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: Aug 05, 2019
To: "Kenneth J. Moise" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-1164

RE: Manuscript Number ONG-19-1164

Fetal Center Designation: Has the Time Come?

Dear Dr. Moise:

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

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

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Aug 26, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This commentary is a description of the process recently undertaken in Texas for the certification of fetal centers. The topic is timely and important and although focused on one state, has relevance for the overall field of fetal therapy. My major suggestion is that the relationship of this discussion and the fetal committee and the state legislative bill is a bit unclear. A timeline or org chart might help (see below for a specific comment).

1. Although the process for discussing this topic in TX was described in detail, you do not clearly report on the current state of the legislation. The abstract notes that "a series of rules was developed", how are such rules enforced?

2. You do not mention whether insurers were involved. Often having insurers provide reimbursement only to certified providers is a path to compliance. Is there a role for such a "stick/carrot" approach in fetal therapy?

3. I think the paper would benefit from some reorganization. For example, in the section "what is a fetal center", there is description of the components of a fetal center, but also woven in is discussion of the rationale for credentialing as well as the motivations, such as financial drivers, on the part of the children's hospital, that are all a bit lost. I'd suggest discussing these as separate sections or at least separate paragraphs. The important fact that children's hospitals now all want to have a fetal center to attract fetal anomalies and patients that will establish care in that hospital is really important but again, a bit lost in this section.

4. Line 83: might consider changing to "sonologists" vs maternal fetal medicine specialists, as radiologists and others perform OB US and also benefit from improved technology.

5. Line 85: Did Nicolaides really establish the field of fetal therapy in Europe? He obviously began NT screening, but I don't think of him as establishing other in utero procedures. Please confirm this is an accurate portrayal.

6. Lines 95-100: It is unclear how the statement that patients from TX with state funded healthcare are often referred out of state despite local options is relevant to the commentary? I'd consider removing this. In this same section, points (2) and (3) both make the same point - that patients do not receive complete or accurate outcomes information.

7. With regard to the subcommittee developed to create guidelines, was there any consideration given to including a patient representative? That perspective seems important, especially as all of the challenges described above involve challenges for patients, esp in obtaining outcomes information.

8. Lines 135-9: as written, the section implies that a high level fetal center must offer BOTH laser and open myelo repair, is this correct? I'd argue that this is not recommended, as this might encourage more centers to do procedures for

which they are not well equipped, in order to earn the high level certification that implies expertise in everything. I'd worry this would defeat the purpose of improving care.

9. Lines 142-43: the term "immediately available" at all times during the care of the patient needs to be defined more precisely. In the hospital? Does this include only care when the patient is an inpatient? During a procedure? On a postpartum or antepartum unit?

10. Line 180: please explain what the "Fetal Think Tank" refers to and how it relates to the Texas legislative effort.

11. It is a bit unclear how the committee was related to the TX legislation, as it sounds like the legislation was passed before the committee was organized (or least before the committee finished their work and recommendations). Somewhere in the document that should be clarified.

12. In various places, you refer to a committee and a subcommittee - were these the same? If not, can you clarify? A timeline and/or an org chart might be helpful to address this and issue #12.

13. Line 221-6: I think with an O/E method, a 3 star center would be the best, correct? Assume this means center ratings are adjusted for case mix, so a center that saw the most complex cases would be expected to have more adverse outcomes and the rating would be adjusted accordingly.

14. Would the model employed by SART (assisted reproduction outcomes) be one that could be employed for fetal centers? There seem to be many similarities in the challenges.

15. Has the TX certification process been implemented? If not, when is the date to start?

16. Table 1: Fetal Echocardiographer is not a standard term. I assume this means a physician with expertise in fetal echo. Arguably this should be a pediatric cardiologist, not an MFM (or sonographer) trained to do echo.

17. I think increasingly genetics expertise will be important for these cases, and a genetic counselor while necessary, is not adequate and a board certified geneticist should be available as part of the team. Deciding if a genomic variant precludes fetal surgery will again be increasing important and requires genetics expertise.

Reviewer #2:

1. The abstract adequately outlines the premise of the paper. It mentions topics of personnel and facility requirements, reporting of outcomes, research, and physician education. Suggest including fetal center levels of care and what distinguishes each level (in general terms) in the abstract. This might also be added to a concluding or summary paragraph. Minor: Would delete "self-declared."

2. Line 52. The authors write that the ACOG/AAP document focused on centers of excellence that might "help to optimize fetal and maternal outcomes." Would address outcomes more fully in this commentary (it seems like the reason to have a designation).

3. Lines 71-73. Do the authors have evidence that the expansion of the number of fetal centers is to expand marketshare for newborns with anomalies? In other words, is 35 fetal centers for a country with 4 million births per year excessive? The authors might comment about non-NAFTNet fetal centers.

4. Lines 78-90. Suggest summarizing up to current function of fetal therapy centers to set stage for why Texas Initiative was necessary, e.g. heterogeneity in what constitutes fetal center, need to protect pregnant woman during innovative procedures, improved access to care. A few more references might be added.

5. Lines 93-100. If the purpose is to convey that the authors invited the state to visit their center to inform them about these 3 concerns, it would be helpful to include supporting data, e.g. the volume of patients referred out of state, given misleading data, or unable to identifying appropriate providers. Wouldn't physicians be the ones referring patients?

6. Lines 102-122. The text is somewhat disjointed. Would move content about the authors testifying in support of a bill and its subsequent passage until after an explanation what the bill contains. The text about when the bill passed and became law in 2015 (lines 103-106) should probably be followed by the text in lines 117-122 about its subsequent development. Please clarify that it is not yet in effect.

7. Lines 127-155. In line 131, would more clearly identify certifications by governing bodies as tenet. In line 136, suggest "Standard of care" as opposed to "norm"

8. Lines 157-171. The back-and-forth about a name in a state bill is not as relevant to a national audience. It is reasonable to write about fetal centers or fetal surgery centers. The content about levels of care appears to differ from the state bill

more substantively than the name.

9. Lines 180-186. Descriptions of dates and meetings might be shortened or omitted, here and elsewhere in the commentary. Colorado seems a little out of place (it is fine for the paper not to be about Texas, but might clarify where you are going with this).

10. Lines 221-225. Please clarify how the 1- to 3-star rating system should be used (why 3 isn't better than 1). Hotel and restaurant ratings might be deleted.

11. Line 286. The paper is without clear conclusion. Would suggest making statement in regard to next steps needed to be taken.

12. Tables.
a. Tables I-IV are from other sources, and table IV is more than 3 pages long (might be supplemental content instead). Given overlap in the content of the tables, it might not be necessary to include all of them.
b. Tables V and VI are about obstetrical and neonatal care. Considering the length of the commentary and the number of other tables specific to fetal surgery, suggest omitting them.
c. Table VII is the most relevant to the paper. Would replace jargon (bladder tap = vesicocentesis), abbreviations (echo), and acronyms (FETO). Also, ACR does not certify fetal MRI programs.

Reviewer #3: This is an editorial that seeks to raise some of the concerns that surround the rise of fetal surgery centers. It uses as the springboard for discussion a law passed in Texas that sought to establish guidelines for centers like this. The top is a timely one, as the number of these centers is clearly increasing. The editorial highlights challenges surrounding how to bring different specialties to the table to agree on standards for assessment, levels of center and simply what metrics/statistics to report. They point out some of the issues that came up after the Texas law, including a couple of things that might have been done differently. The authors offer some suggestions on solutions to some of these problems, suggesting that similar models in other areas (eg, NICU certification, maternity hospital levels) may provide some guidance. They identify some the challenges getting to an agreement on certifications (eg, MFMs won't accept Pedi Surg having all the say and vice versa, getting centers to agree upon how to report outcomes uniformly, etc).

I think this article makes for a good editorial, raising an important question and starting the discussion. They also went into depth in some areas, where they indirectly noted the problem with some database models wherein the lack of transparency of how the outcomes data is obtained or the incompleteness of the data that is entered could lead to disagreements as to the accuracy of the results that come out the other end. Examples of this would be simply quoting survival after TTTS without some scaling for severity of stage at treatment or outcomes generated prior to a critical member of the surgical team leaving. They provide some thoughts on how this might be dealt with. Overall, I feel this is a valuable opinion piece to get a discussion going. My only real criticism is that the editorial just seems to end a little abruptly and unexpectedly. If the ending could be rounded out or a better summarization drawn up as a conclusion, it would feel like it ended on a stronger note.

EDITOR COMMENTS:

1. As you can see from the Reviewers' comments, there is a lot of enthusiasm for a revised submission for your paper. The theme of the reviews as I read them, and I have to say that I agree, is the organization of the paper could be stronger. There's nothing in the reviewer comments that I disagree with.

I'd like to suggest that you consider something like:
A. Define the gap in understanding of what a fetal center is.
B. Why is there a national imperative to define fetal centers?
C. Why and how did Texas approach this problem
   What are the key elements of the legislation?
   What were the major obstacles/areas of disagreement that had to be worked out?
D. What are the lessons learned in this Texan endeavor that a national program must /should consider?

2. 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.

3. 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.

4. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works. Variance is needed in the following sections:

- Lines 80-82 and 88-90 are verbatim from another publication by the author. Please add variance and cite (if necessary) to avoid self-plagiarism.

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: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

7. Title: Please revise your title so that you avoid posing a question.

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. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

10. 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: Current Commentary articles, 250 words. Please provide a word count.

11. 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.

12. 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.

13. 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%").

14. 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.

15. 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.

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 http://edmgr.ovid.com/acd/accounts/ifauth.htm.

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

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

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

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

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August 21, 2019

Nancy Chescheir, M.D.
Editor-in-Chief
Obstetrics and Gynecology

Re: Manuscript # ONG – 19-1164

Dear Dr. Chescheir:

We appreciate the comments from you and the reviewers. Below find our responses to same (all line # references refer to the "track changes' version of our revised manuscript):

Reviewer #1: This commentary is a description of the process recently undertaken in Texas for the certification of fetal centers. The topic is timely and important and although focused on one state, has relevance for the overall field of fetal therapy. My major suggestion is that the relationship of this discussion and the fetal committee and the state legislative bill is a bit unclear. A timeline or org chart might help (see below for a specific comment).

Due to the length of the manuscript we were not able to include a timeline in the form of a chart. Instead we have revised the description of the legislative process extensively to improve clarity (lines # 135 – 167).

1. Although the process for discussing this topic in TX was described in detail, you do not clearly report on the current state of the legislation. The abstract notes that "a series of rules was developed", how are such rules enforced?

The process has not yet been implemented. This has been clarified in line # 40 of the abstract in the revised manuscript. In addition, the process and description of the bill have been amended to improve clarity (lines # 135 – 167).

2. You do not mention whether insurers were involved. Often having insurers provide reimbursement only to certified providers is a path to compliance. Is there a role for such a "stick/carrot" approach in fetal therapy?

Insurers were not involved in the Texas legislative process. The membership of the subcommittee was designated by the Department of Health and Human Services.

3. I think the paper would benefit from some reorganization. For example, in the section "what is a fetal center", there is description of the components of a fetal center, but also woven in is discussion of the rationale for credentialing as well as the motivations, such as financial

drivers, on the part of the children's hospital, that are all a bit lost. I'd suggest discussing these as separate sections or at least separate paragraphs. The important fact that children's hospitals now all want to have a fetal center to attract fetal anomalies and patients that will establish care in that hospital is really important but again, a bit lost in this section.

The initial portion of the paper has been rewritten to improve clarity (lines # 53 – 85).

4. Line 83: might consider changing to "sonologists" vs maternal fetal medicine specialists, as radiologists and others perform OB US and also benefit from improved technology.
The advances in ultrasound technology clearly have accelerated Maternal-Fetal Medicine specialists into a unique position to take on the leading role at Fetal Centers.

This concept has been deleted from the revised manuscript (lines # 115 -116).

5. Line 85: Did Nicolaides really establish the field of fetal therapy in Europe? He obviously began NT screening, but I don't think of him as establishing other in utero procedures. Please confirm this is an accurate portrayal.

This is an accurate portrayal as Kypros, in addition to his many other contributions to fetal medicine, was the earliest adopter of laser therapy for severe twin-twin transfusion after its initial description by DeLia in the U.S. The history section of the previous manuscript has been deleted from a revised manuscript (lines # 109-122).

6. Lines 95-100: It is unclear how the statement that patients from TX with state funded healthcare are often referred out of state despite local options is relevant to the commentary? I'd consider removing this. In this same section, points (2) and (3) both make the same point - that patients do not receive complete or accurate outcomes information.

We agree with the reviewer and have altered the manuscript to include only a single major concern raised with our state legislator (lines # 128 - 133).

7. With regard to the subcommittee developed to create guidelines, was there any consideration given to including a patient representative? That perspective seems important, especially as all of the challenges described above involve challenges for patients, esp in obtaining outcomes information.

We agree that a patient perspective would have been an important aspect of the development of the fetal center guidelines however the membership of the subcommittee was designated by the Department of Health and Human Services and did not include a lay or patient representative.

8. Lines 135-9: as written, the section implies that a high level fetal center must offer BOTH laser and open myelo repair, is this correct? I'd argue that this is not recommended, as this might encourage more centers to do procedures for which they are not well equipped, in order to earn the high level certification that implies expertise in everything. I'd worry this would defeat the purpose of improving care.

The subcommittee felt that the highest level of fetal center in Texas should be able to have the expertise to perform all evidence-based procedures that were recommended as a standard of care by a national medical organization. At the current time, this would involve both open MMC repair and laser therapy for severe TTTS. As pointed out in the discussion regarding an alternate model for three tiers of fetal centers (lines # 224 - 240 and Table V), a multi-level fetal center designation would a allow a center performing only lasers to be designated a level II center while a center performing all evidenced-based procedures would be designated a level III center. No change was undertaken in the manuscript.

9. Lines 142-43: the term "immediately available" at all times during the care of the patient needs to be defined more precisely. In the hospital? Does this include only care when the patient is an inpatient? During a procedure? On a postpartum or antepartum unit?

The subcommittee struggled with defining the exact definition of the availability of the MFM. The key points were felt to be a direct responsibility of the patient's care during fetal intervention procedures and access to bedside care should complications occur post-procedure. "Immediately available" has been removed from the revised manuscript and the language of the final DHHS rules inserted: "be available at all times to the bedside within a time period consistent with current standards of professional practice and maternal-fetal care". (New lines # 188 – 193).

10. Line 180: please explain what the "Fetal Think Tank" refers to and how it relates to the Texas legislative effort.

One of the authors of the current manuscript was involved in both activities. The connection between the two is now better described in lines # 235 – 240.

11. It is a bit unclear how the committee was related to the TX legislation, as it sounds like the legislation was passed before the committee was organized (or least before the committee finished their work and recommendations). Somewhere in the document that should be clarified.

The authors have reworded the description of the Texas legislative process to improve clarity. The relationship between the fetal subcommittee and the Perinatal Advisory Committee are better explained in lines # 135 - 167.

12. In various places, you refer to a committee and a subcommittee - were these the same? If not, can you clarify? A timeline and/or an org chart might be helpful to address this and issue #12.

See response to comment # 11.

13. Line 221-6: I think with an O/E method, a 3 star center would be the best, correct? Assume this means center ratings are adjusted for case mix, so a center that saw the most complex cases would be expected to have more adverse outcomes and the rating would be adjusted accordingly.

The O/E ratios are risk-adjusted. This was stated in line # 273 of the original manuscript. No change undertaken in the manuscript.

14. Would the model employed by SART (assisted reproduction outcomes) be one that could be employed for fetal centers? There seem to be many similarities in the challenges.

SART outcomes were mandated by the CDC. Voluntary reporting of outcomes by fetal centers would be analogous to the current reporting of pediatric cardiovascular surgery programs that report to the Society for Thoracic Surgeons outcomes database. No change in manuscript was undertaken.

15. Has the TX certification process been implemented? If not, when is the date to start? The process has not yet been implemented.

This has been clarified in line # 40 of the revised abstract and in lines # 161 - 165 in the body of the manuscript.

16. Table 1: Fetal Echocardiographer is not a standard term. I assume this means a physician with expertise in fetal echo. Arguably this should be a pediatric cardiologist, not an MFM (or sonographer) trained to do echo.

We would agree with the author however Table I accurately reflects the information provided in a table from reference # 2.

17. I think increasingly genetics expertise will be important for these cases, and a genetic counselor while necessary, is not adequate and a board certified geneticist should be available as part of the team. Deciding if a genomic variant precludes fetal surgery will again be increasing important and requires genetics expertise.

Although we appreciate the opinion of the reviewer, both the think tank and the Texas subcommittee felt that a board-certified genetic counselor with experience in prenatal conditions would be adequate for handling the majority of cases seen at fetal centers. The article reflects the final conclusions of these two groups. No change was made to the revised manuscript.

Reviewer #2:

1. The abstract adequately outlines the premise of the paper. It mentions topics of personnel and facility requirements, reporting of outcomes, research, and physician education. Suggest including fetal center levels of care and what distinguishes each level (in general terms) in the abstract. This might also be added to a concluding or summary paragraph. Minor: Would delete "self-declared."

“Self- declared” was deleted. A general reference to a multi-level of fetal center certification is described in the revised manuscript (lines # 44 - 46).

2. Line 52. The authors write that the ACOG/AAP document focused on centers of excellence that might "help to optimize fetal and maternal outcomes." Would address outcomes more fully in this commentary (it seems like the reason to have a designation).

We wholeheartedly agree with this reviewer. We have addressed the many issues related to outcomes in lines # 260 - 321. In addition, we have modified lines # 291 – 298 in a revised manuscript to better describe the specific recommendations of the fetal subcommittee vs what was published in the final guidelines from the Department of Health and Human Services.

3. Lines 71-73. Do the authors have evidence that the expansion of the number of fetal centers is to expand marketshare for newborns with anomalies? In other words, is 35 fetal centers for a country with 4 million births per year excessive? The authors might comment about non-NAFTNet fetal centers.

This is conjecture on the authors' part as there are no real data to support this statement. We have softened the line to state that this "may" play a role in the drive to establish fetal centers (see line # 99). In addition, we have added a line to describe the known existence of fetal centers outside of the NAFTNet organization (lines # 97 - 98).

4. Lines 78-90. Suggest summarizing up to current function of fetal therapy centers to set stage for why Texas Initiative was necessary, e.g. heterogeneity in what constitutes fetal center, need to protect pregnant woman during innovative procedures, improved access to care. A few more references might be added.

The authors are not aware of any specific peer-reviewed references that point to the need for fetal center designations other than those used in this manuscript.

5. Lines 93-100. If the purpose is to convey that the authors invited the state to visit their center to inform them about these 3 concerns, it would be helpful to include supporting data, e.g. the volume of patients referred out of state, given misleading data, or unable to identifying appropriate providers. Wouldn't physicians be the ones referring patients?

The authors did not have supporting data as to the volume of these referrals. Most of the cases were brought to the authors' attention through social media interactions with the patients. The out-of-state referrals were made by the physicians themselves.

6. Lines 102-122. The text is somewhat disjointed. Would move content about the authors testifying in support of a bill and its subsequent passage until after an explanation what the bill contains. The text about when the bill passed and became law in 2015 (lines 103-106) should probably be followed by the text in lines 117-122 about its subsequent development. Please clarify that it is not yet in effect.

This section has been reorganized at the reviewer's suggestion (new lines # 135 - 167).

7. Lines 127-155. In line 131, would more clearly identify certifications by governing bodies as tenet. In line 136, suggest "Standard of care" as opposed to "norm"

This has been changed in line # 183.

8. Lines 157-171. The back-and-forth about a name in a state bill is not as relevant to a national

audience. It is reasonable to write about fetal centers or fetal surgery centers. The content about levels of care appears to differ from the state bill more substantively than the name.
We disagree with the reviewer. As stated in the manuscript, there was considerable concern by the MFM community during public testimony and conference calls suggesting that the name should have been different than in the original state legislation. This an important concept to consider in any efforts of a national certification process. No change was made in the current manuscript.

As to the reviewer's second point, we discuss the limitations of a single tier fetal center as outlined in the Texas legislation in lines # 224 - 240. The multiple tier approach is presented in Table V as a concept developed at the Fetal Think Tank.

9. Lines 180-186. Descriptions of dates and meetings might be shortened or omitted, here and elsewhere in the commentary. Colorado seems a little out of place (it is fine for the paper not to be about Texas, but might clarify where you are going with this).

This has been clarified in lines # 231 - 240.

10. Lines 221-225. Please clarify how the 1- to 3-star rating system should be used (why 3 isn't better than 1). Hotel and restaurant ratings might be deleted.

The authors do not feel that a 1 – 3 star rating should be used for marketing to the general public. As such there is little use for this system. This is described in lines # 278 - 280. The authors included a description of the star rating commonly used by hotel and restaurants to illustrate how the general public might rate a cardiac center in an analogous fashion. Thus this concept has been retained in a revised manuscript.

11. Line 286. The paper is without clear conclusion. Would suggest making statement in regard to next steps needed to be taken.

See new lines # 342 - 348.

12. Tables.

a. Tables I-IV are from other sources, and table IV is more than 3 pages long (might be supplemental content instead). Given overlap in the content of the tables, it might not be necessary to include all of them.

We would like to retain Tables III-V (new Tables II – IV) since they will be easily accessible in the body of the manuscript for future reference should a national fetal center certification process be discussed. Previous numbered tables V and VI have been deleted from a revised manuscript to improve brevity.

b. Tables V and VI are about obstetrical and neonatal care. Considering the length of the commentary and the number of other tables specific to fetal surgery, suggest omitting them.

See above comment.

c. Table VII is the most relevant to the paper. Would replace jargon (bladder tap = vesicocentesis), abbreviations (echo), and acronyms (FETO). Also, ACR does not certify fetal MRI programs.

The jargon, abbreviations, and acronyms noted above have been changed. The author is correct in that the ACR does not certify "fetal MRI" but does certify the MRI equipment. "Unit" has been added to the table.

Reviewer #3: This is an editorial that seeks to raise some of the concerns that surround the rise of fetal surgery centers. It uses as the springboard for discussion a law passed in Texas that sought to establish guidelines for centers like this. The top is a timely one, as the number of these centers is clearly increasing. The editorial highlights challenges surrounding how to bring different specialties to the table to agree on standards for assessment, levels of center and simply what metrics/statistics to report. They point out some of the issues that came up after the Texas law, including a couple of things that might have been done differently. The authors offer some suggestions on solutions to some of these problems, suggesting that similar models in other areas (eg, NICU certification, maternity hospital levels) may provide some guidance. They identify some the challenges getting to an agreement on certifications (eg, MFMs won't accept Pedi Surg having all the say and vice versa, getting centers to agree upon how to report outcomes uniformly, etc).

I think this article makes for a good editorial, raising an important question and starting the discussion. They also went into depth in some areas, where they indirectly noted the problem with some database models wherein the lack of transparency of how the outcomes data is obtained or the incompleteness of the data that is entered could lead to disagreements as to the accuracy of the results that come out the other end. Examples of this would be simply quoting survival after TTTS without some scaling for severity of stage at treatment or outcomes generated prior to a critical member of the surgical team leaving. They provide some thoughts on how this might be dealt with. Overall, I feel this is a valuable opinion piece to get a discussion going. My only real criticism is that the editorial just seems to end a little abruptly and unexpectedly. If the ending could be rounded out or a better summarization drawn up as a conclusion, it would feel like it ended on a stronger note.

A new conclusion has been added to the revised manuscript (lines # 342 - 348).

EDITOR COMMENTS:

1. As you can see from the Reviewers' comments, there is a lot of enthusiasm for a revised submission for your paper. The theme of the reviews as I read them, and I have to say that I agree, is the organization of the paper could be stronger. There's nothing in the reviewer comments that I disagree with.

I'd like to suggest that you consider something like:

A. Define the gap in understanding of what a fetal center is.

B. Why is there a national imperative to define fetal centers?

[redacted]

C. Why and how did Texas approach this problem

What are the key elements of the legislation?

What were the major obstacles/areas of disagreement that had to be worked out?

D. What are the lessons learned in this Texan endeavor that a national program must /should consider?

The initial portion of the manuscript has been modified as suggested by the editor (lines # 53 – 170).

2. 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.

OPT IN; YES

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

3. 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.

Done

4. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works. Variance is needed in the following sections:

-Lines 80-82 and 88-90 are verbatim from another publication by the author. Please add variance and cite (if necessary) to avoid self-plagiarism.

[redacted]

These lines have been deleted in the revised manuscript.

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://urldefense.proofpoint.com/v2/url?u=https-3A__www.acog.org_About-2DACOG_ACOG-2DDepartments_Patient-2DSafety-2Dand-2DQuality-2DImprovement_reVITALize&d=DwIGaQ&c=bKRySV-ouEg_AT-w2QWsTdd9X__KYh9Eq2fdmQDVZgw&r=m1aR6ltiqYXK93v7BtQtq9dGRTz3-5M3mIFjqwh5MGk&m=qeBT18_BgyaEfDbODihPKbd8JPrcNDIv4i992JqcLRQ&s=vXFRV4rV07jzLNYN2Ch92fFsnBomZLWp-u91WW4U-_M&e= . 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: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

The manuscript is now 22 pages long.

7. Title: Please revise your title so that you avoid posing a question.

This has been changed to: “The Time Has Come for Designation of Fetal Centers”.

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).

[redacted]

9. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

This has been added to page 2 of the revised manuscript.

10. 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: Current Commentary articles, 250 words. Please provide a word count.

The word count of the Abstract is 231 words.

11. Only standard abbreviations and acronyms are allowed. A selected list is available online at https://urldefense.proofpoint.com/v2/url?u=http-3A__edmgr.ovid.com_ong_accounts_abbreviations.pdf&d=DwIGaQ&c=bKRySV-ouEg_AT-w2QWsTdd9X__KYh9Eq2fdmQDVZgw&r=m1aR6ltiqYXK93v7BtQtq9dGRTz3-5M3mIFjqwh5MGk&m=qeBT18_BgyaEfDbODihPKbd8JPrcNDIv4i992JqcLRQ&s=psvIv8JguAVWpM6r86RWnYvV6tsXIm80kVL3FVx0hJY&e= . 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.

12. 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.

This has been accomplished throughout the manuscript and tables.

13. 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%").

14. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: https://urldefense.proofpoint.com/v2/url?u=http-3A__edmgr.ovid.com_ong_accounts_table-5Fchecklist.pdf&d=DwIGaQ&c=bKRySV-ouEg_AT-w2QWsTdd9X__KYh9Eq2fdmQDVZgw&r=m1aR6ltiqYXK93v7BtQtq9dGRTz3-5M3mIFjqwh5MGk&m=qeBT18_BgyaEfDbODihPKbd8JPrcNDIv4i992JqcLRQ&s=RdHjm5GIC1JDwgL-I3uZoBO_hYRP2uMlKckLgeIAK-0&e= .

15. 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://urldefense.proofpoint.com/v2/url?u=https-3A__www.acog.org_Clinical-2DGuidance-2Dand-2DPublications_Search-2DClinical-2DGuidance&d=DwIGaQ&c=bKRySV-ouEg_AT-w2QWsTdd9X__KYh9Eq2fdmQDVZgw&r=m1aR6ltiqYXK93v7BtQtq9dGRTz3-5M3mIFjqwh5MGk&m=qeBT18_BgyaEfDbODihPKbd8JPrcNDIv4i992JqcLRQ&s=04-yNCPrm25XFr1Z_Yr1Wp8uP9o3ZL5Ux5FpnDF3UVc&e= .

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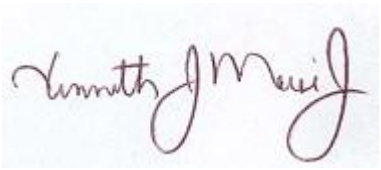
We appreciate the opportunity to revise this manuscript.

If you have any further questions, please do not hesitate to contact me at (713) 486-6552 or by e-mail at Kenneth.J.Moise@uth.tmc.edu.

[redacted]

Sincerely,



Kenneth J. Moise, Jr., M.D.

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Kenneth J. Moise, Jr., M.D.
Department of Obstetrics, Gynecology and Reproductive Sciences
Department of Pediatric Surgery
The University of Texas Health Science at Houston