OBSTETRICS & GYNECOLOGY

NOTICE: This document contains comments from the reviewers and editors generated during peer review of the initial manuscript submission and sent to the author via email.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office: obgyn@greenjournal.org.

Date: Mar 08, 2022
To: "Harvey W. Kaufman" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-150

RE: Manuscript Number ONG-22-150

Impact of updated hepatitis C virus screening recommendations during pregnancy

Dear Dr. Kaufman:

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 as a Research Letter.

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

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

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Mar 29, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

Overall, the CDC, USPSTF, and ACOG (May 2021) have recommended Hepatitis C screening during each pregnancy. The clear goal of such screening is the detection of HCV disease, a potentially devastating, life-changing, life threatening disease with prenatal consequences (HCV infected neonates). Thankfully currently HCV is treatable.

1. My main concern with this submission relates to the study design.

A. This study is limited to HCV screening performed by a single center Quest Diagnostics. This main drawback of this submission is acknowledged by the authors is that only prenatal patients whose obstetrics panel (ObP) was performed by Quest Diagnostics were included in the study. This is clearly outlined in the Methods and as a limitation of the study (see lines # 131-134).

B. I am unconvinced regarding comparison of the HIV screening (with limited recent increase from 91.7% to 96% over a ten year period) to the current clear increase in HCV screening (resulting from implementation of recent recommendations). Screening of these two conditions reflect long-standing recommendations of the former in contrast to the relatively recent recommendation of HCV screening.

C. Similarly, that absolute disparity differences in HCV screening by medical insurance status declined following recent recommendations, is also not surprising.

2. Overall the conclusions regarding "substantial progress in the proportion of pregnant patients screened for HCV following guideline revisions, is not unexpected.

3. Lines # 92 - 95: That patients with commercial insurance were noted to have a higher HCV screening rate in comparison with patients with Medicaid (25.0% versus 18.4%), is not surprising.

4. The final two sentences of the Abstract Conclusions (see lines # 23-27), although possibly correct, are public health projections and NOT findings of this submission.

5. Overall, I note the absence of substantial clinical findings.

Reviewer #2:

The authors present a very unique data set - which describes lab ordering over 10 years - specifically looking at the impact of recent guidelines for universal Hepatitis C screening.

The authors outline the methods clearly. My biggest feedback is simply not that much data. I think the authors could present their data / conclusions with a research letter format much more succinctly without losing any critical aspects.

Specific feedback:
- Intro: Would strengthen the article to better describe the gap in the literature that this article seeks to fill
- Intro: Would be helpful to reword the last sentence into an objective.
- Methods: Why ages 15-44? Can the authors better explain the age limitations?
- Methods: Were there any exclusion criteria?
- Results: The authors describe a 3.5% / quarter increase in HCV screening - is that a median or a mean? I assume that the increased was not uniform over every quarter - more specifics about how this number was calculated would be important in the methods. You describe an average in the next sentence - but is your data normally distributed? Seems like a median might be more correct here.
-Results: The comparison of medicaid vs private insurance (paragraph 3) - is helpful. However, there is not a discussion of HCV increase in the last 3 quarters by insurance rates (though this is in the figure graphically) - I think would be really important and add value to the manuscript. It does not make sense why the authors used 2011-2015 when discussing the HCV increases by insurance status - as the recommendations came out much later.
- Discussion: Would be helpful to add the fact that no uninsured patients are included in this as a limitation - which is a high risk part of the population for these conditions. Similarly, the make up of this population (higher % of privately insured vs medicaid) - does this reflect the general US population as far as insurance make up? (might be helpful to add a citation if it does).
- Discussion: The final thought is an interesting one - less than 1/2 patients were screened - even though universal screening is recommended - I would say we have a LONG way to go. The author might consider not framing quite so optimistically, or at least adding a sentence that we have a long way to go to achieve the goals.

Reviewer #3:

General Comments:
The authors use Quest Diagnostics lab data to assess the impact of UPSTF and CDC screening recommendations on HCV screening in pregnancy. They found an increased rate of HCV screening following introduction of these recommendations.

Specific Comments:

line 2: Need to be specific about the real problem you are trying to assess/address. Neonatal transmission is a small component of the Hep C problem so to state that testing of pregnant persons is the "First step" to reducing transmission and disease burden seems a vast overstatement.

line 55: The time-line for the inclusion of patients makes little sense. What was the thinking behind including data to 2011 for trying to assess the "impact" of a recommendation put out in 2020? What is the percentage of records pertaining to the time around the change in recommendations?

line 59: The other critical factor related to current HIV testing is state or health department mandates for testing during pregnancy. Given this, not certain that it is an appropriate "benchmark".

line 74 and line 133: Nationally, the number of pregnancies that are covered by private insurance is approximately 50% with 40+% covered by Medicaid. how does this impact the interpretation of your results?

STATISTICS EDITOR COMMENTS:

General: This is a large sample (5 M), but during the slightly more than 10 years of the study period, there were ~ 40 M births. Thus this series represents ~ 12% of all births during that time period. To the extent possible from the database, need to provide a demographic profile of those tested (e.g., age, geographic region etc), in order to compare this large sample with the entire US cohort of deliveries during this period.

lines 85-88: The quadratic term does not specifically relate to one year among 2011 to 2021, but rather assigns a coefficient to a (+) quadratic term. Inspection of Fig 1 appears to show a gradual increase from 2011 to 2020Q1. Should use joinpoint analysis to identify the inflection point.

EDITOR COMMENTS:

1. Thank your for submitting this work to Obstetrics and Gynecology. If you opt to submit a revision, please remove the comparison to HIV and format as a Research Letter. The research letter should focus simply on hepatitis C screening rates.

EDITORIAL OFFICE COMMENTS:

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

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

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
* Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

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4. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained." *The manuscript's guarantor.

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

5. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Research Letters should not exceed 600 words and may include no more than two figures and/or tables (2 items total). Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

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

9. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

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

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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%").

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14. Figure 1: okay
Figure 2: Please add tick marks along the x-axis.

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* A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Mar 29, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Torri D. Metz, MD
Associate Editor, Obstetrics

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