Reviewer’s report

Title: Prenatal alcohol history – Setting a threshold for diagnosis requires a level of detail and accuracy that does not exist

Version: 1 Date: 10 Sep 2019

Reviewer: Sandra Jacobson

Reviewer's report:

The authors have done a good job in addressing some of the issues raised in my previous review, particularly in their expansion of the Recommendations section. These include detailed suggestions regarding additional training of clinicians in techniques for obtaining information regarding prenatal alcohol exposure (PAE) and the need to develop a new tool for ascertaining PAE that would also incorporate sources of information suggested by their interviews with the social workers (e.g., third party sources, such as arrest records, emergency room hospital visits, visits to detox centers during pregnancy, and birth records). However, they continue to recommend that the new Canadian guidelines be set aside until such a new tool has been modified and, in the interim, to permit a diagnosis of FASD when level of maternal alcohol consumption is lower than that "consistent with the medical literature" or the "exact amounts are unknown" until this new tool is developed and validated. Extensive validation of such a new tool should not be necessary since such a tool can be readily developed by experienced clinicians and social workers that would have strong face validity. The alternative that the authors advocate would reinstate a system in which a suspicion of pregnancy drinking at low levels is considered adequate for a diagnosis of FASD. As I emphasized in my previous review, given the absence of a distinct neurobehavioral profile in FASD, in cases in which there is no evidence of dysmorphology or growth restriction, there is no basis for diagnosing FASD unless there is some evidence of moderate-to-heavy maternal alcohol consumption during pregnancy.

Another modification to the Canadian guidelines that might be considered would be to reduce the number of facial anomalies required for a diagnosis of FAS from 3 to 2, the criterion commonly used in the US (Hoyme et al., 2005, 2016). A diagnosis of Partial FAS requiring 2 anomalies plus growth restriction or microcephaly could also provide the basis for an inference that moderate-to-heavy PAE was present. This change would permit a diagnosis of FASD for many more individuals, who might have been missed by the more stringent Canadian criterion of 3 features.

In response to my Comments, the authors now make reference to the problem of false positives, i.e., that a child with ADHD symptomatology may respond differently to pharmacological and nonpharmacological treatments depending on whether this symptomatology was derived from PAE. But they argue that the Canadian guidelines and 4-digit code employed in their clinic provides "a rigorous comprehensive assessment to reduce false positives." This argument is not convincing since, as stated above, without evidence and/or confirmation of heavy alcohol use during pregnancy or distinctive FAS dysmorphic features and growth restriction, the
neurobehavioral profile associated with FASD is not specific enough to support an inference that observed neurodevelopmental deficits are attributable to PAE.

Additional comments:

Abstract, Lines 25-26. It would be better to say "between 2011 and 2016."

Discussion, 1st paragraph, lines 25-26. Typo: "at from"

Discussion, 7th paragraph, line 34. Change spelling of principal.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
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Yes

Are the conclusions drawn adequately supported by the data shown?
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