

OBSTETRICS & GYNECOLOGY



NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*
- Email correspondence between the editorial office and the authors*

**The corresponding author has opted to make this information publicly available.*

Personal or nonessential information may be redacted at the editor's discretion.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office:

obgyn@greenjournal.org.

Date: Aug 03, 2018
To: "Heidi Felix" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1255

RE: Manuscript Number ONG-18-1255

A Novel Colposcopy Task Trainer

Dear Dr. Felix:

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 Aug 24, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The procedures and instruments submission by Felix and Lannen describe a ballistic gelatin based task trainer for cervical colposcopy and provides an assessment of its content validity. The description of the model's construction is sufficiently thorough to allow for it to be easily reproduced. The limited assessment of its construct validity suggested it was a reasonable approximation of a real-life procedure and would be helpful in training. My specific comments are as follows:

1. The majority of the survey respondents were trainees. Only 4 were attending physicians. This is a low number. I recommend surveying additional providers with experience in colposcopy. In addition, a more complete description of their colposcopy experience is necessary to understand if they should be considered "experts". For example, if the four attendings had just graduated from residency they would have a different perspective than if they all had 20 or more years of colposcopy experience. Also, it appears as though all of the survey respondents are from the same institution; however, this should be more clearly stated.
2. There are no details on how the survey instrument was constructed. Was it simply created by one of the authors, or was it created based on consensus of a group of experts? Understanding the quality and completeness of the survey is necessary for the reader to appreciate the content validity of the trainer.
3. The model appears to be limited to the visual inspection of the cervix under magnification and identification of "aceto-white" change. This is only part of the colposcopy, which also involves biopsy of these sites. There is not assessment of the fidelity and usefulness of this part of the simulated procedures. Was the simulation of the biopsy not a part of the model's design? If so, assessments of haptic feel of the biopsy itself and the fidelity of the appearance of the biopsy site afterward are aspects of the model that should be included in the survey. If the model is not intended to replicate the biopsy portion of the colposcopy, this should be clearly stated. As this information is important for the readers to have when they consider whether to reproduce the model for their own use.

Reviewer #2: Wow what an incredible amount of work and the pictures look very realistic. I worry about the generalizability of this set up as it is unlikely that most faculty or teachers have the will to put this much effort into creating a model for cervical biopsies.

Does everyone have access to ballistics gel and how much does it cost? Can you use the crock pot for food after you put ballistics gel in it? It seems the other assembly is also quite extensive and would require tools that most amateurs don't have. Although the sausage model is not reusable, it is very inexpensive and requires little time to assemble. In addition to biopsies, you can simulate a LEEP on the sausage model. Are you able to use energy on your model?

Your sample size is very small and to put this much effort into a model, you would need to show improvement in practice and outcomes compared to other low fidelity models.

Reviewer #3: This is a creative use of equipment to train residents and medical students.

I have a few suggestions for revision:

1-in the introduction please update your comments about pap smears to include the use of HPV testing

2-please discuss further the exact educational goals of the simulator. My sense is that you are using it to teach learners how to manually navigate a colposcopic examination. How to take biopsies and to look through a colposcopy while holding a speculum, how to take directed biopsies while looking through a colposcopy and holding a speculum

3- You could consider a table with learning goals.

4- how would you rate achievement of the educational goals.

5- I don't think the trainer you describe replaces using colposcopic photos of lesions for learning of colposcopic evaluation of lesions. You should mention that

6- finally can you add a video of one of your learners using this simulator?

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. We still required a completed author agreement form from Amy Lannen. Please note:

a) Any material included in your submission that is not original or that you are not able to transfer copyright for must be listed under I.B on the first page of the author agreement form.

b) All authors must disclose any financial involvement that could represent potential conflicts of interest in an attachment to the author agreement form.

c) All authors must indicate their contributions to the submission by checking the applicable boxes on the author agreement form.

d) The role of authorship in Obstetrics & Gynecology is reserved for those individuals who meet the criteria recommended by the International Committee of Medical Journal Editors (ICMJE; <http://www.icmje.org>):

* Substantial contributions to the conception or design of the work;

OR

the acquisition, analysis, or interpretation of data for the work;

AND

* Drafting the work or revising it critically for important intellectual content;

AND

* Final approval of the version to be published;

AND

* Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The author agreement form is available online at <http://edmgr.ovid.com/ong/accounts/agreementform.pdf>. Signed forms should be scanned and uploaded into Editorial Manager with your other manuscript files. Any forms collected after your revision is submitted may be e-mailed to obgyn@greenjournal.org.

3. 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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at <http://links.lww.com/AOG/A515>, and the gynecology data definitions are available at <http://links.lww.com/AOG/A935>.

4. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Procedures and Instruments articles should not exceed 8 typed, double-spaced pages (2,000 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and appendixes).

Please limit your Introduction to 250 words and your Discussion to 750 words.

5. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with 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 signature on the journal's author agreement 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).

6. 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: Procedures and Instruments, 200 words. Please provide a word count.

7. 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.

8. 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.

9. 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.

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, that each author has given approval to the final form of the revision, and that the agreement form signed by each author and submitted with the initial version remains valid.

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 Aug 24, 2018, 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

If you would like your personal information to be removed from the database, please contact the publication office.

To Whom It May Concern,

We are submitting the attached article, "Novel Colposcopy Trainer", for consideration of publication in Obstetrics and Gynecology.

The lead author* affirms that this 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 (and, if relevant, registered) have been explained.

Respectfully submitted,

Heidi Felix, DHSc, MPAS, PA-C

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Response to reviewer comments (these have been addressed with the "Track changes" function in the manuscript):

Reviewer 1

1. The majority of the survey respondents were trainees. Only 4 were attending physicians. This is a low number. I recommend surveying additional providers with experience in colposcopy. In addition, a more complete description of their colposcopy experience is necessary to understand if they should be considered "experts". For example, if the four attendings had just graduated from residency they would have a different perspective than if they all had 20 or more years of colposcopy experience. Also, it appears as though all of the survey respondents are from the same institution; however, this should be more clearly stated.

- a. All available attendings that had 10 or more years of colposcopic experience reviewed the task trainer and were from the same institution.*
2. There are no details on how the survey instrument was constructed. Was it simply created by one of the authors, or was it created based on consensus of a group of experts? Understanding the quality and completeness of the survey is necessary for the reader to appreciate the content validity of the trainer.
 - a. The survey instrument was created by the author with input from one of the gynecology attendings.*
3. The model appears to be limited to the visual inspection of the cervix under magnification and identification of "aceto-white" change. This is only part of the colposcopy, which also involves biopsy of these sites. There is not assessment of the fidelity and usefulness of this part of the simulated procedures. Was the simulation of the biopsy not a part of the model's design? If so, assessments of haptic feel of the biopsy itself and the fidelity of the appearance of the biopsy site afterward are aspects of the model that should be included in the survey. If the model is not intended to replicate the biopsy portion of the colposcopy, this should be clearly stated. As this information is important for the readers to have when they consider whether to reproduce the model for their own use.
 - a. The model does allow for simulated biopsy. The methods section also has updated verbiage to better illustrate this concept. The simulation session goals have been incorporated into the manuscript to better illustrate this.*

Reviewer 2

1. Does everyone have access to ballistics gel and how much does it cost? Can you use the crock pot for food after you put ballistics gel in it? It seems the other assembly is also quite extensive and would require tools that most amateurs don't have. Although the sausage model is not reusable, it is very inexpensive and requires little time to assemble. In addition to biopsies, you can simulate a LEEP on the sausage model. Are you able to use energy on your model?
 - a. Ballistics gel is widely available and costs less than \$20 per pound. Our model weighs 0.5 ounces. We recommend dedicating a slow cooker to melting ballistics gel. This model is not appropriate for the demonstration of LEEP or for energy.*

Reviewer 3

1. In the introduction please update your comments about pap smears to include the use of HPV testing
 - a. A comment regarding HPV testing has been added in the introduction*

2. Please discuss further the exact educational goals of the simulator. My sense is that you are using it to teach learners how to manually navigate a colposcopic examination. How to take biopsies and to look through a colposcopy while holding a speculum, how to take directed biopsies while looking through a colposcopy and holding a speculum
 - a. *Educational goals have been added in the experience section: The learners participated in a simulation that included instruction on the use of a colposcope, getting accustomed to viewing through the lenses, holding the speculum, and performing biopsies under the colposcope.*
3. You could consider a table with learning goals.
 - a. *Verbiage was added as opposed to a separate table.*
4. How would you rate achievement of the educational goals.
 - a. *Achievement of goals: An attending was present with the learner to answer any questions and provide immediate feedback following completion of the simulation.*
5. I don't think the trainer you describe replaces using colposcopic photos of lesions for learning of colposcopic evaluation of lesions. You should mention that.
 - a. *A comment was made addressing photographic instruction of lesions: Use of this model can accompany other instructional methods, such as the review of normal and abnormal colposcopic photographic images.*
6. Finally can you add a video of one of your learners using this simulator?
 - a. *We would be happy to create a video.*

Daniel Mosier

From: Felix, Heidi M., DHSc, MPAS [REDACTED]
Sent: Monday, August 27, 2018 10:44 AM
To: Daniel Mosier
Subject: RE: Manuscript Revisions: ONG-18-1255R1
Attachments: 18-1255R1 ms (8-27-18v2).docx

Hello,

With regard to the title, we are fine with the new suggestion.

With regard to “improved fidelity” we are fine with the change to low-cost model as noted in the track changes.

I did make a change on line 155: it should be blacklight gel, not ballistics.

Thank you for your assistance!

Heidi M. Felix, DHSc, MPAS, PA-C

Assistant Professor of Medical Education, Mayo Clinic College of Medicine

Education Specialist, Simulation Center

Mayo Clinic Florida
[REDACTED]

From: Daniel Mosier [mailto:dmosier@greenjournal.org]
Sent: Monday, August 27, 2018 10:10 AM
To: Felix, Heidi M., DHSc, MPAS
Subject: [EXTERNAL] Manuscript Revisions: ONG-18-1255R1

Dear Dr. Felix,

Thank you for submitting your revised manuscript. While the Editors did not have any major queries for you and your co-authors, please do the following:

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
2. LINE 3: May we use a more specific title? How about, “A Colposcopy Trainer to Simulate Visualization and Biopsy of the Cervix”?
3. LINE 35: ‘Improved fidelity’ implies that the model improved performance of real colposcopy – which this study did not demonstrate

If you need to make additional changes, please use the attached version of the manuscript, leave the track changes on, and do not use the “Accept all Changes” function in Microsoft Word.

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 **Wednesday, August 29th**.

Sincerely,
-Daniel Mosier

Daniel Mosier
Editorial Assistant
Obstetrics & Gynecology

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From: [REDACTED]
To: [Stephanie Casway](mailto:Stephanie.Casway)
Subject: RE: O&G Art Query: 18-1255
Date: Wednesday, August 22, 2018 11:20:35 AM

Hello,

Figure 1 represents the PVC joint being outfitted into the pelvic trainer.

Figure 2 represents the ballistics gel cervix prior to being placed into the trainer.

Figure 3 represents the ballistics gel cervix in the end of the PVC cap prior to being placed in the trainer.

Figure 4 represents the speculum view of the cervix prior to colposcopic examination.

Figure 5 represents the colposcopic view of the cervix – bright spots represent the simulated “aceto-white” changes.

Please let me know if you need additional clarification.

Thank you!

Heidi M. Felix, DHSc, MPAS, PA-C

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

From: Stephanie Casway [mailto:SCasway@greenjournal.org]
Sent: Wednesday, August 22, 2018 9:53 AM
To: [REDACTED]
Subject: [EXTERNAL] O&G Art Query: 18-1255

Good Morning Dr. Felix,

We are currently in the process of reviewing the artwork for your manuscript, 18-1255. An editor has requested more detail in your figure legends. Could you please send me updated legends? Thank you so much for your help!

Figure 1. Pelvic trainer.

Figure 2. Cervix models.

Figure 3. Cervix.

Figure 4. Speculum examination.

Figure 5. Colposcopy.

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