

# 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](mailto:obgyn@greenjournal.org).

**Date:** Jan 04, 2022  
**To:** "Ahmet A. Baschat" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-21-2371

RE: Manuscript Number ONG-21-2371

Care Levels for Fetal Therapy Centers

Dear Dr. Baschat:

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).

Please be sure to address the Editor comments (see "EDITOR COMMENTS" below) in your point-by-point response.

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 Jan 25, 2022, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1:

This consensus statement proposes three levels of care for fetal therapy centers based on the resources to carry out interventions and manage maternal, fetal and neonatal risks. The authors make a cogent and compelling case of the need for this kind of stratification. They appropriately build the fetal center stratification on the existing maternal and neonatal levels of care.

Below are a few comments and questions for the authors:

1. Under leadership -- line 140: is there a reason the authors use "fetal medicine" as opposed to "maternal-fetal medicine"?
2. Line 104-- the recommendation around care being better provided at another facility: shouldn't the language regarding referral be stronger as opposed to "may need to be."
3. Line 399-401-- question around best language as per #2 -- should referral recommendation be stronger?
4. While the dimension of "fetal therapy" is typically and appropriately increasingly under the leadership of MFM, the document could leave more room to the expanded role of neonatology in the overall medical direction of a fetal program (reserving fetal therapy leadership to MFM). At least one national program utilizes this leadership approach given the important bridge neonatology plays between fetal and neonatal life, and the continuity that specialty provides.
5. In the same vein as #4 above, a distinction in the document between a "fetal center" and the "fetal therapy arm" of a fetal center could be made clearer. The documents focus on the interventional dimension is understandable but by doing so does not necessarily give the full picture of clinical activity and leadership in a fetal center, and the many possibilities of overall center medical leadership that activity could entail.
6. Table 4 -- the percentages are listed in a varying manner--sometimes ranges, sometimes a single percentage. Presumably this is based on what is in the quoted literature (i.e postoperative pain is precisely 32%). But is there a way of presenting this important information in a more nuanced, less absolute manner?
7. Table 4 -- Fetal death under FBS is listed as 0.4 -- is this 0.4%?
8. Table 4-- the percentages are sometimes preceded by a colon, a dash or nothing -- is there a way to standardize this?
9. Table 5 -- same questions as #6-8
10. Table 6--same questions as #6-8

## Reviewer #2:

This consensus delineates the recommended facilities, personnel, and infrastructure for 3 levels of fetal therapy. Comments and questions follow.

1. Abstract. The abstract is a faithful summary of the consensus. The following are intended to assist with clarity.

- a. Lines 7-11. Not all complications that might arise can be managed, as stated, and all care needs cannot be provided (hence risks of fetal or neonatal death).
- b. Lines 13-14. How does 'dedicated operational infrastructure' differ from 'facilities as well as policies'? How does oversight differ from mechanisms to monitor performance?
- c. Line 24-25. What is moderate prematurity? Since level 1 center cases are defined by not needing, it would be helpful to clarify. Also applies to line 389.
- d. Lines 26-29. As presented, readers may not appreciate the difference between level II and level III. How does "the full range" of level III care go beyond level II maternal ICU or neonatal extreme prematurity management?

2. Introduction. Well-written and clearly presented. The following are minor.

- a. Lines 37-38. Fetal does not require quotation marks (they are fetal interventions). 'Highest level' might be omitted. One assumes the cited evidence meets the standards of the national societies and journal.
- b. Lines 45-46. What do you mean by the statement that care levels are independently assigned and may not coexist at a single institution?
- c. Line 50. Is this document going to stratify resources by the intricacy of such interventions?
- d. Lines 63-65. Do you mean that your objectives have been addressed by several professional societies? If you are referring to endorsement of the current document, might omit the statement.

3. Fetal interventions and the practice of fetal therapy.

- a. Lines 68-70. This background content was previously stated. Suggest trying to streamline the sections (may help with reader engagement).
- b. Line 71. What do you mean by level 1 evidence? Possible to include references for these committee opinions and level 1 evidence? Also in line 85, the authors write that any intervention should be based on the highest level of evidence. Who determines the highest level of evidence?
- c. Line 72. By conservative management, do you mean expectant management without fetal therapy?
- d. Lines 79-82. Possible to provide more specific recommendations? Rather than 'meticulous expert' imaging, perhaps a center with accreditation to perform detailed fetal imaging? Might reference AIUM and the SMFM resolution on this topic. This also applies to the section that begins in line 165. Consider combining to avoid redundancy.
- e. Line 86-87. Would it be possible to define experimental vs. innovative fetal procedures?

4. Universal core components and operational responsibilities of a fetal therapy center.

- a. Lines 137-140. Realizing that fetal medicine is not an established subspecialty (of ACOG), suggest defining it or adding something about qualifications and scope, here or elsewhere in the document. This gets to training of individuals who lead fetal therapy centers or simply practice fetal therapy at centers of different levels.
- b. Lines 177-178. Suggest clarifying that MRI exams be interpreted by a board-certified radiologist with expertise in fetal MRI.
- c. Lines 213-215. Would rephrase to convey that e.g. pregnancy termination may be an option for women who elect it and should be discussed, depending on gestational age, legal availability, and availability to travel as needed.
- d. Lines 240-243. Might include something about future pregnancy outcomes, such as risk for uterine dehiscence.

5. Fetal therapy center care levels - Principal considerations.

- a. Consider combining most of this section with the subsequent section, as both are about levels of care. Content prior to this point in the manuscript is largely considerations. Lines 309-325 might be streamlined. Risks, management options, discussion participants, and the proposal for 3 levels of care have already been discussed.
- b. Lines 327-330. Is every center that performs chorionic villus sampling and amniocentesis a fetal therapy center?

6. Levels of care for fetal therapy centers.

- a. Lines 372-377. Would streamline content that has already been presented.
- b. Line 390. Might provide examples of fetal conditions requiring level I therapy but not resulting in a risk that the neonate would need subspecialty medical or surgical care.
- c. Lines 406-410. I'm not sure what the authors are trying to say about pediatric resources that may (*italics?*) not be immediately available.
- d. Lines 404-424. If a fetal center performs procedures beyond those of a level I fetal center but does not perform all procedures listed for a level II center, which level is it assigned? Or is assignment based on resources to safely perform the selected procedures?

7. Tables.

- a. Table 1.

- 1) Under diagnostic services, might reference AIUM guidelines for detailed fetal anatomic survey and fetal echocardiography. Similarly, might reference ACR guideline for prenatal MRI. Must all laboratory tests be performed at the fetal therapy center, or can some be sent to other laboratories?
- 2) Please clarify the role of Adult Medicine beyond that of the MFM subspecialist, realizing that intensive care unit is a separate line item.
- 3) What is the role of Pediatrics apart from Neonatology?
- 4) Does every level of fetal therapy center require a medical ethicist (even for level 1 procedures)?

b. Tables 2 and 3. As this content is from other entities, suggest making these tables supplemental. They might also be combined.

c. Tables 4-6.

1) In the text, might emphasize that the skill set required for each of these 3 tables differs according to the procedure listed - tables 4-6 do not correspond to the levels listed in table 7. Would consider revising the tables so that they DO correspond to the levels in table 7. This may make the consensus more cohesive. In other words, could introduce table 7 earlier in the text of the document (before tables 4-6) and then use tables 4-6 to support the 3-level classification you are proposing.

2)The following are minor.

Under 'Required Resources - Maternal,' if there is potential for urgent delivery, would also include OB anesthesia for general anesthesia.

Please clarify the statement at the end of the table 4 legend, 'All fetal complication rates are expected to be at the lower range presented.' Is modification of a published range warranted in the absence of evidence?

In the title of table 5, would consider modifying 'larger diameter,' because it is logical only in the context of the other tables. For example, shunts and fetoscopic procedures?

d. Table 7.

Use of complicated and uncomplicated would benefit from clarification. What is an uncomplicated vs. complicated intrauterine transfusion? Is it based on gestational age, or hydrops? Although uncomplicated EXIT has examples, this may be confusing from reader perspective and pose unintended implementation challenges. Suggest listing EXIT simply as Level II (rather than calling it uncomplicated EXIT), with an \*, and then at the bottom of the table specifying those EXIT cases which require resources of a Level III center. If a center has resources to perform a procedure and offers and performs the procedure, it probably manages complications.

Reviewer #3:

This manuscript is a thorough review of fetal procedures and the necessary infrastructure needed to support the administration and use of these treatments. Overall, I think that this manuscript is well written and needs minimal revision. I appreciate that the authors have focused on maternal safety in parallel with fetal benefit. I also appreciate the discussion of the option of pregnancy termination and the need to ensure access to those procedures if that is the decision the family elects.

Three minor points for revision:

1) The bulk of fetal therapy is interventional and this Consensus Statement is primarily focused on these procedures. However, while medical treatment appropriately acknowledged in the introduction (line 34) and in description of Level I fetal therapy centers (line 394) it not represented in any of the accompanying tables. I would like to see maternal medical treatments for treatment of fetal disease, i.e. digoxin for fetal arrhythmia, be added to Table 7.

2) In Table 2, reference is made to a "Level II" obstetric facility, however the resources and services that comprise this level of Obstetric Care Center is not defined in the table or the text.

3) Tables 4-6 are incredibly useful and will likely be highly cited. However, I think that it should be specified that the procedural risks quoted are based on available data specific to those procedures. For example, in Table 5, both Fetal cardiac interventions and Radiofrequency, microwave or interstitial laser ablation are described with 16-18g instruments, yet the maternal risks listed are different. I expect this is based on what the available literature chose to report as outcome measures, however, clinically it is not clear why the use of a 16 gauge instrument would have different maternal risks if used for the different procedures. Perhaps the column title in those tables can be adjusted from "Procedural Risks" to "Reported Procedural Risks."

## EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased 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. 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:

- \* Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
- \* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
- \* 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).
- \* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

4. 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.

5. If any of the below applies to your manuscript please supply the correct checklist. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys

(CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at <http://ong.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

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.

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).
- \* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

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 limit for Executive Summaries, Consensus Statements, and Guidelines are 250 words. Please provide a word count.

9. 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.

10. 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.

11. ACOG avoids using "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

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](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

14. Please review examples of our current reference style at <http://ong.editorialmanager.com> (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources"). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, 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 references you are citing are still current and available. Check the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and 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](mailto:obgyn@greenjournal.org)). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

15. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

16. 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 <https://wkauthorservices.editage.com/open-access/hybrid.html>.

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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 as a Microsoft Word document. 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. Do not omit your responses to the Editorial Office or Editors' comments.

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 Jan 25, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Torri D. Metz, MD  
Associate Editor, Obstetrics

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

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RE: Manuscript Number ONG-21-2371

## Care Levels for Fetal Therapy Centers

To the editors and referees:

Please find attached our revised re-submission of the manuscript entitled "care levels for fetal therapy centers" (ONG-21-2371). Below is a point to point list of responses and revisions made to the document in response to the referee's and editors comments.

Please do not hesitate to contact us if you have any questions or concerns.

Ahmet Baschat, MD

Reviewer #1:

<b>1.</b>	<b>Comment:</b> Under leadership -- line 140: is there a reason the authors use "fetal medicine" as opposed to "maternal-fetal medicine"? <b>Reply:</b> Maternal-Fetal Medicine as practiced in the US is not a universal subspecialty as maternal conditions may be managed by the adult subspecialists. In contrast fetal medicine is universally an obstetric specialty which is the reason this terminology is used here. <b>Change made to the document:</b> no change was made in response to this specific comment. Please see also response # 14 to Reviewer #2. Lines 154-157
<b>2.</b>	<b>Comment:</b> Line 104-- the recommendation around care being better provided at another facility: shouldn't the language regarding referral be stronger as opposed to "may need to be." <b>Reply:</b> We agree with this comment. <b>Change made to the document:</b> Line 99: The wording has been changed to "has to be".
<b>3.</b>	<b>Comment:</b> Lines 399-401-- question around best language as per #2 -- should referral recommendation be stronger? <b>Reply:</b> We agree with this comment. <b>Change made to the document:</b> Wording has been changed to: "If any procedure is felt to be beyond the expertise of the local practitioners, or if the local supportive care resources are insufficient, referral to an institution where these can be met should be initiated, if feasible." Line 393-395
<b>4.</b>	<b>Comment:</b> While the dimension of "fetal therapy" is typically and appropriately increasingly under the leadership of MFM, the document could leave more room to the expanded role of neonatology in the overall medical direction of a fetal program (reserving fetal therapy leadership to MFM). At least one national program utilizes this leadership approach given the important bridge neonatology plays between fetal and neonatal life, and the continuity that specialty provides.

	<p><b>Reply:</b> The role of neonatology in the leadership of a fetal therapy center is now included and should also be implicit since the neonatal care level resources are one of the pillars of fetal therapy care level designation.</p> <p><b>Change made to the document:</b> In the leadership section Neonatology directorship has been added.</p> <p>Line 140: "one led predominantly by pediatric surgery or neonatology"</p>
5.	<p><b>Comment:</b> In the same vein as #4 above, a distinction in the document between a "fetal center" and the "fetal therapy arm" of a fetal center could be made clearer. The document's focus on the interventional dimension is understandable but by doing so does not necessarily give the full picture of clinical activity and leadership in a fetal center, and the many possibilities of overall center medical leadership that activity could entail.</p> <p><b>Reply:</b> The document focuses specifically on centers dedicated to providing fetal therapy. To clarify we have modified the last sentence in the goal of this document.</p> <p><b>Change made to the document:</b> Lines 62-64: Last sentence now reads "We propose three levels of care for centers that offer fetal therapy, with an incremental capacity to care for women undergoing fetal interventions of increasing difficulty and risk". Lines 61-63</p>
6.	<p><b>Comment:</b> Table 4 -- the percentages are listed in a varying manner--sometimes ranges, sometimes a single percentage. Presumably this is based on what is in the quoted literature (i.e. postoperative pain is precisely 32%). But is there a way of presenting this important information in a more nuanced, less absolute manner?</p> <p><b>Reply:</b> The percentages are based on the reported numbers and ranges are provided when there are several publications that provide this information.</p> <p><b>Change made to the document:</b> The column heading has been changed to "Reported procedural risks"</p>
7.	<p><b>Comment:</b> Table 4 -- Fetal death under FBS is listed as 0.4 -- is this 0.4%?</p> <p><b>Reply:</b> This is correct.</p> <p><b>Change made to the document:</b> The percentage sign has been added</p>
8.	<p><b>Comment:</b> Table 4 -- the percentages are sometimes preceded by a colon, a dash or nothing -- is there a way to standardize this?</p> <p><b>Reply:</b> We agree with this comment</p> <p><b>Change made to the document:</b> The punctuation has been standardized in the tables.</p>
9.	<p><b>Comment:</b> Table 5 -- same questions as #6-8</p> <p><b>Reply:</b> We agree with this comment</p> <p><b>Change made to the document:</b> The punctuation has been standardized in the tables.</p>
10.	<p><b>Comment:</b> Table 6 -- same questions as #6-8</p> <p><b>Reply:</b> We agree with this comment</p> <p><b>Change made to the document:</b> The punctuation has been standardized in the tables.</p>

Reviewer #2:

1.	<p><b>Comment:</b> Abstract Lines 7-11. Not all complications that might arise can be managed, as stated, and all care needs cannot be provided (hence risks of fetal or neonatal death).</p> <p><b>Reply:</b> We agree</p> <p><b>Change made to the document:</b> “any” complications and “all” care needs were removed</p>
2.	<p><b>Comment:</b> Abstract Lines 13-14. How does 'dedicated operational infrastructure' differ from 'facilities as well as policies'? How does oversight differ from mechanisms to monitor performance?</p> <p><b>Reply:</b> We agree there is overlap in these terms</p> <p><b>Change made to the document:</b> Sentence has been changed to “To comprehensively address this goal, a fetal therapy center requires a dedicated operational infrastructure to provide the necessary resources, to allow oversight and monitoring of clinical performance and to facilitate multidisciplinary collaboration between the relevant specialties.” Lines 10-13</p>
3.	<p><b>Comment:</b> Abstract Line 24-25. What is moderate prematurity? Since level 1 center cases are defined by not needing, it would be helpful to clarify. Also applies to line 389.</p> <p><b>Reply:</b> This follows the definitions from WHO: Ref 138: <a href="http://www.who.int/news-room/fact-sheets/detail/preterm-birth">www.who.int/news-room/fact-sheets/detail/preterm-birth</a></p> <ul style="list-style-type: none"> <li>• <i>extremely preterm (&lt; 28 wks)</i></li> <li>• <i>very preterm (28 - 32 wks)</i></li> <li>• <i>moderate to late preterm (32 - 37 wks).</i></li> </ul> <p>Line 383 uses same ref.</p>
4.	<p><b>Comment:</b> Abstract Lines 26-29. As presented, readers may not appreciate the difference between level II and level III. How does "the full range" of level III care go beyond level II maternal ICU or neonatal extreme prematurity management?</p> <p><b>Reply:</b> We have expanded the explanation.</p> <p><b>Change made to the document:</b> Sentence now reads: “A level III therapy center could offer the full range of fetal interventions, including open fetal surgery, and could manage any of the associated maternal or neonatal complications that might arise, including the pediatric surgical care needs of babies with congenital anomalies.” Lines 25-28</p>
5.	<p><b>Comment:</b> Introduction Lines 37-38. Fetal does not require quotation marks (they are fetal interventions). 'Highest level' might be omitted. One assumes the cited evidence meets the standards of the national societies and journal.</p> <p><b>Reply:</b> We agree with the comment</p> <p><b>Change made to the document:</b> The wording has been changed to “recommendations are intended to prioritize safety for the pregnant individual and their fetus or neonate based on the available evidence”</p>
6.	<p><b>Comment:</b> Introduction Lines 45-46. What do you mean by the statement that care levels are independently assigned and may not coexist at a single institution?</p> <p><b>Reply:</b> The intended meaning is that the specialties may not all have the same care level at a single institution.</p> <p><b>Change made to the document:</b> We changed wording to</p>

	“may not coexist at the same level at a single institution” Lines 46-47
7.	<p><b>Comment:</b> Introduction Line 50. Is this document going to stratify resources by the intricacy of such interventions?</p> <p><b>Reply:</b> This is the intention of this document. We added the risk profile as an additional consideration to this sentence.</p> <p><b>Change made to the document:</b> wording has been changed to “but have not stratified these resources by the intricacy or risk profile of such interventions.” Line 50</p>
8.	<p><b>Comment:</b> Introduction Lines 63-65. Do you mean that your objectives have been addressed by several professional societies? If you are referring to endorsement of the current document, might omit the statement.</p> <p><b>Reply:</b> We agree with the suggestion.</p> <p><b>Change made to the document:</b> The sentence has been omitted</p>
9.	<p><b>Comment:</b> Fetal interventions &amp; the practice of fetal therapy, Lines 68-70. This background content was previously stated. Suggest trying to streamline the sections (may help with reader engagement).</p> <p><b>Reply:</b> We agree with the comment and suggested revision.</p> <p><b>Change made to the document:</b> We modified the introductory sentence to: “All fetal interventions, whether medical or surgical, are by definition performed on a pregnant individual before the separation of the fetus from the placenta at birth.” Lines 33-34 and omitted the first sentence on lines 68-70: <i>“The goal of fetal therapy may be to achieve a prenatal cure, attenuate or improve sequelae for the infant, or optimize the transition to postnatal life. When presented with a prenatal diagnosis, a pregnant individual may choose to pursue expectant management, fetal therapy, pregnancy termination, active neonatal care or palliation.”</i></p>
10.	<p><b>Comment:</b> Fetal interventions &amp; the practice of fetal therapy, Lines 68-70, Line 71. What do you mean by level 1 evidence? Possible to include references for these committee opinions and level 1 evidence? Also in line 85, the authors write that any intervention should be based on the highest level of evidence. Who determines the highest level of evidence?</p> <p><b>Reply:</b> Level 1 evidence refers to randomized trials. To decrease duplication we removed this sentence and modified the sentence on line 79-80.</p> <p><b>Change made to the document:</b> sentence was modified to “Any intervention should be based on the highest available level of scientific evidence, which demonstrates its benefit and risks”</p>
11.	<p><b>Comment:</b> Fetal interventions &amp; the practice of fetal therapy, Lines 68-70, Line 72. By conservative management, do you mean expectant management without fetal therapy?</p> <p><b>Reply:</b> This is correct.</p> <p><b>Change made to the document:</b> “conservative” has been changed to “expectant” Line 68</p>
12.	<p><b>Comment:</b> Fetal interventions &amp; the practice of fetal therapy, Lines 68-70, Lines 79-82. Possible to provide more specific recommendations? Rather than 'meticulous expert' imaging, perhaps a center with accreditation to perform detailed fetal imaging? Might reference AIUM and the SMFM resolution on this topic. This also</p>

	<p>applies to the section that begins in line 165. Consider combining to avoid redundancy.</p> <p><b>Reply:</b> We have consolidated these two sections by removing the specific comments about diagnostic capabilities in lines 68-70 and expanding in the section beginning in line 168.</p> <p><b>Change made to the document:</b> Section on fetal imaging now states:  “A fetal therapy center needs to have access to the appropriate personnel and diagnostic investigations for all conditions that they intend to manage. This includes imaging specialists, skilled in the performance of detailed fetal ultrasound (US), fetal echocardiography and cardiovascular imaging, fetal well-being assessment and magnetic resonance imaging (MRI). Imaging expertise has to include prognostic staging for conditions such as congenital pulmonary airway malformations (CPAM), congenital diaphragmatic hernia (CDH), congenital heart disease (CHD), fetal hydrops, twin-twin transfusion syndrome (TTTS), as well as US for procedural guidance. MRIs should be interpreted by a board certified imaging radiologist, with specific expertise in fetal MRI. ”  Lines 168-174</p>
13.	<p><b>Comment:</b> Fetal interventions &amp; the practice of fetal therapy, Lines 68-70, Line 86-87. Would it be possible to define experimental vs. innovative fetal procedures?</p> <p><b>Reply:</b> The terms have been defined</p> <p><b>Change made to the document:</b> Wording has been changed to “  “ ... are experimental or subject to ongoing clinical trials, which lack supportive scientific evidence or are considered innovative with, as yet, unproven effect ...” Lines 80-83</p>
14.	<p><b>Comment:</b> Core components, Lines 137-140. Realizing that fetal medicine is not an established subspecialty (of ACOG), suggest defining it or adding something about qualifications and scope, here or elsewhere in the document. This gets to training of individuals who lead fetal therapy centers or simply practice fetal therapy at centers of different levels.</p> <p><b>Reply:</b> We agree with the suggestion. We have added a clarifying statement here but have not further expanded on fetal therapy training, since this is beyond the scope of this document.</p> <p><b>Change made to the document:</b> New sentence added here reads  “While fetal medicine/therapy is not a recognized subspecialty, its practice demands advanced understanding and training in fetal physiology, expertise in prenatal diagnosis, fetal imaging and surveillance and the 3-dimensional perspective, skills and operative dexterity to safely perform challenging fetal interventions”.  Lines 154-157</p> <p><i>Please see also response #1 to Reviewer #1.</i></p>
15.	<p><b>Comment:</b> Core components, Lines 177-178. Suggest clarifying that MRI exams be interpreted by a board-certified radiologist with expertise in fetal MRI.</p> <p><b>Reply:</b> We agree with the comment</p> <p><b>Change made to the document:</b> Sentence has been modified to  “MRIs should be interpreted by a board certified radiologist, with specific expertise in fetal MRI” Line 174-175</p>

16.	<p><b>Comment:</b> Core components, Lines 213-215. Would rephrase to convey that e.g. pregnancy termination may be an option for women who elect it and should be discussed, depending on gestational age, legal availability, and availability to travel as needed.</p> <p><b>Reply:</b> The comment has been modified to reflect this suggestion.</p> <p><b>Change made to the document:</b> The sentence now reads  “For those who choose pregnancy termination, a process should be in place to implement this, considering the gestational age, legal availability and options that are available locally - otherwise referral to another accommodating practitioner or facility should be initiated”.  Lines 216-219</p>
16.	<p><b>Comment:</b> Core components, Lines 240-243. Might include something about future pregnancy outcomes, such as risk for uterine dehiscence.</p> <p><b>Reply:</b> We agree with this comment</p> <p><b>Change made to the document:</b> Sentence now reads  “the frequency with which the intended treatment outcome was achieved, and iv) the impact on future fertility and pregnancy outcomes”.</p>
17.	<p><b>Comment:</b> Care levels - Principal considerations, Consider combining most of this section with the subsequent section, as both are about levels of care. Content prior to this point in the manuscript is largely considerations. Lines 309-325 might be streamlined. Risks, management options, discussion participants, and the proposal for 3 levels of care have already been discussed.</p> <p><b>Reply:</b> Agree with the comment. We have removed duplicate comments in this portion and incorporated them into the consent portion earlier in the document.</p> <p><b>Change made to the document:</b> The section on informed consent is incorporating components previously found on lines 316-323.</p>
17.	<p><b>Comment:</b> Care levels - Principal considerations, Lines 327-330. Is every center that performs chorionic villus sampling and amniocentesis a fetal therapy center?</p> <p><b>Reply:</b> No this is not the case. In this document we are focusing on interventions that are performed in the context of fetal therapies and have categorized the procedures as such. We have changed the heading to reflect this.</p> <p><b>Change made to the document:</b> Heading now states  “US guided needle based fetal interventions (performed in the context of fetal therapy):”</p>
18.	<p><b>Comment:</b> Levels of care for fetal therapy centers, Lines 372-377. Would streamline content that has already been presented.</p> <p><b>Reply:</b> We have specified aspects that determine the tier.</p> <p><b>Change made to the document:</b> See reply to comment 21.</p>
19.	<p><b>Comment:</b> Levels of care for fetal therapy centers, Line 390. Might provide examples of fetal conditions requiring level I therapy but not resulting in a risk that the neonate would need subspecialty medical or surgical care.</p> <p><b>Reply:</b> We have provided examples in the sentence.</p> <p><b>Change made to the document:</b> Sentence includes” ... , for example for conditions such as hydrops, CDH or congenital heart defects.”</p>
20.	<p><b>Comment:</b> Levels of care for fetal therapy centers, Lines 406-410. I'm not sure what the authors are trying to say about pediatric resources that may (italics?) not be immediately available.</p> <p><b>Reply:</b> This implies that specific pediatric subspecialty resources are not present.</p>

	<b>Change made to the document:</b> The sentence now reads “the pediatric specialty resources” Line 442
<b>21.</b>	<p><b>Comment:</b> Levels of care for fetal therapy centers, Lines 404-424. If a fetal center performs procedures beyond those of a level I fetal center but does not perform all procedures listed for a level II center, which level is it assigned? Or is assignment based on resources to safely perform the selected procedures?</p> <p><b>Reply:</b> It is the specific resource setting to safely perform procedures. We have adjusted the second sentence accordingly.</p> <p><b>Change made to the document:</b> Second sentence now reads  “The care level, or tier, of a fetal center is further defined by presence of additional resources tailored to the complexity and maternal, fetal and neonatal risk profile of interventions performed, although the scope of therapies offered may differ between centers in the same tier.” Lines 365-368</p>
<b>22.</b>	<p><b>Comment:</b> Table 1.; Under diagnostic services, might reference AIUM guidelines for detailed fetal anatomic survey and fetal echocardiography. Similarly, might reference ACR guideline for prenatal MRI. Must all laboratory tests be performed at the fetal therapy center, or can some be sent to other laboratories?</p> <p><b>Reply:</b> We clarified in the table that access to the appropriate diagnostic laboratories is required. Because the document includes authorship from the US and Canada we did not specify AIUM and ACR guidelines, but rather accreditation.</p>
<b>23.</b>	<p><b>Comment:</b> Table 1; Please clarify the role of Adult Medicine beyond that of the MFM subspecialist, realizing that intensive care unit is a separate line item.</p> <p><b>Reply:</b> We added that this is intended for management of potential coexisting maternal conditions.</p>
<b>24.</b>	<p><b>Comment:</b> Table 1; What is the role of Pediatrics apart from Neonatology?</p> <p><b>Reply:</b> This is for disease specific management of the neonate and follow-up care and may include pediatric cardiology, hematology, nephrology/urology, neurology and neuro-developmental follow-up as examples.</p>
<b>25.</b>	<p><b>Comment:</b> Table 1.; Does every level of fetal therapy center require a medical ethicist (even for level 1 procedures)?</p> <p><b>Reply:</b> All participating authors agreed that this is required on an “as needed” basis at all fetal therapy centers.</p>
<b>26.</b>	<p><b>Comment:</b> Tables 2 and 3. As this content is from other entities, suggest making these tables supplemental. They might also be combined.</p> <p><b>Reply:</b> We prefer to keep them in the document because readers may not be uniformly familiar with the content.</p>
<b>27.</b>	<p><b>Comment:</b> Tables 4-6; In the text, might emphasize that the skill set required for each of these 3 tables differs according to the procedure listed - tables 4-6 do not correspond to the levels listed in table 7. Would consider revising the tables so that they DO correspond to the levels in table 7. This may make the consensus more cohesive. In other words, could introduce table 7 earlier in the text of the document (before tables 4-6) and then use tables 4-6 to support the 3-level classification you are proposing.</p> <p><b>Reply:</b> The approach we have taken in this document is to describe the procedures first and then slot them into the three levels. This was done because they do not exactly correspond to levels as proposed in table 7. The proposed revision would reverse the order of reasoning but would not change the content. Because this</p>

	<p>would require a significant rewrite, at the discretion of the editor, we would prefer to preserve the current order of narrative and tables.</p> <p><b>Change made to the document:</b> no change was made in response to this comment. We have updated 3 references for procedure related risks.</p>
28.	<p><b>Comment:</b> Under 'Required Resources - Maternal,' if there is potential for urgent delivery, would also include OB anesthesia for general anesthesia.</p> <p><b>Reply:</b> OB anesthesia is uniformly included in the required resources of tables 4, 5 and 6.</p>
29.	<p><b>Comment:</b> Please clarify the statement at the end of the table 4 legend, 'All fetal complication rates are expected to be at the lower range presented.' Is modification of a published range warranted in the absence of evidence?</p> <p><b>Reply:</b> Because the percentages are now presented in a standardized format including the term "up to XX%, we have removed this comment.</p>
30.	<p><b>Comment:</b> In the title of table 5, would consider modifying 'larger diameter,' because it is logical only in the context of the other tables. For example, shunts and fetoscopic procedures?</p> <p><b>Reply:</b> We made the suggested change</p> <p><b>Change made to the document:</b> Title was changed to "Ultrasound guided shunting or fetoscopic fetal interventions"</p>
31.	<p><b>Comment:</b> Table 7; Use of complicated and uncomplicated would benefit from clarification. What is an uncomplicated vs. complicated intrauterine transfusion? Is it based on gestational age, or hydrops? Although uncomplicated EXIT has examples, this may be confusing from reader perspective and pose unintended implementation challenges. Suggest listing EXIT simply as Level II (rather than calling it uncomplicated EXIT), with an *, and then at the bottom of the table specifying those EXIT cases which require resources of a Level III center. If a center has resources to perform a procedure and offers and performs the procedure, it probably manages complications.</p> <p><b>Reply:</b> Complicated fetal blood sampling is clarified in the document as well as the table legend.</p> <p>Lines 389-392:  "Procedures done at earlier gestations, such as IUTs &lt; 20 weeks gestation, in hydropic fetuses or in mothers with a large BMI, are usually more challenging, and accordingly, the skill level of the center's team and its caseload will advise where they should be performed to achieve an optimal outcome".</p> <p>The current listing of EXIT is based on the consensus of the professional representatives participating in the document. This is a compromise that allows for planned EXIT with pre-procedure assurance of adequate case specific resource availability. We have specified this further in the text.</p> <p><b>Change made to the document:</b> Clarifying explanation has been added to the table legend and text (<i>as above</i>)</p>

**Reviewer #3:**



1.	<p><b>Comment:</b> The bulk of fetal therapy is interventional and this Consensus Statement is primarily focused on these procedures. However, while medical treatment appropriately acknowledged in the introduction (line 34) and in description of Level I fetal therapy centers (line 394) it not represented in any of the accompanying tables. I would like to see maternal medical treatments for treatment of fetal disease, i.e. digoxin for fetal arrhythmia, be added to Table 7.</p> <p><b>Reply:</b> We agree with the addition of fetal antiarrhythmic treatment to also cover Sotalol, Flecainide and Amiodarone as appropriate.</p> <p><b>Change made to the document:</b> Transplacental fetal antiarrhythmic treatment has been added to table 7 for fetal therapy centers with pediatric cardiology support. The legend reads “ *** maternal Digoxin, Sotalol, Flecainide or Amiodarone treatment should be undertaken with input from and neonatal follow-up with fetal/pediatric cardiology”.</p>
2.	<p><b>Comment:</b> In Table 2, reference is made to a "Level II" obstetric facility, however the resources and services that comprise this level of Obstetric Care Center is not defined in the table or the text.</p> <p><b>Reply:</b> Agree with the comment.</p> <p><b>Change made to the document:</b> The definition has been added to the table legend.</p>
3.	<p><b>Comment:</b> Tables 4-6 are incredibly useful and will likely be highly cited. However, I think that it should be specified that the procedural risks quoted are based on available data specific to those procedures. For example, in Table 5, both Fetal cardiac interventions and Radiofrequency, microwave or interstitial laser ablation are described with 16-18g instruments, yet the maternal risks listed are different. I expect this is based on what the available literature chose to report as outcome measures, however, clinically it is not clear why the use of a 16 gauge instrument would have different maternal risks if used for the different procedures. Perhaps the column title in those tables can be adjusted from "Procedural Risks" to "Reported Procedural Risks."</p> <p><b>Reply:</b> The risks are not only related to the diameter of the instrumentation but also the degree of manipulation required as well as length of the procedure. To reflect the origin of the numbers the column title was changed as suggested.</p> <p><b>Change made to the document:</b> Column is now named “Reported procedural risks”</p>

**Editorial office comments:**

1.	We <b>opt in</b> to post the revision letter as supplemental digital content .
2.	The revised submission contains on page 1 all information that may have been previously omitted.
3.	The completion and content listed on the electronic copyright transfer agreement has been verified for all coauthors. Listed disclosures are listed on the title page.
4.	Standard obstetric reVITALize definitions are used in the manuscript.

5.	All financial support, manuscript preparation assistance and contribution to the work not meeting author guidelines is acknowledged. The content was not previously presented at a scientific meeting.
6.	The abstract has been checked for accuracy and consistency with the main document and does not exceed 250 words.
7.	Standardized abbreviations and acronyms are used. Virgule symbols are not used in sentences.
8.	Specific healthcare professional categories are used whenever possible.
9.	Compliance with the journal checklist has been verified.
10.	References style meets journal requirements include the DOI and the most recent ACOG guidelines have been quoted.
11.	In the event of acceptance for publication the authors <b>opt in for open access.</b>