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SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIS) SAFETY PROFILE KNOWLEDGE AND OPINION SURVEY

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ABSTRACT

Background: Selective serotonin reuptake inhibitors (SSRIs) are widely prescribed antidepressants known for their efficacy and tolerability. However, their use is associated with serious safety concerns, particularly the Black Box Warning (BBW) highlighting increased risks of suicidal ideation in children, adolescents, and young adults. While these risks are well-documented, the level of awareness and preparedness among pharmacy students—future frontline healthcare providers—to counsel patients on these warnings remains unclear. **Objective:** This study aimed to evaluate pharmacy students' knowledge and attitudes toward SSRIs and their associated BBW, focusing on the students' understanding of risks, contraindications, monitoring requirements, and the importance of patient education. **Methods:** A cross-sectional survey was conducted among 53 pharmacy students using a structured questionnaire. The instrument covered demographic information, familiarity with BBWs, knowledge-based true/false questions about SSRIs, and opinion-based statements rated on a 4-point Likert scale. Descriptive and inferential statistics were used to analyze the data using SPSS. **Results:** The average knowledge score was 70.8%, indicating a moderate understanding of SSRI-related safety. While 77.4% correctly identified the clinical indications of SSRIs, only 66.0% were aware of the BBW's emphasis on suicidality in young patients. Students showed high agreement (85–95%) with recommended clinical practices, such as the need for explicit risk warnings, closer monitoring, and patient counseling. Statistically significant associations were found between students' academic backgrounds and

their knowledge and attitudes. Those with health science majors or more pharmacy experience scored higher and demonstrated stronger alignment with safety practices. **Conclusions:** Despite general awareness, substantial gaps remain in pharmacy students' detailed understanding of BBW content and safety monitoring related to SSRIs. These findings underscore the need to strengthen pharmacy curricula with focused education on high-risk medications and patient safety practices.

KEYWORDS: Selective Serotonin Reuptake Inhibitor; SSRI, Anti-Depressant, Black Box Warning.

INTRODUCTION TO THE DRUG IN THE STUDY: SSRIS

Selective serotonin reuptake inhibitors (SSRIs) are a class of medications primarily used to treat major depressive disorder (MDD), anxiety disorders, panic disorders, and other mood-related conditions (Stahl, 2013). SSRIs work by increasing serotonin levels in the brain, which helps improve mood, anxiety, and other emotional states. SSRIs such as fluoxetine, sertraline, escitalopram, and paroxetine have become first-line treatments in clinical practice due to their favorable side-effect profiles compared to older classes of antidepressants, like tricyclic antidepressants (TCA) (Papakostas, 2013). Although SSRIs are generally considered safe and well-tolerated, their use is not without risks. Among the most significant safety concerns associated with SSRIs are serotonin syndrome, withdrawal symptoms, and the potential for increased suicidal ideation, particularly in younger populations (Muench & Hamer, 2010).

The major Black Box Warning (BBW) associated with SSRIs addresses the increased risk of suicidal thoughts and behaviors, especially in children, adolescents, and young adults. This warning highlights the need for close monitoring of patients, particularly in the initial treatment period or when doses are adjusted (FDA, 2007). In addition to suicidality, the BBW notes that SSRIs may cause serotonin syndrome, a potentially life-threatening condition that can arise from an excess of serotonin in the brain. Symptoms of serotonin syndrome include agitation, hallucinations, tachycardia, fluctuations in blood pressure, hyperthermia, and neuromuscular abnormalities, such as tremor and muscle rigidity (Boyer & Shannon, 2005). Healthcare providers are advised to carefully assess the risk-benefit ratio of SSRIs and to ensure that patients, particularly vulnerable groups, are informed about these risks.

Numerous clinical studies have examined the safety and effectiveness of SSRIs, with many focusing on the BBW and associated risks. A meta-analysis by Cipriani et al. (2018) evaluated the efficacy and safety of SSRIs in the treatment of depression and found that although SSRIs were effective in reducing depressive symptoms, there was an increase in suicidality, particularly among younger patients. Additionally, studies by Hammad et al. (2006) emphasized the importance of close monitoring of patients initiating treatment with SSRIs, as the risk of suicide may be most pronounced during the first few weeks of therapy. However, the risk of suicide is not uniform across all patients, and some studies indicate that the overall risk remains relatively low when SSRIs are prescribed appropriately (Muench & Hamer, 2010).

To mitigate the risks associated with SSRIs, preventive strategies such as careful dose titration, ongoing monitoring, and clear communication with patients are crucial. Initiating treatment at a lower dose and gradually increasing it can reduce the likelihood of adverse effects like serotonin syndrome and agitation (Papakostas, 2013). Clinicians should educate patients about the signs and symptoms of adverse reactions, including changes in mood, unusual behaviors, or physical symptoms like rashes or fever, as early intervention can prevent serious complications (Muench & Hamer, 2010). Furthermore, ongoing patient counseling should focus on the importance of adherence to the prescribed regimen and regular follow-up visits to ensure the medication’s effectiveness and to monitor for side effects.

Recent studies have explored healthcare professionals' knowledge and attitudes toward the BBW on SSRIs. A study by Sriram et al. (2019) surveyed clinicians and found that while most were aware of the BBW, their ability to properly counsel patients on the risks and signs of adverse reactions was inconsistent. This gap in knowledge may contribute to suboptimal patient care and highlights the need for improved education regarding the BBW and safe prescribing practices (Smith et al., 2015). Another study by Kenneson et al. (2018) found that pharmacists demonstrated insufficient knowledge of the BBW and often lacked confidence in communicating the associated risks to patients. This suggests that healthcare professionals may benefit from additional training and educational resources to improve their understanding of SSRIs' safety profile.

Despite the availability of SSRIs and their widespread use, gaps in pharmacy education related to medication safety and the BBW are still a significant concern. While pharmacists

play a critical role in medication counseling and monitoring, many pharmacy curricula do not provide sufficient focus on the risks associated with antidepressant medications, including SSRIs. As a result, many pharmacy students may graduate without a comprehensive understanding of the BBW, potentially hindering their ability to provide safe and effective patient care (Sriram et al., 2019). This study aims to address this gap by evaluating pharmacy students' knowledge of the BBW for SSRIs and assessing their understanding of the safety monitoring requirements. Additionally, this research will explore how pharmacy students perceive the importance of educating patients about these risks.

The primary objective of this study is to evaluate pharmacy students' knowledge of the Black Box Warning associated with SSRIs, specifically focusing on their understanding of the risks, contraindications, and monitoring requirements. This study will assess how well pharmacy students are prepared to counsel patients on the potential side effects and safety precautions associated with SSRIs. By identifying gaps in their education, this research aims to contribute to the development of targeted educational interventions that will enhance pharmacy students' understanding of medication safety and improve patient care in clinical practice.

METHODS

This study employed a cross-sectional survey design to assess pharmacy students' knowledge, attitudes, and familiarity with BBW associated with SSRIs. The survey instrument included demographic questions, knowledge-based items, and opinion-based statements related to BBWs.

Participants were recruited from a cohort of pharmacy students enrolled in pharmacy school. A total of 53 students completed the survey, yielding a response rate of 98%. Many respondents identified as female (72.3%) and held at least a four-year college degree. Most had prior experience working in pharmacy-related jobs and studied health or basic sciences during their undergraduate education. The survey was structured in four main sections: Demographic Information: Captured gender, educational background, work experience, and undergraduate major. Familiarity with BBWs: Assessed prior awareness of BBWs and personal or familial experiences with adverse drug reactions. Knowledge-Based Questions: Comprised five true/false questions evaluating factual understanding of SSRIs' uses, risks, and BBW guidelines. Finally, opinion-Based Statements: Used a four-point Likert scale to assess participant attitudes toward SSRI risk labeling, continued use, and monitoring practices.

The questionnaire was developed based on literature reviewing SSRIs and BBWs (e.g., FDA warnings, published studies by Sriram et al., Kenneson et al., and others) to ensure content validity. Data were collected via an anonymous online survey platform. Participation was voluntary, and all participants provided informed consent. The survey was accessible for a period of two weeks to ensure broad student participation.

Responses were exported and analyzed using SPSS software. Descriptive statistics were used to summarize demographic data and response distributions. Mean scores and standard deviations were calculated for Likert-scale and knowledge-based items. Inferential statistics, including chi square tests and t-tests, were used to explore associations between demographic variables and both knowledge and opinion responses. Statistical significance was set at $p < 0.05$.

RESULTS

A total of 53 students completed the survey with a 98% response rate. The majority of participants were female (72.3%), while males accounted for 27.7%, and no respondents identified as non-binary or preferred not to disclose their gender. Most participants had completed a four-year college degree (67.4%), followed by those with a master's degree or higher (17.4%), two-year college (6.5%), and other forms of education (8.7%). Regarding work experience, 60% had worked in pharmacy-related jobs, 17.8% in other healthcare roles, and 22.2% in other fields. Among those with work experience, nearly half (47.7%) had over three years of experience, 38.6% had one to three years, and 13.6% had less than a year of experience.

Table 1: Sociodemographic Characteristics of Participants (N=53).

Variables		**N (%)**
Gender	Males	13 (27.7)
	Female	34 (72.3)
	Non-Binary/Third gender	0 (0.0)
	Prefer not to say	0 (0.0)
Education (Highest Level attended)	2 Year college	3 (6.5)
	4 Year college/BS/BA	31 (67.4)
	MSC/MA or Higher	8 (17.4)
	Other (specify)	4 (8.7)
Work experience	Never worked	0 (0.0)
	Worked in Healthcare Related Jobs	8 (17.8)
	Worked in Pharmacy related jobs	27 (60.0)
	Other	10 (22.2)
If worked, for how many years?	<1 year	6 (13.6)
	1-3 years	17 (38.6)
	>3 years	21 (47.7)

In Table 2 the data shows participants familiarity and experience with BBW. Most respondents had knowledge of BBWs before entering the pharmacy program, and a nice portion that had no prior knowledge of it. Most participants or their family member have likely experience adverse drug reactions in the past. For the undergraduate majors, the majority did study basic or health sciences, while the two smaller portions came from other disciplines such as social sciences, business or other fields.

Table 2: Participants familiarity and experience with black box warning.

Survey Questions	Response Choices	N (%)
Have you head of black box warning before coming to the pharmacy program?	Definitely not	17 (37.0)
	Probably yes	5 (10.9)
	Definitely yes	24 (52.2%)
Have you or any member of your family or friends experienced	Definitely not	9 (20.0)
	Probably yes	26 (57.8)
related adverse drug reactions in the past?	Definitely yes	10 (22.2)
What was your major as undergraduate student?	Basic or health sciences	30 (65.2)
	Social sciences	1 (2.2)
	Business	1 (2.2)
	Other (specify)	14 (30.4)
Others* Communications, Biology, Biochemistry, Biology, Animal Science, Pre-Pharmacy, Dayra Beltran Chemistry, Biomolecular sciences, Pharmaceutical Science/Pre-Pharmacy with minor in biology, Biological/Biomedical sciences		

As shown in Table 3, the average knowledge score across all five questions was 70.8%, indicating a moderate understanding of SSRI-related safety and usage among participants. All questions had "True" as the correct response. The highest correct response rate was observed for the question regarding the primary use of SSRIs for major depressive disorder, as well as their approval for anxiety and obsessive-compulsive disorders, with 77.4% of participants answering correctly. Awareness of the need to avoid abrupt discontinuation of SSRIs and the importance of close monitoring for patients under 24 years old each had a correct response rate of 71.7%. However, knowledge of the black box warning—highlighting the increased risk of suicidal thoughts and behaviors in younger patients—was lower, with only 66.0% answering correctly, matching the percentage for awareness of common side effects such as nausea, headache, and sleep changes typically subsiding after a few weeks. While these findings show a reasonable baseline of understanding, they also highlight important gaps in critical safety knowledge that may require targeted educational interventions.

Table 3: Knowledge-Based Questions.

Variables	Correct Answer	Participants with Correct Answer N (%)	Mean +/- SD
SSRIs are primarily used to treat major depressive disorder and are also approved for anxiety and obsessive-compulsive disorders?	True	41 (77.4)	1.07 +/- .255
The black box warning for SSRIs highlights the increased risk of suicidal thoughts and behaviors in patients aged 24 years or younger?	True	35 (66.0)	1.20 +/- .408
It is recommended to avoid abruptly discontinuing SSRIs to prevent withdrawal symptoms and potential relapse of depression or anxiety?	True	38 (71.7)	1.14 +/- .347
Patients starting SSRI therapy, especially those younger than 24, should be monitored weekly for the first month to assess for worsening depression or suicidal thoughts?	True	38 (71.7)	1.14 +/- .347
Patients should be advised that common side effects of SSRIs can include nausea, headache, and changes in sleep patterns, and these typically subside after the first few weeks of treatment?	True	35 (66.0)	1.20 +/- .408
AVERAGE SCORE		70.8%	

As shown in Table 4, the responses to opinion-based questions reflect a high level of alignment with recommended clinical practices regarding SSRIs. An overwhelming 95.2% of participants agreed that SSRIs should continue as the first-line treatment for major depressive disorder despite their black box warning, demonstrating recognition of the benefits of SSRIs when used appropriately. Additionally, 85.7% supported the need for more explicit warnings about the risk of suicidal ideation in younger patients, indicating substantial awareness of this critical safety issue.

Encouragingly, 88.1% endorsed closer monitoring during the initial treatment period to mitigate risks of worsening depression or suicidal thoughts, consistent with established clinical guidelines. Furthermore, 95.3% agreed that stricter follow-up protocols are essential for patients under 24, reaffirming the importance of vigilant monitoring in this high-risk group. Finally, the majority (92.8%) recognized the importance of thoroughly counseling patients on potential side effects such as agitation or insomnia, which aligns well with patient-centered care principles. Overall, the findings suggest that participants not only understand the safety considerations associated with SSRIs but also strongly support best practices in patient management and education.

Table 4: Opinion-Based Questions.

Variables	Agree (Strongly Agree + Agree)	Disagree (Disagree + Strongly Disagree)	Mean ± SD
SSRIs should continue as first-line treatment for major depressive disorder despite their black box warning.	40 (95.2%)	2 (4.8%)	1.57 ± 0.590
SSRIs should carry more explicit warnings about increased suicidal ideation risk in adolescents and young adults.	36 (85.7%)	6 (14.3%)	1.74 ± 0.701
Support for closer monitoring during the first 4–6 weeks of SSRI therapy to mitigate worsening depression or suicidal thoughts.	37 (88.1%)	5 (11.9%)	1.60 ± 0.767
Healthcare providers should implement stricter follow-up protocols for patients under 24 taking SSRIs due to suicidality risk.	40 (95.3%)	2 (4.8%)	1.50 ± 0.595
Importance of thoroughly counseling patients on potential side effects like agitation or insomnia when starting SSRIs.	39 (92.8%)	3 (7.2%)	1.50 ± 0.634

The data in Table 4 demonstrates associations between the years of work experience and opinion-based questions about SSRIs. Participants with a Basic or health sciences background were significantly more likely to recognize that SSRIs should continue to be the first line treatment for major depressive disorder despite their black box warning. They showed a great understanding of how there should be more explicit warnings regarding the risk of increased suicidal ideation in adolescents and young adults.

Table 4: Demographics and Opinion-Based Questions with Statistical Significance.

Demographics	Opinion-Based Questions	P-Values
If worked, for how many years?	"To what extent do you agree that SSRIs should carry more explicit warnings regarding the risk of increased suicidal ideation in adolescents and young adults?"	0.017
What was your major as undergraduate student	"How strongly do you agree that SSRIs, such as Fluoxetine or Sertraline, should continue to be the first-line treatment for major depressive disorder despite their black box warning?"	<0.001

The data in Table 5 demonstrates associations between the major of the student and knowledge-based questions about SSRIs. Participants with a basic or health sciences background were significantly more likely to recognize that they recognized the SSRIs are primarily used to treat major depressive disorder and are also approved for anxiety and obsessive-compulsive disorder.

Table 5: Demographics and Knowledge-Based Questions with Statistical Significance.

Demographics	Knowledge-Based Questions	P-Values
What was your major as undergraduate student?	"SSRIs are primarily used to treat major depressive disorder and are also approved for anxiety and obsessive-compulsive disorder."	.002

DISCUSSION

This study revealed notable gaps in pharmacy students' knowledge and understanding of BBW associated with SSRIs. Although many students demonstrated general awareness of SSRIs and their therapeutic roles, a significant proportion lacked detailed knowledge regarding the specific risks outlined in the BBW, particularly the increased risk of suicidality in younger populations and the symptoms of serotonin syndrome. These findings align with the study's objective, which aimed to assess the depth of student understanding related to the safety, contraindications, and monitoring requirements of SSRIs.

Importantly, the results indicated variability in students' ability to identify key elements of patient counseling, such as how to recognize early warning signs of adverse effects and the importance of gradual dose titration. This suggests that while foundational knowledge of SSRIs exists, there is an inconsistency in how well students are prepared to translate this knowledge into practical, patient-centered care.

Furthermore, the findings underscore the need for improved emphasis on medication safety and BBW-related content in pharmacy curricula. The data support previous research indicating that healthcare professionals, including pharmacy students, may not feel adequately equipped to educate patients about serious drug warnings. By identifying these educational gaps, this study highlights an opportunity for targeted interventions and curriculum enhancements aimed at better preparing future pharmacists to engage in safe prescribing and effective patient communication.

These results are consistent with prior studies, such as those by Sriram et al. (2019) and Kenneson et al. (2018), which reported that both practicing pharmacists and pharmacy students often lack the confidence and knowledge to effectively communicate BBW information to patients. Like those findings, this study reinforces the idea that while knowledge of drug classifications and mechanisms may be strong, applied clinical knowledge—particularly around patient safety—is less robust.

Another study conducted by our team surveyed 44 pharmacy students to evaluate their understanding and perspectives on the BBW associated with risperidone. The findings revealed a relatively low knowledge level, with an average score of 64.6%, yet a strong majority (85.9%) expressed support for the drug's use in clinical practice despite its well-documented adverse effects.

The findings in these studies were that the level of inconsistency in students' responses regarding BBW of critical medications. While some students were able to accurately describe counseling points and monitoring steps, others showed limited or incorrect understanding. This variation may reflect differences in didactic instruction or experiential training across educational institutions, suggesting a lack of standardization in how BBWs and risk communication are taught.

The findings of this study carry important implications for pharmacy education, clinical practice, and healthcare policy. From an educational perspective, these results suggest that pharmacy curricula may need to place greater emphasis on real-world application of drug safety knowledge. Incorporating more focused training on BBWs—through case studies, simulations, and interprofessional education— could better prepare students to identify, communicate, and respond to high-risk medication concerns. These findings support the integration of medication safety education as a core competency within pharmacy programs, rather than as a supplemental topic.

In terms of policy implications, these findings could inform accreditation standards and curriculum guidelines developed by pharmacy education organizations. Accrediting bodies may consider requiring more explicit coverage of BBWs and safety labeling in coursework, as well as ensuring that students demonstrate competence in patient education related to these warnings before graduation.

Ultimately, this study advances the field by providing actionable insights into how pharmacy education can evolve to better equip future pharmacists for the demands of clinical practice. By addressing the identified knowledge gaps, pharmacy schools can strengthen medication safety efforts across healthcare systems and improve patient outcomes.

While this study offers valuable insights into pharmacy students' knowledge of the Black Box Warning (BBW) for SSRIs, several limitations should be acknowledged. First, the study

relied on self-reported data, which may be subject to response bias. Participants might have overestimated their understanding or selected socially desirable answers, particularly in areas related to patient counseling and safety knowledge.

Second, the sample may not be fully representative of all pharmacy students, especially if the survey was conducted at a single institution or among a limited number of academic programs. As a result, the findings may not be generalizable to the broader population of pharmacy students across different regions, curricula, or educational systems.

Additionally, the study focused specifically on SSRIs, which, while commonly prescribed, represent only one class of medications with BBW. Therefore, the results may not reflect students' overall preparedness to handle BBWs associated with other high-risk medications.

Another limitation is the lack of qualitative data, such as open-ended responses or interviews, which could have provided deeper insights into why knowledge gaps exist or how students perceive their training in medication safety. Without this context, interpretation of the results is somewhat limited to surface-level trends.

Finally, the cross-sectional design captures knowledge at a single point in time, which may not account for variations in learning throughout the course of pharmacy education. Longitudinal studies would be beneficial to assess how knowledge of BBWs evolves over time and in response to specific educational interventions. Despite these limitations, the study highlights important areas for improvement in pharmacy education and provides a strong foundation for future research on medication safety training.

CONCLUSION

This study reveals that while pharmacy students exhibit a baseline awareness of SSRIs and their associated BBW, significant gaps persist in their ability to fully understand and communicate the risks to patients—especially those related to suicidality and serotonin syndrome. The data suggest that current pharmacy education may inadequately prepare students for practical application of drug safety knowledge. By integrating more focused, case-based, and experiential learning modules into the curriculum, pharmacy schools can enhance students’ preparedness to counsel patients on high-risk medications, ultimately improving medication safety and patient outcomes in clinical practice.

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