Dear Dr Lolu da-Silva,

Please find below our responses to the concerns expressed by the referees detailing the changes made to the manuscript and any extra information requested that we had available.

Responses to reviewer's comments

Reviewer - Alan R Tait

Thank you for your comments regarding our manuscript. We have detailed below our responses to your specific points:

Major Compulsory revisions

1) We have now extended the methods section to include some more detail on questionnaire development. The themes for reasons for participation were taken from a previous questionnaire based study conducted with parents in the Netherlands[7] as these had already been validated in a European population. The questionnaire was not piloted as there were no parents available in hospital who had taken part in research studies at the time of its development. We acknowledge that this is a weakness in its development in terms of checking for content validity.

2) The questionnaire was kept to two sides of A4 paper to try and encourage return. Demographic details of the original study did not include details on parental age, socioeconomic status and race/ethnicity so we were unable to cross reference to this. We acknowledge that not having these details did not allow comparisons to be made on these demographic variables, but believe that by extending the length of the survey we would have decreased our response rate on the primary question on reason for participation.
On the question of children being asked to assent to the study, we have included extra detail in the methods section under informed consent procedure: Information sheets were provided for children aged 7 years and over. Older children and teenagers were asked for their assent and could complete the consent form as well as their parents. We are unsure the exact numbers that were asked to assent as this was at the consenting clinician's discretion. Only 17 children in the sample that completed the questionnaire were over the age of 7 years.

3) We did not ask parent's perceptions of the risks and benefits of the PIVOT trial and were therefore unable to cross reference this to their opinions on the disadvantages of the trial.

4) We included no questions related to the parents understanding of the consent information as this would have increased the length of the questionnaire, and hence response rate as mentioned before. We acknowledge that previous research has shown a link between understanding of this information and consent into a study but we wanted to focus on the reasons that parents gave when they had given a positive consent.

5) We have added to the methods section under informed consent procedure to explain how the views of those who declined consent were collected. If the parents declined consent and volunteered a reason, this was recorded on a separate data collection form anonymously. Therefore we were unable to question these parents further to establish if their belief that IV treatment was superior was a preconceived notion or lack of understanding of treatment.

6) Table 1 has been deleted.

7) We have added into the discussion text a section detailing that our results are based on the responses to a single study, in a general paediatric condition, and thus the results may not be able to be generalised to other studies that have different risk/benefit profiles. We also discuss in more detail that there would also have been a recall bias associated with mailing the questionnaire to all parents at the end of the study. Some parents may have been recruited to the trial up to two years prior to the questionnaire being completed and therefore their recall would have been different to those recruited in the last few months. There was however an equal spread of responses over the recruitment period and the time since recruitment did not statistically alter the responses to the questions of information, time and remembering consent.

Minor Essential Revisions:
8) We have corrected the spelling on page 9 of contributions

Discretionary Revisions:
9) Figure 2 has been updated to use % rather than n values as recommended.

Reviewer Christine Grady

Thank you for comments regarding our manuscript. We have detailed below our responses to your specific points:

Discretionary Revisions:

We have amended the discussion text to detail that there would have been a recall bias associated with mailing the questionnaire to all parents at the end of the study. Some parents may have been recruited to the trial up to two years prior to the questionnaire being completed and therefore their recall would have been different to those recruited in the last few months.

We have added in to the results section information that the age of the child did not statistically influence the parents responses to any of the questions asked.

Formatting changes
The manuscript in the methods has a section on the informed consent process for the original PIVOT trial. We have added in the methods section under the heading of the questionnaire a statement about regarding
consent for the questionnaire. We have also changed the original questionnaire from a figure to a supplementary file.

We hope that we have satisfactorily addressed the comments of the reviewers and look forward to hearing their comments.

Yours sincerely

Dr Helen Sammons  
Associate Professor in Child Health