Reviewer’s report

Title: MAGnesium sulphate for fetal neuroprotection to prevent Cerebral Palsy (MAG-CP) - Implementation of a national guideline in Canada

Version: 0 Date: 19 Jul 2017

Reviewer: Sandra Dunn

Reviewer's report:

This paper describes an implementation study designed to increase optimal use of MgSO4 for fetal NP to 80% in eligible women admitted to participating tertiary centres in very preterm labour. The authors described 4 KT strategies used: (1) the Society of Obstetricians and Gynaecologists of Canada (SOGC) clinical practice guideline on the topic that was published in May 2011; (2) an e-learning module; (3) a 'Barriers and Facilitators Survey'; and (4) site visits and other interactive activities between the central MAG-CP team and individual sites (e.g. monthly newsletter, teleconferences, supportive emails and one-on-one support for questions and advice, provision of KT tools such as pre-printed physician orders, presentation materials, information sheets for staff and women and reminders for women who were being expectantly managed in hospital and at risk of preterm birth at <32 weeks). A robust interrupted time series analysis was completed to measure the effect of the KT strategies to improve use of MgSO4 for fetal NP.

Abstract - Required revisions:

* The abstract includes a clear statement supporting the need for MgSO4 for women at risk of very preterm birth to reduce the likelihood of cerebral palsy in the child, a brief description of the study design, methods, KT strategies used, the primary outcome, key results and conclusions of this project.

* Recommendations:

  a. Include a statement describing the extent of the practice gap (e.g. baseline practice rates compared to optimal)

  b. Explicitly identify this as an implementation study - current wording used is 'managed KT intervention' which is not clear and needs to be defined in the body of the paper if used.

  c. Describe secondary outcomes of interest as well.
Background and supporting literature - Required revisions:

* The authors provided rationale and supporting literature for use of MgSO4 for women at risk of very preterm birth to reduce the likelihood of cerebral palsy in the child.

* They described issues that were perceived to be barriers to uptake of this practice (e.g. concerns about potential effect of MgSO4 on FHR and increased neonatal resuscitation, lack of understanding of neuroprotective mechanism of action and inadequate studies describing long-term adverse pediatric outcomes other than CP).

* The purpose of the study is clearly stated: "increase 'optimal' use of MgSO4 (i.e., MgSO4 use when and only when indicated) to 80% of eligible women over four years (2011-15), as well as document any maternal or fetal adverse effects".

* Recommendations:
  
a. Line 75-76 - 'managed knowledge translation (KT)' should be defined.

b. It would strengthen the manuscript to include data to demonstrate the pre-study variability in use of MgSO4 for fetal NP and provide evidence of the practice gap (e.g. baseline rates, practice variation across sites or regions) to justify the need for this study.

c. Clarify terminology - Need to differentiate between the healthcare intervention being implemented in this study (e.g. use of MgSO4 for fetal NP) and the multi-faceted bundle of implementation strategies that were used to implement the intervention (e.g. guideline, e-learning module, audit and feedback, barriers and facilitators survey and 'other activities' etc.). The terminology used throughout the body of the paper is inconsistent.

d. Provide rationale for the implementation strategies selected and how these are expected to achieve effect. Other than listing the strategies on page 6 and providing a statement that "The benefits and challenges of these types of interventions have been published.[13]" there is no information provided justifying why this particular bundle of interventions was selected to address this particular practice issue within these practice settings. The theoretical framework(s) used to guide this study and inform the design of the KT strategies used should be described.

Methods - Required revisions

* The authors discussed and provided rationale for the ITS analysis and described the data sources used for the ITS.

* The authors also provided general descriptions of the 4 KT strategies used in this implementation study.
* No information was provided about the development or pilot testing of the 'barriers and facilitators survey' nor how the survey data was used to guide interactions with the participating sites.

* Recommendations:

a. Page 6, line 87-88 - revise wording to say - "We used an ITS design to evaluate the effectiveness of a selected bundle of KT strategies to optimize use of MgSO4 for fetal NP

b. To facilitate replication of the methods used in this study by other researchers:

• Provide background information about the development and pilot testing of the 'barriers and facilitators' survey - include a copy of the survey as supplementary information.

* What type of questions - pick list choices or free text? Who completed the survey for each site? Were there multiple respondents for each site - if so how did you handle their data as compared to a site with one respondent? How was the data analyzed? Expect to see some information in the discussion re: limitations of survey data - selection bias, and social desirability bias.

* How was the data from the 'barriers and facilitators' survey used as part of the implementation process?

• c. Figure 1 - provides a schematic of the MAG-CP knowledge translation audit cycle - "monitoring use of MgSO4" and "provide feedback to users" were two components within this cycle - but this audit and feedback process is not listed as one of the distinct KT strategies used in this study (page 6). Given the fact that audit and feedback is a recognized evidenced based KT implementation strategy (supported by a number of Cochrane reviews) I think it has to be included as a discrete strategy in this study and should be described as such and referenced accordingly.

• d. Page 9 lines 167-182 - describes the tracking mechanism used by the researchers to monitor the extent to which the sites participated in the various KT activities. This data has been transformed into an 'engagement' measure. Expected to also see some reference to fidelity measures used to verify that the implementation strategies were delivered as intended. This is an essential component of any implementation study and different from the self-reported use of or access to KT resources.

Results and Discussion - Required revisions:

* Discussion section - The results of the ITS analysis were presented in detail.

* Recommendations:
a. Because there is no justification of the KT strategies used, and no confirmation that the strategies were implemented as intended across all sites - it is difficult to determine whether the change in practice reported was due to the full 'KT bundle' or to specific components of the bundle (e.g. audit and feedback and face-to-face interactions during site visits) or simply due to increased awareness of and perception that 'someone was watching'. The question remains - were all of the implementation strategies built into this study essential to achieving the positive outcomes. This is an important question that has implications for future spread of this intervention and for sustainability of practice change long term. The implementation strategies used do have an associated cost (both in dollars and human resources needed to support the change) so it is important evaluate not only whether change happens, but to also understand why and how it happens and what resources were needed to support the change. At the very least this issue needs to be addressed as a limitation of the study. Spread and sustainability are important factors to consider as well and the authors are encouraged to address these issues in relation to implications for practice, policy change and future research.

b. Page 17 - lines 342-350 - acknowledges the evidence that indicates multifaceted KT approaches are more effective than dissemination alone encouraging adoption of and implementation of new research, changing clinical outcomes and achieving improvements in policy and practice. The KT strategies used in this study were designed as a package rather than tailor made to specifically counter the barriers identified through the barriers and facilitators survey. It's confusing for the reader to clearly understand how the authors differentiate between the effects of the KT strategies the researcher team implemented in the study and the quality improvement processes implemented by each of the participating sites to facilitate practice change and improve use of MgSO4. Clearly the authors associate the change with their KT bundle based on the ITS analysis. But the piece that is missing here is to understand what happened following implementation of the KT strategies. By not taking into consideration the user response effort required, the site specific barriers that were identified and how they were addressed it appears that all sites were exposed equally and responded equally - there's no information provided about how the KT interventions were 'managed' or tailored to address site specific barriers to practice change to understand what really happened? An important point for discussion and directly related to the term 'managed KT' that the authors use in the introduction. What was managed by the research team versus what tailoring happened to meet the needs of each of the participant sites based on the barriers survey?

Limitations

The authors acknowledge three limitations of this project:
* Site investigators had to report local KT activities raising the possibility that some activities affecting MgSO4 may have been over-reported or missed.

* Although the sample size of women was large overall, when examining the effects within individual sites, the study lacked power to determine the effectiveness of the KT strategies that were tracked.

* Variability in application of some of the KT strategies - some were applied at the same time across all centres (i.e., the SOGC guidelines, the e-learning module, and invitations to central MAG-CP activities, such as newsletters and monthly teleconferences); however, other aspects were applied at non-random times across sites (such as site visits and local rounds).

* Recommendations: Additional limitations
  
  - Lack of fidelity measures to verify whether the KT strategies were implemented as intended - which is a different question than whether participants reported using, accessing or attending something.

  - Because there is no justification of the KT strategies used, and no confirmation that the strategies were implemented as intended across all sites - it is difficult to determine whether the change in practice reported was due to the full 'KT bundle' or to specific components of the bundle.

  - Potential implications for social desirability and respondent bias to influence your barriers survey results.

Overall Impression:

Overall, this manuscript addresses an important issue in healthcare and is generally well written. The results of the ITS analysis are significant. My biggest issue is related to lack of completeness and transparency in reporting. Based on the StaRI (Standards for Reporting Implementation Studies) guidelines there are substantial issues related to the content as presented. This was an extensive study and I feel the paper warrants a place in the peer-reviewed literature. I would support it being accepted for publication in Implementation Science with the major modifications recommended above to enhance the information presented and strengthen the content. If revised, this paper could be a valuable resource for clinicians, decision makers and researchers interested in practice change as well as those involved in the provision of perinatal care.

Thank you for the opportunity to review this paper.
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