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)*

**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: Sep 05, 2019
To: "Amanda J Poprzeczny" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-1429

RE: Manuscript Number ONG-19-1429

Patient decision aids to facilitate shared decision-making in obstetrics and gynecology: A systematic review and meta-analysis

Dear Dr. Poprzeczny:

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 Sep 26, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This a systematic review and meta-analysis designed to assess the effectiveness of patient decision aids to facilitate shared-decision making in OBGYN. 35 randomized controlled trails, reporting 9,790 women, were included. The patients decision aids spanned a wide area of clinical scenarios in OBGYN. When compared with usual clinical practice, the use of patient decision aids reduced decisional conflict and improved patient knowledge. There was no difference in patient anxiety or satisfaction. The authors conclude that patient decision aids are effective in facilitating shared decision making and should be used routinely in clinical practice to support patient centered care. Ways in which this manuscript could be improved include:

1. Lines 234-240: Do you worry about the heterogeneity of the types of study? I suppose not, but I would at least address the universality of the approach of patient aids. Other examples of similar studies?

2. Lines 282-284: I would give some more detail here. What evidence exists?

Reviewer #2: As a clinician, I found this manuscript difficult to review. With that said, I believe with the current climate of "shared decision making" emanating from our professional organizations, including ACOG, I find this review timely. The manuscript stresses two major points. The first, that "shared decision making" is very different for "informed decision making," bidirectional versus unidirectional. The second, that there is evidence within our specialty that "shared decision making" reduced decisional conflict, the primary outcome. It also increased patient knowledge, which should not be surprising. That it did not affect patient anxiety or patient satisfaction is of interest.
You did an excellent job of identifying strengths and weakness, foremost that all of the included studies were from "high-income" countries but were not able to stratify populations within the studies. This likely makes the results not applicable to "low-income" countries, as well as "low-income" populations within "high-income" countries.
There are statistical terms that may need elucidating, e.g. Jadad criteria. Table 1 is essential. Figure 1 is interesting but not essential. Figure 2 is essential. Appendix S1 in non-essential. Appendix S2 is interesting but not essential.
I recommend that the Study Selection sections be much abbreviated and clearer.

Reviewer #3: Thank you for a thoughtful and well-written systematic review on the impact that patient decision aids have in the field of obstetrics and gynecology. I think your findings are relevant and timely. I have a few questions and comments regarding your manuscript.

1. Line 159 - is there concern over the safety of patient decision aids? An additional reference might add to this statement.

2. Line 190 - consider adding a statement for readers who are less familiar with patient decision aids as to why you chose decisional conflict as your primary outcome

3. Line 230 - while interesting that the studies were completed in "high-income" countries, I wonder if this is relevant? A subgroup analysis of the populations included in each study might show more a disparate socioeconomic picture.

4. Sources - Please pay attention to your references - you have Dehlendorf on there twice, once for the abstract/meeting publication and once for the manuscript. In table 1 you cite reference #21 as Dehlendorf, but this is the meeting abstract - reference #15 appears to be the published manuscript. I also note that some of the other references also appear to be meeting abstracts (i.e., #24, Madden); if available, please change to the manuscript reference. If the manuscript is not available, you should address the reason for including results from a meeting abstract in your review.

5. Did you gather data on whether or not the use of patient decision aids changed the length of the visit? This is a question that has been posed by several of my colleagues, and I would be interested to know if you found anything related to this.

STATISTICAL EDITOR'S COMMENTS:

1. Fig 2: For the overall I^2 and p-value: The p-value is not = 0, but some increment > 0. Should override the software output and insert a suitable threshold, e.g., $p < .001$

2. Appendix S2: similar comment re: p-value for general benign gyn subgroup. Also, for Urogyn subgroup, there are only two studies, so it makes no sense (poor power) to estimate heterogeneity, so should omit that calculation. Also, for gyn oncology subset, there was only 1 study, so no need to plot the subtotal since it just recapitulates that one study.

3. General: The summary cites results in terms of SMD for reduction/increase ins scores, many of which are statistically significant, in part, due to the aggregation of studies to obtain larger samples. The Authors should give context as to whether the changes in SMD, when statistically significant, have clinical significance.

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. 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:
A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

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.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "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." *The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

4. As of January 1, 2020, authors of systematic reviews must prospectively register their study in PROSPERO (https://www.crd.york.ac.uk/PROSPERO/), an international database of prospectively registered systematic reviews. Please refer to the PROSPERO registration number in your submitted cover letter and include it at the end of the abstract.

5. 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.

6. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Review articles should not exceed 25 typed, double-spaced pages (6,250 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.

7. 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.

8. 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).

9. 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: Reviews, 300 words. Please provide a word count.

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. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

13. 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.

14. The American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it

should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found via the Clinical Guidance & Publications page at https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance.

15. The Journal's Production Editor had the following to say about this manuscript:

"Figure 2: Please upload a higher resolution version of this figure. In addition, we recommend uploading a figure file (eps, tiff, jpeg, etc.) rather than Word."

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.

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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 through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter.

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 Sep 26, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2018 IMPACT FACTOR: 4.965
2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

_____

Professor Nancy Chescheir
Editor in Chief, Obstetrics and Gynecology

Dear Professor Chescheir,

Re: response to reviewer comments

Manuscript Number: ONG-19-1429
Title: Patient decision aids to facilitate shared decision making in obstetrics and gynaecology: a systematic review and meta-analysis
Prospero Registration Number: CRD42018089953
Authors: Amanda J POPRZECZNY, Katie STOCKING, Marian SHOWELL, James M N DUFFY

We thank you for your consideration and comments on our paper. Please find responses to the comments below and in the attached manuscript.

Reviewer #1 comments

1. Lines 234-240: Do you worry about the heterogeneity of the types of study? I suppose not, but I would at least address the universality of the approach of patient aids. Other examples of similar studies?

Thank you for this comment. We have expanded on discussion about heterogeneity in our discussion section – lines 307-313 now read:
"When considering the meta-analysis, there was significant heterogeneity between included trials, which could only be partially explained by the range of clinical scenarios patient decision aids were being evaluated within. While the heterogeneity observed somewhat limits generalizability of our findings, it is also a strength of our review, as we purposely included studies across the range of clinical scenarios faced in obstetrics and gynaecology, and utilizing different forms of patient decision aids, to illustrate their broad applicability and effectiveness in our specialty. Similar findings with regards to heterogeneity between studies have been recognized when pooling data from trials assessing patient decision aids within other specialities[57, 58]."

2. Lines 282-284. I would give some more detail here. What evidence exists?

We have expanded on the discussion about cost savings associated with patient decision aids, and the limited data around this important outcome. Lines 319-323 now read:
"There was limited reporting of the cost-effectiveness of using patient decision aids, with only three trials reporting on this outcome[16, 32, 36]. While all three trials utilized different measures of cost-saving or cost-effectiveness, use of patient decision aids were associated with cost savings in all three trials[16, 32, 36]. Further evidence around potential cost savings and healthcare resource utilization is required."

Reviewer #2 comments

1. There are statistical terms that may need elucidating, e.g. Jadad criteria.

We have attempted to make clearer all statistical concepts in our paper. Lines 170-174 now read:
"Briefly, the Jadad criteria is a standardized tool that assesses quality and risk of bias of randomized trials by asking five questions pertaining to randomization, blinding and reporting of participant withdrawals[12]. Studies are given a score out of five, with higher scores indicating higher quality. Randomized trials that met all criteria were considered high quality."

With regards to some of the statistical terms used, and decisions made, we have included reference to the Cochrane Handbook in multiple places. We have referenced this also in an attempt to abbreviate and increase clarity of the Study Selection section of the paper. In particular, lines 188-190 now read:
"Random effects models were used to calculate summary estimates if there was substantial clinical or statistical heterogeneity, as is recommended in the Cochrane Collaboration Handbook[14]."

3. Table 1 is essential. Figure 1 is interesting but not essential. Figure 2 is essential. Appendix S1 is non-essential. Appendix S2 is interesting but not essential.

Thank you for these comments. We have striven to include only the figures and tables that are required per reporting guidelines and/or increase clarity of the study.

Figure 1 was included to make clear the difference between shared decision making and informed decision making.

Appendix S1 is a requirement of the Prisma reporting guidelines for systematic reviews and meta-analyses.

Appendix S2 has been removed.

4. I recommend that the Study Selection section be much abbreviated and clearer.

Thank you for your comment. We have striven for clarity and brevity, while including important points required by the Prisma reporting guidelines. We have increased referencing to the Cochrane Handbook in an attempt to balance explanation of statistical methodology and word count.

<u>Reviewer #3 comments</u>

1. Line 159 – is there concern over the safety of patient decision aids? An additional reference might add to this statement.

Reference to the safety of patient decision aids has been removed. Line 137-139 now reads:
"We performed this systematic review and meta-analysis to assess the effectiveness of patient decision aids to facilitate shared decision making in obstetrics and gynaecology."

1. Line 190 – consider adding a statement for readers who are less familiar with patient decision aids as to why you chose decisional conflict as your primary outcome.

We have included a statement justifying the use of decisional conflict as the primary variable. Line 179-182 now reads:
"This was selected as the primary outcome because it is a patient-oriented indicator of the decision making process with a validated scale, commonly used in studies on patient decision aids[13]."

2. Line 230 – while interesting that the studies were completed in "high-income" countries, I wonder if this is relevant? A subgroup analysis of the populations included in each study might show more a disparate socioeconomic picture.

Thank you for your comment. We are aware that specifying that the studies were completed in "high-income" countries misses some of the nuance of socioeconomic diversity seen in "high-income" countries. However, we felt this was an important point to make as to the generalizability (or lack thereof) of the use of patient decision aids, and highlight a gap in the evidence base. We did not prespecify a subgroup analysis of populations included in each study, hence feel it would not be an appropriate post hoc analysis to perform. It is however, an important deficiency to consider in the current evidence base on patient decision aids.

3. Sources – please pay attention to your references – you have Dehlendorf on there twice, once for the abstract/meeting publication and once for the manuscript. In table 1 you cute reference #21 as Dehlendorf, but this is the meeting abstract – reference #15 appears to be the published manuscript. I also note that some of the references also appear to be meeting abstracts (i.e. #24 Madden); if available, please change to the manuscript reference. If the manuscript is not available, you should address the reason for including results from a meeting abstract in your review.

Thank you for this comment. We have corrected the references and deleted duplicated references. Please see table 1 for updated referencing. Meeting abstracts were included if published in peer-reviewed journals, and their results were included in meta-analysis if sufficient data was provided in the abstract to allow for their inclusion, per the Cochrane Collaboration Handbook guidelines for performing systematic reviews and meta-analyses. Where there was insufficient data published, we attempted to contact the corresponding authors for further information.

4. Did you gather data on whether or not the use of patient decision aids changed the length of the visit? This is a question that has been posed by several of my colleagues, and I would be interested to know if you found anything related to this.

We did not prespecify an outcome of length of visit with the use of patient decision aids, hence did not gather this data from the included studies. Length of visit was variably and incompletely reported in the included studies, and in some cases was not a relevant outcome i.e. in the case of patient decision aids that were provided to patients prior to or between appointments. The issue of length of visit and time taken using patient decision aids was addressed by the MAGIC programme as a barrier to implementation (see reference 60 and Discussion section of our paper) due to competing clinical demands. It was reported that education and clinician support would increase clinician buy-in and address this barrier.

Statstical editor's comments

1. Fig 2: for the overall I^2 and p-value: the p-value is not = 0, but some increment >0. Should override the software output and insert a suitable threshold, e.g. $p<0.001$

Thank you for this comment. We have removed the p-values from figure 2, as they relate to the heterogeneity rather than the overall analysis, and we felt they were misleading.

2. Appendix S2: similar comment re: p value for general benign gyn subgroup. Also, for Urogyn subgroup, there are only two studies, so it makes no sense (poor power) to estimate heterogeneity, so should omit that calculation. Also, for gyn oncology subset, there was only 1 study, so no need to plot the subtotal since it just recapitulates that one study.

Thank you for this comment. In light of this and other reviewer comments on Appendix S2, we have removed this figure from the manuscript.

3. General: the summary cites results in terms of SMD for reduction/increase in scores, many of which are statistically significant, in part, due to the aggregation of studies to obtain larger samples. The authors should give context as to whether the changes in SMD, when statistically significant, have clinical significance.

The standardized mean difference was used in this manuscript because results of the individual studies are expressed as continuous variables. While there are difficulties converting this into a clinically relevant. We have now reclassified the statistically significant findings of decisional conflict and patient knowledge as somewhat and moderately improved, per the definitions suggested by Faraone (1). We demonstrate a statistically significant difference in decisional conflict when comparing decision aids with routine care, with regards to decisional

conflict and patient knowledge. When reflecting upon this result, we feel they represent a clinically significant finding that supports the introduction of decision aids into routine clinical practice, as outlined in our discussion section.

Editorial office comments

1. OPT-IN: Yes, please publish my point-by-point response letter.
2. I will confirm with my coauthors that they correctly display their disclosures on the manuscript's title page
3. Please see statement from myself, as lead author, below
4. PROSPERO registration number is now included in this cover letter, and at the end of the abstract
5. We have replaced non-standard obstetrics and gynaecology terminology with reVITALize definitions
6. Our paper does not exceed 25 typed, double-spaced pages (6,250 words)
7. Titles are limited to 100 characters (including spaces)
8. All financial support has been acknowledged; appropriate people have been acknowledged; presentation at FIGO has been declared
9. The abstract has been checked and includes a declarative conclusion statement, and does not include information not included in the manuscript
    a. The abstract word count is 224
10. We have removed non-standard abbreviations and acronyms, and only use those outlined in the suggested online list at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf with the exceptions of "decision conflict scale", which is used throughout our manuscript and tables and commonly abbreviated to DCS in other publications on this topic; and "standardized mean difference (SMD)" which is a standard statistical acronym and used throughout our results and tables.
11. All virgule (/) symbols used in sentences have been replaced with words, except where they are used for website addresses
12. We report our results in the abstract, results and table sections as standardized mean differences and confidence intervals. We have omitted P values from the manuscript, as requested, however include them in the tables. The presentation of data has been standardized, as requested.
13. Tables now comply with the journal table checklist, to the best of our ability.
14. All references to ACOG committee opinions are up to date and reference the most recent versions.
15. Production Editor comments:
    a. Please upload a higher resolution version of Figure 2 – done
    b. Please submit art in it's original source file format – done
    c. Please upload each figure as a separate file – done
    d. If figures were created using a statistical program, please submit PDF or EPS files generated directly from the statistical program
    e. Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi

I, Amanda J Poprzeczny, affirm 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 discrpencaies from the study as planned (and, if relevant, registered) have been explained.
We appreciate your consideration of our manuscript.

Kind regards,

Dr Amanda J Poprzeczny
MBBS, B.Med.Sc (Hons)
FRANZCOG
PhD Candidate, University of Adelaide
CMFM Trainee

1. Faraone SV. Interpreting estimates of treatment effects: implications for managed care. P & T : a peer-reviewed journal for formulary management. 2008;33(12):700-11.