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Public Participation in Pharmacovigilance

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Abstract
Adverse drug reactions (ADRs) constitute a significant proportion of hospital admissions globally, with approximately 6.7% attributed to these events. Studies suggest that more than 50% of ADRs could be preventable with cautious prescription practices. The economic burden and strain on healthcare resources associated with managing ADRs are considerable. Despite PvPI efforts, pharmacovigilance remains inadequately practiced due to insufficient understanding and awareness among individuals. This study employed an analytical cross-sectional approach, utilizing a structured questionnaire administered via Google Forms to randomly selected patients and healthcare workers at Sarojini Naidu Medical College, Agra, India. Participation was voluntary and anonymity was ensured. Data analysis was conducted using Microsoft Excel. The results revealed varying levels of awareness among participants regarding ADRs and Pharmacovigilance. While a majority acknowledged the importance of ADR reporting, a significant proportion lacked knowledge regarding reporting procedures and hesitated to report ADRs. These findings underscore the need for enhanced education and support in this domain. Barriers to ADR reporting identified in this study include inadequate knowledge, time constraints and a lack of confidence among healthcare professionals. Addressing these challenges through regular training sessions and support mechanisms could improve reporting rates and quality. Pharmacovigilance plays a crucial role in ensuring drug safety. Comprehensive training and awareness initiatives are essential to overcome barriers to ADR reporting and enhance pharmacovigilance practices among healthcare professionals and individuals.

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Key Words
Adverse drug reaction, health care professionals, pharmacovigilance programme of india

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INTRODUCTION

Adverse drug reactions (ADRs) make up approximately 6.7% of all hospital admissions worldwide[1]. Over 50% of these ADRs happened in patients could have been avoided with cautious prescription and supervision[1]. Research has indicated that dealing with ADRs results in substantial expenses and places a considerable strain on healthcare spending. An ADR is "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function[2,3]." Whereas pharmacovigilance is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems[4]."

The Ministry of Health and Family Welfare's Central Drugs Standard Control Organization in New Delhi launched a nationwide pharmacovigilance program in July 2010 to monitor and report adverse drug reactions (ADRs) in India. The initiative began with just 22 Adverse Drug Monitoring Centers (AMCs) but now there are approximately 150 AMCs nationwide. The National Coordination Centre for this program is the Indian Pharmacopoeia Commission in Ghaziabad. Over 80,000 Individual Case Safety Reports have been added to the Pharmacovigilance Programme of India (PvPI) database since it was established[1].

Still, Pharmacovigilance is not widely practiced among individuals as a result of insufficient understanding and awareness. This study aimed to evaluate the understanding and awareness of Pharmacovigilance among patients and healthcare providers at Sarojini Naidu Medical College in Agra, before and after a Pharmacovigilance Training session.

MATERIALS AND METHODS

This research utilized an analytical cross-sectional approach, utilizing a carefully planned close-ended questionnaire to gather information from randomly chosen patients and healthcare workers at Sarojini Naidu Medical College, Agra, India. Participation was completely optional. Yet, in order to preserve the secrecy of their identity, individuals were not required to include their name on the survey. The survey was distributed in the local language to each participant individually through a Google Form. Guidance on how to complete the questionnaire was provided immediately.

In this study, a random sample of 210 subjects was selected from S N Medical College, Agra. This study focused on patients' awareness and involvement in reporting adverse drug reactions. Data was gathered in an MS Excel spreadsheet and the data analysis was done by utilizing the collected information.

RESULTS AND DISCUSSIONS

The (Table 1) presents responses from patients regarding their knowledge of Adverse Drug Reactions (ADRs) and Pharmacovigilance. Among the participants, 71.9% indicated they had heard about Pharmacovigilance, while 28.1% had not. When asked if they believed Adverse Drug Reporting was necessary, a significant majority, 93.3%, agreed, whereas only 6.7% disagreed. Additionally, nearly half of the respondents, 49%, reported having witnessed Adverse Drug Reactions in either family members or patients, while the remaining 51% had not observed such reactions. These findings highlight varying levels of awareness and experiences with ADRs and the importance of pharmacovigilance efforts in monitoring and reporting adverse reactions to medications.

(Table 2) outlines the awareness and practices related to Adverse Drug Reactions (ADRs) among respondents. A mere 25.7% claimed familiarity with the process of reporting ADRs, while a significant majority of 74.3% did not. Despite this, only 10.5% had actually reported any Adverse Drug Reactions, with a substantial 89.5% indicating they had not. However, there was a strong consensus on the importance of reporting ADRs, as 92.9% acknowledged its significance, contrasting sharply with the 7.1% who disagreed. Interestingly, only 31.4% were aware of where to report ADRs specifically within SN Medical College, Agra, while the majority, 68.6%, were unaware. Moreover, a similar proportion, 10.5%, expressed hesitancy towards reporting ADRs, while 89.5% did not feel hesitant. These findings underscore the gaps in knowledge and practice surrounding ADR reporting and highlight the need for further education and support in this area.

The outcomes of our survey were notable, with a significant proportion (74.3%) of participants demonstrating a lack of awareness regarding the reporting procedures for Adverse Drug Reactions (ADRs) within India's nationwide Pharmacovigilance Programme of India (PvPI). Additionally, a striking 89.5% of the study cohort did not engage in any ADR reporting to the PvPI. Several factors may account for this observation, including insufficient promotion of the PvPI, prioritization of drug efficacy over safety in patient care within the Indian healthcare system, voluntary participation by institutions or hospitals in ADR reporting, the non-binding nature of ADR reporting for physicians and a deficiency in sensitization regarding ADR reporting and its implications during medical education and training. Nevertheless, proactive measures can be taken to heighten awareness among healthcare professionals, such as regular provision of informative lectures and encouragement to report drug-related issues. To address this issue prospectively, initiatives have been initiated to educate undergraduate students about the significance of pharmacovigilance, including how to recognize, complete ADR forms and submit ADR reports.

The study showed that there is little knowledge about ADR occurrence, reluctance to report ADRs

Table 1. Knowledge of study participant to ADR and pharmacovigilance.

Questions	Yes	No
Have you heard about Pharmacovigilance?	71.9%	28.1%
Is Adverse drug reporting Necessary?	93.3%	6.7%
Have you ever seen Adverse Drug reaction in any Person (Family/Patient)?	49%	51%

Table 2. Awareness and practice regarding ADR

Questions	Yes	No
Do you know how to report Adverse drug reaction?	25.7%	74.3%
Have you ever reported any Adverse Drug reaction?	10.5%	89.5%
Do you believe the reporting of Adverse drug reaction is Important?	92.9%	7.1%
Do you know where to report Adverse drug reaction in SN Medical college, Agra?	31.4%	68.6%
Are you hesitant to report an Adverse drug reaction?	10.5%	89.5%

(89.5%), limited awareness of local PV settings and policies and low confidence in discussing ADR reports among healthcare professionals. Many healthcare providers often faced significant barriers. Other studies also found the same obstacles, with most pharmacists lacking knowledge of the lack of reporting forms and procedures, or choosing not to report[5,6]. Nevertheless, this problem can be addressed by providing them with brief and regular hands-on training sessions focused on how to complete a standardized ADR reporting form in a structured manner, which is accessible through PvPI. This is likely to enhance both the frequency and quality of ADR reporting. Furthermore, regular participation in these training sessions helps to eliminate misunderstandings, such as concerns about legal action related to ADR reporting.

The majority of healthcare professionals recognized a challenge in identifying where to report an adverse drug reaction within the health system. Not having access to the online system might discourage healthcare providers from confirming the occurrence of an ADR or not[7,8]. Only a mere 10.5% have practical knowledge of reporting adverse drug incidents. One of the main concerns we have is how we can enhance this percentage. Encouraging doctors to report ADRs is a challenging task. Efforts have been made to raise awareness about the Pharmacovigilance Programme of India in order to promote reporting of adverse drug reactions, with different levels of success. Some ways include linking electronic patient records to an ADR reporting form, automating ADR reports, providing financial incentives, hosting workshops or implementing an educational lecture series and sending periodic text message or email reminders[9-15]. In our organization, we have implemented the practice of sending email reminders, circulating a newsletter, and posting flyers in OPDs and patient wards. Pharmacovigilance rounds were initially started on a weekly basis and have now been increased to twice a week, which we believe is sufficient to promote reporting. A lot of doctors currently communicate their suspicions and many feel uneasy when they don't report after seeing our genuine efforts. Our institution is currently experiencing growth but is lacking clinical faculty. A shortage of time could also be a significant barrier for individuals who are eager to report ADRs. We anticipate that the reporting number will increase as manpower increases.

Healthcare professionals, such as doctors, pharmacists and nurses, have recognized that barriers to reporting adverse drug reactions include a lack of knowledge, time, confidence and support from coworkers regarding the national PV system. Potential drivers for improvement included additional time allocated for reporting ADRs, further training and education, regular reminders and the option to utilize an online ADR reporting platform.

CONCLUSION

Pharmacovigilance stands as the indispensable mechanism to safeguard the safety profile of pharmaceuticals across their entire life cycle. It is imperative that non-healthcare professionals receive comprehensive training in completing Adverse Drug Reaction (ADR) reporting forms tailored to consumers, in their native languages. Augmenting awareness initiatives targeting healthcare professionals and support staff, integrated within their standard curriculum, holds promise as a strategic intervention to bolster ADR reporting efficacy within the Indian healthcare context.

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