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**Knowledge, Attitude, and Perception toward Black-Box and Scheduled
Drug Warnings Among Undergraduate Medical Students**
A Cross-Sectional Study in a Tertiary Medical Institution in Andhra Pradesh, India

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Abstract

Introduction: Black Box Warnings (BBW) issued by the U.S. Food and Drug Administration (FDA) identify serious or life-threatening risks associated with certain medicines. In India, scheduled-drug warnings issued under the regulatory framework of the Central Drugs Standard Control Organisation (CDSCO) restrict the sale and dispensing of specified medicines.

Aim and objectives: To assess knowledge, attitudes, and perceptions regarding BBWs and scheduled-drug warnings among undergraduate medical students, including confidence in identifying medicines carrying such warnings and sources of drug-safety information.

Methods: This was a cross-sectional study conducted at Maharajah's Institute of Medical Sciences, Vizianagaram. Responses were collected using a 29-item structured questionnaire with a Cronbach's alpha of 0.81. A total of 243 complete responses were analysed. Descriptive statistics were used. Knowledge was scored across eight items and categorised as high (>70%), moderate (50–69%), or low (<50%). Percentages are accompanied by 95% confidence intervals (CIs) where appropriate.

Results: The mean age was 19.9 ± 1.4 years, and 69.5% reported formal pharmacology education. The mean knowledge score was 4.07 ± 2.01 , with 24.7% showing high knowledge, 30.9% moderate, and 44.4% low. Only 26.3% of students felt confident identifying medicines carrying BBWs, and textbooks remained the primary source of learning.

Conclusion: Awareness of scheduled-drug warnings and BBWs among the participating medical students was inadequate. Incorporating regulatory-specific clinical pharmacology coursework and structured student evaluation of these warnings may help strengthen medication-safety education and preparedness for prescribing.

INTRODUCTION

Drug-safety regulations such as Black Box Warnings (BBWs) issued by the U.S. Food and Drug Administration (FDA) and scheduled-drug warnings implemented by the Central Drugs Standard Control Organisation (CDSCO) serve as important tools for healthcare providers to recognise serious drug-related risks and promote safe and rational medicine use. The FDA issues BBWs for medicines associated with serious or life-threatening risks, including risks such as teratogenicity, agranulocytosis, or dependence.^{1,2} In India, the CDSCO implements labelling requirements for medicines in Schedules H, H1, and X to regulate their supply and promote rational use.^{3,4}

Multiple studies have shown that, despite formal pharmacology education, many healthcare students have difficulty identifying drug warnings and applying this knowledge in clinical situations.^{5,6,7} Reported contributing factors include limited confidence in relevant skills, insufficient education, limited awareness, and inadequate access to regulatory information within the pharmacology curriculum.^{8,9,10}

The need for such knowledge is important because medication-related harm is common and a substantial proportion is preventable. The World Health Organization (WHO) Global Patient Safety Re-

Keywords: Black Box Warning, Schedule Drugs, Medical Students, Pharmacovigilance, Drug Labelling, KAP Study



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port 2024 estimated that at least 5% of patients worldwide experience preventable medication-related harm, with an estimated 7% occurring in low- and middle-income countries; almost one-quarter of such harm was severe or life-threatening.¹¹ A 2025 systematic review of medication errors in Indian hospitals reported a median incidence of 34.11% (95% CI 20.45–54.56) across 10 studies.¹² The WHO also estimated that the global cost associated with medication-related errors is approximately US\$ 42 billion annually.¹¹ The Pharmacovigilance Programme of India (PvPI) reported 8.94 lakh individual case safety reports by 30 September 2024, illustrating the scale of ongoing pharmacovigilance activity.¹³

Knowledge of drug warnings, particularly BBWs and Schedule H1 and X medicines, is important among undergraduate students because inadequate knowledge may contribute to inappropriate medication use and insufficient patient counselling regarding adverse effects and risks.^{14,15,16,17}

The rationale for this study is the potential gap between theoretical pharmacology education and the practical recognition of labelled drug warnings in clinical settings and their application to patient safety. As undergraduate students progress through their training, they acquire increasing clinical responsibilities, including prescribing medicines and participating in patient counselling. Identification of these warnings is therefore relevant to patient safety. Previous studies have highlighted gaps between undergraduate pharmacology education and preparedness for safe and rational prescribing.¹⁴ Therefore, assessing students' knowledge, attitudes, and perceptions regarding these warnings can help identify educational gaps and provide evidence for strengthening medication-safety education within the undergraduate medical curriculum.

MATERIALS AND METHODS

Study type and design: The present study is a cross-sectional, questionnaire-based KAP study

Study Setting: Maharajah's Institute of Medical Sciences (MIMS), Vizianagaram, Andhra Pradesh.

Study Period: The study was conducted from November 2025 to January 2026.

Study Population: Bachelor of Medicine, Bachelor of Surgery (MBBS) students from the second year to internship who were studying at MIMS, Vizianagaram.

Inclusion Criteria:

1. MBBS students from the second year to internship
2. Students who are willing to provide informed consent

Exclusion Criteria:

1. Students who did not provide informed consent.
2. Incomplete questionnaire responses.

Bias and measure to eliminate the bias

Because convenience sampling was used, selection bias and response

bias cannot be completely excluded. To reduce variation in data collection, the same questionnaire was circulated to eligible students with uniform instructions. Participation was voluntary and no student was forced to participate. Responses were collected anonymously without personally identifying information.

Sample size and sampling technique: Sample size estimation was performed using the formula for descriptive surveys:

$$n = Z^2P(1-P)/d^2$$

Assuming a 95% confidence level, a 5% margin of error, and an expected awareness of 50% (used when no prior estimate of awareness is available). The minimum required sample size was calculated as 240. Convenience sampling was employed because of the accessibility and feasibility of recruiting undergraduate medical students within the study period. A total of 243 complete responses were obtained, exceeding the minimum required sample size, and all 243 eligible complete responses were included in the analysis.

Data Collection Tool

Data were collected using a Google Forms questionnaire. The questionnaire link was circulated to eligible students through their respective WhatsApp groups during the study period. The questionnaire was self-administered after participants provided informed consent online. Participation was voluntary, and responses were collected anonymously.

The 29-item questionnaire consisted of the following domains:

1. Demographic characteristics of participants
2. Knowledge regarding BBWs and scheduled-drug warnings, including Indian scheduled-drug warnings.
3. Attitudes toward the drug safety and regulatory warnings
4. Perceptions, confidence, and intended prescribing behaviours regarding regulated medicines.
5. Sources of information about drug warnings, curriculum exposure, and recommendations for improving education regarding drug safety warnings.

Knowledge scoring

Eight items were scored as 1 for a correct response and 0 for an incorrect response, giving a total score of 0–8. Participants scoring >70% were classified as having high knowledge, those scoring 50–69% as having moderate knowledge, and those scoring <50% as having low knowledge.

Data Analysis

Data were cleaned using Microsoft Excel and analysed using descriptive statistics, including frequencies, percentages, standard deviations, and range. A 95% CI was calculated using the Wilson method. Analysis was performed on the combined study population without year-wise stratification; therefore, differences between second-year students and interns were not assessed in this study.



Ethical Approval

This study was approved by the Institutional Ethics Committee (IEC) of Maharajah's Institute of Medical Sciences, Vizianagaram (IEC approval letter number UG-2-2025/chairman-IEC/MIMS/Ethics Approval). Informed consent was obtained electronically from all the participants before participation. Participation was voluntary; participants were free to withdraw from the study at any time. The questionnaire was administered anonymously, and the privacy of the participants and their responses was maintained throughout the study.

RESULT

A total of 243 responses were analysed. The mean age of the participants was 19.9 ± 1.4 years (range: 17–25 years; numerical age responses, $n = 241$). Of the participants, 148 (60.9%; 95% CI: 54.6–66.8) were male and 95 (39.1%; 95% CI: 33.2–45.4) were female. Formal pharmacology teaching was reported by 169 participants (69.5%; 95% CI: 63.5–75.0), while 130 (53.5%; 95% CI: 47.2–59.7) reported specific training regarding Black Box Warnings (BBWs) or scheduled-drug warnings (**Table 1**).

The proportion of participants answering each knowledge question correctly is presented in **Table 2**. A total of 159 participants (65.4%; 95% CI: 59.3–71.1) correctly identified the definition of a BBW, while 101 (41.6%; 95% CI: 35.5–47.8) recognised that a BBW does not necessarily mean that a medicine should never be used. The FDA was correctly identified as the issuing authority by 98 participants (40.3%; 95% CI: 34.4–46.6).

Regarding specific medicines, 99 participants (40.7%; 95% CI: 34.8–47.0) correctly identified the teratogenic warning associated with isotretinoin, and 111 (45.7%; 95% CI: 39.5–52.0) correctly identified the agranulocytosis warning associated with clozapine. Knowledge of Indian scheduled-drug regulations was comparatively higher: 169 participants (69.5%; 95% CI: 63.5–75.0) correctly identified the Schedule H1 legal requirement, while 149 (61.3%; 95% CI: 55.1–67.2) correctly identified Schedule X restrictions. The role of Schedule H1 in antibiotic stewardship was correctly identified by 102 participants (42.0%; 95% CI: 35.9–48.3).

The mean overall knowledge score was 4.07 ± 2.01 . Based on the predefined knowledge classification criteria, 60 participants (24.7%; 95% CI: 19.7–30.5) demonstrated high knowledge, 75 (30.9%; 95% CI: 25.4–36.9) demonstrated moderate knowledge, and 108 (44.4%; 95% CI: 38.3–50.7) demonstrated low knowledge. Thus, 183 participants (75.3%) were classified as having low or moderate knowledge.

The responses to selected attitude and perception statements are summarised in **Table 3**. A total of 94 participants (38.7%; 95% CI: 32.8–44.9) agreed or strongly agreed that scheduled-drug warnings help prevent drug misuse or abuse. Seventy-three participants (30.0%; 95% CI: 24.6–36.1) agreed or strongly agreed that they would hesitate to prescribe a medicine carrying a BBW even when it was clinically indicated.

Regarding educational preparedness, 89 participants (36.6%; 95% CI: 30.8–42.8) agreed or strongly agreed that their curriculum provided sufficient training on drug-safety warnings. A total of 105 participants

(43.2%; 95% CI: 37.1–49.5) supported explicitly counselling patients about BBW-associated risks, while 103 (42.4%; 95% CI: 36.3–48.7) agreed or strongly agreed that prescribers should check the scheduled status of medicines before prescribing controlled drugs. Furthermore, 94 participants (38.7%; 95% CI: 32.8–44.9) supported highlighting BBWs in textbooks and lecture slides.

Figure 1 shows that only 64 participants (26.3%; 95% CI: 21.2–32.2) agreed or strongly agreed that they were confident in identifying medicines carrying BBWs. The remaining 179 participants (73.7%) were neutral, disagreed, or strongly disagreed with the statement.

The reported sources of information about drug-safety warnings are presented in **Table 4**. Textbooks were the most frequently reported source, cited by 68 participants (28.0%; 95% CI: 22.7–33.9), followed by pharmacology faculty, reported by 64 (26.3%; 95% CI: 21.2–32.2). The internet was reported as a source by 51 participants (21.0%; 95% CI: 16.3–26.5).

Drug compendia and electronic databases were each reported by 20 participants (8.2%; 95% CI: 5.4–12.4). Peers and regulatory websites, including those of the Central Drugs Standard Control Organisation (CDSCO) and the US Food and Drug Administration (FDA), were each reported by 10 participants (4.1%; 95% CI: 2.3–7.4).

DISCUSSION

The present study identified a substantial gap between formal pharmacology exposure and practical knowledge of BBWs and scheduled-drug warnings. Although 69.5% of students reported having received formal pharmacology teaching, the mean knowledge score was 4.07 ± 2.01 and 44.4% of students were in the low-knowledge category. This suggests that routine pharmacology teaching alone may not be sufficient to ensure familiarity with regulatory warnings and their clinical application. Similar concerns have been reported in studies of medication safety and pharmacovigilance education among healthcare students.

In a cross-sectional study by Meher et al. among undergraduate students at a tertiary care centre in South India, students showed relatively better attitudes but inadequate knowledge and practice regarding pharmacovigilance; the authors recommended stronger integration of pharmacovigilance into the undergraduate curriculum.¹⁸ In another multicentric study conducted in India, Katyal et al. surveyed 253 medical students from 71 medical colleges across 17 states and found that only 60% were familiar with the term pharmacovigilance, while gaps remained in practical knowledge of adverse drug reaction reporting.¹⁹ These findings are consistent with the current study, in which formal exposure to pharmacology education was common but gaps remained in the identification of specific drug-safety warnings.

International studies have also reported similar patterns. Alwhaibi et al., in a cross-sectional study of 710 undergraduate students from Saudi Arabia, reported that 60.8% of students correctly defined pharmacovigilance and 40% correctly defined adverse drug reactions; only 39% reported receiving pharmacology education, although attitudes towards pharmacovigilance were generally positive.²⁰ Similarly, Brinkman et al., in a systematic review of final-year medical students



found considerable evidence of inadequate preparedness, self-confidence, knowledge, and skills related to safe prescribing and pharmacovigilance.²¹ These findings support the view that formal pharmacology education does not necessarily translate into practical medication-safety competence.

Knowledge was stronger for some Indian schedule-related concepts than for specific BBW recognition. For example, 69.5% of students correctly identified Schedule H1 requirements and 61.3% correctly identified Schedule X restrictions, whereas fewer students correctly identified the FDA as the issuing authority for BBWs (40.3%), isotretinoin's teratogenic warning (40.7%), and clozapine's agranulocytosis warning (45.7%). These findings support the need to move beyond definitions towards recognition of specific medicines, warnings, and associated adverse reactions.

Only 26.3% of students expressed confidence in identifying medicines carrying BBWs. This is important in the context of medication-related harm, which the WHO reports affects approximately 5% of patients globally, with an estimated 7% occurring in low- and middle-income countries; prescribing is an important stage at which medication-related harm can potentially be prevented.¹¹

Textbooks were the most commonly used source of drug-safety information, whereas regulatory websites were used by relatively few students. Because drug warnings and safety information are updated over time, undergraduate education should also emphasise access to current FDA and CDSCO safety updates.

The positive response towards curricular integration of these warnings indicates an educational opportunity. Short case-based modules, examination-linked questions, simulated prescribing decisions, and periodic review of regulatory alerts could help integrate theoretical knowledge with practical skills in recognising drug warnings in clinical practice. No year-wise stratification was performed in this study, so it was not possible to determine whether knowledge improved with progression through medical training. Future studies should use year-wise stratification and compare knowledge across academic years.

This study has several limitations. First, it was conducted at a single medical institution using convenience sampling, which may have introduced self-selection and response bias and limits the generalisability of the findings to other medical colleges. Although a standard questionnaire, uniform instructions, and voluntary participation were used, these measures cannot completely eliminate selection or response bias. Second, the questionnaire was self-administered, so recall bias and social-desirability bias cannot be completely excluded. Individual responses were not tracked; therefore, a response rate could not be calculated. No year-wise stratification was performed. Finally, as this was a cross-sectional study, it does not permit assessment of changes over time.

CONCLUSION

Knowledge and preparedness relating to BBWs and scheduled drug warnings among medical students remain inadequate. Structured training modules, regulatory database literacy, and simulation-based case exposure may help enhance medication-safety practices.

LIMITATIONS

This study was conducted at a single institution, which may limit generalizability. The absence of year-wise analysis restricted comparison of knowledge levels across different years of study, and the self-administered questionnaire may have introduced response bias.

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CONFLICT OF INTEREST

None Declared

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Self-funded, no external grants.

AI USE DECLARATION

Microsoft Copilot was used for editing, correcting spelling mistakes, and trimming content. ChatGPT was used for graph formation; the result data were provided to ChatGPT for graph formation, not for generation of the results. All content was reviewed by the authors.

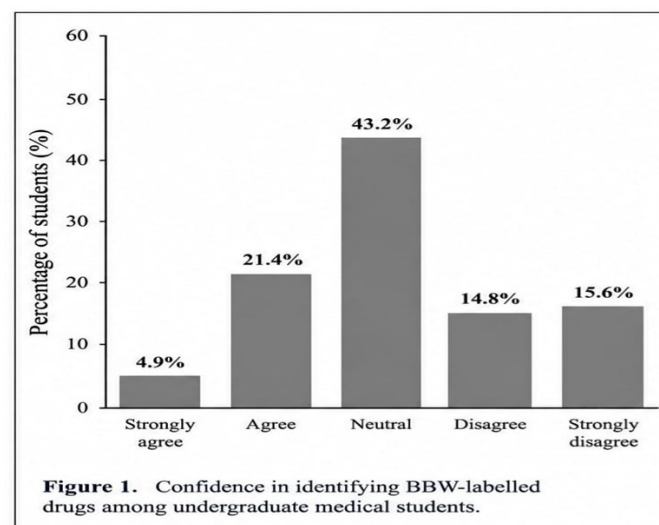


Table 1: Distribution of study participants by age, gender, and exposure to formal pharmacology education.

Variable	Frequency	Percentage	95% CI
Male	148	60.9	54.6–66.8
Female	95	39.1	33.2–45.4
Formal pharmacology teaching	169	69.5	63.5–75.0
Specific BBW/scheduled-warning training	130	53.5	47.2–59.7

Table 2: Distribution of study participants according to knowledge regarding black box warnings and scheduled drug warnings

Knowledge item	Correct Frequency	Correct Percentage	95% CI
BBW definition	159	65.4	59.3–71.1
BBW does not mean that the medicine should never be used	101	41.6	35.5–47.8
FDA as issuing authority	98	40.3	34.4–46.6
Isotretinoin teratogenic warning	99	40.7	34.8–47.0
Clozapine agranulocytosis warning	111	45.7	39.5–52.0
Schedule H1 legal requirement	169	69.5	63.5–75.0
Schedule X restriction	149	61.3	55.1–67.2
Antibiotic stewardship under Schedule H1	102	42.0	35.9–48.3

Table 3: Distribution of study participants according to attitudes and perception indicators

Statement	Agree/strongly agree Frequency	Percentage	95% CI
Schedule warnings (H1, X) help prevent drug misuse/abuse	94	38.7	32.8–44.9
I would hesitate to prescribe a medicine with a BBW even if it were indicated	73	30.0	24.6–36.1
Our curriculum provides sufficient training on drug-safety warnings	89	36.6	30.8–42.8
Patients should be counselled explicitly about BBW risks	105	43.2	37.1–49.5
Prescribers should check schedule status before prescribing controlled drugs	103	42.4	36.3–48.7
BBWs should be highlighted in textbooks and lecture slides	94	38.7	32.8–44.9

Table 4: Distribution of students by sources of drug-safety information

Source	Frequency	Percentage	95% CI
Textbooks	68	28.0	22.7–33.9
Pharmacology faculty	64	26.3	21.2–32.2
Internet	51	21.0	16.3–26.5
Drug compendia	20	8.2	5.4–12.4
Electronic databases	20	8.2	5.4–12.4
Peers	10	4.1	2.3–7.4
Regulatory websites (CDSCO/FDA)	10	4.1	2.3–7.4





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