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Knowledge, Attitude and Practice Concerning Black Box Warnings Among Postgraduate Residents in A Medical College

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ABSTRACT

Background: Black Box warning (BBW) is the highest level of warnings issued by FDA for guiding the physician in cautious and safe prescribing of various drugs. They indicate serious or life-threatening adverse effect. Awareness and appropriate integration of these warnings into prescribing decisions are essential for safe clinical practice. Previous literature suggest that prescriber awareness of such warnings is often suboptimal.
Objective: This study was aimed to evaluate the knowledge, attitudes, and prescribing practices related to BBWs among postgraduate medical residents.
Material and methods: This was a cross-sectional, prospective, observational and questionnaire-based study conducted among 129 postgraduate medical residents. The study was conducted using a self –administered questionnaire through a google form. Composite and domain wise knowledge, attitude and practice (KAP) scores were calculated by summing the respective item scores and were analyzed for comparisons across specialty groups, year of residency, and gender and for correlation independent predictors of good KAP and speciality-based difference in KAP score.
Results: The mean total KAP score was 45.2 ± 9.8 with a median 44 (IQR=14). Good KAP (>75%) in terms of total score was achieved by only 30 (23.2%) of participants. Attitude scores demonstrated a strong positive correlation with practice scores. The pre-/paraclinical group had significantly higher knowledge and better attitude scores compared to medical and surgical specialities whereas practice scores did not differ significantly across specialties. Increasing age was associated with higher overall KAP scores.
Conclusion: Postgraduate medical residents demonstrated modest knowledge but relatively better attitudes and practices regarding black box warnings. Strengthening pharmacovigilance education and reinforcing awareness of drug safety warnings during postgraduate training may help promote safer prescribing practices.

Keywords: *Blackbox warning, BBW, Kap study, post graduate medical students, knowledge, attitude, practice, Drug safety, Medical education.*

INTRODUCTION

Warning and precautions, contradictions, and Black Box Warnings (BBWs) are an integral part of labelling of any pharmaceutical products. They aim to make the labeling of a drug clear, informative, and consistent for easy and correct use (Food and Drug Administration (FDA), 2011). BBWs, also known as Boxed warnings, are the highest safety alerts issued by regulatory authorities such as the U.S. Food and Drug Administration (FDA) and introduced in 1979 (Llamas M, 2025). Black box warning is placed after reasonable evidence on a serious adverse event by a particular drug has been found in post marketing studies or animal studies if clinical data is lacking (FDA, 2011; Adams et al., 2017). BBWs are so named due to its formatting which commonly includes a prominent black border surrounding the cautionary information

written in bold print on a drug label as directed by the regulatory authority (Rajendran et al., 2024). BBWs contain a summary of the critical information for the prescriber which can influence his decision-making process during prescribing that can in turn prevent a serious adverse event or reduce its frequency. By avoiding the serious adverse effects, better quality of life and lower cost of health care can be achieved (Rolfes et al., 2016). Some common black box warning includes tendonitis (ciprofloxacin), suicidal thoughts (SSRIs, SNRIs), abuse/addiction (opioids/benzodiazepines) etc. (Rajendran et al., 2024; Pope C, 2025). Although BBWs play a critical role in ensuring drug safety, multiple studies suggest that prescriber awareness of such warnings is often suboptimal. This is especially concerning in tertiary care hospitals where high-risk medications are routinely prescribed (Lasser et al., 2006; Wagner et al., 2006; Smollin CG et al., 2016; Mallhi et al., 2022). In many healthcare settings, including India, formal training on regulatory drug-safety warnings such as Black Box Warnings (BBWs) is not consistently integrated into undergraduate or postgraduate curricula. Furthermore, although BBWs are intended to influence prescribing decisions, the extent to which in-training physicians recognize and incorporate these warnings into routine clinical practice remains underexplored. This cross-sectional study was aimed to evaluate the knowledge, attitudes, and prescribing practices related to BBWs among postgraduate medical residents at a tertiary-care teaching hospital.

MATERIALS AND METHODS

Study Design

This was a cross-sectional, prospective, observational and questionnaire-based study conducted among post graduate residents of various departments from July–August 2025 in Teerthanker Mahaveer Medical College & Research Center, Moradabad, U.P., India. The study protocol was reviewed and approved by the Institutional review board.

Data collection

This study was conducted using a semi-structured, self –administered questionnaire developed after review of relevant literature (Upadhyaya et al., 2015; Smollin et al.,2016; Adams et al.,2017; Selvan et al., 2026). The questionnaire was reviewed by a panel of subject experts to assess content validity, clarity, comprehensibility, and modifications were made as per expect opinion prior to distribution. The final questionnaire comprised four sections: Section A (demographic details); Section B (10 single- best-answer knowledge items related to black box warnings), Section C (7 five-point Likert-scale statements to assess attitude), Section D (5 five-point Likert-scale statements for evaluating practice). Attitude and practice responses were recorded using a five-point Likert scale (strongly disagree to strongly agree) as originally described by Likert. (Likert, 1932). The questionnaire was administered electronically using Google Forms. The survey link was distributed via institutional email to medical postgraduate residents. Two reminder emails were sent to all screened participants at one-week intervals to enhance response rates. Participation was voluntary with informed consent at the start of google form. The questionnaire was not displayed if the participant did not consent to take part. The names of the participants were not collected to maintain the confidentiality and privacy of participants.

Sample size

The sample size calculation for a single proportion in a cross-sectional study was done assuming a 50% expected adequate knowledge, a 95% confidence level, and 10% absolute precision. The estimated minimum required sample size was 96. Anticipating 10% non-response rate, the target sample size was increased to 106 participants.

Inclusion and Exclusion criteria

Postgraduate medical residents who provided informed consent were eligible for inclusion in the study. Undergraduate students, interns, faculty members, and consultants were excluded. Residents who were on long leave or unavailable during the data collection period were also excluded. In addition, questionnaires with incomplete responses were excluded from the final analysis.

Statistical analysis

For Section B (knowledge assessment), correct response was given a score=1, and the rest of incorrect options were assigned a score=0. The total knowledge score was calculated by totalling the scores achieved among the ten items. Attitude and practice responses were assigned scores ranging from 1 to 5 (strongly disagree = 1, disagree = 2, neutral = 3, agree = 4, strongly agree = 5). Reverse scoring was applied for negatively framed practice statements. Composite attitude and practice scores were calculated by summing the respective item scores.

Mean and standard deviation (SD) or median and interquartile range (IQR) based on the distribution were used for continuous variables. Categorical variables were presented as frequency and proportions. The normality of continuous variables was calculated using the Shapiro–Wilk test. Associations between knowledge, attitude, and practice scores were evaluated using Pearson's correlation coefficient. Comparison of overall and domain-specific KAP scores across specialty groups was performed using the Kruskal–Wallis test. Comparison of overall KAP score across demographic variables (such as gender, year of residency) were performed employing independent Mann Whitney U test or Kruskal-Wallis test, wherever applicable.

Independent predictors of overall KAP score were identified using multivariable linear regression analysis. Variables included in the model were age, gender, specialty group, year of residency, and attendance at continuing medical education

(CME) programs. A two-tailed p-value < 0.05 was considered statistically significant. The statistical analysis was done using SPSS software version 25, and the figures were drawn using Microsoft excel.

RESULTS

Participant characteristics

A total of 139 postgraduate medical residents provided consent to participate in the study, of which 129 residents completed the questionnaire and were included in analysis. Study flow chart is described in figure 1.

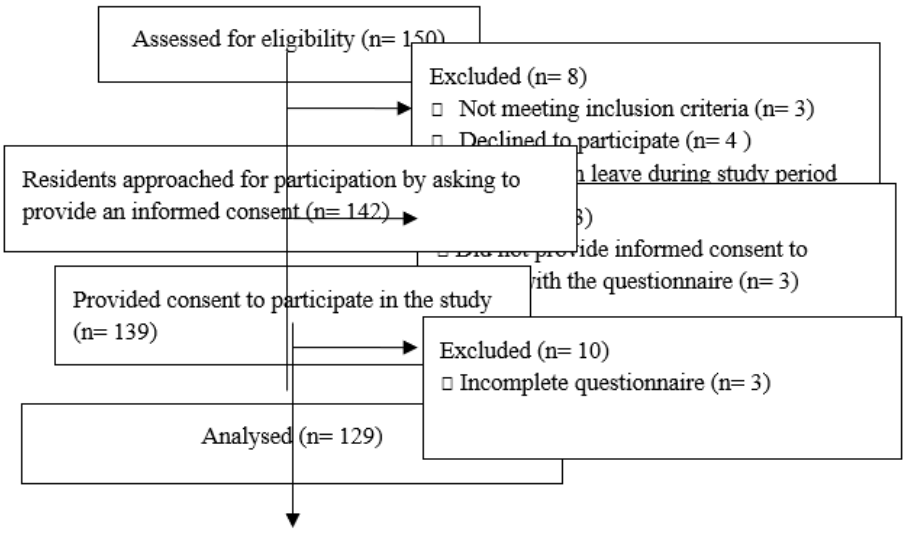

Figure 1: Participant recruitment flowchart

The mean age of participants was 25.5 ± 2.7 years. The majority were in the 22–24-year age group (41.1%), Among participants, 70 (54.3%) were male and 59 (45.7%) were female. In terms of specialty distribution, 50 (38.9%) belonged to medical specialties, 65 (50.4%) to surgical specialties, and 14 (10.8%) to pre-/paraclinical disciplines. Participant details are presented in Table 1.

Table 1: Demographic details of the participants

Variable	Category	Number of participants (%)
Age (Years)	22-24	53 (41.1)
	25-27	49 (37.9)
	28-30	21 (16.3)
	>30	06 (4.6)
Gender	Male	70 (54.3)
	Female	59 (45.7)
Specialty	Medical	50 (38.9)
	surgical	65(50.4)
	Pre and paraclinical	14(10.8)
Year of residency	1st	55 (42.6)
	2nd	58 (44.9)
	3rd	16 (12.4)
Attended Pharmacovigilance/Drug-Safety CME in Past 12 Months	Yes	71 (55)
	No	28 (21.7)
	Maybe	30 (23.2)

Knowledge regarding BBW

The mean score for knowledge was 4.9 ± 2.7 and a median of 5 (IQR=4). Majority of the participants i.e. 78 (58.9%) for the definition and 86 (66.7%) for BBW warning placement on the drug monograph answered correctly. 82 (63.6%) agreed that a drug with BBW should be used with caution and patient counselling. 66 (51.2%) correctly answered that BBW content is mandated by regulators, however, only 51 (39.5%) correctly identified FDA as an issuing authority. 80 (62%) participants correctly Identified neural tube defects as the BBW for Valproate. Other question about BBW for other drugs were mostly answered wrong. Less than 50% of participants had correct knowledge about BBW for some drugs. Response to each knowledge question is presented in Table 2.

Table 2: Responses to knowledge domain of the questionnaire

Knowledge test items	Response options	Number of participants (%)
A Black-Box Warning (BBW) indicates	mild side-effects	20 (15.5)
	dosing schedule	26 (20.2)
	serious or life-threatening risk	76 (58.9)
	marketing restriction	7 (5.4)
BBWs are issued in the United States by	WHO	51(39.5)
	FDA	51(39.5)
	CDC	22 (17.1)
	DEA	5 (3.8)
In a drug monograph the BBW is usually placed	at the end	15 (11.6)
	at the very beginning inside a bold border	86 (66.7)
	in the storage section	21(16.3)
	nowhere	7 (5.4)
Which statement is TRUE	BBWs apply only to OTC drugs	30(23.3)
	BBWs are optional	26 (20.1)
	BBW content is mandated by regulators	66 (51.2)
	BBWs list only mild adverse events	7 (5.4)
A drug with a BBW should be	avoided in all patients	23 (17.8)
	used with caution and patient counselling	82 (63.6)
	given without concern	16 (12.4)
	available only in trials	8 (6.2)
Fluoroquinolones carry a BBW for	hepatotoxicity	42 (32.6)
	tendon rupture	58 (44.9)
	urticaria	19 (14.7)
	cataract	10 (7.6)
Clozapine's BBW highlights risk of	weight gain	26 (20.2)
	sedation	44 (34.1)
	severe neutropenia	48 (37.2)
	insomnia	11 (8.5)
Valproate's pregnancy BBW warns primarily about	pancreatitis	23 (17.8)
	neural-tube defects	80 (62)
	anaemia	21(16.3)
	oligohydramnios	5 (3.9)
Which antihyperglycemic has a BBW for heart-failure exacerbation	metformin	28 (21.7)
	sitagliptin	41 (31.8)
	pioglitazone	48 (37.2)
	acarbose	12 (9.3)
BBW related to SSRIs concerns	serotonin syndrome	42 (32.6)
	weight loss	34 (26.4)
	suicidality in children/young adult	48 (37.2)
	renal stones	5 (3.9)

Attitude regarding BBW

The mean score was 22.8 ± 4.2 with a median of 23 (IQR=6). Positive attitude by 67 (51.9%) participants towards BBW being crucial for safeguarding patients was shown, 60 (46.5%) participants towards BBW influencing prescription choices, 66 (51.1%) participants towards confidence in discussing BBW with patients, 67(51.9%) participants towards highlighting it in electronic prescribing, and 68 (52.8%) participants towards regular training was observed. Only 39(30.2%) agreed with BBW being overstated/unnecessary and 30 (23.3%) felt time constraints hinders the use of BBW. Response towards attitude domain is presented in Table 3.

Table 3: Responses to attitude domain of the questionnaire

Attitude test items	Response options	Number of participants (%)
BBWs are crucial for safeguarding patients	Strongly agree	38(29.4)
	agree	29(22.5)
	neutral	38(29.5)
	disagree	14(10.8)
	Strongly disagree	10(7.7)
BBWs influence my prescribing choice	Strongly agree	29 (22.5)

	agree	31 (24)
	neutral	35 (27.1)
	disagree	21 (16.2)
	Strongly disagree	13(10.1)
BBWs are sometimes overstated and unnecessarily limit therapy.	Strongly agree	14 (10.8)
	agree	25 (19.4)
	neutral	39 (30.2)
	disagree	31 (24)
	Strongly disagree	20 (15.5)
I feel confident discussing BBWs with patients.	Strongly agree	26(20.1)
	agree	40 (31)
	neutral	38 (29.4)
	disagree	11(8.5)
	Strongly disagree	14(10.9)
Time constraints hinder my ability to check BBWs	Strongly agree	10 (7.8)
	agree	20 (15.5)
	neutral	39 (30.2)
	disagree	41 (31.8)
	Strongly disagree	19 (14.7)
BBWs should be highlighted more prominently in e-prescribing software	Strongly agree	35 (27.1)
	agree	32 (24.8)
	neutral	37 (28.7)
	disagree	12 (9.3)
	Strongly disagree	13(10.1)
Regular training on BBWs should be mandatory for residents	Strongly agree	34 (26.4)
	agree	34 (26.4)
	neutral	32 (24.8)
	disagree	18 (13.9)
	Strongly disagree	11 (8.5)

Practice behaviour regarding BBW

The mean score was 17.4 ± 5.2 with a median of 17 (IQR=8). 67(51.9%) admitted to checking for BBWs before prescribing. 65 (50.4%) explain to patients when relevant and 62 (48.1%) document its discussion in their day-to-day practice. 65 (50.4%) report ADR related to BBW. 71 (55.1%) admitted on keeping themselves updated regarding BBWs. Response to this domain is presented in Table 4.

Table 4: Responses to practice domain of the questionnaire

Practice items	**Response options**	**Number of participants (%)**
I check for BBWs before prescribing.	Strongly agree	40 (31)
	agree	27 (20.9)
	neutral	33 (25.6)
	disagree	16 (12.4)
	Strongly disagree	13 (10.1)
I explain BBWs to patients when relevant	Strongly agree	36 (27.9)
	agree	29 (22.5)
	neutral	39 (30.2)
	disagree	15 (11.6)
	Strongly disagree	10 (7.6)
I document BBW discussions in charts	Strongly agree	34 (26.4)
	agree	28 (21.7)
	neutral	36 (27.9)
	disagree	21 (16.3)
	Strongly disagree	10 (7.8)
I report ADRs associated with BBW drugs	Strongly agree	33 (25.6)
	agree	32 (24.8)
	neutral	34 (26.4)
	disagree	18 (13.9)
	Strongly disagree	12 (9.3)
I consult reliable drug-information sources to stay updated on BBWs	Strongly agree	42 (32.6)

	agree	29 (22.5)
	neutral	30 (23.3)
	disagree	16 (12.4)
	Strongly disagree	12 (9.3)

Correlation Between Knowledge, Attitude, and Practice

Correlation analysis demonstrated a moderate positive correlation between knowledge and attitude scores ($r = 0.432$, $p < 0.001$). Knowledge scores showed a weak but statistically significant positive correlation with practice scores ($r = 0.297$, $p = 0.001$). Notably, attitude scores demonstrated a strong positive correlation with practice scores ($r = 0.606$, $p < 0.001$).

KAP performance

Good KAP (>75%) was achieved by 29 (22.5%) in knowledge domain, 30 (23.2%) in attitude domain and 62 (48.1%) in practice domain. Overall good KAP in terms of total score was achieved by only 30 (23.2%) of participants.

Comparison of overall KAP scores (mean = 45.2 ± 9.8, median = 44 (IQR=14)) across specialty groups did not demonstrate a statistically significant difference ($p = 0.065$). However**,** domain-wise comparison revealed significant differences in knowledge **($p = 0.001$),** and attitude scores **($p = 0.016$)** across specialties. These findings are highlighted in figure 2 and figure 3. Post hoc analysis demonstrated that residents in the pre-/paraclinical group had significantly higher knowledge and better attitude scores compared to medical **($p=0.001$)** and surgical **($p=0.01$)** specialities respectively. In contrast, practice scores did not differ significantly across specialties ($p = 0.588$).

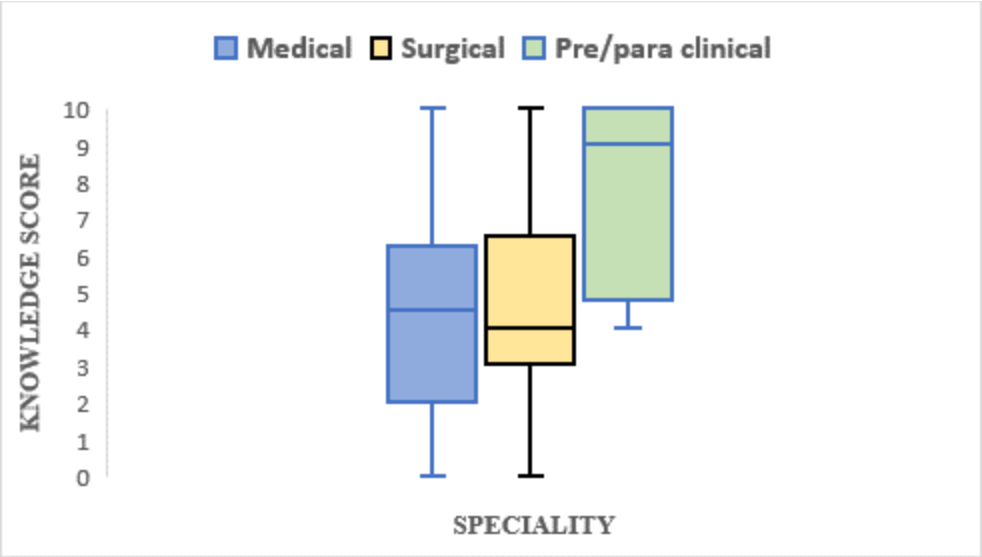

Figure 2: Distribution of knowledge scores across specialty groups. Pre-/paraclinical residents demonstrated significantly higher knowledge scores ($p = 0.001$).

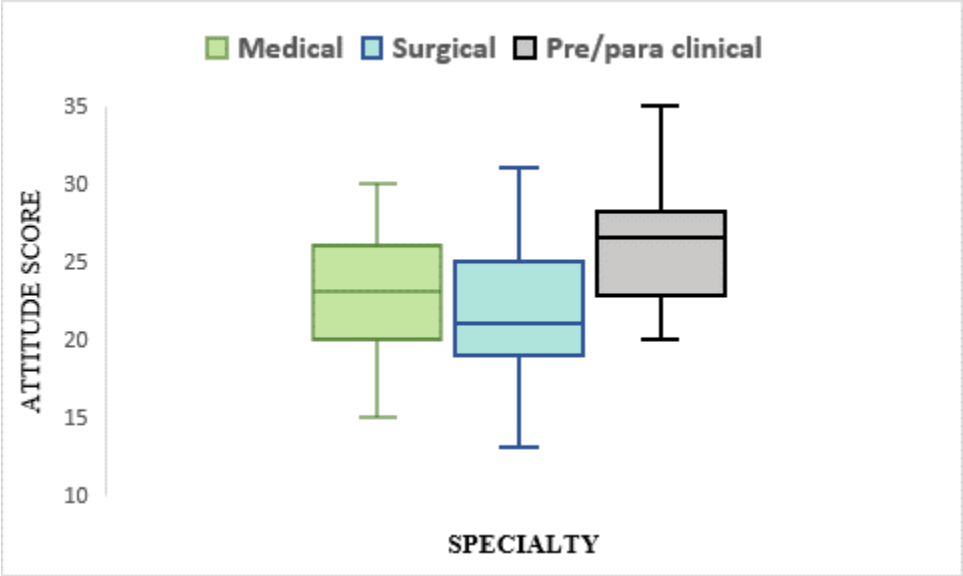

Figure 3: Distribution of attitude scores across specialty groups. Pre/para clinical residents demonstrated significantly higher attitude scores ($p = 0.016$)

There was no statistically significant difference in overall KAP scores between male and female residents. Overall KAP scores did not differ significantly across years of residency (p = 0.555). Knowledge and attitude scores also did not show significant differences across training years. However, as seen in figure 4, practice scores differed significantly across years of residency **(p = 0.046)**. Post hoc pairwise comparisons revealed significantly higher practice scores among third-year residents compared to first-year residents **(p = 0.044)**. Overview of the KAP score comparisons is presented in Table 5. Multivariable analysis showed that increasing age was independently associated with higher overall KAP scores (B = 0.775, 95% CI: 0.088–1.462; **p = 0.027**). Gender, specialty group, year of residency, and CME attendance were not significantly associated with overall KAP score. The model explained 5.3% of the variance in overall KAP scores (R^2 = 0.053).

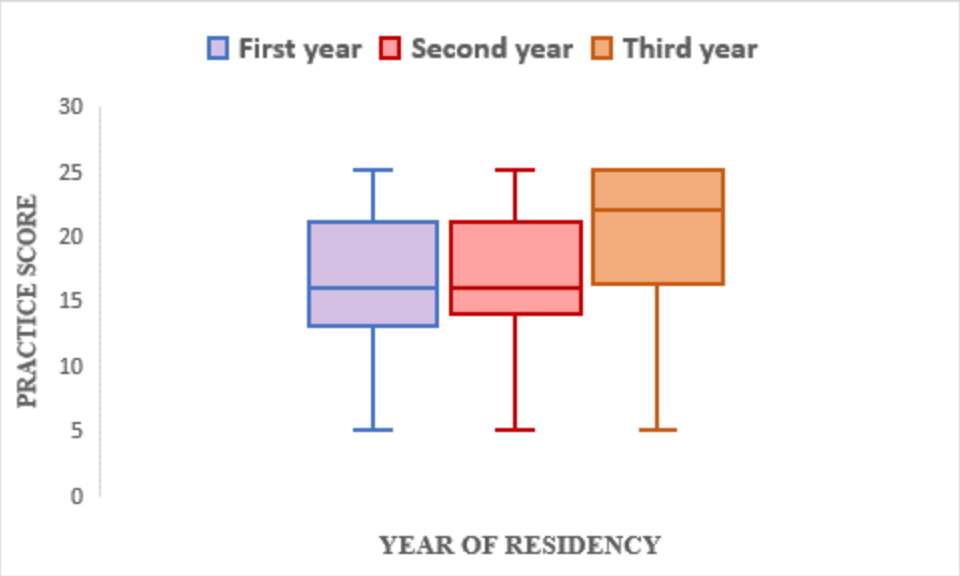

Figure 4: Distribution of practice scores across years of residency. Third-year residents showed significantly higher practice scores (p = 0.046).

DISCUSSION

Black box warnings (BBWs) represent the highest level of risk communication issued by the FDA, highlighting serious or life-threatening adverse effects that require careful prescriber judgment. Despite their regulatory prominence, our findings demonstrate that knowledge and comprehensive understanding of BBWs among postgraduate residents remain suboptimal, with only a minority achieving good KAP status.

Our findings align with previous literature demonstrating limited awareness and understanding of BBWs among healthcare professionals. In a study by Smollin (2016) physicians correctly identified medications with BBWs only 36% of the time, and knowledge of warning content was even lower (13%). Similarly, only 37–52% of physicians reported routinely considering BBWs while prescribing. These findings parallel our observation that although attitudes toward BBWs were relatively positive but translation into consistent high-level knowledge and performance remains incomplete.

While comparing inter-speciality scores, statistically significant difference was observed in knowledge and attitude domains but not in overall KAP score. Pre-/paraclinical residents demonstrated higher median score in knowledge, possibly reflecting a stronger theoretical understanding. It was noted that these differences did not translate into significant difference in overall KAP performance. This suggest that many factors may influence the incorporation of BBWs in prescribing such as clinical perspective, decision-making pressures, and experience etc. only theoretical familiarity alone cannot ensure proper utilization of the knowledge (Gittus et al., 2025; Murshid & Mohaidin, 2017).

There is a moderate-to-strong positive association between scores of attitudes and practice domain. This suggests that a positive perception concerning drug-safety warnings may profoundly impact physicians' prescribing behaviors. However, knowledge showed weak-to-moderate correlation with practice, indicating that only awareness may not translate into safe prescribing practices, attitudinal reinforcement is also important. Increasing age was found to be independently associated with higher overall KAP scores, suggesting the role of greater clinical exposure and experience. However, gender, specialty group, year of residency, and CME attendance were not significant predictors of overall KAP performance. The relatively low explanatory power of the regression model indicates that demographic and training-related variables alone may not fully account for variations in BBW awareness, and other factors such as institutional prescribing culture, exposure to pharmacovigilance activities, or individual engagement with drug safety resources may play an important role (Hamid et al., 2022; Kumari & Prajapati, 2025).

The regulatory perspective further emphasizes the significance of continuous education. O'Connor (2010) asserts that BBWs are mostly introduced after detecting significant safety signals during post-marketing surveillance, sometimes even

years after initial approval. The FDA's Adverse Event Reporting System plays a cardinal role in risk detection for drug use including BBWs. It should be kept in mind that BBWs do not forbid prescribing of a particular drug, rather emphasize on the need for enhanced clinical vigilance.

Gaps in BBW awareness and knowledge is not limited to physicians. Beltran (2025) conducted a survey on fentanyl-related BBWs. They demonstrated that an average knowledge score of 66.6% was achieved among pharmacy students. Students exhibited a strong understanding of pharmacokinetics and mechanism of action but demonstrated notable gaps in classification and safety interpretation. Similar findings were observed in our study, where basic knowledge was present, but execution-level understanding was varied. Moeller (2010) demonstrated that pharmacy students' recognition of BBWs increased significantly with increased years of training. In contrast, overall KAP score did not differ. significantly across years of residency in our study. However, Practice scores were significantly higher among third-year residents compared to first year residents. This suggests that applied training with real-world clinical involvement may favour a safer prescribing behaviour, even if knowledge acquirement does not proportionately increase.

Shifts in the regulatory framework further accentuate the importance of BBWs. Rajendran (2024) analyzed and reported a rising trend in BBW issuance over the past decade. 40% of warnings issued in 2023 alone. Only 29% of the issued warning were a newer BBW. Remarkably, majority of the warnings (78%) were grounded in data gathered from post-marketing surveillance instead of pre-marketing trials. This highlights the ever-evolving nature of drug safety information and the requirement for clinicians to stay vigilant even after a drug approval.

Clinical decision making is becoming more complicated with growing number of BBWs issued in recent decades. Stronger post-marketing risk surveillance has led to an increase in the frequency of boxed warnings over time, as regulatory literature has noted (O'Connor, 2010). Despite the advantage of enhanced patient safety, it may contribute to alert fatigue or cognitive strain among prescribers. Providing structured and regular pharmacovigilance education within postgraduate training has become increasingly essential in today's world. In real-world terms, structured approaches such as the STEPS model (safety, tolerability, effectiveness, price, simplicity) have been proposed to assist and simplify rational prescribing decisions for the prescribers (O'Connor, 2010). Integrating such frameworks into residency training may improve critical appraisal-based decision making while prescribing high-risk medications beyond mere recall of safety warnings.

CONCLUSION

This study found that postgraduate medical residents demonstrated moderate knowledge but relatively better attitudes and practices regarding black box warnings. These findings highlight the need to strengthen awareness and understanding of black box warnings among postgraduate medical residents. While attitudes toward drug safety are generally favorable, improving the integration of this knowledge into clinical practice remains important. Incorporating structured pharmacovigilance training and reinforcing the clinical relevance of safety warnings during postgraduate education may help promote safer prescribing practices and improve patient care.

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