Author's response to reviews

Title: Factors influencing implementation dose and fidelity thereof and related student outcomes of an evidence-based national HIV prevention program

Authors:

Bo Wang (bwang@med.wayne.edu)
Bonita Stanton (bstanton@med.wayne.edu)
Lynette Deveaux (lyndeveaux@yahoo.com)
Maxwell Poitier (m.g.poitier@gmail.com)
Sonja Lunn (slunn@coralwave.com)
Veronica Koci (vkoci@med.wayne.edu)
Richard Adderley (radderley@gmail.com)
Linda Kaljee (lkaljee@yahoo.com)
Sharon Marshall (smarshal@med.wayne.edu)
Xiaoming Li (xiaoli@med.wayne.edu)
Glenda Rolle (grolle54@gmail.com)

Version: 3
Date: 26 February 2015

Author's response to reviews: see over
February 25, 2015

Dr. Anne Sales
Editor-in-Chief, Implementation Science
University of Michigan School of Nursing
400 North Ingalls Building
Ann Arbor, MI 48109-5482
USA

Dr. Michel Wensing
Editor-in-Chief, Implementation Science
Institute for Quality in Healthcare
Radboud University Nijmegen Medical Centre
Geert Grooteplein noord 21
Nijmegen 6525 EZ
Netherlands

Gregory Aarons
Associate Editor, Implementation Science.
University of California, San Diego
School of Medicine
Department of Psychiatry
9500 Gilman Drive (0812)
San Diego, CA 92093-0812
USA

Re: Revised Manuscript (MS#: 6102604181458844)

Dear Dr. Aarons:

We were pleased to receive your letter regarding our manuscript “Factors influencing implementation dose and fidelity thereof and related student outcomes of an evidence-based national HIV prevention program” and greatly appreciate the constructive comments. After carefully considering the comments, we agree with most of the recommended changes. Our detailed item-to-item responses to the reviewers’ comments follow this letter. We genuinely believe that the manuscript is improved through our modifications based on these suggestions.

Enclosed please also find a copy of our revised manuscript. Please let us know if you have any questions regarding our revision and responses.

Thank you for your consideration of our manuscript and we look forward to your response.

Sincerely yours,

Bonita F. Stanton, M.D. (Corresponding author©
Professor of Pediatrics
Vice Dean for Research,
School of Medicine
Wayne State University
313-577-9553 (office)
313-577-9399 (FAX)
Email: bstanton@med.wayne.edu
Response to Reviewer 1 (Dr. Louise Ann Rohrbach):

Major Compulsory Revisions

1. The fifth paragraph in the Introduction ("Given the complex...") includes a description of studies that are not relevant to the present study. I would suggest revising this paragraph to focus on findings from previous school-based studies. Also, I would suggest that the authors look at a recent special issue of the Journal of Adolescent Health (V. 54, S1-S2, 2014) that included several studies of implementation of pregnancy prevention programs that may be relevant to the present paper.

Response 1: We agree with the reviewer and have revised this paragraph with a focus on teacher implementation patterns of school–based prevention programs.

“The literature systematically identifying implementation patterns by teachers of effective HIV prevention programs in schools settings is sparse, but some relevant studies do exist. Klingner et al. categorized teachers who participated in the implementation of four research-based programs into three implementation groups [27] and Shin et al. identified five teachers’ delivery profiles based on teacher engagement and delivery techniques [28]. While informative, these studies are limited by the qualitative nature of data, the modest sample sizes and the non-systematic methods for identification of the implementation clusters. The current study seeks to fill this research gap by identifying teachers’ implementation patterns using cluster analysis and relating implementation patterns to student outcomes.” (Please see page 6, lines 7-15)


2. The Introduction section should establish why it is important to study implementation. Specifically, what have studies shown regarding the association between implementation and outcomes (particularly school-based prevention studies)? For example, see the Durlak and DuPre (2008) review article that is cited in the Discussion section.

Response 2: We agree with the reviewer and have summarized finding regarding the association between implementation and outcomes.

“A recent systematic review reveals that a majority of studies have found that higher implementation dose and/or implementation fidelity are associated with better program outcomes [23]. Blakely and colleagues conducted a comprehensive examination of fidelity and effectiveness assessing seven nationally disseminated education and criminal justice projects and found that implementations conducted with high-fidelity were more effective than low-fidelity implementations [24]. Other studies have found that suboptimal quality delivery of evidence-based programs can result in minimal or null effects [14]. An evaluation of 14 school-based anti-bullying programs found that the majority of programs yielded non-significant outcomes on measures of self-reported victimization and bullying [25]. Derzon et al. assessed intervention effectiveness of drug prevention programs and found no significant
effect on drug use among program participants [26]. These studies suggest that inadequate program delivery may undermine the potential impact of prevention programs [25,26].” (Please page 5, lines 14-23; page 6, lines 1-2)


3. The authors use of the term "sustained implementation" is not consistent with the literature. Usually, sustained implementation refers to implementation of a program over time, after initial implementation (i.e., maintenance or institutionalization of it in an organization). I would suggest that the amount of the intervention that teachers delivered in this study is not a measure of "sustained implementation," but rather a measure of implementation dosage. I would suggest that the authors refer to this measure in a way that is consistent with the implementation literature.

Response 3: We agree with the reviewer and have changed “sustained implementation” to “implementation dose” throughout the text.

4. In the Discussion section, under the header "Teacher's implementation group membership and student outcomes," the authors state that “the quality of implementation was causally related to student outcomes.” This statement is an over-interpretation of the findings. As the title of Table 4 states, the analysis examines an association between implementation and outcomes, not a causal relationship. In order to establish causality, the authors would need to either conduct a randomized design, assigning teachers to implementation groups, or conduct a mediation analysis to determine if varying levels of implementation mediated changes in student outcomes.

Response 4: We agree with the reviewer and have changed the sentence from “quality of implementation was causally related to student outcomes” to “quality of implementation was significantly related to student outcomes (better implementation leads to better outcomes).” (Please see page 22, lines 8-9).

5. In some cases in the Results section, the results are worded as if there was a comparison between two implementation groups (e.g., High/Moderate vs. Low) rather than a comparison among three groups. For example, in the first paragraph under the subheading "Association of teachers’ implementation group membership with teachers’ characteristics and pre- and post-implementation perceptions" (findings regarding length of time as a teacher and island of teacher). Overall, the authors should be consistent in inclusion of the F statistic in parentheses after their statements regarding group differences, to remind readers that the statistic represents a comparison among three groups.

Response 5: We agree with the review and have modified relevant sentences.

[Original-1]“More teachers in the High Implementation Group than teachers in the Moderate Implementation Group had worked as a teacher or guidance counselor for 6 to 10 years. In
contrast, more teachers in the Moderate or Low Implementation Groups than teachers in the High Implementation Group had served as a teacher for over 10 years.”

[Modified-1] “More teachers in the Moderate or Low Implementation Groups than teachers in the High Implementation Group had worked as a teacher or guidance counselor for over 10 years (66% vs. 58% vs. 44%, $\chi^2=15.98$, $p<0.01$). In contrast, more teachers in the High Implementation Group had served as a teacher for 6 to 10 years.” (Please see page 15, lines 11-14)

[Original-2] “More teachers in the High Implementation than in the Low Implementation Group were teaching in Island #1 (the most populous Bahamian island and the island in which FOYC was originally adapted for The Bahamas and tested for efficacy). In contrast, more teachers in the Low Implementation than in the High Implementation Group worked in the other islands constituting The Bahamas (the “Family Islands”).”

[Modofied-2] “More teachers in the High Implementation Group were teaching in Island #1 (the most populous Bahamian island and the island in which FOYC was originally adapted for The Bahamas and tested for efficacy) (73% vs. 58% vs. 45%, $\chi^2=7.45$, $p<0.05$) while more teachers in the Low Implementation Group worked in the other islands constituting The Bahamas (the “Family Islands”)” (Please see page 15, lines 21-23; page 16, line 1)

6. In the last paragraph of the Analysis section, the authors should clarify that in the multi-level analysis, they conducted two comparisons: high vs. low implementers and moderate vs. low implementers. As written, the difference in what is compared in the multi-level analysis relative what is compared in all other analyses in the paper (ANOVA for 3 groups) is not clear.

Response 6: In the mixed-effects model, teachers’ pattern of implementation is included as a categorical variable (High, Moderate and Low Implementation Groups). Only one category serves as the reference group (in this case, the Low Implementation Group) while the other two categories are compared with the reference group; this strategy is different from the strategy employed by ANOVA post-hoc paired comparisons. We have indicated the reference group in the Analysis section.

“The association of teachers’ patterns of implementation (High, Moderate and Low Implementation Groups, with the Low Implementation Group serving as the reference group) with student outcomes was examined using mixed-effects modeling...” (Please see page 13, lines 1-3)

7. In the Discussion section, the authors should discuss the differences in findings from the multi-level analysis and the ANOVA analysis reported in Table 3, and what they mean.

Response 7: We agree and now further discuss the differences in student outcomes in terms of teachers’ implementation group.

“Our study reveals that quality of implementation was significantly related to student outcomes (better implementation leads to better outcomes). Students whose teachers were in the High and/or Moderate Implementation Groups demonstrated greater improvements in three student outcomes (knowledge, skills and intention) compared to students whose teachers belonged to the Low Implementation Group. Students whose teachers were in the High
Implementation Group demonstrated greater improvements in HIV/AIDS knowledge and reproductive health skills compared to students whose teachers belonged to the Moderate Implementation Group. These findings are consistent with previous research suggesting that implementation dose and implementation fidelity influences program outcomes [23].” (Please see page 22, lines 8-16)

Minor Essential Revisions
1. In the Introduction, fourth paragraph, I would not describe the literature that suggests adaptations are inevitable as "robust." Many authors have suggested or offered an opinion that this is true, in at least some cases based on anecdotal evidence; there is not a strong body of research on the extent and nature of adaptation of evidence-based programs when they are implemented in the "real world."

Response 8: We agree with the reviewer and have revised the introduction section. The sentence “A robust literature documents that adaptation of interventions as they are implemented by different trainers and/or in different sites is inevitable” was deleted.

2. In the Introduction, fourth paragraph, the sentence "A particularly comprehensive examination of fidelity...” needs a citation.

Response 9: We agree and have now provided a citation.

“Blakely and colleagues conducted a comprehensive examination of fidelity and effectiveness assessing seven nationally disseminated education and criminal justice projects and found that implementations conducted with high-fidelity were more effective than low-fidelity implementations [24].” (Please see page 5, lines 16-19)


3. Introduction, paragraph 6, "as it was shown to be effective" is an awkward wording. I would suggest using "as it was designed" or "as it was implemented in efficacy/effectiveness trials” or something similar.

Response 10: We agree and now explain the advantages of using the probability estimates to examine the impact of one or more risk factors on the trajectory group membership.

[Original] “Understanding whether and why teachers did and did not implement an intervention as it was shown to be effective is important.”

[Modified] “Understanding whether and why teachers did and did not implement an intervention as it was designed is important.” (Page 6, line 16-17)

4. Methods section, first paragraph under "Intervention" has a typo in the sentence that begins, "The intervention...."

Response 11: We agree and have modified the sentence.

[Original] “The intervention, including games, interactive discussions, stories, lectures, homework activities and exercises to reinforce main messages and to increase knowledge and
skills regarding sexual risk avoidance, effective communication, negotiation and condom use.”

[Modified] “The intervention includes games, interactive discussions, stories, and exercises to reinforce main messages and increase knowledge and skills regarding sexual risk avoidance, effective communication, negotiation and condom use [30].” (Page 8, lines 1-3)

5. Analysis section, second paragraph, the sentence that begins "The differences in..." I would revise this to make clear which differences are being examined.

Response 12: We agree and have modified the sentence.

[Original] “The differences in teachers’ pre-implementation characteristics, teaching and training experiences and attitudes towards HIV prevention between the clusters were examined using chi-square test.”

[Modified] “The differences in teachers’ education, total years as a teacher, attendance of training workshop, training in interactive training, prior experience of teaching FOYC or other HIV prevention programs and perceptions of importance of HIV prevention or FOYC to grade 6 youth between the clusters were examined using chi-square test.” (Page 12, lines 5-8)

6. Results section, first paragraph, there is a typo: "....twenty-eight (13.5%) taught more than 40 all activities...."

Response 13: We have modified the sentence.

[Original] “Sixteen (7.7%) taught 28 or more core activities; twenty-eight (13.5%) taught more than 40 all activities; fifty-six (27%) teachers taught seven or eight sessions of FOYC curriculum.”

[Modified] “Sixteen (7.7%) teachers taught \( \geq 28 \) core activities; twenty-eight (13.5%) taught \( \geq 40 \) core and non-core activities; fifty-six (27%) taught seven or eight sessions of FOYC curriculum.” (Page 13, lines 17-19)

Discretionary Revisions

1. I would consider including a figure or schematic that shows the conceptual framework for your study. You are looking at a number of variables, and it would be helpful to show your hypotheses about their interrelationships.

Response 14: We agree that this is interesting but do not have sufficient space in this article to accommodate an additional figure and/or text. However, on page 11 we do now make reference to a previous publication in which we examined the interrelationships among variables and included a hypothesized theoretical model:

“Hypothetical relationships among these variables are discussed in a prior publication [34]” (Page 10, line 10)

2. Another limitation of the study is that it does not tell us much about differences between High and Moderate implementation groups. What are the practical implications of differences between these levels of implementation?

Response 15: We have also run the mixed-effects models using the Moderate Implementation Group as the reference group and discuss the practical implications of the differences between three levels of implementation.

“The mixed-effects models were rerun using the Moderate Implementation Group as the reference group. Compared to students whose teachers belonged to the Moderate Implementation Group, students whose teachers were in the High Implementation Group demonstrated higher levels of HIV/AIDS knowledge (β=0.48, SE=0.18, t=2.64, p=0.008) and reproductive health skills (β=0.24, SE=0.07, t=3.46, p=0.0005).” (Please see page 19, lines 7-12)

Also:

“Our study reveals that quality of implementation was significantly related to student outcomes (better implementation leads to better outcomes). Students whose teachers were in the High and/or Moderate Implementation Groups demonstrated greater improvements in three student outcomes (knowledge, skills and intention) compared to students whose teachers belonged to the Low Implementation Group. Students whose teachers were in the High Implementation Group demonstrated greater improvements in HIV/AIDS knowledge and reproductive health skills compared to students whose teachers belonged to the Moderate Implementation Group. These findings are consistent with previous research suggesting that implementation dose and implementation fidelity influences program outcomes [23]” (Please see page 22, lines 8-16)

3. In the Discussion section, I would add that these results provide some support for the validity of self-reported measures of implementation. In the school-based literature, a few studies have called into question whether self-reported implementation measures are valuable, compared to direct observation of implementation.

Response 16: We agree and have discussed the validity of self-reported measures of implementation.

“The teacher and observer reports on activities covered in these sessions were compared to determine the level of agreement; in general we found that the observer-teacher agreement was high (over 80%), indicating that teacher’s self-reports of their implementation of the intervention curriculum in their classrooms are reliable. (Please see page 22, lines 21-23; page 23, line 1)
Response to Reviewer 2 (Dr. Wynne Norton):

Major Compulsory Revisions
--The authors should consider streamlining the manuscript, especially the a) data analysis and b) results sections. Utilize the text to highlight the critical aspects of the findings and refer the reader to the tables for additional information.

Response 17: We have modified the analysis and results sections, using five subheadings in results section.

--The authors should include a more thorough review and synthesis of the literature in the introduction section. There are many other articles (including those in HIV/AIDS and in school settings) that discuss the degree to which EBIs are or are not implemented with fidelity and individual implementers’ characteristics associated with full/moderate/low implementation of EBIs. The authors need to make a stronger argument for how this study makes a unique contribution to the literature above and beyond what we already know about fidelity and its association with implementer characteristics.

Response 18: We agree with the reviewer and have summarized findings regarding the association between implementation and outcomes (please also see our responses 1 and 2 to reviewer #1).

“A recent systematic review reveals that a majority of studies have found that higher implementation dose and/or implementation fidelity are associated with better program outcomes [23]. Blakely and colleagues conducted a comprehensive examination of fidelity and effectiveness assessing seven nationally disseminated education and criminal justice projects and found that implementations conducted with high-fidelity were more effective than low-fidelity implementations [24]. Other studies have found that evidence-based programs can result in minimal or null effects if delivered with poor quality [14]. An evaluation of 14 school-based anti-bullying programs found that the majority of programs yielded non-significant outcomes on measures of self-reported victimization and bullying [25]. Derzon et al. assessed intervention effectiveness of drug prevention programs and found no significant effect on drug use among program participants [26]. These studies suggest that inadequate program delivery may overshadow the potential impact of prevention programs [25,26].” (Please page 5, lines 14-23; page 6, lines 1-2)

We also now discuss the contribution of our paper to the literature:

“The literature systematically identifying implementation patterns by teachers of effective HIV prevention programs in schools settings is sparse... The current study seeks to fill this research gap by identifying teachers’ implementation patterns using cluster analysis and relating implementation patterns to student outcomes.” (Please also see our response 1 to reviewer #1)

--The authors may consider providing definitions of (and appropriate citations for) their terms, including sustained implementation. Is there a particular timeframe for which the authors are using to conceptualize sustained implementation (e.g., implement core components for more than 1 year?) vs. actual or full implementation? The literature of sustainability may be useful here in making a distinction between sustainability and full implementation.
**Response 19:** We have now changed the term “sustained implementation” to “Implementation dose” throughout the text (please also see our response 3 to reviewer #1).

--*I think one of the strengths of the manuscript is students’ reported outcomes. The authors may consider streamlining the focus of their manuscript to emphasize this a bit more.*

**Response 20:** We agree and now emphasize the association of teachers’ implementation patterns and student outcomes in the introduction and discussion.

“Our study reveals that quality of implementation was significantly related to student outcomes (better implementation leads to better outcomes). Students whose teachers were in the High and/or Moderate Implementation Groups demonstrated greater improvements in three student outcomes (knowledge, skills and intention) compared to students whose teachers belonged to the Low Implementation Group. Students whose teachers were in the High Implementation Group demonstrated greater improvements in HIV/AIDS knowledge and reproductive health skills compared to students whose teachers belonged to the Moderate Implementation Group. These findings are consistent with previous research suggesting that implementation dose and implementation fidelity influences program outcomes [23].” (Please also see our response 7)