Author’s response to reviews

Title: Gastro-oesophageal reflux: A mixed methods study of infants admitted to hospital in the first 12 months following birth in NSW (2000-2011)

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Author’s response to reviews:

Thank you for these reviews. We have addressed each query below and believe the changes have enhanced this paper significantly.

Reviewer One

The authors aimed to explore the maternal and infant characteristics, obstetric interventions, and reasons for clinical reporting of Gastro-oesophageal reflux and Gastro-oesophageal reflux disease (GOR/GORD) The paper is of potential interest; however, in my opinion, the lack of a specific definition related to the diagnosis of GOR/GORD and of the associated diagnostic iter followed to make the diagnosis (it is just written that the condition was coded according to the International Classification of Diseases) largely limits the validity of the data reported (although on a very large sample size) and, hence, the conclusion drawn.
Thank you for your comment. The ICD-10-AM definition for GOR/GORD is in the methods section. The clinical coders would look only for those diagnoses in the medical records. If a clinician gave the diagnosis then the record would be coded for that, or if it was in the history of the patient. The inclusion of the diagnosis by a clinician in the notes is as valid for GOR and GORD as it is for any condition we study when using population data- it is not necessarily "proven" by tests results in the medical record for example. This is always a limitation of any epidemiological work. In order to make this limitation clear we have added more detail to the limitations.

Added to Limitations:

In addition clinical coders will look for a diagnoses of GOR/GORD in the medical records. If a clinician gave the diagnosis then the record would be coded for that, or if it was in the history of the patient. The inclusion of the diagnosis by a clinician in the notes does not mean it is not necessarily confirmed by test results.

Reviewer Two

Thank you for the opportunity to review, "Gastro-esophageal reflux: a mixed methods study of infants admitted to hospital in the first 12 months following birth in NSW." The paper is well written and although factors such as prematurity are well known in connection with GERD, this paper does a nice job of tying together a group of factors that are associated with the disease. The paper would be of interest to clinicians who work with Infants who have GERD and their families.

Thankyou we agree.

Abstract.

The abstract is clear and presents the study well. NSW is not written out until page 7. Many readers may not know that it means New South Wales. Please write it out in the abstract.
We have now written NSW in full in the abstract

Literature Review

The literature review is comprehensive and sets up a good rationale for the study.

Thankyou

Methods

Pg 7, line 46. Change "was" to "and."

This has been changed

Pg 7, line 49. Please define the comparison groups better. I believe you mean infants with GOR and GORD versus infants with neither diagnosis, but it could be stated more clearly.

We have made this clearer now

Infants admitted up to one year of age, recorded in the APDC, who were coded with the International Classification of Diseases (ICD-10-AM) codes K21.0 and K21.9, comprised the cohort of infants with GOR/GORD. Any baby with a congenital abnormality was removed from the cohort in order to eliminate other potential structural defects as a cause of GOR/GORD. The comparison cohort consisted of infants with no ICD-10-AM codes K21.0 and K21.9 documented

Phase1 and Phase 2. Would mothers and infants be in both groups or were they completely separate? Please make this clear.
The mother and infant records have been linked in Phase 1 and in Phase 2 the baby is admitted and has a separate medical file and the mother also has file but they are held together. We have added some extra information to make this clear.

Phase 3. It would be helpful to have some examples of questions. It seems odd to mention on pg 11, that GOR/GORD was raised by the participants in 6 of the groups and mentioned a total of 22 times, when the focus of the groups must have been GOR/GORD. How were the discussions started? Was GOR/GORD not the focus?

Thank you for this question. We realise that we did not make this part clear. The questions asked are listed below. I have put a couple of examples in the paper to make this clear

1) From your perspective, what are the main reasons for admission to RPS for a mother with an infant under 12 months of age?

2) Have you seen these reasons for admission change in the past decade?

3) Can you describe some of the characteristics of the mothers, their partners and infants that you admit to RPS?

4) We have observed that the women have RPS are from higher socioeconomic classes and often privately insured what could the service do to diversify and make it acceptable to a wider range of families?

5) What are some of the more common events that precede admission to RPS?

6) What services have women and families typically used prior to admission?
7) What would prompt a referral to RPS and do you think this has changed in the past decade?

8) What could be missing in the current maternity/universal services that could be leading to increased admissions to RPS?

9) From your perspective why is there such a demand for RPS?

10) Do you observe that parents with boys are admitted to RPS more frequently than with girls and if so why would that be?

11) What are training and development needs of staff?

12) Have these needs changed in the past decade?

I have added the following on page 11

Questions asked in the focus groups included but were not limited to: ‘From your perspective, what are the main reasons for admission to RPS for a mother with an infant under 12 months of age? Have you seen these reasons for admission change in the past decade? Can you describe some of the characteristics of the mothers, their partners and infants that you admit to RPS?’

Pg 9, line 15, remove the word "during"

Thanks we have changed this

Pg 9, line 33. Insert a comma in the number 869,188.
We have added this

Pg 9, line 41. I am a little confused why "born in Australia" is mentioned as a finding. The study was done in Australia, so would it not be expected that most mothers were born there - or is there some special significance to this? It is mentioned several times as a result (including in the abstract), but never discussed so seems to be a rather insignificant finding. Please indicate why it was included and its meaning to the group of factors associated with GERD.

In Australia around 35% of the population is not born in Australia and they are much less likely to access Residential Parenting Services and also have increased morbidity in several areas. This is why they are of interest. We have published several papers on these different outcomes between Australian born and non Australian born women. Australia is a highly multicultural nation. While ethnicity would be a better measure this is not reported in the linked data we are using.

Pg 15. Disturbance of the microbiome. I think the infant microbiome is worth speculation, even though it was not a variable in the study. However, antibiotic use really is a stretch without more explanation. More explanation is needed in this section.

We have published about this issue previously and I have now added a section to page 15 to elaborate.

Evidence on the potential risks associated with the use of antibiotics (both given to the mother during pregnancy/labour and birth and to the baby after birth), includes increased rates of asthma in early childhood [50, 51], infant allergies to cow’s milk [52]; and higher rates of obesity [53].

Pg 17, lines 22-24. This sentence would be better stated as a suggestion for future research instead of a "should" statement. Findings of this study as written did not include examining any interventions. The entire paragraph could be focused on future research.
Future research could focus on active normalising of GOR for parents through a discussion which emphasises that reflux rarely requires further investigation or treatment. The National Institute of Clinical Excellence (NICE) guidelines[26] offer recommendations for the management of the infant with GOR which feature the stepwise trialling of management strategies to reduce symptoms of GOR and the avoidance of routine investigation or treatment for GORD until overt signs of GORD exist [26]. Notably there are no references to psychological and emotional support for parents included in the guidelines despite the negative effects of adverse infant behaviour being well documented [69, 71, 83, 85, 86]. This needs to be an urgent focus of future research. Health care providers such as midwives, neonatal nurses and child and family health nurses may be better placed to normalise infant behaviour and reduce over diagnosis. They also spend more time with parents where conversations can occur that elicit other possible factors.