Reviewer’s report

Title: Infant skin-cleansing product versus water: A pilot randomized, assessor-blinded controlled trial

Version: 1 Date: 5 November 2010

Reviewer: Luke C Mullany

Reviewer’s report:

The authors have presented a simple description of a pilot RCT of a mild cleanser vs water wash and relative impact on TEWL, pH, and skin score, to advance appropriate design of a subsequent trial. The document is clearly written, but could benefit from some relatively minor rearrangements or rewording (listed below in Minor Essential Revisions).

Major Compulsory Revisions

1. The authors need do more to convince the reader that this information will be useful to those beyond the investigators of the original trial. If this exercise only provides direction to these investigators on design of their larger non-inferiority trial, they could easily summarize this activity in a few sentence in a subsequent publication of that large trial, rather than have a separate publication here.

Minor Essential Revisions

1. Abstract-Methods - note the number of times cleansing was promoted (i.e. single vs. multiple) - later in the manuscript this is explained as "minimum of three times a week"; I think this might be added to this section also

2. Abstract-Results - Hard to read/interpret the consecutively listing of 95% CI; is the baseline CI combined across groups? [Note same concern when this is again listed in the Results section]

3. Background - first sentence of 1st full paragraph on page7 - awkward, possibly reword

4. Background - in general, seems a bit long - could be cut to about half its current length

5. Background - last paragraph - the magnitude of the difference to expect between groups should not be the driving force behind the "difference parameter" in a subsequent sample size calculation; rather it should be "the minimal possible difference that is of public health or clinical importance" for which the trial should be powered

6. Methods - did you record then number of times babies were washed?

7. Results - the description of changing to home measurements should be in Methods as well as the statement that an analysis was done to compare in-home
vs. in-facility measurements. The results of this sub-analysis should be in Results sections

8. Results - first sentence says 225 approached; but 600 were stated to be approached in the methods - explain?

Figure 1 - hard to read

Table 2 - figures not aligned, hard to read

**Level of interest:** An article of limited interest

**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.