

Review of: "Could a Simple Barcode Enhance Patient Safety by Raising Awareness of Black Box Warnings? How Can We Bridge the Knowledge Gap in Medication Risks Among Health Professionals?"

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Potential competing interests: No potential competing interests to declare.

Dears,

Thank you for the opportunity to review this interesting article.

This manuscript addresses the critical issue of awareness and management of black box warnings for drugs, essential for patient safety and effective risk management, and suggests a novel approach for displaying the black box warning. Please find my comments below that would improve the manuscript's readability and consistency:

- The title is appropriate as it effectively captures the main themes of the content, addressing both the potential of a barcode to enhance patient safety and the need to bridge the knowledge gap among healthcare professionals regarding medication risks. However, it could be streamlined for clarity and conciseness as follows:

Enhancing Patient Safety: Addressing the Knowledge Gap in Medication Risks with Bar-coded Black Box Warnings

- The abstract could be more impactful by directly stating the primary research objective. Please provide a clear objective for the study.
- Streamlining details about drug discoveries and focusing more on the direct impact of black box warnings on patient safety would strengthen the narrative.
- Ensure consistency with terminology and punctuation. Pay attention to the consistency of terms (e.g., black box warnings vs. black box warnings) to maintain professionalism and readability.
- The history of black box warnings on FDA labels dates back to the 1970s, implemented to draw attention to serious or life-threatening risks associated with specific prescription drugs. This section could be strengthened with additional context on the specific events that led to the implementation of these warnings.
- The description of the black box warnings section is clear and accessible. Further enriching this section with an explanation of how the FDA determines and updates these warnings could provide insight into the regulatory process.
- Consider using a table or statistics to illustrate the growth in the number of warnings, and linking this increase to broader trends in drug development would offer a more analytical perspective.
- Your clinical examples effectively illustrate the potential dangers of overlooking black box warnings in clinical practice. You can start each clinical example with a brief contextualization, connecting it to the broader discussion on black box

warnings.

- Your question regarding cigarettes makes an important comparison between warning labels on cigarettes and black box warnings on pharmaceutical drugs, highlighting the difference in visibility between the two. Please find below some feedback on your inquiry and how it relates to the previous sections:
1. Connect your question to the broader discussion on black box warnings by emphasizing the shared goal of raising awareness about potential health risks associated with certain products.
 2. To provide context for your question regarding cigarettes, further explore the regulatory differences between tobacco products and pharmaceutical drugs.
 3. Highlight the public health implications of warning labels on cigarettes and black box warnings on drugs to underscore their respective impacts on consumer behavior and health outcomes.
 4. Highlight the importance of collaboration among healthcare professionals, pharmacists, and other stakeholders in implementing preventive measures and improving patient safety.
- Please rewrite the following sentence: "This example of the logo of the black box was created by us to put on the front of drug packs like Adalimumab, as this drug has a black box warning." A suggestion to re-write it: The researcher designed this black box logo for prominent display on the packaging of drugs like Adalimumab, which includes a black box warning.
 - In the conclusion section, either omit the reference to previous cross-sectional studies since the manuscript did not include any such reference, or cite new references within the body of the manuscript. To leave a lasting impression, end with a strong statement about the expected benefits of the proposals.
 - References:
 1. Please ensure that the references follow the Vancouver citation style guidelines. Each reference should include author names, article or web-page title, journal or website name, publication date, volume (if applicable), page numbers (if applicable), DOI (if available), and PMID/PMCID (if available). For online sources, URLs are also required, along with the date of your citation. Example ref. #1: Warnings and precautions, contraindications, and boxed warning sections of labeling for human prescription drugs and biological products [Internet]. The original citation date for this reference was September 2015. Please correct it.
 2. Please include a reference to the following paragraph: The existing literature and cross-sectional studies have inadequately addressed this critical area of concern. Consequently, a notable gap persists in our collective knowledge regarding the awareness of and adherence to black box warnings among healthcare professionals. We must bridge this gap to ensure the well-informed and judicious use of these medications in clinical practice.
 3. Please rewrite the paragraph, without duplication, and also avoid personal pronouns (this should be applied to the whole document): "Watch for these changes and call your healthcare provider right away if you notice new or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if they are severe. Pay particular attention to such changes when sertraline is started or when the dose is changed. Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: new or worsening depression;

thinking about harming or killing yourself, or planning or trying to do so; extreme worry; agitation; panic attacks; new or worsening anxiety; difficulty falling asleep or staying asleep; aggressive behavior; irritability; acting without thinking; severe restlessness; and frenzied abnormal excitement. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own".

4. Please rephrase the following text to clarify if it is intended as a comparison or an inquiry. Avoid using personal pronouns. "If cigarettes may, after a long time of use, cause serious health problems and there are logos for the warning, why does the US Food and Drug Administration (FDA) require pharmaceutical companies to include a black box warning on the packaging of certain drugs, such as monoclonal antibodies?"