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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

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RE: Manuscript Number ONG-22-541

Office hysteroscopy: implementation of a safe and feasible approach to the evaluation and treatment of intrauterine pathology

Dear Dr. Orlando:

Thank you for sending us your work for consideration for publication in Obstetrics & Gynecology. Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors would like to invite you to submit a revised version for further consideration.

If you wish to revise your manuscript, please read the following comments submitted by the reviewers and Editors. Each point raised requires a response, by either revising your manuscript or making a clear argument as to why no revision is needed in the cover letter.

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, STATISTICAL EDITOR COMMENTS (if applicable), and EDITORIAL OFFICE COMMENTS below. Your manuscript will be returned to you if a point-by-point response to each of these sections is not included.

The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting).

Your submission will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by May 17, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

I have reviewed the manuscript submitted for consideration for publication entitled "Office Hysteroscopy: implementation of a safe and feasible approach to the evaluation and treatment of intrauterine pathology" I found the manuscript interesting and extremely informative. However, I have the following considerations.

Line 191-193: I would recommend adding 2 important refences to the sentence "In light of these data, the use of blind D&C alone for the diagnosis or treatment of endometrial lesions should be abandoned". (Loffer FD PMID:30980989) (Ramshaw N PMID:31080752)

Line 217: There is no scientific evidence to support recommending procedure lasting "no more than 30 minutes" I would agree that in office procedures should be short but citing 30 minutes as the limit is speculative and not evidence based. I would limit to recommend "short procedures" without assigning time limit.

Line 222 to 238. Absolute contraindications to office hysteroscopy. I strongly disagree in stating that "viable intrauterine pregnancy" is an absolute contraindication. There is ample scientific evidence supporting the safety of hysteroscopic removal of retained IUD during pregnancy (Sanders PMID: 30503139) (Assaf PMID: 3213670) (Cohen PMID: 28461175) just to cite a few.

Line 225: Known uterine cancer is also NOT an absolute contraindication for hysteroscopy. The role of hysteroscopy in patients with desire of "uterine sparing treatment" of early endometrial cancer is well supported by scientific evidence (Garzon PMID: 332056) (Dong PMID:34155733)

Moreover, the authors contradict themselves stating known uterine cancer as an absolute contraindication to hysteroscopy and then stating in the last line of the same paragraph that "... in patients with leyomiosarcoma showed that hysteroscopy was associated with improved preoperative detection of malignancy" I would recommend to revise the entire paragraph of "Patient selection and counseling". The only "absolute" contraindication of hysteroscopy is known active uterine infection.
Line 243: Recommend changing "shortly after menstruation" for "during the early proliferative phase of the menstrual cycle"

Line 344: By definition, office hysteroscopy precludes the use of parenteral, regional or general anesthesia. Add reference to this sentence. In this manuscript is reference 12

Line 352: There is a typo: "with special attention PAIN to patients... The word pain should be deleted.

Line 353: Use of warmed instruments and heating pads, allowing space for a support person and the visit and practicing trauma-informed pelvic exam and gynecologic care. These interventions are NOT supported by evidence. I recommend deleting the entire sentence. Please define trauma-informed pelvic exam.

Line 413: The word "respectively" should be deleted.

Line 417: Intrauterine visibility and hysteroscopic view are redundant.

Line 421: "One or more operative channels" is not correct. There is no hysteroscope with more than 1 operative channel, those that have 2 channels, only one is operative, the other channel is only for outflow and do not accommodate instruments. All operative hysteroscopes have "only one" operative channel. The authors failed to mention the use of disposable hysteroscopes that are also very popular in clinical practice. I would recommend mentioning the disposable hysteroscopes as a valid alternative for in office hysteroscopy.

Line 544: "Placing a cold compress on the patient's forehead" This intervention for the treatment of vasovagal reaction is not supported by evidence.

Line 569: I would recommend adding the word "Prophylaxis" is not "routinely" indicated at the time of hysteroscopy, leaving the option opened in cases of chronic endometritis or hydrosalpinx in patients with infertility in which case its use is considered appropriate.

Line 618: I would change the word "excellent office reimbursement" to "adequate office reimbursement"

Also, the authors could consider adding a paragraph with "future applications" of hysteroscopy such as in the evaluation of the fallopian tube for the early detection of ovarian cancer and in Embryoscopy in which case, hysteroscopy in gaining a very important role.

Reviewer #2:

Review of Manuscript ONG-22-541 "Office hysteroscopy: implementation of a safe and feasible approach to the evaluation and treatment of intrauterine pathology"

A manuscript that is part of the Clinical Expert Series has been submitted whose stated purpose is to provide a comprehensive summary of the role and application of office hysteroscopy in modern gynecology. The authors have selected and provided cogent summaries for many of the issues one should consider as they continue and/or transition to office-based hysteroscopy. In addition, they have provided meaningful figures illustrating several key points. I have the following questions and comments.

Title - No comments.

Précis - No comments.

Abstract - Line 59 - How bout "...potentially averting..."?

Introduction - Line 104 - What about the role of both residency as well as ongoing education for this technique?

Line 161 - Please label the Table as Table 1 (see comments below).

Line 166-7 - Other options? Is one superior to the other or is this personal preference?

Line 225 - What about suspected uterine cancer - You do address this a bit later.

Line 270 - Which patients are these. Can you provide more information since this is a common challenge?

Line 390 - You previously commented on comparing sensitivity and the like with hysteroscopy and blind D&C. Does this hold true for newer and smaller instrumentation as well?
More than a century....

Not sure how I feel about the stethoscope comparison since it evaluates only a portion of gynecologic pathology whereas the stethoscope is seemingly fundamental to a much larger group of issues.

Tables - Table 1

Make this Table 1 - Consider creation of Table 2 with key salient details, checklist perhaps to mirror the topics you discussed?

Figures - No comments. All appropriate and informative.

EDITORIAL OFFICE COMMENTS:

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
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   * Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
   * Name the IRB or Ethics Committee institution in the Methods section (if applicable).
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Clinical Expert Series: 6,250

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* 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 or indicate whether the meeting was held virtually).
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* Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.

9. Provide a short title of no more than 45 characters, including spaces, for use as a running foot. Do not start the running title with an abbreviation.

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In addition, the abstract length should follow journal guidelines. Please provide a word count.

Clinical Expert Series: 250 words

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Please make sure your references are numbered in order of appearance in the text.

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

Again, your manuscript will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by May 17, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

John O. Schorge, MD
Deputy Editor, Gynecology

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

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Dear Editorial Board of Obstetrics and Gynecology:

Thank you for reviewing our manuscript. See below for responses and revisions to our Clinical Expert Series submission: “Office hysteroscopy: implementation of a safe and feasible approach to the evaluation and treatment of intrauterine pathology.” Please contact us with any remaining questions.

In addition, we did not receive comments on the video content uploaded and wanted to ensure this was received by the editorial board.

Sincerely,

Megan Orlando, MD  
Department of Obstetrics and Gynecology  
Women’s Health Institute  
Cleveland Clinic  
9500 Euclid Ave  
Cleveland, OH 44195

REVIEWER COMMENTS:

Reviewer #1:

I have reviewed the manuscript submitted for consideration for publication entitled "Office Hysteroscopy: implementation of a safe and feasible approach to the evaluation and treatment of intrauterine pathology" I found the manuscript interesting and extremely informative. However, I have the following considerations.

Line 191-193: I would recommend adding 2 important references to the sentence "In light of these data, the use of blind D&C alone for the diagnosis or treatment of endometrial lesions should be abandoned". (Loffer FD PMID:30980989) (Ramshaw N PMID:31080752)

We thank the reviewer for this comment and have added these references to the manuscript.

Line 217: There is no scientific evidence to support recommending procedure lasting "no more than 30 minutes" I would agree that in office procedures should be short but citing 30 minutes as the limit is speculative and not evidence based. I would limit to recommend "short procedures" without assigning time limit.

We appreciate this comment and have removed the above time limit from our recommendation. The sentence now reads, “We recommend selecting procedures with
an anticipated short duration to be performed in the office setting.” (Page 8, Line 238-239)

Line 222 to 238. Absolute contraindications to office hysteroscopy. I strongly disagree in stating that "viable intrauterine pregnancy" is an absolute contraindication. There is ample scientific evidence supporting the safety of hysteroscopic removal of retained IUD during pregnancy (Sanders PMID: 30503139) (Assaf PMID: 3213670) (Cohen PMID: 28461175) just to cite a few.

Line 225: Known uterine cancer is also NOT an absolute contraindication for hysteroscopy. The role of hysteroscopy in patients with desire of "uterine sparing treatment" of early endometrial cancer is well supported by scientific evidence (Garzon PMID: 332056) (Dong PMID:34155733)

Moreover, the authors contradict themselves stating known uterine cancer as an absolute contraindication to hysteroscopy and then stating in the last line of the same paragraph that "… in patients with leyomiosarcoma showed that hysteroscopy was associated with improved preoperative detection of malignancy" I would recommend to revise the entire paragraph of "Patient selection and counseling". The only "absolute" contraindication of hysteroscopy is known active uterine infection.

We thank the reviewer for these excellent points and have revised the paragraphs accordingly as below:

“There are few absolute contraindications to office hysteroscopy. These include active reproductive tract infection such as pelvic inflammatory disease or active or prodromal herpes infection. Pregnancy can be reliably excluded for most patients with a urine pregnancy test performed at the start of the office visit. Scheduling the procedure during the follicular phase of the patient’s cycle shortly after cessation of menses (see below) is also helpful. Pelvic inflammatory disease is diagnosed clinically, with characteristic signs and symptoms that include subacute onset of abdominal pain, mucopurulent cervical discharge, cervical erythema, and tenderness on bimanual examination. If active genital tract infection is suspected at the time of exam, hysteroscopy should be deferred due to risk of intraabdominal dissemination of infection through the uterine tubes.

Conversely, although dissemination of malignant cells has been proposed in cases of uterine malignancy, undergoing hysteroscopy is not associated with positive peritoneal cytology in early-stage endometrial cancer and does not impact prognosis. A 2021 meta-analysis investigating the use of hysteroscopy in the diagnosis of suspected endometrial cancer found that maintaining an intrauterine distension pressure below 80 mmHg is highly unlikely to result in positive peritoneal cytology. In fact, a 2021 retrospective cohort study involving patients with leiomyosarcoma showed that hysteroscopy was associated with improved preoperative detection of malignancy and greater likelihood of undergoing optimal surgical management.” (Page 8-9, Line 244-270)
Line 243: Recommend changing "shortly after menstruation" for "during the early proliferative phase of the menstrual cycle."

_We thank the reviewer for this comment. We prefer the simplified phrasing as is currently written in this sentence, and clarify the reviewer’s point in the following sentence regarding the early proliferative phase of the menstrual cycle: “This corresponds with the early proliferative phase of the uterus when the endometrial lining is thinnest.” (Page 9, Line 276-277)._

Line 344: By definition, office hysteroscopy precludes the use of parenteral, regional or general anesthesia. Add reference to this sentence. In this manuscript is reference 12.

_We have added the reference as recommended by the reviewer._

Line 352: There is a typo: "with special attention PAIN to patients… The word pain should be deleted.

_Thank you for this comment. We have edited so that the sentence now reads, “We recommend implementing baseline comfort measures for all patients, with special attention paid to patients with chronic pain conditions.” (Page 12, Line 407-409)._}

Line 353: Use of warmed instruments and heating pads, allowing space for a support person and the visit and practicing trauma-informed pelvic exam and gynecologic care. These interventions are NOT supported by evidence. I recommend deleting the entire sentence. Please define trauma-informed pelvic exam.

_We thank the reviewer this recommendation. We believe that these low-risk and low-resource suggestions may provide comfort to patients and are important to present. Given the lack of evidence mentioned, we have changed our language to be less prescriptive. We have also expanded upon our recommendation regarding trauma-informed care._

_“We suggest implementing baseline comfort measures for all patients, with special attention paid to those with chronic pain conditions. These can include warmed instruments, heating pads, music, guided visualization, transcutaneous electrical nerve stimulation (TENS), and allowing space for a support person at the visit if desired. We recommend practicing trauma-informed care, which incorporates practices to respect and aid trauma survivors in engaging with gynecologic care. These universal trauma precautions should include patient-centered communication and ensuring that patients have choices and control over how and when to undergo gynecologic exams.” (Page 13, Line 407-415)"

Line 413: The word "respectively" should be deleted.
We have amended the sentence as recommended by the reviewer.

Line 417: Intrauterine visibility and hysteroscopic view are redundant.

We have removed “intrauterine visibility” from the sentence, which now reads, “Although rigid hysteroscopes were associated with greater patient discomfort, they demonstrated improved hysteroscopic view and diagnostic accuracy.” (Page 14-15, Line 489-490)

Line 421: "One or more operative channels" is not correct. There is no hysteroscope with more than 1 operative channel, those that have 2 channels, only one is operative, the other channel is only for outflow and do not accommodate instruments. All operative hysteroscopes have "only one" operative channel.

We thank the reviewer for this point and have amended the sentence as follows: “Most operative hysteroscopes contain a rigid sheath and an operative channel. This allows for passage of various instruments such as scissors, graspers, and mechanical morcellators or tissue shavers.” (Page 15, Line 491-493).

The authors failed to mention the use of disposable hysteroscopes that are also very popular in clinical practice. I would recommend mentioning the disposable hysteroscopes as a valid alternative for in office hysteroscopy.

Thank you for this suggestion. We have added the following information regarding disposable hysteroscopes to this section: “Disposable, digital hysteroscopes are also available as an alternative to reusable instrumentation for office practice. These incorporate a single-use cannula with an image projected onto a hand-held viewing screen. Certain models contain an operative channel that can allow for visually-directed biopsy, polypectomy or foreign body removal.” (Page 15, Line 497-501)

Line 544: "Placing a cold compress on the patient's forehead" This intervention for the treatment of vasovagal reaction is not supported by evidence.

We have removed this statement from the above-mentioned sentence.

Line 569: I would recommend adding the word "Prophylaxis" is not "routinely" indicated at the time of hysteroscopy, leaving the option opened in cases of chronic endometritis or hydrosalpinx in patients with infertility in which case its use is considered appropriate.

We appreciate this suggestion and have amended the sentence to read, “Given the low rate of infection, limited evidence of benefit, and potential for adverse events, prophylactic antibiotics are not routinely indicated at the time of hysteroscopy.” (Page 20, Line 664-666)

Line 618: I would change the word "excellent office reimbursement" to "adequate office reimbursement"
We have changed this description as suggested by the reviewer.

Also, the authors could consider adding a paragraph with "future applications" of hysteroscopy such as in the evaluation of the fallopian tube for the early detection of ovarian cancer and in Embryoscopy in which case, hysteroscopy in gaining a very important role.

We appreciate this comment and have drafted a section entitled Future Applications, that details novel techniques of office hysteroscopy.

“Potential applications for office hysteroscopy continue to evolve with the emergence of new technologies and evidence. Novel approaches include the use of a hysteroscopic collection device to obtain cytologic sampling of the distal fallopian tubes to screen for ovarian cancer. The feasibility of this technique was demonstrated in a 2020 pilot study, which showed a 68% yield from visualized tubal ostia and high concordance with surgical pathology. Other proposed techniques for hysteroscopy include primary management of missed abortion, embryoscopy in cases of fetal anomalies, endometrial evaluation following missed abortion, and tubal patency assessment in cases of difficult cannulation. Further research is needed to investigate and establish the utility of these techniques.” (Page 21-22, Line 718-732)

Reviewer #2:

Review of Manuscript ONG-22-541 "Office hysteroscopy: implementation of a safe and feasible approach to the evaluation and treatment of intrauterine pathology"

A manuscript that is part of the Clinical Expert Series has been submitted whose stated purpose is to provide a comprehensive summary of the role and application of office hysteroscopy in modern gynecology. The authors have selected and provided cogent summaries for many of the issues one should consider as they continue and/or transition to office-based hysteroscopy. In addition, they have provided meaningful figures illustrating several key points. I have the following questions and comments.

Title - No comments.

Précis - No comments.

Abstract - Line 59 - How bout "...potentially averting..."?

We have edited the sentence as recommended by the reviewer.

Introduction - Line 104 - What about the role of both residency as well as ongoing education for this technique?
Thank you to the reviewer for this comment. We have added this point to both the Introduction and Strategies for implementation and cost effectiveness.

“In this review, we describe appropriate candidates, equipment, and techniques for office hysteroscopy. We aim to provide clinical pearls, address myths surrounding barriers to implementation, and suggest feasible strategies for developing an office-based hysteroscopy practice that is safe, simple, and cost-effective. We advocate for comprehensive residency training and continuous education for physicians in practice to increase access to office hysteroscopy broadly.” (Page 4, Line 104-109)

“We advocate for the integration of office hysteroscopy techniques into residency training. Once in practice, continuous education via simulation and apprenticeship models can aid individuals and the clinical team in staying up-to-date on new techniques.” (Page 21, Line 709-712)

Line 161 - Please label the Table as Table 1 (see comments below).

We appreciate the suggestion and have re-labeled the table as Table 1.

Line 166-7 - Other options? Is one superior to the other or is this personal preference?

Thank you to the reviewer for this question. We have edited the paragraph as below for clarity.

“For patients undergoing in vitro fertilization, hysteroscopy is considered the gold standard for diagnosing intrauterine pathologies, and may be especially important in cases of recurrent implantation failure or to investigate positive findings on transvaginal ultrasound, SIS, or hysterosalpingogram.7,16” (Page 6, Line 174-177)

Line 225 - What about suspected uterine cancer - You do address this a bit later.

We have edited this paragraph in accordance with recommendations by both reviewers and removed uterine malignancy as a contraindication. We provide additional information regarding the safety of hysteroscopy in early-stage or suspected endometrial cancer.

“Conversely, although dissemination of malignant cells has been proposed in cases of uterine malignancy, undergoing hysteroscopy is not associated with positive peritoneal cytology in early-stage endometrial cancer and does not impact prognosis.29,30 A 2021 meta-analysis investigating the use of hysteroscopy in the diagnosis of suspected endometrial cancer found that maintaining an intrauterine distension pressure below 80 mmHg is highly unlikely to result in positive peritoneal cytology.29 In fact, a 2021 retrospective cohort study involving patients with leiomyosarcoma showed that hysteroscopy was associated with improved preoperative detection of malignancy and greater likelihood of undergoing optimal surgical management.” (Page 9, Line 261-270)
Line 270 - Which patients are these. Can you provider more information since this is a common challenge?

We have re-ordered this paragraph to try to clarify which patients are at highest risk of cervical stenosis:

“Given that almost half of complications related to hysteroscopy are associated with difficulties with dilation,35,36 preoperative pharmacologic cervical softening or ripening may be considered for patients at highest risk of cervical stenosis. These include postmenopausal patients, those with a history of cervical stenosis, previous cesarean section or cervical surgery, and patients undergoing procedures with larger hysteroscopic devices ≥5mm in diameter. Cervical preparation may decrease peri-procedural discomfort and increase the likelihood of successful completion of the procedure.” (Page 10, Line 310-317).

Line 390 - You previously commented on comparing sensitivity and the like with hysteroscopy and blind D&C. Does this hold true for newer and smaller instrumentation as well?

Yes. We have amended the above-mentioned sentence for clarity and added two recent references that demonstrate the high accuracy of office hysteroscopy using miniaturized hysteroscopes.

“In particular, hysteroscopes <5mm in diameter appear to cause the least discomfort and maintain high diagnostic sensitivity.70–72” (Page 14, Line 461-461)

Line 618 - "More than a century….”

Thank you for noticing this mistake. We have edited the sentence as indicated.

Line 629 - Not sure how I feel about the stethoscope comparison since it evaluates only a portion of gynecologic pathology whereas the stethoscope is seemingly fundamental to a much larger group of issues.

We thank the reviewer for this comment. We believe that this comparison expresses the fundamental importance of hysteroscopy for the modern gynecologist. We have revised the sentence to better specify the utility in evaluating intrauterine health as follows: “As gynecologists, our hysteroscope is our stethoscope for evaluating intrauterine health.” (Page 22, Line 744-745).

Tables - Table - Make this Table 1 - Consider creation of Table 2 with key salient details, checklist perhaps to mirror the topics you discussed?
We thank the reviewer for this recommendation and have created a Table 2 as suggested, entitled Components of a safe and effective office hysteroscopy practice.

Figures - No comments. All appropriate and informative.

EDITORIAL OFFICE COMMENTS:

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.

We thank the editors for the information.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
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   * Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
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There was no funding, clinical trial registration, or IRB approval required for this manuscript.

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We believe this has been completed by all authors.

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We have ensured the use of person-first language throughout the manuscript.

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6. 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 data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

We have no problems with using the reVITALize definitions.

7. Make sure your manuscript meets the following word limit. The word limit includes the manuscript body text only (for example, the Introduction through the Discussion in Original Research manuscripts), and excludes the title page, précis, abstract, tables, boxes, and figure legends, reference list, and supplemental digital content. Figures are not included in the word count.

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We have acknowledged the illustrator for our manuscript, Erika Woodrum, in the acknowledgements section with written permission obtained.

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A short title has been added to the Title Page.

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We have removed this symbol except in measurement.

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We have changed all instances of the term “provider” in the manuscript as indicated except in the case of “insurance providers” on Page 21, line 693.

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We believe that the Tables conform to journal style, and are happy to revise as the Editors deem appropriate.

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References are numbered in order of appearance. We have removed one reference involving an unpublished data and cited this in on the line parentheses. We believe references conform to Obstetrics & Gynecology style, and can make edits as necessary.

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