Date: Jan 04, 2019
To: "Elizabeth E. Krans" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-2085

RE: Manuscript Number ONG-18-2085

National Partnership for Maternal Safety: Consensus Bundle on Obstetric Care for Women with Opioid Use Disorder

Dear Dr. Krans:

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 Jan 25, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

This paper is a consensus bundle on obstetric care for women with opioid use disorder. Given the high incidence and severity of this disease, this is an important issue to address. However, this paper provides an ideal and does not address the reality of how to obtain insurance payment for treatment, access to treatment programs for pregnant women, staff education, funding for institutions to set up these treatment program, and other practical advice to overcome the many barriers that exist in the medical care of this patient population. The addition of this type of information will make this a stronger paper and of practical use and guidance for ob providers, institutions, and the community.

1. Line 106 - reference here please

2. Line 110 - please quantify the decreased life expectancy

3. Line 113-115 - what are reasons for greater increase in women? Please expand

4. Line 117 - please quantify "quadrupled"

5. Line 126 - and fetal safety

6. Line 133 - which states?

7. Line 160-163 - are these free?

8. Line 164-175 - partnership with pediatrics/neonatology personnel for this part? What about education on possible NICU admission, need for extended hospital stay, etc.?

9. Line 181-184 - resources and funding for staff education?

10. Line 196- 204 - please define what is meant by the term "trauma" here in more detail (examples)

11. Line 217-231 - do these resources exist in all communities and if they do, are they able to care for all pregnant women in their community? If they don't exist or limited access due to greater demand, costs, location, etc., how do these programs get started? If they don't exist, pathways can't be developed to link services or keep a list. Please address how to establish these vital services in communities lacking them, especially in smaller, rural areas.

12. Line 232-246 - what about pain management specifically in women on buprenorphine or methadone?

13. Line 244-246 - include pre-delivery anesthesia/pain service consult recommendation

14. Line 250 - and/or

15. Line 258-259 - please explain what is meant by "stable treatment protocols"?

16. Line 265-284 - please include here how providers, health care institutions, communities, and legal institutions should advocate for changes to laws requiring reporting and criminalization of substance abuse by pregnant women.

17. Line 271 - please define civil commitment

18. Line 279-281 - healthcare providers should also consult with social services, risk management, and legal at their institution when deciding whether to report substance abuse and be advised of the implications that may result for themselves, the patient, and the healthcare institution if they do not report as required

19. Line 285-293 - do resources exist throughout the country to carry out these "Plan of Safe Care"?

20. Line 300 - does evaluated here mean screened?

21. Line 303-306 - include recommendations to ensure pregnant women answer the screening questions honestly. What about repeat screening at other points during pregnancy?

22. Line 380-390 - please address how to overcome barriers of lack of access to this care and payment/insurance

23. Line 400-402 - by whom - CPS, healthcare providers, multiple entities?

24. Line 425-430 - debrief whom? Perform RCAs if not involved in the patient's care

25. Line 431-440 - must ensure patient privacy and confidentiality with data sharing

26. Line 449-452 - are AIM resources free?

27. Box 1 - #1 - last line - what about advocating for laws to require access to care and insurance reimbursement? Please provide more detail here as to how team can best obtain reimbursement

28. Box 2 - include patient family and/or friends when providing narcan, also, this is not addressed in the body of the paper and should be

REVIEWER #2:

This Consensus Statement details evidence-based care recommendations in the form of a patient safety bundle to facilitate standardization and improvement of healthcare services provided to pregnant women with opioid use disorders. Overall, this manuscript is well-organized and clear, and a timely aide for healthcare systems trying to grapple with developing an organized response to the opioid crisis in maternity care settings.

I have a few comments that the authors might consider.

Page 11, line 247-254. I foresee that for a significant portion of underinsured or uninsured women with substance use disorders, continued engagement in treatment services after delivery remains the biggest challenge due to unstable insurance (Medicaid) coverage before and after pregnancy (ref). For this population especially, limited access to pharmacologic treatment and appropriate mental health treatment services hinder implementation of both antenatal and postpartum clinical pathways proposed by the authors. How do the authors propose bridging the gap between supply and demand for patients unable to afford or access pharmacologic treatment and other substance use treatment services during pregnancy, and especially postpartum, before the needed infrastructure exists?

Ref: D'Angelo DV, Le B, O'Neil ME, et al. Patterns of Health Insurance Coverage Around the Time of Pregnancy Among Women with Live-Born Infants Pregnancy Risk Assessment Monitoring System, 29 States, 2009. MMWR Surveill Summ 2015;64:1-19

Page 17, Section 9. Collaborate with local child welfare officials to develop individualized "Plans of Safe Care" after delivery. How do the authors propose implementing a workable plan of action involving Child Protective Services, when in some healthcare systems and cities, the involvement of this organization prior to discharge from the hospital has a clearly punitive connotation for a mother working towards recovery? Perhaps a new approach could be considered in educating families early in pregnancy regarding the vital role this agency plays in extended postpartum home visitations, early

intervention services, and recovery supports for mothers. Although I don't have a solution, I can attest to the fact that in our healthcare system, the potential for CPS involvement deters women from returning to our hospital for delivery, even when treatment and stabilization during pregnancy is successful.

REVIEWER #3:

General Comment-
Thank you sincerely for your dedication to the advancement of our field and the wellbeing of patients. This was a consensus bundle for the management of obstetric care in women with opiate use disorder. Congratulations on your thorough review.

Specific Comments (by section and line number)-

1. Abstract- Well organized and concise. Purpose is to "reduce adverse maternal and neonatal health outcomes associated with substance use." Consider expanding on purpose ie reducing unintended social consequences associated with unintended incorrect reporting or stigmatization.

2. Overall formatting- No specific format required for this article type. The article may benefit from being pared down to an explanation of the recommendations within the checklist.

3. Introduction- Excellent explanation of epidemiology and burden associated with this health problem.

4. Introduction lines 119-121: These references (9 and 10) from CO and MA do not support the conclusion that morbidity and mortality from substance use exceeds that from any other cause nationally.

5. Body- Overall clear and concise.

6. Number 3- This may be the most important section. Please highlight more in abstract.

7. Number 5- Consider adding a link to statewide reporting procedures. This would be very useful to clinicians who are concerned about their reporting duties.

8. Number 8- There is considerable subjectivity in this section, and it may benefit from some nuance regarding the size of centers and how to tailor care to these patients. It may not be feasible for women in underserved areas to leave their primary physician in order to seek care at a patient centered medical home.

9. Discussion- Well written, but may benefit from discussion which is geared toward how general obstetrician gynecologists can utilize this information in a stepwise approach to be able to care for these patients safely and compassionately.

REVIEWER #4:

Thank you for the opportunity to review this manuscript. I was familiar with the online resources related to this issue and am pleased to see that the authors have prepared a peer-reviewed manuscript. Overall, this is a very strong manuscript. I also reviewed a similar publication in this journal for another consensus bundle as this manuscript was organized in a similar way. This topic is currently of critical importance in the U.S. and elsewhere.

Some points for your consideration:

1- Abstract and line 106 - would everyone agree this is the greatest public health crisis of our time? Is it in general, or during pregnancy?

2- Line 118 - is this cost for mothers only or mothers and neonates?

3- Under the bundle domains - I would recommend an overall paragraph or statement to introduce the areas of focus

4- Do you want to use the term "patients"? Especially as these actions also happen outside a hospital context

5- I am thinking you are intentionally using clinical setting to show that care happens in places other than in a hospital? It might be worth having something before the domains that is about describing these settings and demonstrating the breadth of providers involved with these families. Some of this may also fit under #1.

6- Harm reduction is only mentioned "lightly" - I would recommend strengthening this throughout - and having it to do with more than the substance - related to determinants of health, improving conditions of daily living

7- Responses bundle - all domains appear to be at the system level - are there domains that need to take place at the

client level?

8- somewhere in the paper - does it need to be talked about that what happens to women and families (ie. reporting to CPS) can be biased based on race, socioeconomic status etc? This issue more than other clinical issues that have bundles needs good context, politics, legal, ethics etc.

9- #6 - screening - can there be something relational in here - to have this screening take place within the context of a trusting relationship and not just be really biomedical (then is also more trauma informed and non-stigmatizing etc). This improves disclosure by women over time.

10- #11 - please include nurses in the provider list. Lines 207-209 - also include nursing organizations in this list and midwives if they have statements/courses

11- Line 217 - add "Providers in.." right at the beginning of the sentence

12- LARC paragraph on page 11 - perhaps consider including something addressing coercion - there are groups in the US who pay women to be sterilized etc. This is also biased related to factors such as race and SES

12- reference #10 - needs details at the end

13- reference #87 - needs name of document

14- references - some formatting needed, inconsistent

REVIEWER #5:

Thank you for the opportunity to review this article on the important and timely topic of OUD in pregnancy. In general, the manuscript is very well-written. References are extensive and mostly current, although somewhat limited to the medical/obstetrical and psychiatric literature. Strengths of the manuscript include comprehensive instructions for evidence-based clinical care (Box 2 and associated sections). The sections on screening and pain management are particularly useful, and the authors are to be commended for stressing a compassionate, non-punitive approach.

One obvious weakness to me, as a rural health clinician/researcher in a poor state, is that the system-based suggestions are less useful and specific. The overall focus is on the individual pregnant woman and her fetus/baby, and the proposed guidelines do not adequately address the social context and underlying issues of poverty, legal exposure, and lack of referral mechanisms, particularly in rural areas. Since a higher proportion of pregnant women with OUD reside in rural areas, and MAT providers may be few and far between, this issue should to be specifically addressed in order for this bundle to be useful for a significant percentage of providers.

My specific suggestions for improvement are as follows:

1. Page 6, lines 139-151, #1: Please provide more detail about how an "implementation team" can be recruited and resourced at various types of facilities, particularly in rural and underserved areas with a shortage of providers.

2. Page 8, lines 194-195, #3: "Exploring the larger context of patient's lives" should also include more background information on family context. Specifically, providers should be aware of intergenerational OUD in families and the likelihood that women's partners often do NOT have access to treatment. This reality often affects women's ability to adhere to a treatment program, leads to sharing or selling of MAT prescriptions, etc.

3. Page 9, lines 201-204, #3: Agree that it is crucial to acknowledge psychological trauma, but add that women may often become addicted in the first place due to chronic pain or injury as well.

4. Pages 9-11, Box, #4: no specific suggestions for improvement, this is a very useful section from a clinical perspective.

5. Page 12, lines 276-285, #5: I applaud ACOG's position of patient advocacy regarding mandatory testing and reporting. Women who are jailed as a result have poorer infant outcomes due to treatment inconsistency and withdrawal symptoms.

6. Page 13, lines 28-293, #5: Are there available statistics yet on how well the Plan of Safe Care is working?

7. Page 13-14, lines 307-319, #6: Agree with the emphasis on screening tools over universal urine screening. This should also be a bullet point for Box 2 under Antepartum Care. Since positive ("dirty") urine screens are directly reportable and have unavoidable legal consequences in some states, this point deserves to be emphasized in the checklist.

8. Page 17, lines 383-390, #8: While ensuring that all patients receive the pharmacotherapy that aligns with their needs and personal preferences is a notable ideal, the statement seems to ignore the reality of two-year waiting lists for

methadone clinics and a severe shortage of experienced buprenorphine prescribers. It might be useful to add something here about using ECHO or telehealth to assist inexperienced or isolated providers to collaborate via videoconferencing with experts to review cases.

9. Page 19, lines 436-440, #12: This section is somewhat vague. Since there is often little coordination and communication between local providers and the criminal justice system, please provide some more specific details on coordinating care between the two.

EDITOR #1 COMMENTS:

The reviewers were thorough in their content and feedback assessment. Therefore, my comments focus on being inclusive of the various providers involved in maternity care:

1. Line 84 and throughout: Please use maternity care instead of obstetric care.

2. Line 97: Please use maternity care settings rather than maternity settings.

3. Line 124 and throughout: Please use maternity care providers rather than obstetric providers.

4. Line 147 and throughout: Please use maternity care instead of obstetrics.

5. Line 237 and throughout: Please use birth instead of delivery.

6. Line 281: ACNM's "Substance Use Disorders in Pregnancy" position statement should be cited here along with similar statements from other organizations represented by the manuscript's authors.

7. Line 364: Assure should be ensure.

8. Lines 422: Midwives and nurses should be included in this list of providers.

EDITOR #2 COMMENTS:

I highly recommend replacing the word "impact" throughout with affect or effect as appropriate.

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

2. 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.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

3. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology 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.

4. 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).

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

6. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Executive Summaries, Consensus Statements, and Guidelines, 250 words. Please provide a word count.

7. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com/ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

8. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

9. 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.

10. 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.

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If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors 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, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

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University of Pittsburgh

SCHOOL OF MEDICINE
Department of Obstetrics, Gynecology and Reproductive Sciences

February 14th, 2019

Obstetrics & Gynecology
409 12th Street, SW
Washington, DC 20024-2188

RE: Manuscript Number ONG-18-2085

Dear Editors,

Enclosed please find our revised consensus statement for consideration for publication in *Obstetrics & Gynecology* entitled: "**National Partnership for Maternal Safety: Consensus Bundle on Obstetric Care for Women with Opioid Use Disorder."** The authors thank the reviewers for their thoughtful comments and suggestions following the review of this manuscript. We have included detailed response to each of the reviewer's comments below. Page and line numbers for reviewer reference refer to the clean copy of the revision.

As the lead author, I affirm that this manuscript is an honest, accurate, and transparent account of the material being reported; that no important aspects have been omitted; and that any discrepancies have been explained. All authors have made a substantial contribution to this work and have met criteria for authorship. The manuscript has not been previously published and is not currently under consideration for publication elsewhere.

Disclosures: Elizabeth E. Krans is an investigator on grants to Magee-Womens Research Institute from the National Institutes of Health, Gilead and Merck outside of the submitted work. None of the other authors have any financial or material support to disclose and did not report any potential conflicts of interest.

Thank you for your consideration of our manuscript.

Sincerely,

Elizabeth E. Krans, MD, MSc
[redacted]

[redacted]

RE: Manuscript Number ONG-18-2085

National Partnership for Maternal Safety: Consensus Bundle on Obstetric Care for Women with Opioid Use Disorder

REVIEWER COMMENTS:

REVIEWER #1:
This paper is a consensus bundle on obstetric care for women with opioid use disorder. Given the high incidence and severity of this disease, this is an important issue to address. However, this paper provides an ideal and does not address the reality of how to obtain insurance payment for treatment, access to treatment programs for pregnant women, staff education, funding for institutions to set up these treatment program, and other practical advice to overcome the many barriers that exist in the medical care of this patient population. The addition of this type of information will make this a stronger paper and of practical use and guidance for ob providers, institutions, and the community.

Response: Thank you for these recommendations. In our revision, the authors have added several links to specific and pragmatic resources that can help providers overcome barriers to high quality care for this population.

Comment 1: Line 106 - reference here please

Response to Comment 1: A reference has been inserted.

Comment 2: Line 110 - please quantify the decreased life expectancy

Response to Comment 1: We have quantified the decrease in life expectancy from opioids.

Opioid use has reached such epidemic proportions that mortality from drug use now exceeds deaths due to motor vehicle accidents and has contributed to a loss of 0.21 years in life expectancy in the United States (Page, Lines).

Comment 3: Line 113-115 - what are reasons for greater increase in women? Please expand.

Response to Comment 3: We have expanded on reasons for greater increases in women compared to men.

A greater prevalence of co-morbid psychiatric disorders, gender-based violence, physical and sexual abuse and chronic pain disorders likely contribute to disproportionate rates of opioid use and misuse among women compared to men (Page, Lines).

Comment 4: Line 117 - please quantify "quadrupled"

Response to Comment 4: We have quantified “quadrupled.”
Between 1999 and 2014, the prevalence of opioid use disorder during pregnancy increased from 1.5 to 6.5 per 1,000 hospital births per year and maternal and neonatal hospitalizations due to substance use have resulted in $944 million in healthcare costs (Page, Lines).

Comment 5: Line 126 - and fetal safety

[redacted]

Response to Comment 5: "Fetal safety" has been added.

Comment 6: Line 133 - which states?

Response to Comment 6: Leadership from 14 states helped to create implementation resources which we have now listed.

To facilitate the implementation process necessary to incorporate evidence-based recommendations into maternity care settings, leadership from perinatal quality collaboratives across 14 states (MD, VA, OK, IL, OH, NM, TN, TX, NJ, NY, ME, VT, NH, MA) collaborated with workgroup members to create a series of implementation resources to help institutions translate guidelines into clinical practice. (Page, Lines)

Comment 7: Line 160-163 - are these free?

Response to Comment 7: Thank you for this question. The SAMHSA fact sheets are available for download from the SAMHSA website, http://store.samhsa.gov.

The Substance Abuse and Mental Health Services Administration (SAMHSA) has created a series of evidence-based, patient educational materials designed for pregnant women with opioid use disorder which explain the treatment process and are available for download at http://store.samhsa.gov (Page, Lines).

Comment 8: Line 164-175 - partnership with pediatrics/neonatology personnel for this part? What about education on possible NICU admission, need for extended hospital stay, etc.?

Response to Comment 8: Thank you for this comment. We have added education on possible NICU admission and need for extended hospital stay.

Because additional interventions may be warranted, patients should also receive education regarding the pharmacologic treatment process for NOWS (i.e. medications are started at low doses and slowly titrated to control symptoms) and possible need for neonatal intensive care unit (NICU) admission and an extended neonatal hospitalization. Patients should also be counseled that even if medications are used, ongoing maternal involvement in care and continued non-pharmacologic interventions remain integral to improving outcomes.[28] To ensure consistency in approach, patient education, counseling and training regarding NOWS and NOWS interventions should be developed in partnership with pediatric and neonatology providers (Page, Lines).

Comment 9: Line 181-184 - resources and funding for staff education?

Response to Comment 9: Thank you for this question. We have added a link to on-line training and resources for staff education.

SAMHSA has created the Provider's Clinical Support System (PCSS) to address the clinical training and education needs of providers regarding the prevention, identification and treatment of substance use disorders with a focus on opioid use disorders. Online modules, webinars and clinical practice simulations are available through the PCSS website at https://www.asam.org/education/resources/pcss-mat (Page, Lines).

Comment 10: Line 196- 204 - please define what is meant by the term "trauma" here in more detail (examples)

Response to Comment 10: Thank you for this question. We have defined trauma more specifically and put in an example of a history of physical and sexual abuse as a cause of trauma-related symptoms.

Trauma is an intense physical and psychological stress reaction that results from an event or series of events that is experienced as harmful or threatening and has lasting adverse effects on an individual's functioning and physical, social, emotional and spiritual well-being.[36] Among women in substance use treatment, 55-99% report a history of physical or sexual abuse which often results in trauma-related symptoms consistent with post-traumatic stress disorder (PTSD).[9](Page, Lines)

Comment 11: Line 217-231 - do these resources exist in all communities and if they do, are they able to care for all pregnant women in their community? If they don't exist or limited access due to greater demand, costs, location, etc., how do these programs get started? If they don't exist, pathways can't be developed to link services or keep a list. Please address how to establish these vital services in communities lacking them, especially in smaller, rural areas.

Response to Comment 11: Thank you for this important question. While each community and geographic region will have differential access to MAT and associated services, the SAMHSA Behavioral Health Treatment Locator is a national, web-based resource that can help providers identify substance use treatment services in their community. We have added information regarding the SAMHSA treatment locator to the manuscript.

The SAMHSA Behavioral Health Treatment Locator, https://www.findtreatment.samhsa.gov/, is an on-line resource that can help providers search for substance use treatment programs, mental health services and buprenorphine providers by state, county and distance in miles and identifies which providers accept Medicaid for services.

Comment 12: Line 232-246 - what about pain management specifically in women on buprenorphine or methadone?

Response to Comment 12: Thank you for this question. We discuss postpartum pain management strategies specifically for women on opioid pharmacotherapy (i.e. buprenorphine or methadone) which include continuation of opioid pharmacotherapy plus additional modalities (multi-modal, opioid-sparing interventions) to treat acute delivery-related pain.

Because the analgesic needs of women on opioid pharmacotherapy may increase by 40-70% after cesarean delivery, intrapartum and postpartum pain management pathways should be developed in coordination with anesthesia providers and typically include the continuation of opioid pharmacotherapy with additional modalities to treat acute birth-related pain.[41,42] Approaches should prioritize multi-modal, opioid-sparing interventions and typically include a fixed regimen of acetaminophen and non-steroidal anti-inflammatory agents (NSAIDs), neuraxial opioid or additional regional blocks (e.g. transverse abdominal plane blocks or catheters), and other agents (i.e. ketamine).[43](Page, Lines)

Comment 13: Line 244-246 - include pre-delivery anesthesia/pain service consult recommendation

[redacted]

Response to Comment 13: Thank you for this comment. We have added a recommendation to coordinate with anesthesia regarding postpartum pain control.

Because the analgesic needs of women on opioid pharmacotherapy may increase by 40-70% after cesarean delivery, intrapartum and postpartum pain management pathways should be developed in coordination with anesthesia providers and typically include the continuation of opioid pharmacotherapy with additional modalities to treat acute birth-related pain.[43,44] (Page, Lines)

Comment 14: Line 250 - and/or

Response to Comment 14: Thank you for this comment. However, per journal guidelines, and/or is not allowable.

Comment 15: Line 258-259 - please explain what is meant by "stable treatment protocols"?

Response to Comment 15: Thank you for this clarification. We have replaced “stable treatment protocols” with “engaged in substance use treatment.”

Breastfeeding and breastmilk have been shown to confer both maternal and infant benefits and is encouraged in women with opioid use disorder engaged in substance use treatment (Page, Lines).

Comment 16: Line 265-284 - please include here how providers, health care institutions, communities, and legal institutions should advocate for changes to laws requiring reporting and criminalization of substance abuse by pregnant women.

Response to Comment 16: Thank you for this question. We have provided the link to ACOG Advocacy for provider to become engaged in advocacy activities sponsored by ACOG.

ACOG Advocacy provides a mechanism to engage lawmakers at the state and federal level to stop legislation that harms women and children and can be accessed at https://www.acog.org/About-ACOG/ACOG-Departments/Government-Relations-and-Outreach (Page, Lines)

Comment 17: Line 271 - please define civil commitment

Response to Comment 17: Thank you for this question. Civil commitment is also known an involuntary hospitalization. We have added this definition.

Over twenty states and the District of Columbia define prenatal substance use as child abuse under civil law, and at least three include prenatal substance use as grounds for civil commitment or involuntary hospitalization.[51]

Comment 18: Line 279-281 - healthcare providers should also consult with social services, risk management, and legal at their institution when deciding whether to report substance abuse and be advised of the implications that may result for themselves, the patient, and the healthcare institution if they do not report as required.

[redacted]

Response to Comment 18: Thank you for this comment. We have added a sentence about the importance of consulting with social services providers.

Providers should consult with social services providers to assist with reporting decisions as they can assist with patient evaluations and reporting requirements. (Page, Lines)

Comment 19: Line 285-293 - do resources exist throughout the country to carry out these "Plan of Safe Care"?

Response to Comment 19: Thank you for this important question. We have now provided a link to "Plan of Safe Care" resources provided by the National Center on Substance Abuse and Child Welfare.

The National Center on Substance Abuse and Child Welfare has complied a series of on-line resources for infants with prenatal substance exposure including several Plan of Safe Care examples developed by state and local child welfare agencies, https://ncsacw.samhsa.gov/resources/substance-exposed-infants.aspx.

Comment 20: Line 300 - does evaluated here mean screened?

Response to Comment 20: We have replaced "evaluated" with "screened."

Comment 21: Line 303-306 - include recommendations to ensure pregnant women answer the screening questions honestly. What about repeat screening at other points during pregnancy?

Response to Comment 21: Thank you for this comment. We have added the following sentence to address the need to repeat screening after prenatal entry and the need to take a patient-centered approach to encourage honest answers to screening questions.

If the concern for substance use persists, repeat screening should occur during pregnancy using a patient-centered, non-judgmental approach (Page, Lines).

Comment 22: Line 380-390 - please address how to overcome barriers of lack of access to this care and payment/insurance

Response to Comment 22: Thank you for this important question. We added information on how to find opioid treatment providers across the country and especially those providers who accept Medicaid for services.

The SAMHSA Behavioral Health Treatment Locator, https://www.findtreatment.samhsa.gov/, is an on-line resource that can help providers search for substance use treatment programs, mental health services and buprenorphine providers by state, county and distance in miles and identifies which providers accept Medicaid for services (Page, Lines).

Comment 23: Line 400-402 - by whom - CPS, healthcare providers, multiple entities?

Response to Comment 23: Thank you for this question. Home visitation services are provided by a variety of agencies including CPS, social services and state and local entities. As there may be significant variation across states, the authors wanted to leave the agency that should provide home visitation services open to tailoring by each individual health system.

[redacted]

Comment 24: Line 425-430 - debrief whom? Perform RCAs if not involved in the patient's care

Response to Comment 24: Thank you for this comment. We have revised this sentence to include the need to perform RCAs.

The case review team should provide opportunities to debrief serious maternal (i.e. respiratory depression, overdose, overdose death) and neonatal (i.e. accidental death, sudden infant death syndrome (SIDS), child removal cases) adverse events and perform a root cause analysis to identify actionable ways to improve clinical pathways, care coordination and provider practice patterns to eliminate or prevent future adverse events. (Page, Lines)

Comment 25: Line 431-440 - must ensure patient privacy and confidentiality with data sharing

Response to Comment 25: Thank you. We have added this important point.

Importantly, any data collection and sharing efforts must ensure patient privacy and confidentiality. (Page, Lines)

Comment 26: Line 449-452 - are AIM resources free?

Response to Comment 26: Yes, the AIM resources are free and available on the AIM website which is listed in the manuscript.

Comment 27: Box 1 - #1 - last line - what about advocating for laws to require access to care and insurance reimbursement? Please provide more detail here as to how team can best obtain reimbursement

Response to Comment 27: Thank you for this important question. We added a recommendation to share hospital-level data with Medicaid managed care organizations to better advocate for insurance reimbursement initiatives to expand treatment access.

- ✓ *Use data to engage child welfare, public health agencies, Medicaid managed care organizations, court systems, and law enforcement to drive initiatives to expand treatment access and improve maternal and neonatal outcomes*

Comment 28: Box 2 - include patient family and/or friends when providing narcan, also, this is not addressed in the body of the paper and should be

Response to Comment 28: Thank you. We have added the importance of providing Narcan prescriptions and instructions for patients, family members and friends.

Box #2: Provide Narcan prescriptions and instructions to patients, family members and friends

REVIEWER #2:
This Consensus Statement details evidence-based care recommendations in the form of a patient safety bundle to facilitate standardization and improvement of healthcare services provided to pregnant women with opioid use disorders. Overall, this manuscript is well-organized and clear, and a timely aide for healthcare systems trying to grapple with developing an organized response to the opioid crisis in maternity care settings.

[redacted]

I have a few comments that the authors might consider.

Comment 1: Page 11, line 247-254. I foresee that for a significant portion of underinsured or uninsured women with substance use disorders, continued engagement in treatment services after delivery remains the biggest challenge due to unstable insurance (Medicaid) coverage before and after pregnancy (ref). For this population especially, limited access to pharmacologic treatment and appropriate mental health treatment services hinder implementation of both antenatal and postpartum clinical pathways proposed by the authors. How do the authors propose bridging the gap between supply and demand for patients unable to afford or access pharmacologic treatment and other substance use treatment services during pregnancy, and especially postpartum, before the needed infrastructure exists?

Ref: D'Angelo DV, Le B, O'Neil ME, et al. Patterns of Health Insurance Coverage Around the Time of Pregnancy Among Women with Live-Born Infants Pregnancy Risk Assessment Monitoring System, 29 States, 2009. MMWR Surveill Summ 2015;64:1-19

Response to Comment 1: Thank you for this important comment. This consensus statement is intended to guide healthcare systems and providers in the clinical approach to caring for pregnant women with OUD within their existing infrastructure. While there is a critical shortage of the number of treatment providers, closing this gap is an active area of public health research and outside of the scope of our objective. However, we have provided a link to a treatment provider locator maintained by SAMHSA which providers can use to identify treatment programs in their area, which should continue to increase in number as health policy initiatives designed to expand treatment services are implemented.

The SAMHSA Behavioral Health Treatment Locator, https://www.findtreatment.samhsa.gov/, is an on-line resource that can help providers search for substance use treatment programs, mental health services and buprenorphine providers by state, county and distance in miles and identifies which providers accept Medicaid for services. (Page, Lines)

Comment 2: Page 17, Section 9. Collaborate with local child welfare officials to develop individualized "Plans of Safe Care" after delivery. How do the authors propose implementing a workable plan of action involving Child Protective Services, when in some healthcare systems and cities, the involvement of this organization prior to discharge from the hospital has a clearly punitive connotation for a mother working towards recovery? Perhaps a new approach could be considered in educating families early in pregnancy regarding the vital role this agency plays in extended postpartum home visitations, early intervention services, and recovery supports for mothers. Although I don't have a solution, I can attest to the fact that in our healthcare system, the potential for CPS involvement deters women from returning to our hospital for delivery, even when treatment and stabilization during pregnancy is successful.

Response to Comment 2: The authors agree with the reviewer's important comment. Thus, we have added a sentence to this section, discussing the important role of positively characterizing the role that social services can play early in pregnancy.

Patients and family members should also receive education early in pregnancy about the positive role that social services agencies, including CPS, can play in providing resources and interventions for both mothers and babies after delivery. For example, post-discharge care plans for mothers and newborns should include home visitation, early intervention services and

recovery supports and should be of sufficient duration (i.e. beyond the 6-week postpartum period) to ensure the increased likelihood of family stability. (Page, Lines)

REVIEWER #3:
Thank you sincerely for your dedication to the advancement of our field and the wellbeing of patients. This was a consensus bundle for the management of obstetric care in women with opiate use disorder. Congratulations on your thorough review.

Comment 1: Abstract- Well organized and concise. Purpose is to "reduce adverse maternal and neonatal health outcomes associated with substance use." Consider expanding on purpose ie reducing unintended social consequences associated with unintended incorrect reporting or stigmatization.

Response to Comment 1: Thank you for this comment. The authors consider stigmatization and incorrect reporting to be adverse maternal outcomes associated with substance use and therefore conceptually included in our purpose. We provide a detailed description of the harms associated with stigma and incorrect reporting in Section 3 and Section 5 of the manuscript.

Comment 2: Overall formatting- No specific format required for this article type. The article may benefit from being pared down to an explanation of the recommendations within the checklist.

Response to Comment 2: The numbered sections in the manuscript correspond with the numbered sections in the checklist.

Comment 3: Introduction- Excellent explanation of epidemiology and burden associated with this health problem.

Response to Comment 3: Thank you.

Comment 4: Introduction lines 119-121: These references (9 and 10) from CO and MA do not support the conclusion that morbidity and mortality from substance use exceeds that from any other cause nationally.

Response to Comment 4: Thank you for this correction and we have edited this sentence.

Pregnancy-associated morbidity and mortality due to substance use highlights the need to prioritize substance use as a major patient safety issue. (Page, Lines)

Comment 5: Body- Overall clear and concise.

Response to Comment 5: Thank you.

Comment 6: Number 3- This may be the most important section. Please highlight more in abstract.

Response to Comment 6: Thank you for this comment. The authors are unfortunately limited to a word count in the abstract which has already been reached.

Comment 7: Number 5- Consider adding a link to statewide reporting procedures. This would

be very useful to clinicians who are concerned about their reporting duties.

Response to Comment 7: Thank you for this comment. However, the authors are unaware of a link to statewide reporting procedures that is representative of all 50 states.

Comment 8: Number 8- There is considerable subjectivity in this section, and it may benefit from some nuance regarding the size of centers and how to tailor care to these patients. It may not be feasible for women in underserved areas to leave their primary physician in order to seek care at a patient centered medical home.

Response to Comment 8: Thank you for this comment. Our intention was not to recommend that patients leave an existing care provider who is able to provide comprehensive services. Instead, the authors wanted to provide an example of a healthcare model that may be particularly useful for clinical settings which do not have an existing approach.

Comment 9: Discussion- Well written but may benefit from discussion which is geared toward how general obstetrician gynecologists can utilize this information in a stepwise approach to be able to care for these patients safely and compassionately.

Response to Comment 9: Thank you for this comment. The authors agree that the bundle is very complex. Therefore, to assist with the bundle adoption process, we have created an Implementation Guide which provides a stepwise approach.

Because clinical practice change regarding the care of women with substance use disorders during pregnancy may be particularly challenging, an Implementation Guide was created to highlight the bundle's core components (Box 1). (Page, Lines)

REVIEWER #4:
Thank you for the opportunity to review this manuscript. I was familiar with the online resources related to this issue and am pleased to see that the authors have prepared a peer-reviewed manuscript. Overall, this is a very strong manuscript. I also reviewed a similar publication in this journal for another consensus bundle as this manuscript was organized in a similar way. This topic is currently of critical importance in the U.S. and elsewhere.

Comment 1: Abstract and line 106 - would everyone agree this is the greatest public health crisis of our time? Is it in general, or during pregnancy?

Response to Comment 1: Thank you. We have revised this sentence accordingly.

The opioid epidemic is a profound public health crisis (Page, Lines).

Comment 2: Line 118 - is this cost for mothers only or mothers and neonates?

Response to Comment 2: Thank you for this question. This cost estimate is for maternal and neonatal hospitalizations and we have revised this sentence accordingly.

Between 1999 and 2014, the prevalence of opioid use disorder during pregnancy increased from 1.5 to 6.5 per 1,000 hospital births per year and maternal and neonatal hospitalizations due to substance use have resulted in $944 million in healthcare costs. (Page, Lines)

Comment 3: Under the bundle domains - I would recommend an overall paragraph or statement to introduce the areas of focus.

Response to Comment 3: Thank you for this comment. Due to journal page limitations, the authors were unable to include an additional paragraph introducing the areas of focus.

Comment 4: Do you want to use the term "patients"? Especially as these actions also happen outside a hospital context

Response to Comment 4: Thank you for this question. We only use the term patients when we are describing the clinical/hospital context. Outside of the hospital context, we use term pregnant women with opioid use disorder.

Comment 5: I am thinking you are intentionally using clinical setting to show that care happens in places other than in a hospital? It might be worth having something before the domains that is about describing these settings and demonstrating the breadth of providers involved with these families. Some of this may also fit under #1.

Response to Comment 5: Yes, the authors chose clinical setting to describe a broad range of settings where healthcare can occur including inpatient and outpatient settings and hospital-based vs. community-based settings.

Comment 6: Harm reduction is only mentioned "lightly" - I would recommend strengthening this throughout - and having it to do with more than the substance - related to determinants of health, improving conditions of daily living.

Response to Comment 6: The authors agree that harm reduction is an important competent of both clinical and the public health care of people with opioid use disorder. However, the term “harm reduction” can be off-putting, and although the bundle is grounded in harm reduction principles, we believe that a "lighter" approach is the more efficacious approach**.**

Comment 7: Responses bundle - all domains appear to be at the system level - are there domains that need to take place at the client level?

Response to Comment 7: The Response domain inherently involves provider and health system approaches to addressing client level problems (i.e. opioid use disorder).

Comment 8: somewhere in the paper - does it need to be talked about that what happens to women and families (ie. reporting to CPS) can be biased based on race, socioeconomic status etc? This issue more than other clinical issues that have bundles needs good context, politics, legal, ethics etc.

Response to Comment 8: Thank you for this important comment. Section 5 (Reporting) and 9 (Plan of Safe Care) provide an extensive review of how to navigate reporting and provide a Plan of Safe Care for all women with opioid use disorder without bias.

Comment 9: #6 - screening - can there be something relational in here - to have this screening take place within the context of a trusting relationship and not just be really biomedical (then is also more trauma informed and non-stigmatizing etc). This improves disclosure by women over time.

Response to Comment 9: Thank you for this comment. We have added a sentence about the need to approach screening with a patient-centered, non-judgmental approach.

If the concern for substance use persists, repeat screening should occur during the pregnancy using a patient-centered, non-judgmental approach. (Page, Lines)

Comment 10: #11 - please include nurses in the provider list. Lines 207-209 - also include nursing organizations in this list and midwives if they have statements/courses

Response to Comment 10: Thank you. We have included nurses in the provider list.

Case review teams should be composed of a multidisciplinary group of providers including obstetricians, nurse midwives, addiction medicine providers, pediatricians, anesthesiologists, nurses and social services providers and should meet regularly to review clinical care and guideline implementation processes, adverse maternal and neonatal events and identify ways to continue to improve health system approaches to substance use care (Page, Lines).

Comment 11: Line 217 - add "Providers in.." right at the beginning of the sentence

Response to Comment 11: “Providers in” has been added.

Comment 12: LARC paragraph on page 11 - perhaps consider including something addressing coercion - there are groups in the US who pay women to be sterilized etc. This is also biased related to factors such as race and SES.

Response to Comment 12: Thank you for this important comment. We have revised the LARC sentence to include a provision that contraceptive counseling should align with women’s reproductive health goals.

Due to a high prevalence of unintended pregnancy among women with substance use disorders, women should receive contraceptive counseling that aligns with their reproductive health goals (Page, Lines).

Comment 13: reference #10 - needs details at the end

Response to Comment 13: Details have been added to reference 10.

Comment 14: reference #87 - needs name of document

Response to Comment 14: We have added the name of the document.

Comment 15: references - some formatting needed, inconsistent

Response to Comment 15: We have corrected the references.

REVIEWER #5:

Thank you for the opportunity to review this article on the important and timely topic of OUD in pregnancy. In general, the manuscript is very well-written. References are extensive and mostly

current, although somewhat limited to the medical/obstetrical and psychiatric literature. Strengths of the manuscript include comprehensive instructions for evidence-based clinical care (Box 2 and associated sections). The sections on screening and pain management are particularly useful, and the authors are to be commended for stressing a compassionate, non-punitive approach.

One obvious weakness to me, as a rural health clinician/researcher in a poor state, is that the system-based suggestions are less useful and specific. The overall focus is on the individual pregnant woman and her fetus/baby, and the proposed guidelines do not adequately address the social context and underlying issues of poverty, legal exposure, and lack of referral mechanisms, particularly in rural areas. Since a higher proportion of pregnant women with OUD reside in rural areas, and MAT providers may be few and far between, this issue should to be specifically addressed in order for this bundle to be useful for a significant percentage of providers.

My specific suggestions for improvement are as follows:

Comment 1: Page 6, lines 139-151, #1: Please provide more detail about how an "implementation team" can be recruited and resourced at various types of facilities, particularly in rural and underserved areas with a shortage of providers.

Response to Comment 1: Thank you for this question. Because the mix of administrators, providers and community champions may differ across clinical locations, we intentionally left the mechanism for recruitment at the discretion of providers and healthcare systems to allow for local customization.

Comment 2: Page 8, lines 194-195, #3: "Exploring the larger context of patient's lives" should also include more background information on family context. Specifically, providers should be aware of intergenerational OUD in families and the likelihood that women's partners often do NOT have access to treatment. This reality often affects women's ability to adhere to a treatment program, leads to sharing or selling of MAT prescriptions, etc.

Response to Comment 2: Thank you for this comment. We have revised this sentence to include social relationships that may impact substance use behaviors.

Understanding the extent and nature of a woman's substance use within the larger context of her life (i.e. partner, family members or friends with untreated substance use) is essential for careful diagnosis and successful treatment. (Page, Lines)

Comment 3: Page 9, lines 201-204, #3: Agree that it is crucial to acknowledge psychological trauma but add that women may often become addicted in the first place due to chronic pain or injury as well.

Response to Comment 3: Thank you for this comment. However, chronic pain is a very distinct disorder from substance use and therefore, is largely outside of the focus of our objective.

Comment 4: Pages 9-11, Box, #4: no specific suggestions for improvement, this is a very useful section from a clinical perspective.

Response to Comment 4: Thank you.

[redacted]

Comment 5: Page 12, lines 276-285, #5: I applaud ACOG's position of patient advocacy regarding mandatory testing and reporting. Women who are jailed as a result have poorer infant outcomes due to treatment inconsistency and withdrawal symptoms.

Response to Comment 5: Thank you.

Comment 6: Page 13, lines 28-293, #5: Are there available statistics yet on how well the Plan of Safe Care is working?

Response to Comment 6: Thank you for this important question. The authors are unaware of any statistics on how well the Plan of Safe Care is working, although this data is desperately needed.

Comment 7: Page 13-14, lines 307-319, #6: Agree with the emphasis on screening tools over universal urine screening. This should also be a bullet point for Box 2 under Antepartum Care. Since positive ("dirty") urine screens are directly reportable and have unavoidable legal consequences in some states, this point deserves to be emphasized in the checklist.

Response to Comment 7: Thank you for this comment. However, Box 2 is intended to provide examples of a clinical pathways for women with opioid use disorder and not the general population which is the target population for universal self-reported screening vs. universal urine screening.

Comment 8: Page 17, lines 383-390, #8: While ensuring that all patients receive the pharmacotherapy that aligns with their needs and personal preferences is a notable ideal, the statement seems to ignore the reality of two-year waiting lists for methadone clinics and a severe shortage of experienced buprenorphine prescribers. It might be useful to add something here about using ECHO or telehealth to assist inexperienced or isolated providers to collaborate via videoconferencing with experts to review cases.

Response to Comment 8: Thank you for this comment. We have added a sentence regarding provider training initiatives such as Project ECHO.

In rural areas where treatment access is limited, provider training initiatives, such as Project ECHO (Extension for Community Health Outcomes), have been successfully used to educate and train providers to adopt evidence-based practices regarding OUD. (Page, Lines)

Comment 9: Page 19, lines 436-440, #12: This section is somewhat vague. Since there is often little coordination and communication between local providers and the criminal justice system, please provide some more specific details on coordinating care between the two.

Response to Comment 9: Thank you for this question. Developing connections between health systems and community partners is an emerging area of importance. However, specific details on coordinating care between the two will need to be tailored to each maternity care setting and region. Therefore, the authors wanted to introduce the importance of community linkages and provide some specific examples of community partners that could be engaged.

EDITOR #1 COMMENTS:
The reviewers were thorough in their content and feedback assessment. Therefore, my comments focus on being inclusive of the various providers involved in maternity care:

[redacted]

Comment 1: Line 84 and throughout: Please use maternity care instead of obstetric care.

Response to Comment 1: Thank you for this comment. The authors changed obstetric care to maternity care in the body of the manuscript. However, the formal title of the patient safety bundle is Obstetric Care for Women with Opioid Use Disorder. Thus, the authors were hesitant to change obstetric care to maternity care when this phrase is used in the title of the bundle. We defer to the journal editors on final decision-making for this issue.

Comment 2: Line 97: Please use maternity care settings rather than maternity settings.

Response to Comment 2: This change has been made throughout the manuscript.

Comment 3: Line 124 and throughout: Please use maternity care providers rather than obstetric providers.

Response to Comment 3: This change has been made throughout the manuscript.

Comment 4: Line 147 and throughout: Please use maternity care instead of obstetrics.

Response to Comment 4: This change has been made throughout the manuscript.

Comment 5: Line 237 and throughout: Please use birth instead of delivery.

Response to Comment 5: This change has been made throughout the manuscript.

Comment 6: Line 281: ACNM's "Substance Use Disorders in Pregnancy" position statement should be cited here along with similar statements from other organizations represented by the manuscript's authors.

Response to Comment 6: The position statements of SAMHSA, ACNM and NPWH have been added to ACOG and ASAM.

ACOG, ASAM, SAMHSA, the American College of Nurse Midwives (ACNM) and the National Association of Nurse Practitioners in Women's Health (NPWH) oppose mandatory testing for substance use in pregnancy and caution against laws or regulations that require healthcare providers to violate confidentiality by reporting pregnant patients with current or past drug use to legal authorities or child welfare agencies in the absence of evidence of child abuse and neglect. [55-59] *(Page, Lines)*

Comment 7: Line 364: Assure should be ensure.

Response to Comment 7: Assure has been changed to ensure.

Comment 8: Lines 422: Midwives and nurses should be included in this list of providers.

Response to Comment 8: Midwives and nurses have now been included.

Case review teams should be composed of a multidisciplinary group of providers including obstetricians, nurse midwives, addiction medicine providers, pediatricians, anesthesiologists,

[redacted]

nurses and social services providers and should meet regularly to review clinical care and guideline implementation processes, adverse maternal and neonatal events and identify ways to continue to improve health system approaches to substance use care. (Page, Lines)

EDITOR #2 COMMENTS:

Comment 1: I highly recommend replacing the word "impact" throughout with affect or effect as appropriate.

Response to Comment 1: “Impact” was replaced throughout the manuscript with affect or effect.

EDITORIAL OFFICE COMMENTS:

Comment 1: The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

Response to Comment 1: OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.

Daniel Mosier

From: Krans, Elizabeth [redacted]
Sent: Wednesday, May 15, 2019 10:43 AM
To: Daniel Mosier
Subject: RE: Manuscript Revisions: ONG-18-2085R2
Attachments: 18-2085R2 ms (5-14-19v3) (002) - EEK comments.docx

Hi Daniel,

I have attached the revised document. I made some minor changes in the document (via track changes). I rejected a few of the edits to maintain the original message, but most edits were fine (done in track changes as well).

Our team also feels strongly about using the Bundle's Implementation Guide for Box 1 vs. the full bundle as it is much shorter and I cut and pasted the implementation guide into the attached document. I believe this has already been agreed upon by our team and ACOG etc.

Melinda Campopiano has been notified to complete the CTA.

Line 74 – the disclosure looks great.

Please let me know if you have any questions etc. about the attached – thank you!!!

Liz Krans

1. Please note the edits and deletions made throughout. Please let us know if you disagree with any of these changes.
2. LINE 10: Melinda Campopiano will need to complete our electronic Copyright Transfer Agreement, which was sent to her through Editorial Manager.
3. LINE 74: This disclosure must appear on all bundles going forward. See the correction being published in the journal's June 2019 issue, available online after 5:00 pm ET on May 23.

From: Daniel Mosier <dmosier@greenjournal.org>
Sent: Wednesday, May 15, 2019 8:25 AM
To: Krans, Elizabeth [redacted]
Subject: RE: Manuscript Revisions: ONG-18-2085R2

Dr. Krans,

You can send the revised manuscript to me by email.

Please let me know if you have any other questions or concerns.

Sincerely,
-Daniel Mosier

Daniel Mosier
Editorial Assistant
Obstetrics & Gynecology
Tel: 202-314-2342

From: Krans, Elizabeth [redacted]
Sent: Tuesday, May 14, 2019 4:38 PM
To: Daniel Mosier <dmosier@greenjournal.org>
Subject: RE: Manuscript Revisions: ONG-18-2085R2

Hi Daniel,

Do you want me to send you my revisions or upload them on Elisver?

Thanks! Liz Krans

From: Daniel Mosier <dmosier@greenjournal.org>
Sent: Tuesday, May 14, 2019 12:49 PM
To: Krans, Elizabeth [redacted]
Subject: Manuscript Revisions: ONG-18-2085R2

Dear Dr. Krans,

Thank you for submitting your revised manuscript. We apologize for the delay in revisiting this. It has now been reviewed by the editor, and there are a few issues that must be addressed before we can consider your manuscript further:

1. Please note the edits and deletions made throughout. Please let us know if you disagree with any of these changes.
2. LINE 10: Melinda Campopiano will need to complete our electronic Copyright Transfer Agreement, which was sent to her through Editorial Manager.
3. LINE 74: This disclosure must appear on all bundles going forward. See the correction being published in the journal's June 2019 issue, available online after 5:00 pm ET on May 23.

When revising, use the attached version of the manuscript. Leave the track changes on, and do not use the "Accept all Changes"

Please let me know if you have any questions. Your prompt response to these queries will be appreciated; please respond no later than COB on **Thursday, May 16th.**

Sincerely,
-Daniel Mosier

Daniel Mosier
Editorial Assistant
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Daniel Mosier

From: Daniel Mosier
Sent: Monday, March 11, 2019 2:58 PM
To: 'Krans, Elizabeth'
Subject: Manuscript Revisions: ONG-18-2085R2
Attachments: 18-2085R1 ms (3-5-19v1).docx

Dr. Krans,

You should have received an email from Editorial Manager a short time ago, detailing the Associate Editor's request for a reduction in the length of your manuscript. As mentioned, Manuscript Editor had taken a look at your revision prior to the Associate Editor's appraisal, and has a few queries for you and your co authors to address. Because she has already made edits to your submission, we request that you use that version when trimming your manuscript and do your best to address her queries where appropriate.

When revising, use the attached version of the manuscript. Leave the track changes on, and do not use the "Accept all Changes"

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
2. LINE 72: Drs. Campopiano, Goodman, Kendig, Main, D'Oria, and Mitchell will need to complete our electronic Copyright Transfer Agreement, which was sent to them through Editorial Manager.
3. REFERENCES: Reference 81 was replaced by Committee Opinion No. 757. Please review CO 757 to see if it supports your statement: https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions-List
4. BOX 1: Per bundle manuscripts we've previously published, Box 1 has been replaced with the bundle. The Editorial Office will get permission from ACOG to reprint the bundle.
5. BOX 3: To which citation are you referring?

Please let us know if you have any questions or concerns.

Sincerely,
-Daniel Mosier

Daniel Mosier
Editorial Assistant
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