and 03 of practice) a suitable means of assessing the essential knowledge, attitude, and practice of pharmacovigilance. The questionnaire was distributed among the healthcare professionals from March 2024 to April 2024.

Result: 390 pretested questionnaires were circulated among healthcare professionals, and 332 of them were answered by the respondents i.e., the response rate was 85.12 %. Among all the respondents 63.25 % were males and 36.74 % were females. It was observed in this study that healthcare professionals have limited theoretical knowledge about pharmacovigilance. Despite a positive attitude toward the requirement of reporting adverse drug reactions, healthcare professionals showed less reporting practice.

Conclusion: Healthcare professionals lack adequate knowledge and skill in reporting adverse drug reactions but have a positive attitude toward pharmacovigilance programs. Incorporation of adverse drug reaction reporting concepts in education curriculum, training, and voluntary participation of healthcare professionals in adverse drug reaction reporting is very crucial in achieving safety goals and safeguarding public health.

Keywords: Adverse drug reactions; Pharmacovigilance; spontaneous reporting

Highlights

Underreporting is the main issue facing India's pharmacovigilance program.

Lack of understanding of pharmacovigilance and a careless approach to ADR reporting are found the main causes of underreporting.

There is a critical necessity to implement regular awareness programs to enhance their understanding and improve the practice of ADR reporting.

Introduction

An adverse drug reaction (ADR) is defined by the World Health Organization (WHO) as any harmful, unexpected, and undesirable outcome that occurs as a consequence of administering a medication at doses typically used in preventive, diagnostic, or therapeutic settings for human subjects[1]. Adverse drug reactions (ADRs) present a significant challenge to the safety of the patient and the quality of life, while also resulting in a substantial increase in healthcare costs. ADRs are a crucial contributor to morbidity and mortality on a global scale. The main thing is to ensure the safety and effectiveness of drugs throughout their lifecycle[2].

After the Thalidomide tragedy, in 1968 WHO with the cooperation of other countries started the International Drug Monitoring System (IDM)[3]. The National Drug Monitoring Centers of these involved countries collected and analyzed the ADR reports from the healthcare system and sent them to the IDM center located in Uppsala, Sweden. Currently, more than 150 countries are the members of WHO program for IDM (PIDM)[4,5]

In 1998, India also joined the PIDM, but due to a lack of financial and manpower support, it was not successful. Pharmacovigilance in India was restarted in 2005 with the name National Pharmacovigilance Program[6]. In 2010 it was renamed Pharmacovigilance Program of India (PvPI) with AIIMS, New Delhi as the National Coordination Center (NCC). In 2011, NCC shifted to the Indian Pharmacopoeia Commission (IPC) Ghaziabad[7,8].

When compared to other nations like the USA and Europe, which have well-established Pharmacovigilance systems in place due to technological advancement and other resources, India's PV initiatives are still in their infancy. As India is the world's largest manufacturer of pharmaceuticals and a significant center for clinical research, a more rigorous PV infrastructure is necessary[9].

Currently, 250 pharmacovigilance centers under the PvPI are established to strengthen the pharmacovigilance program and create a culture of reporting all over India. One of the most noteworthy concerns in India is related to the underreporting of Adverse Drug Reactions (ADRs). It is the primary responsibility of healthcare professionals to promptly and effectively report any adverse drug reactions (ADRs)[10].

Uppsala Monitoring Centre (UMC, WHO) estimated that only 6-10 % of all ADRs are reported[11], hence it is crucial to develop a tendency for ad-hoc reporting among healthcare practitioners as a strategic objective to enhance the Pharmacovigilance Programme of India (PvPI). The Knowledge, attitude, and practice (KAP) approach is an efficient tool for assessing the reporting of adverse drug reactions and the comprehension of healthcare professionals on the critical domains of patient safety and pharmacovigilance[12,13]. The present study was carried out to evaluate the knowledge, attitude, and practice among, healthcare professionals (HCPs).

Methods

Study setting

It was a cross-sectional questionnaire-based study conducted on resident doctors, intern doctors, nurses, and pharmacists in the various hospitals located in the satellite cities of the northern region of Uttar Pradesh from March 2024 to April 2024. This study aimed to evaluate the level of adequate knowledge, positive attitude, and sound practice of pharmacovigilance and ADR reporting among them.

Study Design

A questionnaire was created using Google Forms after a comprehensive literature review of past studies. Before the initiation of the survey, informed consent was received from the participants. The questionnaire was subjected to scrutiny by an expert committee to assess the clarity and relevance of the inquiries concerning the subject matter of the research. The pilot study was conducted to pre-test and review the questionnaire[14].

The questionnaire is designed with multiple-choice questions with only one right answer. The questionnaire utilized in the study was structured into four distinct sections. The initial segment was designed to gather demographic information of each participant (age, sex, occupation, etc)[15]. In the second section, eight questions were designed to assess each participant's level of knowledge about pharmacovigilance. The questions were multiple-choice, and the accuracy of the answers determined whether the response was correct or incorrect[16].

The third segment of the study was comprised of five inquiries that were intended to elicit the attitudes of each participant toward pharmacovigilance. Responses were gathered in the form of binary options, either 'agree' or 'disagree'. The fourth and final section, in its entirety, is comprised of three distinct inquiries that were specifically designed to furnish a comprehensive and detailed account of how each of the participants executed the practice of pharmacovigilance. The responses to these inquiries were collected and recorded in the form of a two-choice either 'yes' or 'no'.

In the present study, questionnaires were distributed among 390 HCPs. Out of which, 332 were collected successfully.

Ethical Approval: The study was approved by the Institutional Ethical Committee before its initiation.

Statistical analysis: The statistical analysis was conducted using Microsoft Excel, for data collection and computation. To determine the correlation between two attributes, the Chi-square test was employed at a level of significance of $P < 0.05$.

Results

Demographic Data:

During the investigation, the researchers were able to obtain 332 responses out of a total of 390, resulting in a response rate of 85.12 %. Analysis of the compiled dataset reveals that male subjects account for 63.25 % (n=210), while female subjects account for only 36.74 % (n=122). The study was primarily conducted with input from professionals in the field, with pharmacists representing the majority of contributors at 61.74 % (n=205). In addition, 24.09 % (n=80) of the contributors were doctors, while nurses constituted 14.15 % (n=47) of the sample. The study revealed that the age bracket of 18-25 had the largest pool of participants, constituting 69.27 % (n=230). In contrast, a smaller proportion of 20.78 % (n=69) of participants belonged to the age range of 25-45. Finally, only (n=33) of the population was classed as older than 45. Demographic detail is shown in Table 1.

Table 1: Demographic Study of HCPs

Category	Frequency (%)
Gender	
Male	210 (63.25)
Female	122 (36.74)
Age	
18 to 25	230 (69.27)
25 to 45	69 (20.78)
above 45	33 (9.93)
Occupation	
Doctors	80 (24.09)
Nurses	47 (14.15)
Pharmacists	205 (61.74)

Assessment of knowledge of HCPs of Pharmacovigilance

In the present study, it has been observed that among the HCPs, pharmacists 70.73 % (n=145) possess more knowledge about the theoretical aspects, specifically the definition, of Pharmacovigilance in comparison to doctors 17.50 % (n=14), and nurses 21.28 % (n=10). The objectives of pharmacovigilance are not well understood by healthcare professionals as per the observations. The accuracy of responses provided by pharmacists was found to be the highest, with approximately 58.54 % (n=120) of correct answers coming from their profession. The level of understanding of the international drug monitoring center is higher among physicians 97.50 % (n=78) and nurses 95.74 % (n=45), whereas pharmacists 72.68 % (n=149) have a relatively limited comprehension of the same. (Table 2).

Table 2: Assessment of Knowledge of HCPs of Pharmacovigilance

Knowledge about Pharmacovigilance and ADR reporting Centre	Participants				
		Doctors (N=80) n(%)	Nurses (47) n(%)	Pharmacists (205) n(%)	p value
Definition of Pharmacovigilance.	Correct Answer	14 (17.5)	10 (21.28)	145 (70.73)	0.00
	Incorrect Answer	66 (82.50)	37 (78.72)	60(29.26)	
Objective of Pharmacovigilance.	Correct Answer	12 (9.6)	12 (25.53)	120 (58.54)	0.00
	Incorrect Answer	68 (85.00)	35(74.46)	85(41.46)	
Is there an official document available for communicating Adverse Drug Reactions (ADRs)?	Correct Answer	42 (52.5)	24 (51.06)	156 (76.10)	0.00
	Incorrect Answer	38 (47.50)	23(48.93)	49(23.90)	
Do you have knowledge about the ADR reporting and monitoring system that exists in India?	Correct Answer	13 (16.25)	14 (29.79)	146 (71.22)	0.00
	Incorrect Answer	67(83.75)	33(70.21)	59(28.78)	
Is there any International Drug Monitoring System?	Correct Answer	78 (97.5)	45 (95.74)	149 (72.68)	0.00
	Incorrect Answer	2(2.5)	2(4.25)	56(26.92)	
Where National Centre of Pharmacovigilance is located?	Correct Answer	25 (31.25)	22 (46.81)	94 (45.85)	0.07
	Incorrect Answer	55(68.75)	25(53.19)	111(54.14)	
Which types of Adverse Drug Reactions (ADRs) are required to be reported?	Correct Answer	77 (96.25)	41 (87.23)	188 (91.71)	0.17
	Incorrect Answer	3(3.75)	6(12.76)	17(8.29)	
There is any regulatory body for monitoring of ADR in India.	Correct Answer	11 (13.75)	15 (31.91)	143 (69.76)	0.00
	Incorrect Answer	69(86.25)	32(68.08)	62(30.24)	

Attitude of HCPs towards reporting of ADR

The study comprised a total of five questions that sought to test the attitude of HCPs toward the reporting of Adverse Drug Reactions (ADRs). The study results demonstrate that HCPs are in agreement regarding the importance of reporting Adverse Drug Reactions (ADRs) to the healthcare system. The findings of the study indicate that there is a consensus among the participants especially 79.00 % (n=63) physicians, 59.57 % (n=29) nurses, and 83.90 % (n=172) pharmacists, that the submission of ADR forms has the potential to enhance patient safety. The inclusion of a collection box in the clinical setting was evaluated by HCPs to obtain their expert opinion. The results of the survey showed that nurses, 85.11 % (n=40), and pharmacists, 85.85 % (n=176) were predominantly in favor of the proposal, while physicians exhibited a relatively modest inclination towards the idea, with only 58.75 % (n=47) showing support. Pharmacists 72.68 % (n=149), nurses 74.47 % (n=35), and physicians 43.75 % (n=35) hold the view that the involvement of healthcare students is of utmost importance in disseminating awareness about adverse drug reaction (ADR) reporting (Table 3).

Table 3: Attitude of HCPs toward ADR reporting

Attitude related to ADR reporting		Doctors (N=80) n(%)	Nurses (47) n(%)	Pharmacists (205) n(%)	p value
Do you believe that the reporting of adverse drug reactions (ADRs) is an essential requirement for the healthcare system?	Agree	49(61.25)	31(65.96)	175(85.37)	0.00
	Disagree	35(44.00	16(34)	30(15)	
Is it your view that the submission of reports on Adverse Drug Reactions would contribute to enhancing patient safety?	Agree	63(79.00)	28(59.57)	172(83.90)	0.001
	Disagree	17(21.25)	19(40)	33(16)	
Is it essential to consult with healthcare experts and colleagues before reporting an Adverse Drug Reaction (ADR) to any medication?	Agree	37(46.25)	27(57.45)	159(77.56)	0.00
	Disagree	43(54)	20(43)	46(22)	
Do you believe that the implementation of a collection receptacle in every clinical sector would have a favorable impact on the facilitation of appropriate reporting?	Agree	47(58.75)	40(85.11)	176(85.85)	0.00
	Disagree	33(41)	7(15)	29(14)	
Do you believe that the participation of students in healthcare could potentially enhance their awareness of adverse drug reaction (ADR) reporting?	Agree	35(43.75)	35(74.47)	149(72.68)	0.00
	Disagree	45(56)	12(26)	56(27)	

Practice related to ADR reporting-

The study has revealed that a substantial proportion of HCPs, including physicians 62.5 % (n=50), nurses 57.44 % (n=27), and pharmacists, 51.70 % (n=106), did not report any ADR. However, it is noteworthy that only a relatively smaller fraction, namely 31.25 % (n=25) of physicians, 40.43 % (n=19) of nurses, and 40.48 % (n=83) of pharmacists, maintain the records about the reported ADRs. It is of particular significance to observe that a minute proportion of medical doctors 18.75% (n=15), registered nurses 25.53 % (n=12), and pharmacists 38.53 % (n=79) communicate the reported adverse drug reactions (ADRs) to the relevant regulatory authorities (Table 4).

Table 4: Assessment of Practice of HCPs for ADR reporting

Practice towards Pharmacovigilance and Reporting		Doctors (N=80) n (%)	Nurses (47) n (%)	Pharmacists (205) n (%)	p Value
Have you reported any observed adverse drug reactions (ADRs) in the past?	Yes	30(37.5)	20(42.55)	99(48.29)	0.243
	No	50(62.5)	27(57.44)	106(51.70)	
Do you follow the documentation regarding adverse drug events?	Yes	25(31.25)	19(40.43)	83(40.48)	0.493
	No	51(63.75)	28(59.57)	122(59.51)	
Have you ever reported the occurrence of an adverse drug reaction suspected to be caused by a pharmaceutical agent to any relevant regulatory agency?	Yes	15(18.75)	12(25.53)	79(38.53)	0.016
	No	57(71.25)	32(68.08)	126(61.46)	

Discussion

Worldwide, ADRs are regarded as significant causes of illness and mortality. Drug-related issues account for about 6 % of hospital admissions, while major adverse drug reactions (ADRs) affect 6–15 % of inpatients[17]. Therefore the present study was designed to explore the knowledge, attitude, and practice of pharmacovigilance among HCPs. In this study, an 85.12 % response rate was observed which is higher than in a similar study conducted by Srinivasan et.al[18]. 50.90 % of participants understood the definition of pharmacovigilance, and 43.37 % were able to know the objectives of pharmacovigilance which reflects the lack of knowledge in HCPs that may be a major contributing factor of underreporting which was reflected in our study and coinciding findings have been previously reported[19]. Empirical data suggest that HCPs show a notable lack of awareness concerning the National Center for pharmacovigilance, with merely 42.46 % supplying accurate answers that closely parallel observations reported by researchers in Turkey[20] It can be improved and overcome by educational intervention programs and workshops on pharmacovigilance.

An interesting observation emerged indicating that 76.80 % of participants exhibit a positive attitude, contrary to research done in Brazil[21] that reporting ADR is the prime requirement for a robust healthcare system which is higher than the published study[22]. Such findings of the study recommend an improvement in the awareness among HCPs[23].

65.96 % of the participants agreed that students associated with the healthcare profession may inculcate awareness of ADR reporting in contrast to the study conducted by Behara et al.

Despite a positive attitude, HCPs demonstrate inadequate adherence to ADR reporting protocol as evidenced by data indicating only 45 % of HCPs have even reported ADR that other research endeavors have also corroborated[24], which is the biggest challenge

There may be several potential determinants of underreporting, including insufficient time to accurately complete the ADR documentation and the lack of proactive engagement in following up on ADRs due to professional obligations, apprehension regarding the perception of incompetence, which may the patient's trust, and inadequate knowledge about the reporting process, including the appropriate channels for submitting the complete ADR forms, even within the framework of the national pharmacovigilance program. According to some research, there is a need for assurance among HCPs that ADR reporting has no legal issues[25]. The practice of ADR reporting is the moral responsibility of HCPs that can be inculcated by conducting workshops and awareness programs.

Conclusion

The finding showed that HCPs do not have adequate knowledge about pharmacovigilance which is the crucial reason for underreporting. All HCPs showed a positive attitude toward ADR reporting and agreed that it is essential for enhancing patient safety but the outcome has shown that having a positive attitude did not significantly improve HCPs practice of reporting ADR. Reporting of ADR is the core part of the system that must be strengthened. It is recommended that HCPs receive frequent educational training in pharmacovigilance to enhance their practice of reporting ADRs.

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