

OBSTETRICS & GYNECOLOGY



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- 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: May 14, 2021
To: "Grace J Johnson" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-815

RE: Manuscript Number ONG-21-815

Electronic fetal heart rate monitoring, pH and newborn outcomes – This is as good as it gets

Dear Dr. Johnson:

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 Jun 04, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The presented manuscript is a retrospective analysis of a cohort of term singleton deliveries of non-anomalous fetuses from a single institution from March 2012 to July 2020. Umbilical cord gases were obtained universally and correlated with Apgar scores to evaluate whether EFHRM may be able to ultimately reduce the risk of long term neonatal outcomes.

1. Abstract, background: recommend drawing the link between neonatal acidemia and fetal outcomes as part of the ability of EFHRM to impact long term outcomes.
2. Introduction, lines 66-68: It isn't entirely clear to me that this supports your main argument. The data that cooling improves neurologic outcomes for infants born at a wide variety of pH may have more to do with the benefit of cooling itself.
3. Introduction, line 83: Need further data on the ability of the Apgar score to predict long term neurologic injury.
4. Methods, lines 93-95: Did the review of infants who underwent cooling pull different records than the primary search?
5. Methods: What was the primary outcome? Were there any corrections for multiple analyses? Was a power analysis performed?
6. Methods, lines 106-107: Please explain why these specific cut-points were chosen.
7. Results, lines 111-113: Recommend including a figure that describes the reasons for the drop-off from 47,626 to 29,787 infants.
8. Results, line 113: Please discuss the data in table 1. What statistical analysis was performed? Most of the comparisons were statistically significant and should be discussed.
9. Results, lines 114-119: Recommend describing the data similarly (using same direction of > or < and Apgar cut-offs) at least initially for easier reader interpretation.
10. Results, lines 130-132: Recommend placing this after line 113 as it is more descriptive of the population. It would be more interesting to know how many of the primary cesarean deliveries were performed with the ONLY diagnostic code being concern for fetal well-being.
11. Discussion, lines 138-141: This sentence should be re-written as it is unclear.
12. Discussion, line 185: What are the criteria for cooling at your institution and did they change over the study time period?
13. Discussion, lines 190-191: I think the authors need to be careful in presenting their data as association of birth pH or metabolic acidemia with early outcomes, not FHR pattern and HIE. These are not interchangeable.
14. Discussion, line 249: Please include a final concluding statement.
15. Table 2. Is the presented data in the columns probabilities or the actual data?

Reviewer #2: This is a retrospective cohort studying evaluating the relationship between fetal cord blood pH and Apgar score as means of exploring the utility EFHRM in interpreting fetal tolerance of labor and neonatal outcomes. This is a strong study. The clinical question is highly relevant. The study design is very clean and simple. The statistical analysis is sound.

While I personally agree with the authors' caution about the misuse of EFHRM in clinical practice and its contribution to unnecessary C-sections, the ultimate conclusion of this study -- that EFHRM rests on its potential for predicting cord blood pH, which may be a faulty marker for fetal tolerance of labor -- is potentially problematic by the use of only the Apgar score as a neonatal outcome. The authors themselves acknowledge that Apgar score has a poor correlation to long-term neurologic outcomes, so to link a wide range of pH values to a wide range of Apgar scores as a way of question the use of pH, only to acknowledge that Apgar may not be itself as useful as we would like, is problematic. Believers like myself of the fallibility of EFHRM will see this as further proof that EFHRM is too wild in its correlations to actual fetal tolerance to be used dogmatically in the way we do now. Detractors will say that this undermines the argument of the study, since Apgar score is not a sufficiently accurate way of assessing long-term outcomes from potential intolerance of labor. Ultimately, I feel this study sheds further light on the problems we have created by our over-reliance on EFHRM, and as such, is a valuable contribution to the literature.

Reviewer #3: 1. Title: This study does not really evaluate intrapartum electronic fetal monitor tracing interpretation's predictive ability for cord arterial pH or the Apgar score. It does evaluate the ability of the umbilical artery pH and base deficit to predict the 1 and 5 minute Apgar scores. The title should be revised to reflect what actually was studied.
 2. Abstract: The abstract's conclusion also makes claims about the predictive ability of electronic fetal monitoring for newborn condition. However the actual study that was performed did not evaluate fetal monitor tracings or assign fetal heart rate categories and their ability to predict low Apgar scores.
 3. Introduction: The introduction is well written but dwells at length on electronic fetal monitoring technology which is not being evaluated in this study. I would recommend for the authors to revise the introduction to focus on prior knowledge and published literature on the associations between cord arterial pH and base excess abnormalities and low Apgar scores, since this is the actual area under study.
 4. Lines 81-88. The hypothesis is stated but brings in again electronic fetal heart rate monitoring, which is not directly evaluated in the current study. The authors could move the sentence about "fundamental assumptions" of EFM to the discussion section.
 5. Methods: The methods section appears well presented.
 6. Results: There are significance values presented in Table 1. (Demographics). It was unclear to me what comparisons or tests of association were carried out to yield these P-values.
 7. Discussion: The discussion focuses heavily on EFM and its history. I would recommend to reframe the discussion toward what was actually studied, cord arterial pH values and base deficits and their association with 1 and 5 minute Apgar scores. The discussion might include brief paragraph dealing with the fact that EFM was designed to predict cord blood gases which were at the time thought to be predictive of risk for HIE and cerebral palsy. The authors might compare their findings to prior studies in the literature evaluating associations between the components of umbilical cord gases and and Apgar scores with HIE.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Table 1: For the column with N = 84, all %s should be rounded to nearest integer %, not cited to 0.1% precision. For LOS, should format all row entries as IQR or range, not as mean (SD). For neonatal demise, although the stats are correct, the counts are low and there is insufficient power to generalize the NS findings.

Table 2: Need to include CIs for all %s, which is especially important for the pH < 7 cohort, in which they are relatively wide, compared to the other cohorts with much larger samples. Also, for the pH < 7 cohort, should round all %s to nearest integer, not cite to 0.1% precision. There is a comma in the pH > 7.2, Apgar < 4, fraction entry, but it should be expressed as a fraction

Fig 1: The p values are redundant, since CIs are included, should omit the p-values.

Should include a separate Table of the sensitivities and specificities outlined in the Fig 1 legend, and those should include CIs.

General: A distinction is made in the pH range adjacent to 7.20 (e.g., from 7.18 to 7.22 etc). Should indicate the reproducibility and accuracy of the measurement of pH, and base excess in the lab utilized. Also, how was base excess measured? Directly or by calculation based on the pCO₂ and pH? That is, the values for pH and base excess are taken to be exact in the statistical analysis, but how much variability is present in actual lab values and how might that contribute to errors in estimating the relationship of pH or BE with Apgar scores?

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this

revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

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

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (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. Each of your coauthors received an email from the system, titled "Please verify your authorship for a submission to Obstetrics & Gynecology." Each author should complete the eCTA if they have not yet done so.

The following authors need to complete the form:

Stacie G Denning (sgdenning@texaschildrens.org)

Michael A Belfort (belfort@bcm.edu)

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

*The manuscript's guarantor.

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

4. 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.

5. 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 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

6. Please revise your title to include only wording that matches the study conclusion. Remove "This is as good as it gets." Avoid declarative phrasing in the title and running title. Spell out "EFRM" in the running title.

7. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

* All financial support of the study must be acknowledged.

* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.

* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.

* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

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

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

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

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

We do not use "EFHRM," but we do use "FHR" for "fetal heart rate." Please change this acronym to read, "electronic FHR monitoring" throughout and spell out "FHR" the first time it is used in the abstract and body text.

10. 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%).

11. 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.

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

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the 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 at the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top).

13. When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

Figure 1: Please upload as a figure file on Editorial Manager.

14. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at <http://links.lww.com/LWW-ES/A48>. The cost for publishing an article as open access can be found at <https://wkauthorservices.editage.com/open-access/hybrid.html>.

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.

You will be receiving an Open Access Publication Charge letter from the Journal's Publisher, Wolters Kluwer, and instructions on how to submit any open access charges. The email will be from publicationservices@copyright.com with the subject line 'Please Submit Your Open Access Article Publication Charge(s)'. Please complete payment of the Open Access charges within 48 hours of receipt.

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. 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 Jun 04, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2019 IMPACT FACTOR: 5.524

2019 IMPACT FACTOR RANKING: 6th out of 82 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: <https://www.editorialmanager.com/ong/login.asp?a=r>). Please contact the publication office if you have any questions.

REVIEWER COMMENTS: (RESPONSES IN BOLD TYPE)

Reviewer #1: The presented manuscript is a retrospective analysis of a cohort of term singleton deliveries of non-anomalous fetuses from a single institution from March 2012 to July 2020. Umbilical cord gases were obtained universally and correlated with Apgar scores to evaluate whether EFHRM may be able to ultimately reduce the risk of long term neonatal outcomes.

1. Abstract, background: recommend drawing the link between neonatal acidemia and fetal outcomes as part of the ability of EFHRM to impact long term outcomes. **IN THE ABSTRACT (CONCLUSION) THIS HAS BEEN MORE EXPLICITLY DRAWN WITH SPECIFIC REFERENCE TO FETAL OUTCOMES.**
2. Introduction, lines 66-68: It isn't entirely clear to me that this supports your main argument. The data that cooling improves neurologic outcomes for infants born at a wide variety of pH may have more to do with the benefit of cooling itself. **WE DO NOT UNDERSTAND THIS COMMENT; OF COURSE IMPROVED OUTCOMES FOR INFANTS UNDERGOING COOLING IS A BENEFIT OF COOLING ITSELF, AND THE BENEFIT OF COOLING TO IMPROVE OUTCOMES OVER A WIDE RANGE OF PH VALUES IS WELL DOCUMENTED IN THE 4 CITATIONS AT THE END OF LINE 87 (ref 9-12). HOWEVER, OUR SUBSTITUTION OF THE WORD "UNEVENTFUL" FOR THE WORD "NORMAL" MAY GIVEN SOME CLARIFICATION.**
3. Introduction, line 83: Need further data on the ability of the Apgar score to predict long term neurologic injury. **THIS HAS BEEN CLARIFIED IN THE DISCUSSION SECTION, LINES 224-225, 232-234, AND ASSOCIATED REFERENCES.**
4. Methods, lines 93-95: Did the review of infants who underwent cooling pull different records than the primary search? **YES. THIS HAS BEEN CLARIFIED FURTHER IN LINE 121-123.**
5. Methods: What was the primary outcome? Were there any corrections for multiple analyses? Was a power analysis performed? **THIS WAS NOT A CLINICAL TRIAL, NOR A COMPARISON OF OUTCOMES FOR ANY TWO GROUPS OF PATIENTS. RATHER, AS CLEARLY SPELLED OUT IN LINES 109-112, WE SOUGHT TO DEFINE AND CHARACTERIZE THE CORRELATION, IF ANY, BETWEEN pH /BASE EXCESS AND APGAR SCORE. HENCE A POWER ANALYSIS (DESIGNED TO ALLOW INVESTIGATORS TO DETERMINE THE RELIABILITY OF A FINDING OF NO DIFFERENCE) IS NOT RELEVANT, NOR REALLY IS THE DEFINITION OF A SPECIFIC PRIMARY OUTCOME. HOWEVER, WE HAVE ADDED THE WORDS "PRIMARY OBJECTIVE" IN LINE 135 TO CLARIFY OUR PRIMARY OBJECTIVE. MULTIPLE ANALYSES WERE NOT PERFORMED.**
6. Methods, lines 106-107: Please explain why these specific cut-points were chosen. **THE LOWER THRESHOLD (<4) FOR DEPRESSION IS UNIVERSALLY RECOGNIZED AS SUCH, AND REFERENCED. WE DEBATED WHETHER TO USE 7 OR 8 AS A CUTOFF FOR COMPLETE ABSENCE OF DEPRESSION BUT CHOSE 8-10 (IE >7) TO MOST UNEQUIVOCALLY DEFINE NORMAL. A RECENT AAP REFERENCE IN THIS REGARD HAS BEEN ADDED AND THE CORRESPONDING CHANGES MADE IN THE TEXT, LINES 139-141. IF REQUESTED BY THE EDITORS, WE WOULD BE HAPPY TO PROVIDE STATISTICS USING >6 RATHER THAN >7 FOR NON-DEPRESSION, BUT THIS WOULD NOT CHANGE OUR CONCLUSIONS. WE NOTE THAT THE OTHER REVIEWERS DID NOT HAVED A PROBLEM WITH THE USE OF THIS UPPER THRESHOLD.**
7. Results, lines 111-113: Recommend including a figure that describes the reasons for the drop-off from 47,626 to 29,787 infants. **WE FEEL THIS WOULD BE REDUNDANT; IT GOES WITHOUT SAYING THAT THE EXCLUDED PATIENTS WERE THOSE WHO DID NOT MEET THE DEFINED INCLUSION CRITERIA. HOWEVER, WE HAVE ADDED AN EXPLANATORY SENTENCE TO THIS EFFECT (LINES 146-148) IN LIEU OF AN EVEN MORE SPACE CONSUMING AND REDUNDANT FIGURE. IF THE EDITOR REQUEST, WE WILL BE HAPPY TO ADD A FIGURE SAYING THE SAME THING AS LINES 146-148.**

8. Results, line 113: Please discuss the data in table 1. What statistical analysis was performed? Most of the comparisons were statistically significant and should be discussed. **WE HAVE ADDED A BREIF DISCUSSION OF THESE DIFFERENCES IN LINES 235-236 OF THE REVISED DISCUSSION SECTION.**
9. Results, lines 114-119: Recommend describing the data similarly (using same direction of > or < and Apgar cut-offs) at least initially for easier reader interpretation. **WE ARE UNABLE TO DO SO WITHOUT MAKING THIS READ VERY AWKWARDLY. HOW DO YOU SAY THAT FEW INFANTS WITH PH >7.2 HAD APGAR SCORES WHICH WERE SEVERELY DEPRESSED (< 4) WITHOUT USING BOTH > AND < IN THE SAME SENTENCE? WE BELIEVE THAT USING VERBIAGE SUCH AS “APGAR SCORES NOT > 4” IN ORDER TO MAKE ALL THE SIGNS POINT IN THE SAME DIRECTION IS MUCH MORE AWKWARD THAN SAYING “APGAR SCORES < 4.” AGAIN, WE WOULD BE HAPPY TO MAKE THESE CHANGES IF THE EDITORS FEEL IT NECESSARY.**
10. Results, lines 130-132: Recommend placing this after line 113 as it is more descriptive of the population. It would be more interesting to know how many of the primary cesarean deliveries were performed with the ONLY diagnostic code being concern for fetal well-being. **THIS HAS BEEN MOVED TO LINES 149-151 AS SUGGESTED.**
11. Discussion, lines 138-141: This sentence should be re-written as it is unclear. **RE-WRITTEN AND CHANGED TO 2 SENTENCES IN LINES 180-196**
12. Discussion, line 185: What are the criteria for cooling at your institution and did they change over the study time period? **STANDARD AAP AND LITERATURE RECOMMENDATIONS. THIS HAS BEEN CLARIFIED, ALONG WITH REFERENCES DESCRIBING CURRENT COOLING RECOMMENDATIONS IN LINES 254-255.**
13. Discussion, lines 190-191: I think the authors need to be careful in presenting their data as association of birth pH or metabolic acidemia with early outcomes, not FHR pattern and HIE. These are not interchangeable. **WE AGREE. WE FELT WE HAD MADE THIS CLEAR THROUGHOUT THE TEXT BUT MUST NOT HAVE- THIS APPEARS TO ALSO HAVE BEEN UNCLEAR TO REVIEWER 3. THUS WE HAVE COMPLETELY CHANGED OUR CONCLUDING PARAGRAPH. WE BELIEVE THIS NEW PARAGRAPH BETTER CLARIFIES THIS POINT AS WELL AS SIMILAR CONCERNS OF REVIEWER 3.**
14. Discussion, line 249: Please include a final concluding statement. **A NEW CONCLUDING STATEMENT HAS BEEN PROVIDED, LINES 337-349**
15. Table 2. Is the presented data in the columns probabilities or the actual data? **BOTH – PROBABILITIES CALCULATED FROM OUR DATA, AS EXPLAINED IN THE METHODS SECTION.**

Reviewer #2: This is a retrospective cohort studying evaluating the relationship between fetal cord blood pH and Apgar score as means of exploring the utility EFHRM in interpreting fetal tolerance of labor and neonatal outcomes.

This is a strong study. The clinical question is highly relevant. The study design is very clean and simple. The statistical analysis is sound.

While I personally agree with the authors' caution about the misuse of EFHRM in clinical practice and its contribution to unnecessary C-sections, the ultimate conclusion of this study -- that EFHRM rests on its potential for predicting cord blood pH, which may be a faulty marker for fetal tolerance of labor -- is potentially problematic by the use of only the Apgar score as a neonatal outcome. The authors themselves acknowledge that Apgar score has a poor correlation to long-term neurologic outcomes, so

to link a wide range of pH values to a wide range of Apgar scores as a way of questioning the use of pH, only to acknowledge that Apgar may not be itself as useful as we would like, is problematic. Believers like myself of the fallibility of EFHRM will see this as further proof that EFHRM is too wild in its correlations to actual fetal tolerance to be used dogmatically in the way we do now. Detractors will say that this undermines the argument of the study, since Apgar score is not a sufficiently accurate way of assessing long-term outcomes from potential intolerance of labor. Ultimately, I feel this study sheds further light on the problems we have created by our over-reliance on EFHRM, and as such, is a valuable contribution to the literature. **WE THANK THE REVIEWER FOR THE FAVORABLE COMMENTS. IT APPEARS THAT NO CHANGES WERE RECOMMENDED.**

Reviewer #3: 1. Title: This study does not really evaluate intrapartum electronic fetal monitor tracing interpretation's predictive ability for cord arterial pH or the Apgar score. It does evaluate the ability of the umbilical artery pH and base deficit to predict the 1 and 5 minute Apgar scores. The title should be revised to reflect what actually was studied. **TITLE CHANGED AS REQUESTED (LINES 1-2)**

2. Abstract: The abstract's conclusion also makes claims about the predictive ability of electronic fetal monitoring for newborn condition. However the actual study that was performed did not evaluate fetal monitor tracings or assign fetal heart rate categories and their ability to predict low Apgar scores. **WE HAVE ADDED A CLARIFICATION OF EXACTLY WHAT OUR DATA DO ADDRESS IN LINE 60-62 OF THE ABSTRACT CONCLUSION.**

3. Introduction: The introduction is well written but dwells at length on electronic fetal monitoring technology which is not being evaluated in this study. I would recommend for the authors to revise the introduction to focus on prior knowledge and published literature on the associations between cord arterial pH and base excess abnormalities and low Apgar scores, since this is the actual area under study. **OUR DATA INDEED ONLY EVALUATE THE RELATIONSHIP BETWEEN PH AND NEWBORN OUTCOME. HOWEVER, THIS RELATIONSHIP IS ONLY IMPORTANT IN TERMS OF ITS IMPLICATIONS FOR EFHRM. WE STRONGLY FEEL THAT THE DISCUSSION OF EFHRM IN THE INTRODUCTION IS VITAL FOR AN UNDERSTANDING, NOT OF OUR DATA PER SE, BUT FOR THE IMPORTANCE AND IMPLICATIONS OF OUR DATA. WITHOUT THIS BACKGROUND INFORMATION, THE LACK OF CORRELATION DEMONSTRATED BY OUR DATA HAS LITTLE SIGNIFICANCE. THE REVISED CONCLUDING PARAGRAPH SHOULD HELP IN THIS REGARD AS WELL.**

4. Lines 81-88. The hypothesis is stated but brings in again electronic fetal heart rate monitoring, which is not directly evaluated in the current study. The authors could move the sentence about "fundamental assumptions" of EFM to the discussion section. **THESE LINES SET OUT THE RATIONALE FOR THE STUDY WHICH, AS NOTED ABOVE SIMPLY CANNOT BE STATED WITHOUT "BRINGING IN" A MENTION OF EFHRM. WE BELIEVE THAT THIS BRIEF BACKGROUND DESCRIPTION IS APPROPRIATE IN THE INTRODUCTION AS IT CLARIFIES WHY THE READER SHOULD BE INTERESTED IN THE REST OF THE PAPER.**

5. Methods: The methods section appears well presented.

6. Results: There are significance values presented in Table 1. (Demographics). It was unclear to me what comparisons or tests of association were carried out to yield these P-values. **WE HAVE ADDED A FOOTNOTE TO THE TABLE CLARIFYING THIS.**

7. Discussion: The discussion focuses heavily on EFM and its history. I would recommend to reframe the discussion toward what was actually studied, cord arterial pH values and base deficits and their

association with 1 and 5 minute Apgar scores. The discussion might include brief paragraph dealing with the fact that EFM was designed to predict cord blood gases which were at the time thought to be predictive of risk for HIE and cerebral palsy. The authors might compare their findings to prior studies in the literature evaluating associations between the components of umbilical cord gases and Apgar scores with HIE. **THIS IS AGAIN THE SAME OBJECTION TO OUR INCLUSION OF ANY DISCUSSION OF EFHRM, WHICH AS OUTLINED ABOVE GOES TO THE HEART OF THE PAPER, AS RECOGNIZED BY REVIEWERS 1 AND 2. IN FACT THIS DISCUSSION OF EFHRM IN PARAGRAPH 2 COMPRISES LESS THAN 15% OF THE DISCUSSION SECTION. THE EXISTING DISCUSSION SECTION ADDRESSES THE OTHER CONCERNS OF THIS REVIEWER; WE HAVE DISCUSSED THE RELATIONSHIP BETWEEN BOTH CORD PH AND APGAR SCORE WITH SEVERAL REFERENCES IN THE MANUSCRIPT. SINCE THESE CORRELATIONS ARE VERY WEAK, WE HAVE NOT USED A LOT OF SPACE TO DESCRIBE THEM, BUT RATHER SIMPLY STATED THE RELATIONSHIPS AND REFERENCES FOR OUR STATEMENTS. (SEE LINES 231-235, 329-331, 331-334 AND ASSOCIATED REFERENCES.) IF THE EDITORS REQUEST IT, WE WOULD BE HAPPY TO EXPAND OUR DISCUSSION OF THESE FACTORS, BUT FEEL IT HAS LITTLE RELEVANCE TO THE MAJOR POINTS OF OUR PAPER. AS OUTLINED ABOVE, WE FEEL THE COMPLETELY NEW CONCLUSION PARAGRAPH SHOULD CLARIFY THE IMPORTANCE OF THIS FHR DISCUSSION AND SATISFY THE REQUESTS OF THE REVIEWER.**

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Table 1: For the column with N = 84, all %s should be rounded to nearest integer %, not cited to 0.1% precision. For LOS, should format all row entries as IQR or range, not as mean (SD). For neonatal demise, although the stats are correct, the counts are low and there is insufficient power to generalize the NS findings. **THE REQUESTED CORRECTIONS HAVE BEEN MADE. LOS IS NOW REPORTED AS IQR RANGE AND P VALUE STATISTIC CALCULATED WITH KRUSKAL-WALLIS NON-PARAMETRIC TESTING. WE AGREE THE LOW COUNTS OF NEONATAL DEMISE MAKE THIS DATA NON-GENERALIZABLE. IT IS INCLUDED HERE FOR COMPLETENESS BUT WE WOULD BE HAPPY TO REMOVE THESE DATA IF THE EDITORS FEEL IT IMPORTANT.**

Table 2: Need to include CIs for all %s, which is especially important for the pH < 7 cohort, in which they are relatively wide, compared to the other cohorts with much larger samples. Also, for the pH < 7 cohort, should round all %s to nearest integer, not cite to 0.1% precision. There is a comma in the pH > 7.2, Apgar < 4, fraction entry, but it should be expressed as a fraction. **THE REQUESTED CHANGES HAVE BEEN MADE.**

Fig 1: The p values are redundant, since CIs are included, should omit the p-values. **THE P VALUES HAVE BEEN EXCLUDED.**

Should include a separate Table of the sensitivities and specificities outlined in the Fig 1 legend, and those should include CIs. **A SEPARATE TABLE OF SENSITIVITIES AND SPECIFICITIES (TABLE 4) HAS BEEN ADDED.**

General: A distinction is made in the pH range adjacent to 7.20 (e.g., from 7.18 to 7.22 etc). Should indicate the reproducibility and accuracy of the measurement of pH, and base excess in the lab utilized. Also, how was base excess measured? Directly or by calculation based on the pCO₂ and pH? That is, the values for pH and base excess are taken to be exact in the statistical analysis, but how much variability is present in actual lab values and how might that contribute to errors in estimating the relationship of pH or BE with Apgar scores? **THIS HAD BEEN CLARIFIED WITH CORRELATION COEFFICIENTS FOR INTRA AND INTER ASSAY PRECISION IN LINES 131-133.**

EDITOR COMMENTS:

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

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

OPT IN

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (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. Each of your coauthors received an email from the system, titled "Please verify your authorship for a submission to Obstetrics & Gynecology." Each author should complete the eCTA if they have not yet done so.

The following authors need to complete the form:

Stacie G Denning (sgdenning@texaschildrens.org)

Michael A Belfort (belfort@bcm.edu)

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

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

4. 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://urldefense.proofpoint.com/v2/url?u=https-3A_www.acog.org_practice-2Dmanagement_health-2Dit-2Dand-2Dclinical-2Dinformatics_revitalize-2Dobstetrics-2Ddata-2Ddefinitions&d=DwIGaQ&c=ZQs-KZ8oxEw0p81sqgiaRA&r=gjV0wdZSL2i9e5QBE4upGN4ZU_miKndXUQQfAHHFgNc&m=lgcGC40dr_kj-XZ6LiDF-YpcrkBBrPZdc0kXEc5UfoA&s=f6b0HO2t6HD9SFInMfi-JkkAKHtIYKMSnp8_6_uGwxE&e= and the gynecology data definitions at https://urldefense.proofpoint.com/v2/url?u=https-3A_www.acog.org_practice-2Dmanagement_health-2Dit-2Dand-2Dclinical-2Dinformatics_revitalize-2Dgynecology-2Ddata-2Ddefinitions&d=DwIGaQ&c=ZQs-KZ8oxEw0p81sqgiaRA&r=gjV0wdZSL2i9e5QBE4upGN4ZU_miKndXUQQfAHHFgNc&m=lgcGC40dr_kj-XZ6LiDF-YpcrkBBrPZdc0kXEc5UfoA&s=xfsrZ1tfbW6fCSYCGddVnKswqk0Lb5sz260SBpHVvWU&e= . If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

5. 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 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

6. Please revise your title to include only wording that matches the study conclusion. Remove "This is as good as it gets." Avoid declarative phrasing in the title and running title. Spell out "EFRM" in the running title. **THE TITLE HAS BEEN REVISED AND THIS PHRASE WAS REMOVED.**

7. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

- * All financial support of the study must be acknowledged.
- * Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
- * All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
- * If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
- * If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

8. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain

information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count. **REVISED ABSTRACT WORD COUNT 297**

9. 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=ZQs-KZ8oxEwOp81sqgiaRA&r=gjV0wdZSL2i9e5QBE4upGN4ZU_miKndXUQQfAHHFgNc&m=lgcGC40dr_kj-XZ6LiDF-YpcrkBBrPZdc0kXEc5UfoA&s=93BHUaYC92Npo_54S6yDupZAev1puNJNAUGGO3iuxwQ&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.

We do not use "EFHRM," but we do use "FHR" for "fetal heart rate." Please change this acronym to read, "electronic FHR monitoring" throughout and spell out "FHR" the first time it is used in the abstract and body text. **THESE REQUESTED CHANGES HAVE BEEN MADE THROUGHOUT THE TEXT**

10. 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 (NNT_h). 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%).

11. 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=ZQs-KZ8oxEwOp81sqgiaRA&r=gjV0wdZSL2i9e5QBE4upGN4ZU_miKndXUQQfAHHFgNc&m=lgcGC40dr_kj-XZ6LiDF-YpcrkBBrPZdc0kXEc5UfoA&s=Bl0pigOCmPYcqLyfqkpr8qWnn3GnbQ-Qrq96ku6EmY&e= .

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journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

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13. When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

Figure 1: Please upload as a figure file on Editorial Manager.