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: Jan 11, 2019
To: "Margaret Parker" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-2246

RE: Manuscript Number ONG-18-2246

Optimal Timing of First Milk Expression Among Mothers of Very Low Birth Weight Infants

Dear Dr. Parker:

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 Feb 01, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

Overall Comments: The authors describe a data driven approach to determine cut points for the optimal timing of first milk expression after delivery in very low-birth-weight infants. They wish to determine the time of first milk expression that predicts maximal duration of mother's milk provision during hospitalization in the Neonatal Intensive Care Unit. This is a clinically relevant question as, typically in the immediate postpartum period of especially very low-birth-weight infants, hospital staff are dealing with a number of issues with respect to the mother and, therefore, it is important to determine or consider the evidence supporting timing of tasks in terms of optimizing the structure of postpartum care. Hazard ratios comparing the probability of continued provision of mother's milk during hospitalization between mothers who initiated milk expression before versus after cut points were determined; the first cut point was less than 8 hours after delivery versus 9-24 hours after delivery, adjusting for birth weight, gestational age, maternal race ethnicity, and clustering by hospital. It was noted that first expressed milk less than 8 hours optimized continued milk production.

Specific Comments:

Title: Good.

Short Title: Good.

Precis: Would consider revising to first milk expression less than or equal to 8 hours "after delivery" was superior to 9-24 hours with respect to maximal duration of mother's milk provision for very low-birth-weight infants.

Abstract: Please consider taking out of the first person in the writing. Was there any quantification of amount of milk produced by these mothers and was there any determination of the mother's desire to breastfeed initially and after discharge?

Introduction: Good and provides the rationale for the study.

Methods were well explained.

Results: Was there any association of mother's milk production and infant sequelae or persistence of breastfeeding after the baby was out of the NICU?

Discussion: Described the data well in the context of existing literature. Tables and figures were good.

Reviewer #2: This study is a "through the looking glass" piece with little understanding of lactation and the human woman or the many influences that determine choice of lactation, attitudes on its success, medical interference related to health concerns of mother and baby, support from medical personnel, etc.

Questions you should have addressed before any attempt is made to determine time-related influences on lactation success and continuation are many. It is well known that the success or failure of lactation is multifactorial, but cannot be observed on a bland, population grouping basis. It often succeeds or fails based on how badly the mom wants it to do so and how much expert help she gets in dealing with difficulty, how much she wants to breast feed a machine vs. her child, and how able the child is to encourage the process.

One needs to know when breast feeding was first offered; what the maternal health, comfort and medication state might be; what was the condition of the baby and the optimism that any milk derived will be of use; what did the mom want to do vs. what she was encouraged to do; what was she able to do and when was it proposed; all these things influence timing and success under ordinary circumstances, let alone those of a LBW baby.

I find little merit in this piece nor any feeling that the population, however generous in size, can possibly be rendered into a meaningful database for any further insight.

Reviewer #3:

ONG-18-2246

Full Title: Optimal Timing of First Milk Expression Among Mothers of Very Low Birth Weight Infants

The manuscript describes a retrospective analysis of data collected as a part of a statewide (Ma) Quality Initiative concerning breast feeding support. The focus of the analysis is the effect of timing of onset of maternal milk expression of milk production in VLBW neonates. The obstetrician is critical component of that timing as they can get the nursing service to support the mother in expression. The manuscript has the additional value of statistically defining a better goal for initiation than the current arbitrary deadline, "of as soon as possible". The manuscript will be highly cited and of great interest to general obstetrician and maternal-fetal medicine specialists.

I have several questions whose answers would improve the manuscript.

1) Line 87- The inclusion criteria < 1500 gram OR 30 weeks includes a relatively large group of with a grey definition, for example a 31- week infant weighing 1400 grams.

2) Produce a figure describing the loss subjects analyzed. A 405 loss is a lot. Are there demographic differences between the group analyzed and those excluded? Please report that in the discussion.

3) Line 116: was mode of delivery analyzed as a covariate?

4) Line 184-191: were the variables, Baby Friendly Certification status, intent to breastfeed, and distance from the mother's home, analyzed?

5) Add a column to Table 1 the accumulative percent of expression initiation

6) Please provide the mean/median of discharge vs transfer DOL.

7) Figure 2 should include a separate 8- hour point rather than a 7-8 point

STATISTICAL EDITOR COMMENTS:

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

lines 24-25, 29-30, Table 2: Need to define the primary outcome. From Table 2, there are two definitions of milk (ANY vs EXCLUSIVE) and 3 time points, of which discharge/transfer appears to be a closer fit of "maximum". On the other hand,

the definition of the threshold for discrimination of cut-point for initiation of milk expression also appears to be a primary endpoint (Fig 2). If multiple primary endpoints, then need to adjust the threshold for inference testing to more restrictive than $p < .05$.

Table 1: Since one of the categories was npo, how were the proportions at each time point adjusted for those neonates who were npo?

lines 133-135: How is the analysis by relevant timing categories not data-driven? It seems that all the analyses are data-driven.

General: Since the study design was observational, that is, time to first milk expression was not randomized, the results are all associations and language implying causation or that encouragement of earlier milk expression would necessarily result in higher probability of longer milk consumption are not proven by this study design nor these data.

Table 2: Need to include CIs for the predicted probabilities.

Fig 1: Need to include, along the x-axis at the indicated time points, the number in each cohort remaining.

EDITOR COMMENTS:

1. Thank you for submitting your manuscript. Please make sure you avoid causal language throughout your paper. As observational data, you really cannot draw causal conclusions and your language should be associative. You will receive a PDF with my comments that also need to be addressed.

As you will see, I have concerns about your conclusions from this work as I believe you have set up a false dichotomy. As noted by reviewer 2, there are multiple maternal factors that are important to consider. You've not reported anything about the mother--not even the route of delivery. It is well established that women who are deliver by CS have a lower rate of breast feeding, for instance. You seem to dismiss the importance and complexity of care provided to the mother in the immediate post partum period and by so doing, this obstetricians (who works at a place with one of the most passionate breast feeding supporter, Dr Alison Stuebe and who is strongly influenced by her) gets the feeling that the mother is being reduced to a pair of breasts. No doubt this is not intended, but it feels that way. In the case of term births, many hospitals now have mother-baby dyad care--this isn't very realistic when a child is in the NICU. Mothers who deliver preterm often do so because of maternal morbidities such as preeclampsia or abruption. Their pregnancies have been truncated, perhaps before they have committed to method of infant feeding, or before attending any sort of breast feeding classes. They may feel doubly inadequate--having delivered preterm and now being ill prepared to breast feed their child.

By altering your conclusions, perhaps by incorporating some brainstorming with a breast feeding friendly obstetrician or post partum nurse, you could develop some different ideas about how to achieve a more favorable time to first milk expression--a goal that you've shown is important. As it reads now, however, this false dichotomy isn't acceptable.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.

PDF COMMENTS:

- can you make it clearer what you mean by optimal?

- The Journal style doesn't not use the virgule (/) except in numeric expressions. Please edit here and in all instances.

- earlier in the neonate's hospitalization

- as well, mothers of VLBW babies are at higher risk for cesarean delivery, maternal co-morbidities and severe maternal morbidity such as preeclampsia, abruption, etc.

- As noted in the paragraph, there are alot of tasks for nursing to do in the immediate post partum period so that decisions about prioritizing milk expression has to be not just based on long term lacatation success but has to include the maternal health and status. As I noted above, mothers who deliver VLBW infants are more likely to be ill or have significant morbidies and CS than mothers of term infants. The balance of these competing interests needs to be considered, or system s in place for someone other than the primary nurse needs to be tasked for this function.

- highlighted section is part of methods. Please move these lines.

- planned 2nd analysis?

- do you have any NICU's without a birth center?

- in which

- Journal style does not include subheadings

- For the QI project, was this an added field for nursing or lactation support to record in the EMR? For the QI project, was the need to record this emphasized to nursing, lactation support staff?

- Why didn't you record any maternal factors other than race and ethnicity?

- This is part of results, not methods

- Since WHO defines optimal time as 6 hours, why did you not also use < 6 and > 6 in your analysis to assess their recommendations' validity?

- to be clear, infants of mothers who expressed < 8 hours were more likely to be receiving some mothers milk at discharge/transfer but of those infants receiving NO mothers milk at transfer, the mothers who expressed < 8hours stopped expressing earlier in the infants hospitalization. Is that correct? Could you state it something like this? I had to go back and reread this section a bit to figure out your meaning.

- just give the actual number rather than a > figure

- It seems though that intention to breast feed prior to the birth may be an important issue. A later start to milk expression may be related to having to be convinced of the importance. Interesting that women who expressed later, if they quit, quit later.

- perhaps at least important to assess the assignment of different tasks to different people. I think its important to avoid setting up a conflict between maternal health priorities and neonatal ones. As written, it seems like you are doing that.

Perhaps it would be better to suggest some additional layers of support that could be called upon if the primary nurse cannot get to this particular issue:

Lactation educators and support staff; NICU nurse caring for the infant (perhaps some of the tasks caring for the infant could be prioritized so that the NICU nurse could come help with milk expression); assigning some of the maternal care to a non RN, etc.

I think this sort problem solving suggestions could have been strengthened by including an obstetrician or obstetrical nurse to your writing teams or QI team.

- You only presented data on one cut point.

- a very major limitation is you collected no data about the mother's health status. I unfortunately feel like you are reporting this data as if the mother is being reduced to her breasts in this.

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

3. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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.

4. Please submit a completed STROBE checklist with your revision.

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), 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, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

5. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

6. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 26 typed, double-spaced pages (6,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

7. 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).

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 limits for different article types are as follows: Original Research articles, 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.

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

11. 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. Figures 1 and 2 may be resubmitted as-is.

13. 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.

14. 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 Feb 01, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

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

_____
In compliance with data protection regulations, please contact the publication office if you would like to have your personal information removed from the database.