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Original Research Article

Bridging knowledge and practice gaps in pharmacovigilance: a study among medical interns in Uttar Pradesh

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ABSTRACT

Background: Adverse drug reactions (ADRs) are a major public health concern globally, contributing to significant morbidity and mortality. Despite the presence of pharmacovigilance systems, underreporting is common within medical colleges and antimicrobial stewardship programs, particularly in India. Medical interns are pivotal in ADR reporting, but gaps persist between their knowledge and practical application. By integrating pharmacovigilance into medical curricula, healthcare professionals can be better equipped to identify and report ADRs, ultimately enhancing patient outcomes. This study aims to evaluate the knowledge, attitudes, and practices (KAP) of ADR reporting among medical interns at Sarojini Naidu Medical College, Agra, and identify barriers to reporting.
Methods: A cross-sectional study was conducted among 125 medical interns using a pre-tested, structured questionnaire to assess their KAP regarding ADR reporting. Data were analyzed using descriptive statistics in Microsoft Excel.
Results: While 95% of interns were aware of ADRs and 70% understood the need to report them, only 25% had reported an ADR. Barriers included time constraints, lack of training, and legal concerns.
Conclusion: The study highlights high awareness but low reporting rates among medical interns, emphasizing the need for targeted educational interventions and streamlined reporting systems to improve pharmacovigilance practices.

Keywords: Adverse drug reactions, Pharmacovigilance, Medical interns, Knowledge-attitude-practice, ADR reporting, India

INTRODUCTION

Adverse drug reactions (ADRs) are defined by the World Health Organization (WHO) as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function".[1,7] Globally, ADRs account for approximately 3-5% of hospital admissions and contribute to over 100,000 deaths annually in the United States alone.[1] In developing countries like India, the burden is exacerbated by factors such as polypharmacy and limited regulatory oversight.[2]

The Pharmacovigilance Programme of India (PvPI), established in 2010, aims to monitor and report ADRs through a network of ADR monitoring centres (AMCs).[3,8] Despite these efforts, reporting rates remain low, with studies indicating that only 6-10% of ADRs are reported in Indian healthcare settings.[2,9] This underreporting hinders the ability to detect drug safety signals and implement timely interventions.[4]

This paper explores the barriers to ADR reporting in Indian medical colleges, reviews the role of AMCs, and recommends strategies for curriculum integration to foster a culture of pharmacovigilance among future healthcare professionals.[5,6,10]

METHODS

Study type

A cross-sectional study design was employed using a pre-tested and validated structured questionnaire to assess interns' KAP regarding ADR reporting.

Study place

The study was conducted at Sarojini Naidu Medical College, a tertiary care hospital in Agra, Uttar Pradesh.

Study period

This cross-sectional questionnaire study was conducted in the month of June 2025.

Selection criteria of the patients

A representative sample of 125 medical interns was selected to ensure a diverse range of responses.

Procedure

Confidentiality and voluntary participation were prioritized throughout the data collection process. Before conduction of the study, The KAP questionnaire toward pharmacovigilance and ADRs was developed and verified for suitability. The questionnaire was semi structured, predesigned, pretested, and validated for data collection.

Few changes were made as per our study need and the conclusive version of the KAP questionnaire had following number of questions.

Knowledge questionnaire comprised of 6 questions, attitude questionnaire had 4 questions and practice component had 5 questions.

Details of questionnaire

The following questions were included in the questionnaire to assess the interns' knowledge, attitudes, and practices regarding ADRs.

Consent for participation

"I agree to participate in the survey and consent for the data to be used for record and research purposes."

Knowledge-based questions

It included: Are you aware of the term ADR? What best describes ADR? Which adverse drug reactions need to be reported? Are you aware that drugs are also banned due to relevantly reported ADRs? Are you aware of any AMC in Agra? Mode of ADR reporting in India is?

Attitude-based questions

It included: Who can report ADR? Is ADR reporting necessary? Do you think ADR reporting will improve mortality and morbidity of patients in clinical practice? Do you think information on ADR reporting should be taught to all healthcare students in their curriculum?

Practice-based questions

It included: Have you reported any ADR yet? If yes, how many and what was their mode of reporting? Do you mention ADRs in patient records? Have you been sensitized on ADR reporting? What factors discourage you from ADR reporting? (e.g., managing the patient being more important, patient confidentiality issues, legal liability issues, lack of knowledge on how to report).

Statistical analysis

The collected data was recorded and analysed by Microsoft Excel version 16.90.2.

RESULTS

Demographic details of the participants were presented in Table 1.

Knowledge

ADR awareness

95% of interns were familiar with ADRs and could describe them accurately as harmful, unintended drug reactions. Cutaneous adverse drug reactions are among the most frequently reported ADRs in tertiary care hospitals in North India (Figure 1).

Table 1: Demographic details of the participants.

Variables	Value
Number of interns	125
Batch	2020
Mean age (years)	23.4
Gender	Not recorded

Reporting awareness

About 70% of participants knew that all ADRs should be reported, although 47% were unaware of the ADR Monitoring Centres (AMCs) in Agra (Figure 2).

Benefits of ADR reporting is shown in Figure 3.

Modes of reporting

Around 65% were aware of multiple reporting mechanisms for ADRs, including submission forms and online portals (Figure 4).

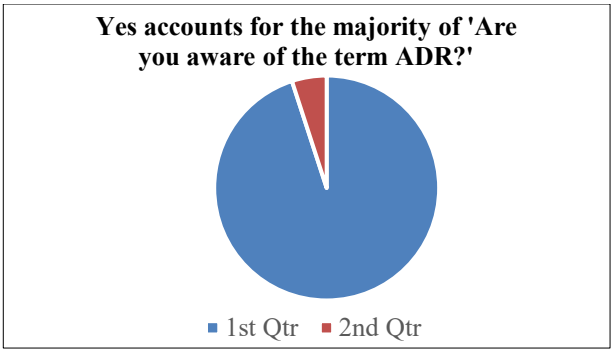

Figure 1: ADR awareness.

Underreporting awareness

Approximately one-third were not sensitized about the significance of ADR reporting, indicating a knowledge gap.

Attitude

Professional obligation

A significant 95% of interns felt that reporting ADRs is a professional duty, reflecting a generally positive attitude towards pharmacovigilance.

Educational importance

73% agreed that ADR reporting should be integrated into medical training curriculums, suggesting a widespread recognition of the need for early education on ADR documentation.

Impact on public health

Many interns believed that ADR reporting contributes to reducing patient morbidity and mortality by facilitating drug safety measures.

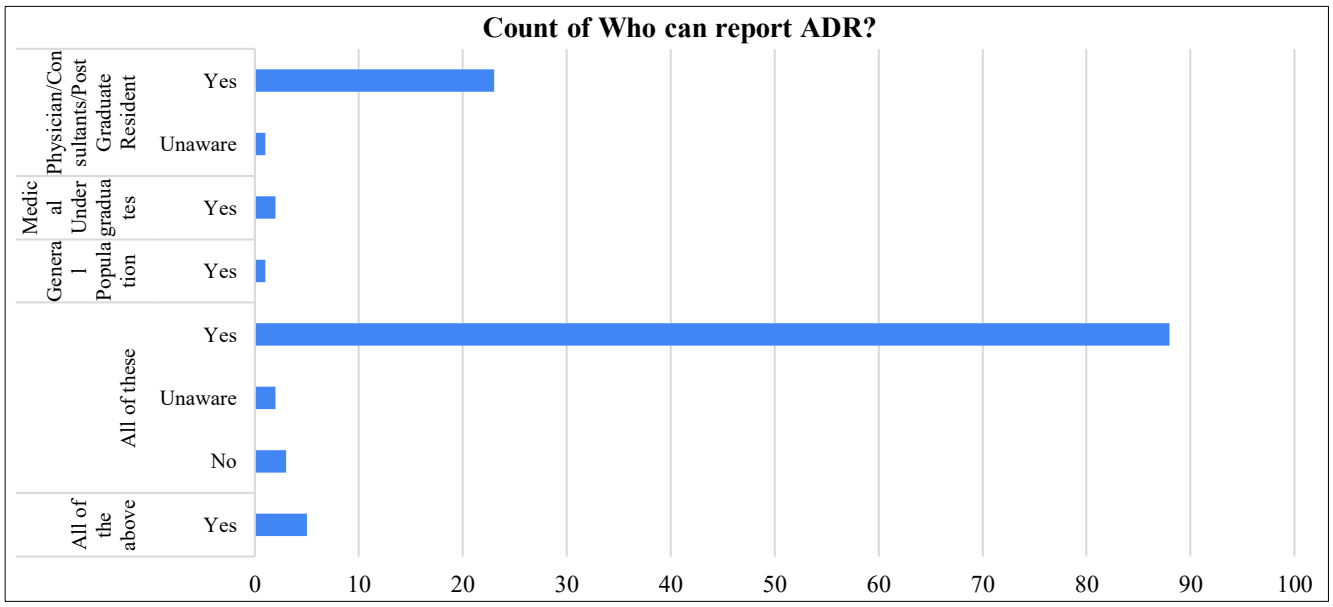

Figure 2: ADR reporting.

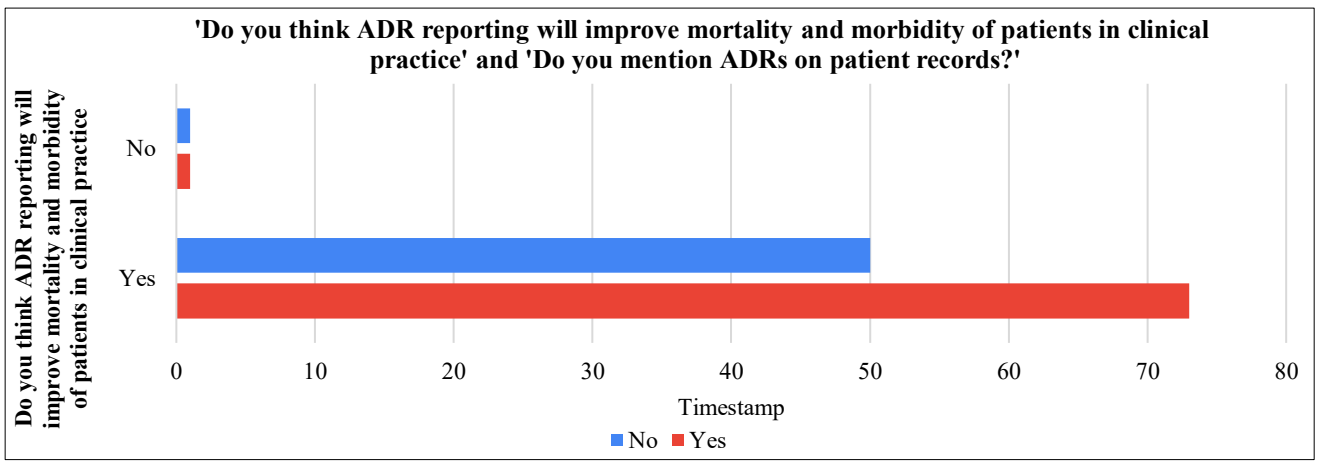

Figure 3: Benefits of ADR reporting.

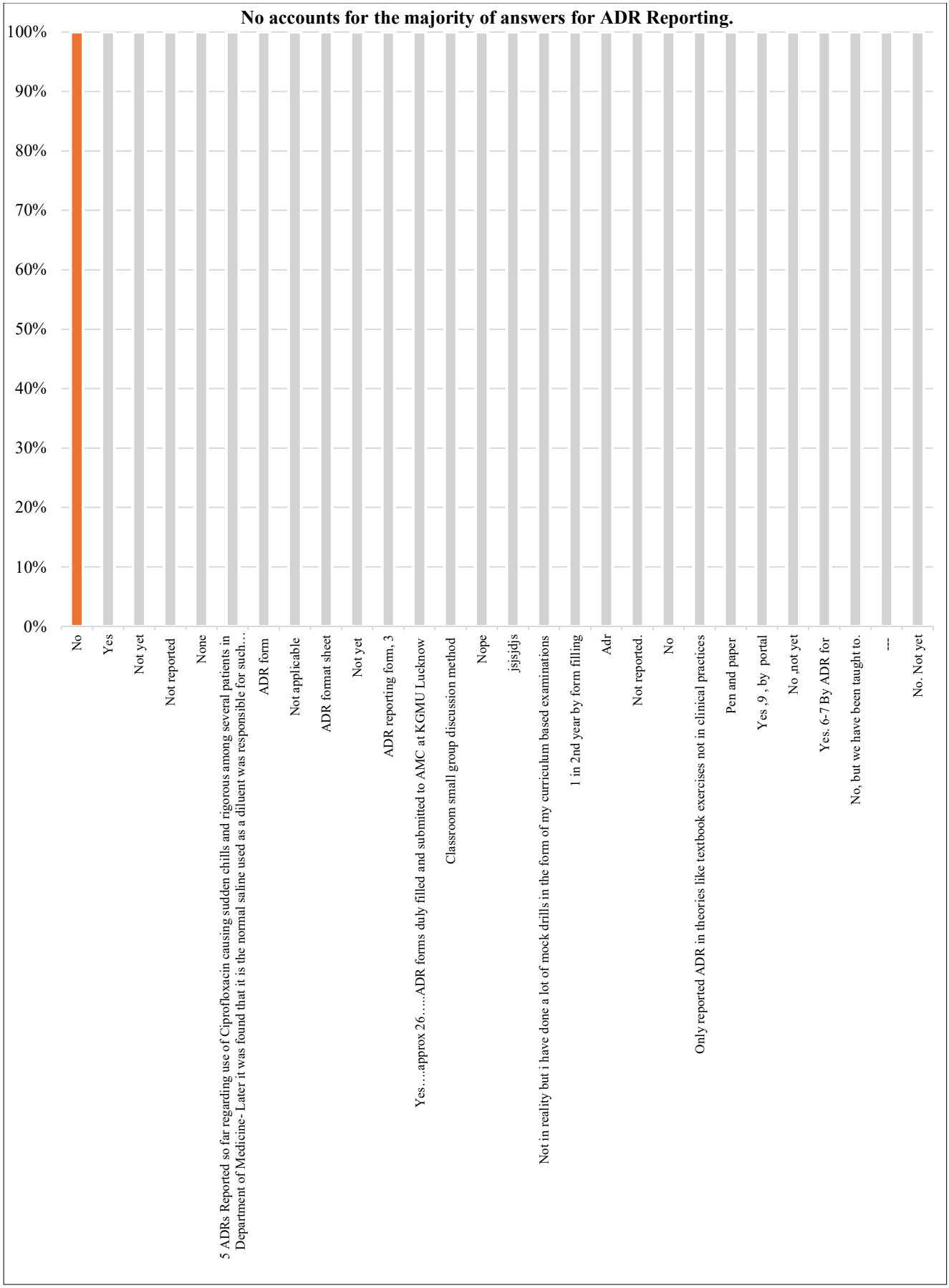

Figure 4: Modes Of ADR reporting.

Practice

Only 25% had reported an ADR. Barriers included: time constraints (50%), lack of training (34%), concerns over legal liability and patient confidentiality (20%).

DISCUSSION

Barriers to ADR reporting

Several barriers impede effective ADR reporting in Indian medical institutions. A primary challenge is the lack of awareness among healthcare providers about reporting procedures, with surveys showing that 40-50% of physicians are unfamiliar with PvPI guidelines.[2,12] Time constraints and heavy workloads further discourage reporting, as clinicians often prioritize patient care over documentation.[2,9]

Additionally, fear of legal repercussions and a perceived lack of feedback from reporting systems contribute to underreporting.[6,12] In a study conducted in West Bengal, only 25% of medical students demonstrated positive attitudes toward ADR reporting, highlighting attitudinal barriers.[6,13] Institutional factors, such as inadequate infrastructure in AMCs, also play a role, with many centres lacking dedicated staff or digital tools for efficient reporting.[4,14]

Antimicrobial agents, which account for 20-30% of reported ADRs in India, exemplify these issues.[4,11] Misuse of antibiotics in medical colleges often leads to resistance and adverse events, yet reporting remains sporadic due to these barriers.[4]

Current reporting mechanisms and the role of AMCs

The PvPI provides standardised guidelines for ADR reporting, including the use of a suspected ADR reporting form available online or via mobile apps.[3,8] AMCs, typically located in medical colleges, serve as nodal centres for collecting and analysing ADR data, forwarding it to the national coordinating center.[3]

Patel et al emphasize the importance of AMCs in promoting antimicrobial stewardship, recommending regular training workshops and integration with hospital pharmacies to streamline reporting.[4] Despite these mechanisms, challenges persist, including inconsistent data quality and delays in processing reports.[2,14]

Strategies for improvement: educational integration

To address these barriers, integrating pharmacovigilance education into medical curricula is essential.[5,10] Datta and Giri propose incorporating ADR modules in undergraduate pharmacology courses, including case-based learning and simulations to build reporting skills.[5,10] This approach can enhance knowledge and attitudes, as evidenced by improved reporting rates in institutions with dedicated pharmacovigilance training.[6,13]

Limitations

This study was conducted in a single institution with a limited sample size, which may limit generalizability. Data were collected using self-reported questionnaires, leading to recall or social desirability bias. Future studies across multiple centres and with larger, more diverse populations are recommended.

CONCLUSION

Underreporting of ADRs in India poses a threat to public health, but through improved education and institutional support, medical colleges can play a pivotal role in strengthening pharmacovigilance. Adopting these recommendations will not only boost reporting but also cultivate a generation of vigilant healthcare professionals committed to patient safety.

Recommendations

Curriculum reforms

Mandatory pharmacovigilance sessions in MBBS programs, focusing on PvPI guidelines and practical reporting exercises.[5]

Institutional initiatives

Establishing student-led ADR monitoring committees in medical colleges to encourage peer reporting.[4]

Technology integration

Utilizing mobile apps for real-time ADR reporting to overcome time barriers.[3]

Attitude enhancement

Workshops addressing misconceptions and fostering a positive reporting culture.[6] Implementing these strategies could increase reporting rates by 20-30%, based on pilot studies in similar settings.[2,5,15]

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