Reviewer’s report

Title: A Childhood Immunization Education Program for Parents Delivered during Late Pregnancy and One-month Postpartum: A Randomized Controlled Trial

Version: 0 Date: 11 Jun 2019

Reviewer: Matthew F. Daley

Reviewer's report:

General comments:

1. The authors present the findings of a randomized controlled trial of the effectiveness of two educational sessions (one during pregnancy, one at one month of age) at improving immunization receipt. The primary outcome was self-reported hepatitis B vaccination at 2 months of age, a vaccine considered "optional" in Japan at the time of the study.

2. The topic is important, and the methods are appropriate to the question of interest.

3. This is a revision of a previously submitted manuscript; the authors appear to have addressed the majority of the issues raised by the prior reviewers.

4. Because of the large effect observed, I am going to speculate that "optional" vaccines are often ignored or de-emphasized in vaccination conversations in Japan for infants?

Specific comments:

Title:

5. Good, although it may be helpful to include the timing of the intervention, such as "delivered during pregnancy and early infancy."
Abstract

6. The phrase "vaccinations required under law are nevertheless voluntary" seems redundant with the immediately prior phrase.

7. Results in abstract: for the knowledge and literacy scores, it is not clear what the numbers represent. These are scores on a 10-point composite scale?

8. Are hepatitis B and rotavirus vaccines "recommended but optional?"

9. Were immunization rates self-reported on the follow-up survey? If so, please describe as self-reported in the abstract.

Introduction

10. The introduction is well-written; however, it may be possible to shorten it while emphasizing the most important points.

Methods

11. I was confused by the sentence: "Participants assigned to the intervention group were provided with the guidebook and infant immunization schedule prior to the intervention after group assignment." This wasn't provided during the first educational session?

12. I am not familiar with assessing knowledge using a 3-point Likert scale. Does this produce valid, reproducible results?

13. Analyses: Assuming that hepatitis B vaccination was the primary study outcome, what was the analytical method to determine the effectiveness of the intervention? A Fisher's exact test, without controlling for any covariates?

Results

14. Clearly written

15. Excellent survey response rate.
Discussion

16. Regarding the sentence: "Intent among parents to immunize their child is a clear predictor of actual vaccination." While I agree in general, it is important to recognize that intention does not always predict behavior.

17. Regarding the sentence: "Health literacy was higher…" Does this refer to immunization-specific health literacy?

18. Regarding the sentence: "The main reason was that immunization education was sufficient for involving fathers in shared decision-making on optional childhood vaccinations." Do the authors have quantitative data to support this statement, or is it speculation?

Competing interests

19. Appropriately acknowledged

Human subjects research protections

20. Appropriately acknowledged

Tables and Figures

21. Table 2: please consider adding "self-reported" to the title.

References

22. There are several content and formatting issues with the references. For example, it is helpful to provide the Access Date for internet references.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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