Author’s response to reviews

Title: Improving accuracy of medication identification in an older population using a medication bottle color symbol label system

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Response to Reviewers

We thank both reviewers for their thoughtful and constructive comments. We appreciate their help in improving the quality of this manuscript. By incorporating their comments, our paper has been strengthened and the quality of the paper has improved. We have included our response to the reviewers’ comments.

Reviewer 1

Comment:
“…there should have been a discussion of the study population of NorTex and how representative the sample is.”

Response:
Discussion of NorTex has been expanded in the study population section, and generalizability of study results have been noted in the discussion.

Comment:
“In the discussion, the authors mentioned that this sample mirror general American population. This statement needs to be double checked since there are more females in the 65+ age while 54% of the sample is male.”

Response:
This statement has been removed from the manuscript.

Comment:
“Secondly, there is no comparison group. Since TCOM labels were added right after the pre-test, authors can’t rule out the immediate recalling factor without a comparison group.”

Response:
Discussion of recall bias and lack of comparison group has been added to the last paragraph of the discussion section.

Comment:
“…the representativeness of its sample is questionable. The data analysis is appropriate given its design. Power analysis was performed. The effective size should be calculated and discussed. Authors need to discuss what 7% improvement after using labels means. They stated that: ‘Calculations assumed participants would incorrectly identify at least one medication in the pre-measurement and would correctly identify all medications in the post-measurement.’ Whether or not the finding supporting this assumption is not discussed.”

Response:
There was a seven percent improvement in the ability of participants to correctly match their medication to the prescribed indication. This has been clarified in the Phase II
results section. The assumption that at least one medication would be identified incorrectly prior to measurement and all medications would be identified correctly post-measurement was used as an assumption to conduct the power analysis, rather than a hypothesis. Cohen’s $d$ has been provided to address the observed versus the expected effect size of 20%. An effect size of 0.25 was found for the pre/post test conducted at a distance of two feet, as expected since the results were found to be significant at that distance. An effect size of 0.15 was found for the pre/post test conducted in front of participants.

Comment:
“The discussion is balanced and supported by the data, except for the representativeness issue mentioned above.”

Response:
Discussion of the generalizability of the study results and representativeness of the study sample has been added to the discussion section.

Comment:
“There are other limitations besides what the authors stated, such as lack of comparison group, lack of a random sample, and other design flaws.”

Response:
Limitations have been expanded on in the discussion portion of the manuscript.

Comment:
“This is a very interesting topic that has promising practical implication to health care among the elderly, but the design flaws need to be addressed before publication.”

Response:
Design flaws have been addressed in the discussion section.

Reviewer 2

Abstract

Comment:
“Indicate right up front that this is a pilot study, could say … the purpose of this “pilot” study…”

Response:
The word “pilot” has been added at the beginning of the abstract, the last paragraph of the methods section, the second paragraph of the discussion, and in the conclusions.

Comment:
“Method tells me you will be measuring identification of medications, purpose of medications, and dosing of medication…but I didn’t find all three of these in the results section.”

Response:
The methods section of the abstract has been changed to say the study measured “…the participants’ ability to accurately match their medication to the indication for which it was prescribed when placed in front of participants and then at a distance of two feet.” The results section of the abstract and the last paragraph of the study procedures section have been modified to reflect the same.

Comment:
“Results in abstract reflect the focus groups enthusiasm for the TCOM system versus a summary of the results of the focus group…the only results noted in the abstract were about recognition of medications within each bottle…”

Response:
The abstract has been updated to include a more thorough summary of focus group results.

Comment:
“Abstract conclusion makes a large leap from correctly identifying medications to decreasing medication errors which I don’t see substantiated in the results of this study.”

Response:
Abstract conclusion has been changed to indicate that the labeling system is a promising adjunct to efforts in addressing medication misuse in the home.

Background

Comment:
“You begin by discussing medication errors and provide data about adverse drug events. You then suggest that we need to examine factors associated with medication errors and cite hospital costs and associated ADE which led me to think the study would be about delivery of drugs in institutional settings…not patient identification of drugs they take themselves. Suggesting that the impetus behind this study was medication errors didn’t feel like the appropriate background – focusing on what we know about medication adherence or patient knowledge of their medications would have provided a better background for the study carried out. It didn’t make sense to me that we should change labels to enhance patient identification of their drugs to decrease the medication errors and ADE that occur in hospitals where typically patients don’t select or administer their own medications.”

Response:
The first paragraph of the introduction has been revised to focus on medication misuse and adherence among elderly adults.
Comment:
“The comment that research should examine factors that may be associated with medication errors sounds like a need to examine the delivery of medications by health care providers not a patient’s ability to identify the medication, the purpose, and the dosing schedule.”
Response:
This statement has been removed.

Comment:
“Clarify if you are referring to “general” literacy or “health” literacy when discussing association to comprehending medication labels.”
Response:
This refers to health literacy. The word “health” has been added to clarify.

Comment:
“The last sentence of this paragraph is confusing as written – is your intent to say that older adults have a higher prevalence of limited health literacy and combined with the high number of prescription medications older adults take; they face challenges in comprehending the medication labels and taking the medications as prescribed?”
Response:
Yes, thank you for clarifying. The statement has been revised to state: “Older adults are particularly vulnerable to experience adverse health outcomes related to medication adherence and comprehension due to higher rates of medication use and lower health literacy than the general U.S. population.”

Comment:
This discussion is most relevant to your study and could provide the background to set the stage for what you actually did.
Response:
Thank you. This part of the background has been left as it is.

Comment:
“The purpose is stated as “Assess whether the TCOM system would increase accuracy and rapid identification of prescribed medications.” What accuracy refers to isn’t clear (is it correctly reading the label, is it correctly identifying the action of the drug? Is it correctly describing the ideal dosage of the drug. And, what do you mean by “rapid” identification of prescribed medications? I see no indication that you timed how long it took someone to identify a medication…."
Response:
This has been revised in the background and the abstract to indicate that the purpose of the study was to “assess whether this system would increase the accuracy with which
patients 65 years of age and older could match their medication to the indication for which it was prescribed.”

Methods

Comment:
“This description of the TCOM system needs a ‘header’ like ‘Development or Preliminary Work.’”

Response:
The header has been changed to “Development of the Tachygraphic Color Organized Medication System (TCOM).”

Comment:
“Good description of the study population and study procedures. The second sentence in the first paragraph of this section should be in the development section.”

Response:
The second and third sentences of study procedures have been deleted. The example given in the third sentence (“The heart symbol and the color red…”) has been moved to the Development section.

Comment:
“I think you need to address the two assessments (first having the patient identify their medications without the TCOM label and then with the TCOM label) – it seems like there would be some learning/remembering that might occur with the test/retest model you used.”

Response:
A discussion of recall bias has been added in the discussion section (page 16).

Comment:
“At the end of this paragraph it looks as if you switched the sequencing of the assessment, hand held and then from 2 feet versus from 2 feet and then hand held.”

Response:
Yes, the assessment was done hand held, and then at a distance of two feet, as indicated in the last paragraph of the study procedures. The abstract lists results from a distance of two feet first because these results were found to be significant. To clarify, the line “…dosing information when placed in front of a participant and then at a distance of two feet” has been added in the methods section of the abstract.

Comment:
“The selection of the 2 feet distance perhaps could be expanded to include kitchen counter, cupboard, top of dresser or location than the medicine cabinet since many medications should not be stored in bathrooms given the moisture.”
Response:
Thank you for the suggestion. This has been added to the last sentence in the study procedures section: “The procedure was repeated from a distance of two feet, representing the distance needed to identify a medication bottle from common medication storage locations such as kitchen counters, medicine cabinets, cupboards, or dressers.”

Comment:
“You refer to NVIVO but it isn’t clear if you used this system or not. Sounds like you did content analysis, or a version of qualitative description. Clarification of your approach to the qualitative data would be beneficial.”

Response:
NVIVO was not used in the study. Thematic content analysis was conducted, and research team members reviewed the coded themes and used them to modify and refine the medication labeling system before Phase II of the study. The qualitative methods section has been revised to reflect these procedures.

Comment:
“You don’t mention that you collected data relating to the patients knowledge of what the drug was for (indication) and the dosing of the drug yet you suggest that was part of the methods in the abstract….need to be consistent with reporting out what it is you said.”

Response:
Methods have been clarified in last paragraph of the study procedures section (page 10). Participants were asked to identify their medications, their associated dosages, and the indications for which they were taking medications. They were then asked to match each medication with the appropriate medication without the label when placed directly in front of them, and then with the addition of the label. This was repeated at a distance of two feet. The results listed in the quantitative measures and analysis are consistent with these methods.

Phase I Results

Comment:
“It would be helpful to identify major themes that arose from analysis of the focus group data and then perhaps give a few examples to support the themes. You may be able to put the themes into a table format.”

Response:
A table has been added to the manuscript.

Comment:
“Discussion about medication costs (last 2 paragraphs) in the first paragraph of this section was a distraction – not sure how it even came up since we didn’t see the interview guide used in the focus groups.”
Response:
Medication costs emerged as a theme under “other comments” included in the table added to the manuscript. This was not specifically asked, but was consistently brought up by focus group participants.

Comment:
“I was led to believe the focus groups would be asking questions about understanding the colors and symbols used to identify classes of drugs based upon indication for drug actions. Providing more detail of the type of questions posed to the focus group might be helpful.”

Response:
Focus groups asked questions regarding colors and symbols, as well as other questions which have been included in the summary table of focus group results.

Phase II Results

Comment:
“Not exactly sure what you mean by correctly identifying medication – does this mean they could read the label, that they could tell you what it was for?”

Response:
Correct identification refers to correctly matching the medication to the indication for which the medication was prescribed. The following sentence has been changed to clarify results: “…88.6% of the medications were correctly matched to their prescribed indication when placed in front of participants.”

Comment:
“Do you have any results about the correct dosing of the medication or correct indication for taking the medication? In the abstract you suggest the ability to identify the medication, the purpose, and the dosing would all be assessed…”

Response:
Medication identification, purpose and dosing were assessed at the beginning of the pre-post test. The pre-post test measures the number of medications participants were able to correctly match to the appropriate indication. Clarifications have been made in the abstract, methods, and phase II results sections.

Discussion

Comment:
The first few sentences in the discussion seem irrelevant as they are related to institutional issues/costs of ADE.

Response:
These sentences have been removed.

Comment:
Your comments about Medicare part D lowering cost-related non-adherence and reducing medication errors from misuse at home could be moved to the introduction / background section of the paper.

Response:
Thank you for the suggestion. Because the background and discussion section have been revised, comments about Medicare part D have been removed from the discussion.

Comment:
“At the end of the first paragraph in this section you suggest that use of the TCOM labeling system is beneficial for health care providers and pharmacies – I wonder if it wouldn’t be better to say it would be beneficial to older adults as it would enhance their correct use of medications at home and potentially decrease adverse events associated with misuse or incorrect use of prescribed medications.”

Response:
A sentence has been added to the end of paragraph 1 to address this issue (“The TCOM system may empower older adults with an accessible system to enhance correct use of medications…”)

Comment:
“In the second paragraph you state a finding from Hwang and colleagues that contradict your findings – good to include but why do you think you got different results? Can you offer a plausible explanation that might make the readers understand why the discrepancy?”

Response:
Hwang and colleagues found that visual aids currently used on medication labels can be ambiguous and/or misleading in some cases. The current study used focus group input to develop the symbols and colors used in the proposed labeling system to ensure they were relevant to the target population (adults 65 and older). Quantitative results indicate that the labeling system does significantly improve medication recognition at a distance of two feet. This suggests that the proposed labeling system may be a helpful visual addition to bottle labels, since visual aids currently used on bottle labels may not be effective. Wording has been changed in paragraph 2 of the discussion to clarify.

Comment:
“You suggest that activating the visual senses improves cognition and may decrease error – it would have been helpful to address this in the background section of the paper as support for why you did what you did.”

Response:
This statement has been removed from the manuscript.
Comment: “You need to clearly add a “Limitations” section.”

Response: The limitations section has been expanded in the last paragraph of the discussion section.

Conclusions

Comment: “I don’t think these results indicate that the TCOM labeling system will reduce medication errors but rather that the TCOM labeling system enhanced identification of medications by older adults - this in turn may mean less error of taking the wrong medication but that wasn’t the question studied.”

Response: The conclusion has been revised to state: “Pilot study results show a promising addition in efforts to address the issue of medication misuse in the home through the improvement of medication labeling and health literacy.”

Comment: “I’m still not clear about what “identification of” medications means (is it being able to read the label correctly, is it being able to describe what the medication is for? Does it include being able to describe the correct dosing schedule of a particular drug?”

Response: Medication identification as used in this manuscript refers to the ability to match the correct medication with the indication for which it was prescribed. This has been revised to be more clear in the methods and results section of the manuscript.

Minor Essential Revisions

Comment: “Suggest you delete beginnings of sentences like, ‘however,’ ‘overall.’”

Response: These have been deleted where possible.

Comment: “Add ‘years’ when reporting average age of participants.”

Response: This has been updated in the phase II results section, paragraph 1.

Comment:
“Avoid use of “et al.” within the sentence (it is reserved for used with parentheses when citing a reference within the text. Instead use something like ‘and colleagues’.”

Response:
We have changed “Hwang et al.” to “Hwang and colleagues” in the second paragraph of the discussion.

Comment:
“Describe this as a pilot study right from the beginning rather than waiting until the conclusions.”

Response:
Thank you, this has been noted at the beginning of the abstract.

Comment:
“Lack of consistency in taking medications as prescribed is a problem that often leads to undesired health outcomes. Examination of a strategy to enhance medication identification, purpose and dosing is important and relevant especially for older adults who frequently take multiple medications for multiple co-morbidities. While the methods, analysis, and results are well described I think the background and discussion need revisions as they lead the reader to think this paper will be about medication errors and reducing adverse events but rather it is on helping adults identify their medications with an assumed goal that correct identification will lead to taking them correctly.”

Response:
The background and discussion have been revised.