Reviewer’s report

Title: Phenobarbital versus Morphine in the management of Neonatal Abstinence Syndrome, a randomized control trial

Version: 4 Date: 13 October 2014

Reviewer: Elisha M Wachman

Reviewer’s report:

Major Compulsory Revisions

1) I am still concerned that pharmacologic treatment is being encouraged for a population of non-opioid exposed infants who historically do not require medication. The authors site 2 articles in their first comment (Fulroth R 1989 and Smith L 2003) in regards to need for pharmacologic treatment for cocaine and methamphetamine exposed infants. The rates of treatment needed for infants in these studies were 4-6%. This needs to be emphasized in the manuscript. In the present study, it is not stated how many infants were exposed and how many were treated. I would add this percentage to the result section text or to Figure 1. I would also add these 2 references within the introduction section, stating limited data on cocaine and methamp only exposed babies but overall most do not require pharm treatment.

2) The statement in line 70-71 that “27-91%” of illicit drug exposed infants require medical interventions is vague. I would expand here, commenting on treatment rates for opioid exposed infants (typically 60-70%) vs cocaine and methamphetamines (<10%).

3) Line 102: Need to define population in this sentence – change from “drug dependent mothers” to indicate those with illicit drug use, some non-opioid or polypharm exposed.

4) Would add to limitations section the generalizability of findings given exclusion criteria used.

Minor Essential Revisions

None

Discretionary Revisions

1) Would take out numbering in the discussion section (lines 251 – 258 and lines 269-275) and just state in paragraph format.

2) Would add to intro, as well stated in comments to reviewers, that this is an under-studied population and what this study will add by looking at this population. Can also add this to the discussion section.
3) The authors do a nice job in comments of describing typical use of PB for polysubstance use, but this is not as clear in the introduction section.

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

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.