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Original Research Article

Awareness of black box warnings and high-risk medications among second-year MBBS students: a cross-sectional study

Navneeth Selvan*, Kiran Adithya, Manju Priya, Jacob Verghese

Department of Pharmacology, Indira Medical College and Hospitals, Thiruvallur, Tamil Nadu, India

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***Correspondence:**
Dr. Navneeth Selvan,
Email: navneeth01@gmail.com

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ABSTRACT

Background: Black box warnings (BBWs) are the strongest medication safety alerts issued by regulatory authorities. This study evaluates awareness, knowledge, attitudes, and practices toward BBWs among second-year MBBS students.
Methods: A descriptive cross-sectional online survey was conducted among 150 students using a validated questionnaire. Knowledge was assessed using a 7-item key. Descriptive statistics summarized findings.
Results: Only 28% were aware of BBWs. Mean knowledge score was 2.18±1.4, with 61.3% classified as poor knowledge. Attitude scores were positive (mean 14.6±2.9). Only 17% had ever checked BBWs.
Conclusions: Students demonstrated low BBW awareness but strong willingness to learn, supporting the need for BBW-focused curriculum revision.

Keywords: Black box warnings, MBBS students, Cross-sectional study

INTRODUCTION

Black box warnings (BBWs) are the highest-level safety alerts issued by regulatory authorities to highlight severe, life-threatening, or irreversible adverse effects associated with medications.[1-3] BBWs exist for drugs such as clozapine (agranulocytosis), isotretinoin and valproate (teratogenicity), and fluoroquinolones (tendon rupture, aortic aneurysm risk).[4-7] Medical students in India encounter pharmacology in the second year of MBBS, making this an essential period to introduce drug-safety concepts.[8] However, several studies have documented inadequate awareness of high-risk drugs and pharmacovigilance among undergraduates.[9-12] Despite National Medical Commission (NMC) emphasis on rational prescribing, BBWs remain poorly taught.[13]

This study assesses awareness, knowledge, attitudes, and practices regarding BBWs among second-year MBBS students.

METHODS

This descriptive cross-sectional study was conducted among second-year MBBS students at Indira Medical College and Hospitals, Tiruvallur, India, during the period from November 2025 to December 2025.

Students who had completed their pharmacology postings during the study period and were willing to participate were included in the study. Students who were absent at the time of data collection or who did not provide informed consent were excluded.

After obtaining ethical clearance from the Institutional Ethics Committee, eligible students were approached during routine academic sessions and informed about the objectives and methodology of the study. Written informed consent was obtained electronically from all participants prior to data collection. Data were collected using a pre-tested and validated structured questionnaire

administered through a Google Form. The questionnaire link was shared with the participants, who were instructed to complete the form independently without discussion with peers. Adequate time was provided to complete the questionnaire, and settings were enabled to prevent multiple submissions from the same participant.

The questionnaire consisted of five sections. The first section collected demographic details of the participants. The second section assessed awareness related to the study topic. The third section evaluated knowledge using seven multiple-choice questions (MCQs), with each correct response awarded one mark based on a pre-approved answer key. Knowledge scores were categorized as poor (0-2), fair (3-4), good (5-6), and excellent (7). The fourth section assessed attitude using a four-item Likert scale, with responses scored from 1 (strongly disagree) to 5 (strongly agree), yielding a total score ranging from 4 to 20. The fifth section assessed practices related to the study topic.

Responses were automatically recorded in a secure database and screened for completeness and consistency. Incomplete or duplicate responses, if any, were excluded from the final analysis. Participant anonymity was maintained throughout the study, and no personally identifiable information was collected.

Ethical approval for the study was obtained from the Institutional Ethics Committee of Indira Medical College and Hospitals, Tiruvallur, India, prior to commencement of the study.

Data were entered into Microsoft Excel and analyzed using descriptive statistical methods. Categorical variables were expressed as frequencies and percentages, while continuous variables were summarized using mean and standard deviation.

RESULTS

A total of 150 second-year MBBS students participated in the study. The demographic characteristics of the participants are presented in Table 1. The majority of students were female (62%), while males constituted 37% of the study population. The mean age of the participants was 19.8±0.9 years, reflecting a relatively homogeneous undergraduate cohort.

Only 28% of students reported prior awareness of BBWs. Among those who were aware, online sources (10%) and textbooks (9%) were the most common sources of information

Table 1: Demographic characteristics of participants.

Variable	Category	Frequency (%)
Gender	Male	37
	Female	62
Age	19.8±0.9 years	—

Of the 150 second-year MBBS students included in the study, the majority were female (62%), while males constituted 37% of the participants. The mean age of the study population was 19.8±0.9 years, indicating a relatively homogenous age distribution typical of second-year undergraduate medical students.

Awareness of black box warnings

Only 28% of students reported prior awareness of BBWs. Among those aware, online sources (10%) and textbooks (9%) were the most common sources of information, highlighting limited formal curricular exposure to BBWs.

Table 2: Knowledge item-wise correct responses.

Knowledge item	Correct (%)
Purpose of BBW	38
Clozapine BBW	22
Isotretinoin BBW	29
Fluoroquinolone exception	18
Valproate BBW	35
Non-high-risk drug	41
Placement of BBW	33

Overall knowledge regarding BBW was poor. Correct responses varied across individual items, with the highest proportion correctly identifying non–high-risk drugs (41%), followed by the purpose of BBWs (38%) and valproate-related BBWs (35%). Knowledge regarding specific high-risk drugs such as clozapine (22%) and fluoroquinolones (18%) was notably low, indicating gaps in drug-specific safety awareness.

Table 3: Attitude scores.

Attitude statement	Agreement (%)
BBWs improve drug safety	76
BBWs should be taught clearly	82
BBWs influence prescribing	69
BBW information difficult to access	64

Despite poor knowledge levels, students demonstrated a predominantly positive attitude toward Black Box Warnings. A majority agreed that BBWs improve drug safety (76%) and should be clearly taught during undergraduate training (82%). Nearly two-thirds felt that BBWs influence prescribing decisions (69%), although 64% perceived BBW-related information as difficult to access.

The distribution of knowledge scores revealed that the majority of students (61.3%) fell into the poor knowledge category. A smaller proportion demonstrated fair knowledge, while very few students achieved good or excellent knowledge scores. The mean knowledge score was 2.18±1.4, reflecting overall inadequate understanding of BBWs among the participants.

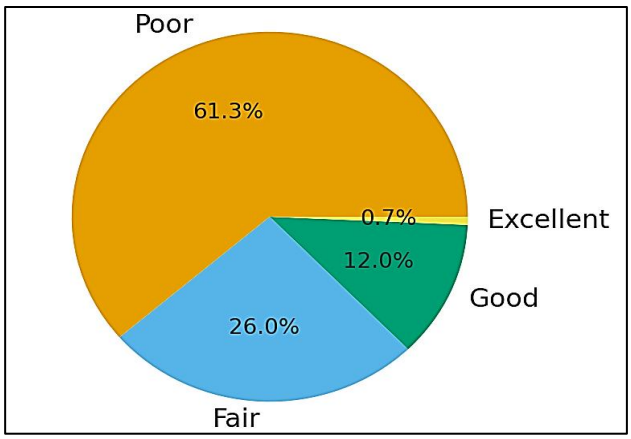

Figure 1: Distribution of knowledge scores.

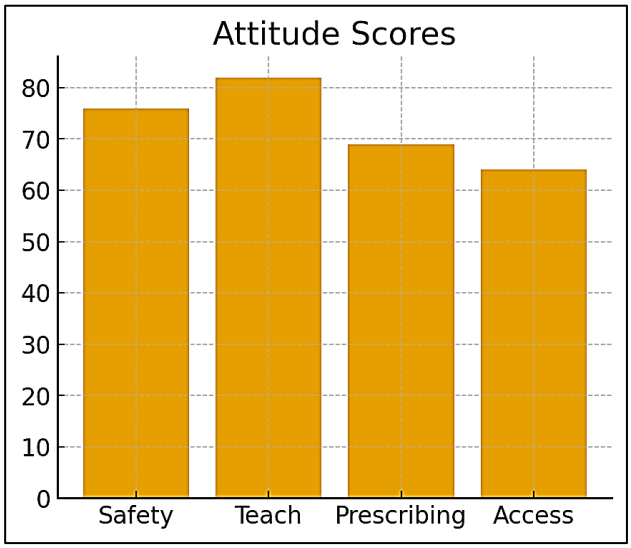

Figure 2: Attitude score distribution.

Attitude score distribution showed a clustering toward higher scores, with a mean attitude score of 14.6±2.9. This indicates a generally favorable perception of BBWs and a willingness among students to engage with drug safety information.

Practice patterns

In terms of practice, only 17% of students reported ever checking a Black Box Warning prior to prescribing or studying a drug. However, a large majority (89%) expressed a preference for learning about BBWs through mobile applications, suggesting receptiveness to digital learning tools.

DISCUSSION

The present study assessed awareness, knowledge, attitudes, and practices related to Black Box Warnings among second-year MBBS students. The findings reveal low awareness and poor knowledge of BBWs, despite a generally positive attitude toward drug safety warnings.

Only 28% of participants were aware of BBWs, indicating limited exposure to regulatory drug-safety alerts during undergraduate training. Similar findings have been reported in previous studies among medical undergraduates and junior doctors, where awareness of BBWs and high-risk medications was found to be suboptimal.[9-12] This suggests that BBWs remain inadequately emphasized in undergraduate pharmacology curricula.

Knowledge assessment showed that more than half of the students (61.3%) had poor knowledge scores, with a mean score of 2.18±1.4. Knowledge gaps were particularly evident for high-risk drugs such as clozapine and fluoroquinolones. Comparable deficiencies have been documented by Gurumurthy et al and Ahmad et al, who reported insufficient understanding of drug safety warnings among medical trainees.[9-11] These findings underscore the need for structured teaching of BBWs using drug-specific examples.

Despite poor knowledge, students demonstrated a favorable attitude toward BBWs, with most agreeing that BBWs improve drug safety and should be taught clearly during undergraduate training. This aligns with earlier studies showing that medical students recognize the importance of medication safety even when their factual knowledge is limited.[10-12] The positive attitude observed in the present study represents an opportunity for effective educational interventions.

Practice-related findings revealed that only 17% of students had ever checked a BBW, reflecting limited real-world application of drug safety knowledge. However, the majority preferred mobile applications as a learning tool, consistent with evidence suggesting that digital and e-learning platforms enhance pharmacology and patient safety education.[14] Incorporating BBW-focused digital modules, case-based discussions, and visual drug charts may improve both knowledge and practice.

Overall, the findings highlight a clear gap between attitude and actual knowledge and practice regarding BBWs, emphasizing the need for early integration of drug safety alerts into competency-based medical education.

Limitations

This study has certain limitations. Being a single-center study conducted among second-year MBBS students, the findings may not be generalizable to students in other institutions or at different stages of medical training. The use of a self-administered online questionnaire may have introduced response bias. Additionally, the cross-sectional design limits the ability to assess changes in knowledge or attitudes over time or after educational interventions. Future multicentric and longitudinal studies are

recommended to better evaluate the impact of structured BBW-focused teaching on prescribing competence

CONCLUSION

Students exhibit low BBW awareness and knowledge but strong motivation to learn. Incorporating BBWs into the pharmacology curriculum can foster safer prescribing practices.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee, Indira Medical College and Hospitals. Electronic informed consent obtained.

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