Date: Apr 11, 2019
To: "Lori Cory" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-390

RE: Manuscript Number ONG-19-390

The Impact of Educational Interventions on Human Papillomavirus Vaccine Acceptability: A Randomized Controlled Trial

Dear Dr. Cory:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by May 02, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This is a RCT for evaluation of the impact of educational activity on HPV vaccine acceptability (NCT03337269). The study showed that targeted educational interventions increase HPV vaccine acceptability and knowledge among young women. The study did an exploratory qualitative research to identify the problem and the best educational materials.

Main issues:

1- This paper included 2 studies, both are well designed and well presented. Please consider providing more information about the rationale for the 2 studies in the method section.

2- Table 2 show some significant differences between the 3 groups in education and income levels, please consider adding a multi-variable regression to address these potential confounders' effects on the outcome

Specific issue:

3- Title and abstract: please include some reference to the exploratory part of the study if possible

4- Introduction: well written

5- Methods:
a. Did the authors used a validated questions about the knowledge and acceptability? Please include references if possible
b. Line 121: please include number of participant and selection in the result section
c. In the introduction, authors suggested that this study target population was minorities. However in the methods; I did not see any specific selection criteria that matches this. Please explain

6- Results:
a. Please consider adding a multivariable regression to adjust for potential confounders between the 3 groups (e.g. educational level and income)
b. Table 2: Please include the p values for comparing the demographic at baseline
c. Figure 1: why did the educational video group have more subjects?
d. Please add Supplement table B to the main manuscript tables

7- Discussion:

a. Can be shorter
b. Please consider adding some emphasis on the HPV vaccinations in minority and how the results of this paper applies to the US population

Reviewer #2: This is a well done educational intervention study by Cory and colleagues. The novel finding of the study is that a video intervention was helpful in learning and lead to a increased willingness to be vaccinated. I have no major criticisms. One potential strength of the study that the authors do not acknowledge is their use of the exploratory phase to drive the educational materials. The author do not review other similar interventions on the acceptance of the HPV vaccine. This topic should be reviewed briefly in the discussion.

Reviewer #3:

1. This is a "Randomized Controlled Trial" (a definition which although possibly technically correct, I find overstated and possibly misleading), in which the authors attempt to assess the impact of "targeted educational interventions" upon HPV vaccine "ACCEPTABILITY and knowledge among young women".

2. The authors are correct in identifying that vaccines which are 98% effective at preventing strain-specific HPV related high-grade cervical intraepithelial neoplasia, are not widely utilized. Regretfully, as correctly referenced by the authors the CDC National Immunization Survey - Teen 2016 found that vaccine uptake has been suboptimal, with only 65.1% and 43% of females aged 13 to 17 receiving 1 or 3 doses of the HPV vaccine, respectively (reference # 6).

3. A more appropriate / pertinent, and clinically significant outcome parameter would have been subsequent COMPLETION of HPV vaccination ("HPV vaccine uptake") and not "ACCEPTABILITY", as the latter is a vague, non committing, theoretical parameter.

4. While any effort to increase patient acceptance / completion of a validated vaccination course approved by governing bodies (CDC, ACOG, SGO), is beneficial, I am not surprised that following considerable measures to increase patient understanding, "acceptance" of this preventive modality of a potentially lethal condition, is increased, yet as mentioned above, "ACCEPTABILITY" does not infer / prove completion of this vaccination the ultimate (and only clinical significant) outcome parameter.

5. In my assessment, this study entails considerable drawbacks / limitations (noted by the authors themselves - see lines 288 - 290), namely potential election bias and generalizability. In my opinion the authors would have been better served in selecting a different population not entailing these concerns. I also believe that in order to achieve wider acceptance, measures far beyond local efforts are warranted, possibly at a Local, State or National / Federal level.

6. I would avoid speculative statements such as "It would seem most relevant to focus ongoing efforts in improving vaccine acceptability etc.. " (see lines # 268-270) and "Effort to improve education regarding the prophylactic HPV vaccine may increase acceptability, knowledge and subsequent uptake" (see lines # 292-293).

7. I suggest that the authors avoid promissory statements such as those detailed in the final paragraph (see lines # 295-298).

8. I agree with the authors comment regarding the likelihood that participants may have already refused the vaccine (see line # 287), and thus have a strong predilection to decline the vaccine. This concern in my assessment should have resulted in a different stud design, targeting women without previous exposure to HPV vaccine promotion campaigns.

9. The second sentence / statement in the Abstract Conclusion (see lines # 69 -70), reflects the clear inherent weakness of this study. Completion of a HPV vaccination series is the true ultimate objective, not ""HPV vaccine acceptability". See previous point #3.

10. In my assessment, the authors might be better served by submission of this study to Journal oriented to Public / Community Health and or Epidemiology.

STATISTICAL EDITOR'S COMMENTS:

1. lines 60-61: Since the groups were randomized, why would there be any expectation of baseline differences?

2. lines 159-163 and general: The primary aim was properly designated and powered to compare two interventions for detection of a 20% difference in vaccine acceptability. That should be more explicitly and prominently shown as the primary outcome in the Results and Tables. Other analyses are secondary outcomes and should have less prominence.

3. Table 2 (subject demographics), should be the first Table. For the footnote, there are no "otherwise specified", so that is not needed.

4. There are no stats tests (nor should there be, since these groups were randomized) and therefore there is no need to cited stats tests.

5. Table 1: As stated above, this Table should be later in order and all of these are secondary outcomes. Again, there are no "otherwise specified".

6. Table 3: It appears that all entries are either n(%) or median(IQR), not mean(SD). Again, these are all secondary outcomes and should come after the primary outcome (vaccine acceptance).

7. Fig 1: The women who declined participation were a relatively small group, but did they have demographic characteristics that might have limited generalizability of the analysis? A significant proportion of eligible women were excluded because they had initiated or completed HPV vaccination. Therefore it should be made clearer that these proportions and conclusions were conditional. That is, this does not necessarily represent the results from all women, but rather women who had not already elected to receive HPV vaccine.

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

3. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the Methods section.

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

6. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

7. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

* All financial support of the study must be acknowledged.
* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.

* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

8. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

9. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here: http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf. Please edit your abstract as needed.

10. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com /ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

11. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

12. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

13. The Journal's Production Editor had the following to say about the figures in your manuscript:

"Please add a figure legend to your manuscript. You may place it after "

When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce.

14. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at http://links.lww.com/LWW-ES/A48. The cost for publishing an article as open access can be found at http://edmgr.ovid.com/acd/accounts/ifauth.htm.

Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

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If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to

each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by May 02, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

_____

May 1, 2019

Lori Cory, MD
[redacted]

Obstetrics & Gynecology
Editorial Office
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Washington, DC 20024-2188
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Fax: 202-479-0830

Re: Revisions for Manuscript Number ONG-19-390

Dear Editor,

Thank you for reviewing our original manuscript, "The Impact of Educational Interventions on Human Papillomavirus Vaccine Acceptability: A Randomized Controlled Trial" for consideration of publication in *Obstetrics & Gynecology*. We have carefully reviewed the comments and critiques of each referee and editor. Each comment has been addressed below and organized by the originating referee or editor. Changes have also been highlighted within the attached manuscript using the "track changes" function.

All authors, including Beda Cha; Susan Ellenberg, PhD; Hillary R Bogner, MD MSCE; Wei-Ting Hwang, PhD; Jennifer S. Smith, PhD; Ashley Haggerty, MD MSCE; Mark Morgan, MD; Robert Burger, MD; Christina Chu, MD; Emily Ko, MD MSCR and myself have reviewed and provided approval of the revised version to be published. As the lead author, I affirm that this revised manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Thank you for consideration of this revised manuscript.

Sincerely,

Lori Cory, MD

Reviewer #1:

This is a RCT for evaluation of the impact of educational activity on HPV vaccine acceptability (NCT03337269). The study showed that targeted educational interventions increase HPV vaccine acceptability and knowledge among young women. The study did an exploratory qualitative research to identify the problem and the best educational materials.

Main issues:

1. This paper included 2 studies. Both are well designed and well presented. Please consider providing more information about the rationale for the 2 studies in the method section.

   The methods section now starts with the following, "An exploratory phase of this study was first completed in order to explore barriers and motivators to vaccine uptake in order to facilitate the later development of targeted interventions aimed at increasing HPV vaccine acceptability."

2. Table 2 show some significant differences between the 3 groups in education and income levels. Please consider adding a multi-variable regression to address these potential confounders' effects on the outcome.

   Although we agree with the statistical reviewer that performing hypothesis tests for differences in baseline variables is inappropriate in this case, we compared demographic characteristics between the three groups using a Kruskal-Wallis test (continuous variables) or Wald X^2 test (categorical variables) to ensure that our randomization was successful in that demographic characteristics were equally distributed among groups. No statistically significant differences were found among demographic characteristics between groups and the differences among treatment groups are well within the bounds of expected variability. Given similar demographic distribution across study arms, we do not believe there were any variables to adjust for within a multivariable regression analysis. While the p-values were not presented in "Table 2: Subject Demographics in the RCT by Intervention Arm" (original submission) given the randomized controlled trial design, p-values are provided below as a reference to the reviewers.

Table 2: Subject Demographics in the RCT by Intervention Arm

Demographic	Control (n=85)	Handout (n=84)	Video (n=87)	*P**
Age (years)	22 (20-24)	23 (20-25)	23 (20-25)	.36
Race				
American Indian or Alaskan Native	0 (0.0)	1 (1.2)	2 (2.3)	
Asian	4 (4.7)	4 (4.8)	1 (1.1)	
Black	73 (85.8)	60 (71.4)	74 (85.1)	.27
Native Hawaiian or other Pacific Islander	0 (0.0)	2 (2.4)	1 (1.1)	
White	3 (3.5)	6 (7.1)	4 (4.5)	
Other	5 (5.9)	11 (13.1)	5 (5.7)	
Insurance				
Medicaid	67 (78.8)	69 (82.1)	68 (78.2)	.50
Commercial	15 (17.6)	9 (10.7)	12 (13.8)	
Unknown	3 (3.5)	6 (7.1)	7 (8.0)	
Number of children	1 (0-1)	1 (0-2)	1 (0-1)	.99
Education				
Elementary School	1 (1.2)	0 (0.0)	0 (0.0)	
Middle School	3 (3.6)	3 (3.6)	2 (2.4)	
High School	53 (63.1)	48 (57.8)	62 (72.9)	.36
College	15 (17.9)	15 (18.1)	8 (9.4)	
Graduate School	3 (3.6)	2 (2.4)	1 (1.2)	
Trade School	9 (10.7)	11 (13.2)	11 (12.9)	
Other	0 (0.0)	4 (4.8)	1 (1.2)	
Household income				
Less than $25,000	44 (51.8)	32 (38.1)	47 (54.0)	
$25,000 to <$50,000	9 (10.6)	17 (20.2)	16 (18.4)	.37
$50,000 to <$75,000	3 (3.5)	4 (4.8)	3 (3.5)	
Greater than or equal to $75,000	1 (1.2)	1 (1.2)	0 (0.0)	
Unsure	28 (32.9)	30 (35.7)	21 (24.1)	
Family History of Cervical Cancer				
Yes	4 (4.7)	5 (6.0)	6 (6.9)	.83
No	81 (95.3)	79 (94.0)	81 (93.1)	

Data are median (interquartile range) or n (%) unless otherwise specified.
* Corresponds to a Kruskal-Wallis test (continuous variables) or Wald X^2 test (categorical variables).

Specific issue:

3. Title and abstract: please include some reference to the exploratory part of the study, if possible.

   Due to character limitations on the title, we are unable to lengthen the current title of the paper. If the journal would allow for a lengthened title, we would be happy to include a reference to the exploratory part of the study within the title. However, we did modify the abstract to reference the exploratory phase. The methods section of the abstract now begins with: "An exploratory phase of the study was conducted in order to determine baseline acceptance of the prophylactic HPV vaccine and barriers to acceptance. Based on the results of that phase of the study, a randomized controlled trial of 256 women aged 12 to 26 at a single institution was completed."

4. Introduction: well written

   Thank you for taking the time to review our manuscript and provide comments.

5. Methods:

a. Did the authors used a validated questionnaire about the knowledge and acceptability? Please include references, if possible.

We did not use a validated questionnaire about knowledge and acceptability. To our knowledge, there is not a well-validated questionnaire about knowledge and acceptability of the HPV vaccine. The methods section that introduces the survey now includes the following statement: "At the time of study design and implementation, a well-validated questionnaire about knowledge and acceptability of the HPV vaccine did not exist."

b. Line 121: please include number of participants and selection in the result section.

The results section now includes the following statement: "Fifteen of the 200 survey participants were randomly selected to complete a semi-qualitative structured interview. Themes driving acceptance and non-acceptance of the prophylactic HPV vaccine were identified utilizing the semi-qualitative structured interviews of the exploratory phase (Supplement A)."

c. In the introduction, authors suggested that this study target population was minorities. However, in the methods; I did not see any specific selection criteria that matches this. Please explain.

There was not a specific inclusion criterion to be a minority for enrollment in this study. The study was, however, completed at university-based clinics that serve largely minority women. For this reason, the majority of women in the exploratory and randomized controlled trial phases of this study were minorities. We modified the methods section to clarify this with the following statement: "Following the development of these educational interventions, a single institution, randomized controlled trial was completed at Obstetrics and Gynecology clinics affiliated with the University of Pennsylvania Healthcare System that historically have primarily served minority women."

6. Results:
   a. Please consider adding a multivariable regression to adjust for potential confounders between the 3 groups (e.g. educational level and income).

Although we agree with the statistical reviewer that performing hypothesis tests for differences in baseline variables is inappropriate in this case, we compared demographic characteristics between the three groups using a Kruskal-Wallis test (continuous variables) or Wald X^2 test (categorical variables) to ensure that our randomization was successful in that demographic characteristics were equally distributed among groups. No statistically significant differences were found among demographic characteristics between groups and the differences among treatment groups are well within the bounds of expected variability. Given similar demographic distribution across study arms, we do not believe there were any variables to adjust for within a multivariable regression analysis. While the p-values were not presented in "Table 2: Subject Demographics in the RCT by Intervention Arm" (original submission) given the randomized controlled trial design, p-values are provided below as a reference to the reviewers.

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Data are median (interquartile range) or n (%) unless otherwise specified.
* Corresponds to a Kruskal-Wallis test (continuous variables) or Wald X^2 test (categorical variables).

b. Table 2: Please include the p values for comparing the demographic at baseline.

We did not include p-values in "Table 2: Subject Demographics in the RCT by Intervention Arm" (original submission) because these measured variables were randomized by design. As such, we know that any differences arose by chance. Nevertheless, there were no statistical differences between the groups when performing bivariable analyses to ensure adequacy of distribution of variables by randomization. The statistical editor later comments that no statistical tests should be included in this table and we agree with this statement.

c. Figure 1: why did the educational video group have more subjects?

A randomization table was generated using a statistical program prior to initiation of the randomized controlled trial. This table was followed until at least 84 subjects were enrolled in each of the three study arms, as pre-determined by the sample size calculation in order to detect a 20% difference in vaccine acceptability among arms. Utilizing this

randomization table resulted in the following distribution of subjects: control (n=85), educational handout (n=84) or educational video (n=87). Enrollment was concluded when each of the three arms had at least 84 subjects.

d. Please add Supplement Table B to the main manuscript tables.

Supplement B has been added to the main manuscript tables.

7. Discussion:
   a. Can be shorter.

An effort has been made to shorten the original discussion with additional emphasis and information included as recommended by this and other reviewers (please see track changes document).

b. Please consider adding some emphasis on the HPV vaccinations in minority and how the results of this paper applies to the US population.

The following has been added to the discussion addressing the relevance of this study to minority populations: "Previous studies have also demonstrated that racial disparities exist surrounding HPV vaccine knowledge[19] and have identified a need for ongoing efforts to decrease such healthcare disparities within the United States.[20]"

Reviewer #2:

This is a well done educational intervention study by Cory and colleagues. The novel finding of the study is that a video intervention was helpful in learning and led to an increased willingness to be vaccinated. I have no major criticisms. One potential strength of the study that the authors do not acknowledge is their use of the exploratory phase to drive the educational materials. The authors do not review other similar interventions on the acceptance of the HPV vaccine. This topic should be reviewed briefly in the discussion.

The discussion now includes a statement on the cited strength as follows, "Additionally, the exploratory phase was utilized to identify themes driving non-acceptance of the vaccine and to guide development of educational interventions."

Regarding other interventions, the following has now been including in the discussion: "While previous studies have demonstrated that educational interventions (i.e. in-person talks, videos) can increase knowledge and, in some cases, acceptability of the HPV vaccine, they have not utilized targeted interventions and have not compared multiple educational interventions to determine which is most effective.[16-18]".

Reviewer #3:

1. This is a "Randomized Controlled Trial" (a definition which although possibly technically correct, I find overstated and possibly misleading), in which the authors attempt to assess the impact of "targeted educational interventions" upon HPV vaccine "ACCEPTABILITY and knowledge among young women".

The terminology of randomized controlled trial was used as the subjects were randomized to one of three intervention arms to allow for a comparison of the impact of different educational

interventions on HPV vaccine acceptability and knowledge. The first phase of the study was exploratory in nature and used largely to guide the development of educational interventions for the randomized controlled trial phase. An effort was made throughout the manuscript to distinguish the two separate phases of the study and identify that the exploratory phase was completed to identify the needs of educational interventions. In order to further clarify this, the methods section now includes the following: "An exploratory phase of this study was first completed in order to explore barriers and motivators to vaccine uptake in order to facilitate the later development of targeted interventions aimed at increasing HPV vaccine acceptability."

2. The authors are correct in identifying that vaccines which are 98% effective at preventing strain-specific HPV related high-grade cervical intraepithelial neoplasia, are not widely utilized. Regretfully, as correctly referenced by the authors the CDC National Immunization Survey - Teen 2016 found that vaccine uptake has been suboptimal, with only 65.1% and 43% of females aged 13 to 17 receiving 1 or 3 doses of the HPV vaccine, respectively (reference # 6).

   Thank you for taking the time to review our manuscript and provide comments.

3. A more appropriate / pertinent, and clinically significant outcome parameter would have been subsequent COMPLETION of HPV vaccination ("HPV vaccine uptake") and not "ACCEPTABILITY", as the latter is a vague, non-committing, theoretical parameter.

   As acknowledged in the discussion of the paper, we agree that additional efforts should focus on increasing initiation and completion of the vaccine series. However, the aim of this study was to determine the impact of educational interventions on HPV vaccine acceptability and knowledge. It is the hope of our team that this manuscript will inform future studies assessing the impact of such interventions on vaccine uptake. We believe that the information presented in this study can aide in the further development, implementation and assessment of interventions to increase vaccine uptake.

4. While any effort to increase patient acceptance / completion of a validated vaccination course approved by governing bodies (CDC, ACOG, SGO), is beneficial, I am not surprised that following considerable measures to increase patient understanding, "acceptance" of this preventive modality of a potentially lethal condition, is increased, yet as mentioned above, "ACCEPTABILITY" does not infer / prove completion of this vaccination the ultimate (and only clinical significant) outcome parameter.

   Please see response to comment #3.

5. In my assessment, this study entails considerable drawbacks / limitations (noted by the authors themselves - see lines 288 - 290), namely potential election bias and generalizability. In my opinion the authors would have been better served in selecting a different population not entailing these concerns. I also believe that in order to achieve wider acceptance, measures far beyond local efforts are warranted, possibly at a Local, State or National / Federal level.

   While we acknowledge that selection bias may exist in that the enrolled women may have a strong predilection towards non-acceptance of the vaccine, we believe that it is still important to educate these women on the HPV vaccine in order to improve acceptability and knowledge. As outlined in the paper, minority women and those of low socioeconomic status (who comprise the majority of our study population) are vulnerable to HPV infection and vaccine non-receipt. As such, we feel it is important to understand why these women remain at risk and to develop interventions

specific to their needs. Similar to offering smoking cessation counseling to patients who smoke on more than one occasion, we believe there is a group of women who may need additional education regarding the vaccine.

Additionally, while we agree that State or National/Federal efforts may be important in obtaining wider acceptance, these efforts have not yet achieved optimal acceptance/uptake and, as such, we think it is equally important to explore alternative efforts while still pursuing these State or National/Federal efforts. In other words, in light of the lack of widespread success of National/Federal campaigns, very personal and local efforts are what may ultimately prove to be the most effective in increasing HPV vaccine acceptability and uptake. In fact, studies have demonstrated the relative ineffectiveness of governmental messages in influenza vaccine uptake (Telford R and Rogers A. What influences elderly peoples' decisions about whether to accept the influenza vaccination? A qualitative study. Health Education Research 2003; 18(6): 743–753) and mistrust of national recommendations as a reason for vaccine non-acceptance (MacDougall DM, Halperin BA, MacKinnon-Cameron D, et al. The challenge of vaccinating adults: attitudes and beliefs of the Canadian public and healthcare providers. BMJ Open 2015; 5:e009062). In contrast, several studies have identified personalized care and one-on-one interactions with providers as factors in willingness to get vaccinated (Taylor JA, Darden PM, Slora E, Hasemeier CM, Asmussen L, Wasserman R. The influence of provider behavior, parental characteristics, and a public policy initiative on the immunization status of children followed by private pediatricians: a study from Pediatric Research in Office Settings. Pediatrics 1997;99(2):209-215; Kennedy A, Basket M, Sheedy K. Vaccine attitudes, concerns, and information sources reported by parents of young children: results from the 2009 HealthStyles survey. Pediatrics 2011;127(suppl 1):S92-S99; Yeung M, Lam F, Coker R. Factors associated with the uptake of seasonal influenza vaccination in adults: a systematic review. Journal of Public Health 2016; 38 (4): 746-753).

6. I would avoid speculative statements such as "It would seem most relevant to focus ongoing efforts in improving vaccine acceptability, etc." (see lines # 268-270) and "Effort to improve education regarding the prophylactic HPV vaccine may increase acceptability, knowledge and subsequent uptake" (see lines # 292-293).

   These statements have been modified as follows:

   - *Lines 268 – 270 (original manuscript) now read: "Additional efforts are needed to determine if such interventions can increase prophylactic HPV vaccine uptake among this population in order to decrease disparities among women receiving the HPV vaccine." We have emphasized the importance of assessing the efficacy of such interventions on vaccine uptake in order to help address the reviewer's concern that vaccine uptake is the more important outcome.*
   - *Lines 292-293: This statement has been removed from the manuscript.*

7. I suggest that the authors avoid promissory statements such as those detailed in the final paragraph (see lines # 295-298).

   This statement has been removed from the manuscript.

8. I agree with the authors comment regarding the likelihood that participants may have already refused the vaccine (see line # 287), and thus have a strong predilection to decline the vaccine.

This concern in my assessment should have resulted in a different study design, targeting women without previous exposure to HPV vaccine promotion campaigns.

When looking to increase vaccine acceptance (and ultimately uptake) among a population we feel it is critically important to gain a better understanding of why women are currently declining the vaccine and assess if interventions can be effective in targeting reasons for non-acceptance. In other words, in order to increase vaccine acceptance among a population, it is important to target those women currently not willing to accept the vaccine. As such, we think the population enrolled in this study (i.e. those who may have a strong predilection to decline the vaccine) may provide information important to increasing vaccine acceptance on a larger scale.

9. The second sentence / statement in the Abstract Conclusion (see lines # 69 -70), reflects the clear inherent weakness of this study. Completion of a HPV vaccination series is the true ultimate objective, not ""HPV vaccine acceptability". See previous point #3.

   This study was intended to assess the potential of our interventions to improve willingness to take the vaccine. We agree that the ultimate goal is to improve vaccine uptake, but we believe our findings are an important step toward that goal. We have made adjustments to the manuscript as outlined above to emphasize that future studies should focus on the efficacy of educational interventions in increasing vaccine series uptake and completion.

10. In my assessment, the authors might be better served by submission of this study to Journal oriented to Public / Community Health and or Epidemiology.

    We feel that this topic is most important for obstetricians and gynecologists who are often on the "front lines" discussing HPV infection and vaccination with patients. With a national crisis of sub-optimal vaccination rates, we believe that it is important to equip obstetricians and gynecologists with the information and tools necessary to effectively discuss and educate women on the HPV vaccine.

Editorial Comments – Statistical Editor:

1. Lines 60-61: Since the groups were randomized, why would there be any expectation of baseline differences?

   This statement has been removed from the manuscript.

2. Lines 159-163 and general: The primary aim was properly designated and powered to compare two interventions for detection of a 20% difference in vaccine acceptability. That should be more explicitly and prominently shown as the primary outcome in the Results and Tables. Other analyses are secondary outcomes and should have less prominence.

   A separate table (Table 4, revised manuscript) now highlights the results of the impact of educational interventions on vaccine acceptability.

3. Table 2 (subject demographics), should be the first Table. For the footnote, there are no "otherwise specified", so that is not needed.

   The tables have been rearranged as follows:

Table 1: Subject demographics for the exploratory phase
Table 2: Vaccine knowledge by acceptor status in the exploratory phase
Table 3: Subject demographics for the randomized controlled trial phase
Table 4: Prophylactic Human Papillomavirus Vaccine acceptance and utility of educational interventions by intervention arm
Table 5: Vaccine knowledge by study arm in the randomized controlled trial phase

For the footnote, "otherwise specified" has been removed. Tables are ordered sequentially as they are introduced in the manuscript with data from the exploratory phase introduced prior to data from the randomized controlled trial phase.

4. There are no stats tests (nor should there be, since these groups were randomized) and therefore there is no need to cited stats tests.

   This has been removed from the table footnote.

5. Table 1: As stated above, this Table should be later in order and all of these are secondary outcomes. Again, there are no "otherwise specified".

   Tables have been re-organized. Tables are ordered sequentially as they are introduced in the manuscript with data from the exploratory phase introduced prior to data from the randomized controlled trial phase as follows:

   Table 1: Subject demographics for the exploratory phase
   Table 2: Vaccine knowledge by acceptor status in the exploratory phase
   Table 3: Subject demographics for the randomized controlled trial phase
   Table 4: Prophylactic Human Papillomavirus Vaccine acceptance and utility of educational interventions by intervention arm
   Table 5: Vaccine knowledge by study arm in the randomized controlled trial phase

   The statement "otherwise specified" has been removed from the table footnote.

6. Table 3: It appears that all entries are either n (%) or median (IQR), not mean (SD). Again, these are all secondary outcomes and should come after the primary outcome (vaccine acceptance).

   Tables have been re-organized as previously outlined. Table 3 (original manuscript) is now Table 5 (revised manuscript) so that it follows data on the primary outcome (vaccine acceptance). Additionally, the footnote has been revised to read: "Data are median (interquartile range) or n (%)."

7. Fig 1: The women who declined participation were a relatively small group, but did they have demographic characteristics that might have limited generalizability of the analysis? A significant proportion of eligible women were excluded because they had initiated or completed HPV vaccination. Therefore, it should be made clearer that these proportions and conclusions were conditional. That is, this does not necessarily represent the results from all women, but rather women who had not already elected to receive HPV vaccine.

We unfortunately do not have demographic data on women who declined to participate, as we did not have IRB approval to collect data on individuals who did not consent to participate in the study. As such, it is difficult to comment on if this group may limit generalizability. Regarding women who were excluded due to prior initiation or completion of the vaccine series, prior initiation or completion of the HPV vaccine series is listed as an exclusion criterion within the methods section. To further highlight this in the figure, the box on excluded women is characterized by those who declined versus those who met exclusion criteria (and which specific criterion they met).

Editorial Office Comments:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

   OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

   Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

   Myself and co-authors are aware of this new process.

3. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the Methods section.

   Not applicable. We do not believe the current study meets the criteria for a clinical trial as outlined below:

   a. *Does the study involve human participants? Yes*
   b. *Are the participants prospectively assigned to an intervention? Yes*

c. *Is the study designed to evaluate the effect of the intervention on the participants? Yes*
d. *Is the effect being evaluated a health-related biomedical or behavioral outcome? No – the effect being evaluated is an opinion of whether or not they would be willing to accept the HPV vaccine (we do not believe that this fulfills the NIH definition of a health-related biomedical or behavioral outcome).*

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

   There are no issues with utilization of the reVITALize definitions.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

   Our manuscript meets the limitations as outlined:
   Pages: 21
   Words: 3,802

6. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

   The main title "The Impact of Educational Interventions on Human Papillomavirus Vaccine Acceptability" is 85 characters with spaces. A separate subtitle, "A Randomized Controlled Trial" is also included.

7. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:
   * All financial support of the study must be acknowledged.
   * Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
   * All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions.

Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

These rules have been followed.

8. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

   In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

   These guidelines have been followed. The word count of the abstract is 297 words.

9. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here: http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf. Please edit your abstract as needed.

   The abstract has been edited as needed to follow the journal guideline.

10. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

    Only standard abbreviations have been used and are spelled out the first time they are used.

11. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

    The manuscript itself does not contain the virgule symbol. It is used in the references as part of a article title referenced.

12. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

    Tables have been edited as needed to comply with journal guidelines.

13. The Journal's Production Editor had the following to say about the figures in your manuscript:

    "Please add a figure legend to your manuscript. You may place it after "

    A figure legend has been added after Figure 1.

    When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

    Not applicable.

    When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

    Not applicable.

    If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

    Not applicable.

    Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

    Not applicable.

    Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce.

    Not applicable.

Daniel Mosier

From: Cory, Lori [redacted]
Sent: Wednesday, May 15, 2019 7:35 AM
To: Daniel Mosier
Subject: RE: Manuscript Revisions: ONG-19-390R1
Attachments: Cory, Lori - HPV Vaccine Acceptability Revision 5 14 19.docx

Mr. Mosier,

Thank you for your email. Please see comments highlighted below:

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes. We agree with the changes made throughout the manuscript.
2. LINE 6: The journal does not use "impact" to mean "effect" or "affect." This will be changed throughout your paper. If "Association With…" is more appropriate, please edit the paper accordingly. We agree with the changes made throughout the manuscript.
3. LINE 30: The following co-authors will need to complete our electronic Copyright Transfer Agreement, which was sent to them through Editorial Manager: Hillary Bogner, Jennifer S Smith. Drs. Bogner and Smith have been asked to complete the electronic Copyright Transfer Agreement. Both have agreed to complete this by the close of business on May 16, 2019.
4. LINE 231: Just clarifying since this is highlighted in the Discussion – it is a statistically sig difference between 33% and 28%? The p-value reported here is the global p-value for comparison of the three groups. To make this statement more clear, it has been edited as follows: "Women in the educational video arm reported the highest vaccine acceptance rates at 51.7% (n=45) compared with 33.3% (n=28) in the educational handout arm (p=.02) and 28.2% (n=24) in the control arm (p<.01).". Additionally, the corresponding statement in the discussion has been revised as follows: "Greater acceptability was reported among the educational video arm (51.7%, n=45) than among the educational handout arm (33.3%, n=28; p=0.02) and the control arm (28.2%, n=24; p<.01).". The abstract and Table 4 still report the global value.
5. LINE 376: For articles submitted to O&G after July 1, 2018, we require a data sharing statement indicating what we've listed here. Your answers may be different from what I've listed here. If so, please edit the responses accordingly. The answers are correct as listed.

Please let me know if there are any questions or concerns.

Thank you,

Lori Cory

_____
From: Daniel Mosier [dmosier@greenjournal.org]
Sent: Tuesday, May 14, 2019 3:23 PM
To: Cory, Lori
Subject: [External] Manuscript Revisions: ONG-19-390R1

Dear Dr. Cory,

Thank you for submitting your revised manuscript. It has been reviewed by the editor, and there are a few issues that must be addressed before we can consider your manuscript further:

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.

2. LINE 6: The journal does not use “impact” to mean “effect” or “affect.” This will be changed throughout your paper. If “Association With…” is more appropriate, please edit the paper accordingly

3. LINE 30: The following co-authors will need to complete our electronic Copyright Transfer Agreement, which was sent to them through Editorial Manager: Hillary Bogner, Jennifer S Smith

4. LINE 231: Just clarifying since this is highlighted in the Discussion – it is a statistically sig difference between 33% and 28%?

5. LINE 376: For articles submitted to O&G after July 1, 2018, we require a data sharing statement indicating what we’ve listed here. Your answers may be different from what I’ve listed here. If so, please edit the responses accordingly.

When revising, use the attached version of the manuscript. Leave the track changes on, and do not use the “Accept all Changes”

Please let me know if you have any questions. Your prompt response to these queries will be appreciated; please respond no later than COB on Thursday, May 16th.

Sincerely,
-Daniel Mosier

Daniel Mosier
Editorial Assistant
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Web: http://www.greenjournal.org<http://www.greenjournal.org/>

From: [redacted]
To: Denise Shields
Subject: Re: [External] RE: figure in your Green Journal manuscript (18-390R1)
Date: Wednesday, May 15, 2019 4:18:38 PM

Hi Denise,

Thanks for getting back to me. Looks good!

Lori

Sent from my iPhone

> On May 15, 2019, at 4:17 PM, Denise Shields <DShields@greenjournal.org> wrote:
>
> Hi Lori,
>
> Here is the edited figure. Please let me know if this looks okay.
>
> Thank you,
> Denise
>
> -----Original Message-----
> From: Cory, Lori [redacted]
> Sent: Thursday, May 9, 2019 12:15 PM
> To: Denise Shields <DShields@greenjournal.org>
> Subject: RE: figure in your Green Journal manuscript (18-390R1)
>
> Hi Denise,
>
> Thank you for your email. Would it make sense to adjust the figure as follows:
>
>
> * Move allocation to align with the block "Randomized"
> * Combine follow up and analysis together
>
> If you could let me know if you think that makes sense, I would really appreciate it.
>
> Thanks,
>
> Lori
> _____
> From: Denise Shields [DShields@greenjournal.org]
> Sent: Thursday, May 09, 2019 9:44 AM
> To: Cory, Lori
> Subject: [External] figure in your Green Journal manuscript (18-390R1)
>
> Re: "Effects of Educational Interventions on Human Papillomavirus Vaccine Acceptability: A Randomized Controlled Trial"
>
> Dear Dr. Cory,
>
> Your figure has been edited and is attached for your review. Please review the attachments CAREFULLY for any mistakes.
>

> PLEASE NOTE: Any changes to the figure must be made now. Changes made at later stages are expensive and time-consuming and may result in the delay of your article's publication.
>
> To avoid a delay, I would appreciate a reply no later than Monday, 5/13. Thank you for your help.
>
> Best,
> Denise
>
>
> Denise Shields
> Senior Manuscript Editor
> Obstetrics & Gynecology
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>
> <19-390R1 figure 1 (05-15-19 v3).pdf>