Author's response to reviews

Title: Description of the Methodology Used in an Ongoing Pediatric Care Interventional Study of Children Born with Cleft Lip and Palate in South America [NCT00097149]

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Author's response to reviews:

Dear Editor,

Thank you for reviewing our submitted manuscript titled "Description of the Methodology Used in an Ongoing Pediatric Care Interventional Study of Children Born with Cleft Lip and Palate in South America". We describe here the revisions made to the first submitted version of the manuscript and are enclosed in the resubmitted version. We have deleted all text that pertains to study progress, challenges faced, and lessons learned to date. Below is a summary of the specific changes made:

1- Removed "and Progress to Date" from the study's title.
2- In the abstract's discussion section, changed "share ongoing experiences" to "share the methods used in ongoing studies"; deleted "and progress" and "as well as main challenges observed and lessons learned to date" from the second sentence.
3- In the sixth paragraph of the Background section, deleted "progress, challenges, and lessons learned so far" from the first sentence; replaced "optimally implement" with "optimally design and implement" in the fifth sentence; replaced "share ongoing experiences with relevant large-scale interventional trials" with "share methods of ongoing large-scale interventional trials" in sixth sentence; replaced "our experience to date" with "our study methods" in last sentence.
4- Deleted the subsections of "Ongoing Subject Recruitment" and "Compliance with Study Visits to Date" from the Methods/Design section and Figures 2, 3, and 4.
5- In the Discussion section, deleted "and progress" in the first sentence of the first paragraph; deleted the second paragraph discussing the enrollment and visit compliance rates; deleted the subsection of "General Challenges and Lessons to Date"; deleted the subsection title "Study Expandability" but kept the subsection paragraphs in the Discussion section; changed "The progress to date suggests that the study implementation strategies are acceptable and have low cost by relying on an existing infrastructure" to "The study implementation strategies have a relatively low cost as they rely on an existing infrastructure" in the second sentence of the last paragraph in the Discussion section.

We hope that this revised version addresses the points you have raised in your review.

Sincerely,

Jeff Murray