Reviewer comments and author responses (in bold)

Article ID: CMAJOpen-2022-0139

Article title: Understanding what patients and physicians need to improve their decision-making about late preterm antenatal corticosteroids: a qualitative framework analysis

Article authors: Hannah Foggin MD, Rebecca Metcalfe PhD, Jennifer A. Hutcheon PhD, Nick Bansback PhD, Jason Burrows MD, Eda Karacebeyli MD, Sandesh Shivananda MD, Amelie Boutin PhD, Jessica Liauw MD

Reviewer 1: Dr. Dawn Stacey / University of Ottawa, Ottawa Hospital Research Institute

One point that was not clear – if you have the corticosteroids at 34 to 36 gestation but deliver at 40 weeks, is there still a risk of hypoglycemia? Or is this risk only present if you deliver immediately after receiving this medication?

The answer to this question is not known. The largest randomized trial on antenatal corticosteroids identified and increased risk of hypoglycemia in those exposed to betamethasone compared with placebo, and a recent secondary analysis of hypoglycemia in this cohort reported that the risk of hypoglycemia did not seem to be related to earlier versus later gestational age at randomization (i.e. 34 vs. 36 weeks) (Gyamfi-Bannerman C et al. Evaluation of Hypoglycemia in Neonates of Women at Risk for Late Preterm Delivery: An Antenatal Late Preterm Steroids Trial Cohort Study. *Am J Perinatol*. 2021 May 27:10). Other recent cohort studies suggest that the risk of hypoglycemia may be higher for those who deliver soon after receiving antenatal corticosteroids (e.g., 12 to 71
hours after medication administration) (McElwee ER et al, Latency of late preterm steroid administration to delivery and risk of neonatal hypoglycemia. *Am J Obstet Gynecol MFM.* 2022 Sep;4(5):100687). However, in our opinion this association is yet to be robustly demonstrated.

More major feedback:
The title indicates this is qualitative study but there is no description in the abstract methods or the manuscript methods on the study design. According to COREQ, "What methodological orientation was stated to underpin the study? e.g., grounded theory, discourse analysis, ethnography, phenomenology, content analysis"

In the title and abstract we have clarified that framework analysis was the methodological orientation.
"Understanding what patients … a framework analysis"; "Using a qualitative

framework analysis method …"

Title, Abstract – Methods

The concept of decisional needs is confusing the way it is applied in this paper based on the reference used. It seems to be very limited to only focused on preferred role in decision making and as such I suggest you change from decisional needs to role in decision making.

As noted in our response to "Additional Editorial comments # 9", we have made this change in the title and other mentions of "decisional needs".

I am unclear on how the analysis was done and the results do not clearly link the themes with the quotes provided. Also the analysis is not described in the abstract.

We have clarified our methodology using framework analysis in the abstract and analysis sections. We have also added Figure 1 to clarify how the analysis was done. We have re-organized the tables by our analytic framework categories to clarify how they link with the quotes.

See below sections

Abstract – Methods; Methods – Data analysis; Figure 1.

Did you analyze the pregnant participants' interviews separately from the physicians' interviews? For "no new concepts" identified – was this for both groups and was it only in the final 40th interview?

In the 'Methods: Analysis' section, we clarified that we analyzed patient and physician participant data separately. In the results, we have clarified that no new concepts emerged in the last few (of 20) interviews for each group.

"Patient and physician participant data were analyzed separately."

"For pregnant and physician participant groups, in conducting the last few interviews, interviewers noted that no new concepts emerged."

P.8, *Data analysis*; P.9, 1st paragraph under RESULTS

In qualitative research, it is important to discuss the strengths of the study to improve credibility, transferability, and trustworthiness. These are not discussed and instead there

is only a discussion of limitations. I encourage you to focus on the strengths of the qualitative study rather than the limitations.

We have added a discussion of strengths in the Interpretation section.

"To our knowledge, no previous study has qualitatively examined the need for support in assessing harms and benefits or preferred roles for decision-making with respect to antenatal corticosteroids. Prior quantitative studies for decision-making for antenatal corticosteroids have included a Markov decision analysis model to optimize timing of antenatal corticosteroids (i.e., immediate vs. delayed administration after deciding that treatment is warranted)[24], and a decision tree model to assess administration in the context of maternal COVID-19 infection[25]. Our use of semi- structured interviews and framework analysis with patients, obstetricians, and pediatricians allowed us to explore diverse perspectives and ensure participants understood the decision problem, while still effectively answering the main study questions."
P.14-15, *Strengths*

Minor feedback:
Many different terms are used for pregnant participants – sometimes patients, sometimes pregnant study participants. I suggest you use a term consistently throughout the paper. In the results section at one point you said "a few participants did not think that – or were unsure if – a tool would help decision -making" – was this pregnant participants or physicians or both?

We have standardized terminology to "pregnant participants". When describing the same individuals in the study objective in the 'Introduction' and in the 'context' paragraph of the 'Methods' (i.e., pregnant individuals who have not become participants), as well as in the 'Conclusion' (i.e., generalizing to non-participants), we refer to "pregnant individuals". Also, we clarified "a few participants" to "a few physician and pregnant participants".
Small changes in multiple locations.

What were the minor revisions to the interview questions after you tested them? Did these first few transcripts remain in the data set after you made changes to the interview questions?

We clarified the minor revisions, and the fact that the interviews were retained in the data set, under Methods: study procedures:
"Initially, we discussed all benefits and harms of antenatal corticosteroids in one

question. However, the review suggested this may have been difficult to follow for participants, so we subsequently separated this question into two (questions #2 and #4 in Appendix 1). The first two interviews were retained in the dataset."
P.7, 2nd paragraph under *Study procedures*

There are several publications from the International Patient Decision Aid Standards Collaboration on communicating probabilities in patient decision aids. They would be other key resources on this topic.

Thank you for this suggestion. Among cited publications, we cite from this Collaboration in the 'Interpretation' section of this manuscript: Trevena LJ, Zikmund- fisher BJ, Edwards A, et al. Presenting quantitative information about decision outcomes: a risk communication primer for patient decision aid developers. *BMC Med Inform Decis Mak*. 2013;13(Suppl 2).

"Current risk communication guidelines recommend the use of absolute risks[17–19,21] and representation of uncertainty by confidence intervals with explanations or by specifying sample sizes and quality of studies[22,23]."
P.14, 3rd paragraph under INTERPRETATION

Reviewer 2: Jarreg Garfinkle

One aspect of ACS provision that is not discussed: what is meant by "high risk for preterm birth"? I think this is a major area of vagueness in all the ACS guidelines. For example, if the risk for preterm birth at 34 weeks is 90%, then the physicians/patients may be more likely to prescribe/agree to ACS than if the risk for preterm birth is 10% (even if 10% if still elevated). The interviews, in my opinion, did not address this very important area of vagueness. Unfortunately, it is likely too late to ask interviewees about how they interpret "high risk for preterm birth" or "might deliver your baby four to six weeks early," but this could be addressed in the limitations or stated as a future direction. In other words, before discussing relative risks or absolute risks, we should try to understand patient and physician perspectives on the meaning of "high risk for preterm birth".

Indeed, the major limitations are (1) the interviewing of a patient population without the actual problem being studied (i.e., the patients interviewed were not at increased risk for late preterm birth) and (2) the homogeneity of the patient population interviewed (i.e., all patients had at least

university education). Some of my below comments address these limitations.

We have addressed the "meaning of 'high risk for preterm birth'" as an area for future research under the "Limitations" section. We have also elaborated on the limitations of the study population.
"Lastly, an area for future research is to understand patient and physician perspectives on what it means to be "at high risk" for preterm birth; achieving optimal timing of antenatal corticosteroid administration (within 7 days of delivery) is a ubiquitous clinical challenge, which adds complexity to discussing risks and decision-making."
P.15, *Limitations*

Other comments:

Introduction and/or Interpretation: are the authors putting together a decision support tool? If this qualitative study is the first step in the creation of a decision support tool, it could be worth stating this to provide context to this study. I might have missed this.

We added more specifically in the Introduction that this is towards our (the authors') goal to create a decision support tool.
"We also wanted to understand their informational needs, preferences for decision-making roles, and whether creation of a decision support tool for this treatment decision would be useful."
P.5, 2nd paragraph of INTRODUCTION

Introduction: "the absolute benefit of antenatal corticosteroids at later preterm gestations is lower than at earlier preterm gestations." Can the authors be more specific?

We have removed this point from the introduction for word count purposes, but have raised this point in the interpretation, and added a reference which describes how the absolute benefit of antenatal corticosteroids decreases with advancing gestational age. We would be happy to elaborate further on this point if the editors and reviewers would find this helpful but have kept it brief for now to accommodate the other revisions within the word count.
"Clinicians may not be accustomed to having detailed conversations about harms and benefits of antenatal corticosteroids because at early preterm gestations the benefits more clearly outweigh the harms[16]"

P.13-14, 2nd paragraph of INTERPRETATION

Results: Can the authors provide a breakdown of ethnicity in the patient population? This will give a better idea about its representativeness.

We did not collect demographic information on the ethnicity of the pregnant participants and agree that this is a limitation in fully interpreting our data. This has been added to the limitations.
"We did not collect information on race, ethnicity, or other socio-demographic details which may influence perspectives."
P.15, *Limitations*

Interpretation: I would encourage the authors to elaborate on the limitation of having only well-educated patients involved in the interviews. Are the informational needs of well-educated patients different from those of patients without university degrees – has this been previously studied? I am not sure but would be worth discussing, so that the reader can assess the importance of this limitation.

We elaborated on the limitation of having only well-educated patients in the interviews and the likely impact on health literacy, as well as the resultant reduced transferability of our findings.
"Our study population's health literacy may be higher than the general population's, limiting the transferability of our results[26]."
P. 15, *Limitations*

Interpretation: Is there any plan to interview patients who received ACS after they have given birth? This population may be accessible and may have already reflected on some of the questions in the interview.

Yes, a study that addresses patients' experiences of receiving counseling on ACS – patients facing the true clinical context of being at high risk for late preterm birth – is underway.