Reviewer's report

Title: Incidence and serotype distribution of invasive group B streptococcal disease in young infants: a multi-country observational study

Version: 2  Date: 28 August 2014

Reviewer: Christine Jones

Reviewer's report:

Overall comments:
This is a prospective observational study that evaluates the incidence, serotype distribution and case fatality of invasive GBS in infants under 3 months of age in sites in Latin America and Asia. There is a paucity of data from Asia and this study aims to address this. The numbers of infants enrolled in the study overall are small, however it is acknowledged that the endpoint of invasive GBS is a rare event; caution should be observed when drawing conclusions about how well these figures represent country and regional incidence. No cases were identified in Bangladesh, which the authors acknowledge is likely to be due multiple factors including case ascertainment, meaning that this study may not reflect the incidence in other areas of Bangladesh or even indeed the real incidence at the study site. This study effectively underlines the contribution of GBS to neonatal morbidity and mortality. The high observed incidence coupled with the extremely high CFR at some sites (up to 40%) highlights the need for a GBS vaccine in resource-constrained countries. The serotype distribution observed in the study suggests a GBS vaccine currently progression through clinical trials would cover 87% of EOD and 100% of LOD.

Minor essential revisions:
1. Introduction, paragraph 1: GBS would manifest as sepsis rather than as bacteremia.

2. Introduction, paragraph 2: Provide reference to support statement that GBS identified in cultures of recto-vaginal swabs is a “recognized risk factor for perinatal infection”, eg Ref 1: Heath, Lancet 2004

3. More information about the study sites should be provided in the methods paragraph 1. More information is gleaned throughout the manuscript, but it would be helpful to the reader to have this information given upfront to allow conclusions to be drawn more easily as data is interpreted. Crucially this information may help elucidate the reasons for the significant differences between sites 1 and 2 in the Dominican Republic.

4. Results Paragraph 1: Infants enrolled in the study should be called participants, rather than subjects.
5. Table 1: The title describes the high median age at disease onset, however this information is not given in the table.

6. Table 1: The total numbers in the racial origin/ethnicity section of table 1 do not add up correctly. “Other” is given a 1 for Panama, but none listed for other sites, total is given as 15(27%). Hispanic total adds up to 58 but is given as 34(37%).

7. Table 1: Gestational age (weeks), needs definition of whether this is birth gestation or gestation at disease onset.

8. Table 3: Why is the range of number of days down to 0 days? Were these babies not admitted to hospital, rather assessed and had cultures taken then sent home? Did they represent again later and get counted twice?

9. Figure 2: needs description of figure 2A in caption.

10. Discussion paragraph 2: needs editing of references Chang and Tsu

11. Discussion paragraph 7: Needs a comment about yield of blood cultures and CSF cultures if antibiotics have been administered before cultures taken.

12. Discussion paragraph 8: Need to add a comment about case ascertainment significantly adding to the lack of cases identified. The health care facility in Bangladesh was a private institution, could this mean that parent did not present to the facility if their child was ill if they could not afford to pay? Could cultural practices about healthcare for very young infants have influenced presentation to hospital?

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests