

Galactagogues use Among Mothers with Preterm Births: A Systematic Review and Meta-Analysis

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The *Journal of Human Lactation* has retracted the article by Ezenwa and colleagues, *Galactagogues use Among Mothers with Preterm Births: A Systematic Review and Meta-Analysis*, first published online 26th of May 2020. We are taking this action after a reader and an independent reviewer identified clear evidence that the reported findings are unreliable, as a result of miscalculations and major errors in the authors' methodology which are grounds for retraction according to international guidelines established by the Committee on Publication Ethics (2019). These major concerns are described in greater detail below.

The question the authors were seeking to answer is: "Does the use of galactagogues increase mother's milk production?" To accomplish this, they aimed to "evaluate the influence of galactagogues on milk production" by extracting outcome data from all the selected studies, creating a database of these data and conducting their analysis.

The authors extracted the difference in volume of human milk production between galactagogues and controls by comparing first a standard mean difference, and then they repeated the process using a pooled mean difference. For each model they also analyzed the results of herbal galactagogues and domperidone separately.

The studies in this analysis included multiple different herbal preparations as well as domperidone (galactagogues) taken by study participants at different points in time postpartum, making the reported differences from these various studies heterogeneous and difficult to compare. The decision to include this a wide range of outcomes might have been reduced with carefully considered and described statistical approach, but no discussion of these measures was included. For example, Ezenwa and colleagues do not note the methods used to manage the differences that were very likely to exist in this heterogeneous group of studies regarding length of time

participants spent in the study. They also chose a fixed effect model for the standard mean difference, instead of an analytical approach that included an underlying assumption of heterogeneity, or inequality, among the items measured (random effects model). Using a fixed effect model could result in greater statistical significance with a smaller number of trials, but also makes the assumption that reviewed studies have been conducted under similar conditions with similar substances, in this case (Borenstein et al., 2010; Fleiss & Gross, 1991). Therefore, their results are misleading; a concern of major importance considering the outcome of conducting this type of research guides decisions about whether mothers should be encouraged to take particular substances or not.

As written, it also appears that study selection, review, and extraction was performed by a single author with no indication that another researcher was involved in cross-checking that process, which is considered best practices when conducting this type of research. Another area of concern is the authors' inconsistency in extracting outcome data from some of the studies (concerns have been raised about Asztalos et al., 2017; Peila et al., 2015; Zecca et al., 2016) used in their meta-analysis. The combination of all these areas of concern make the decision to retract this article based on unreliable findings clearly necessary.

The retraction of a meta-analysis, which is considered the gold standard for assisting clinicians and policymakers in their decision making, is particularly important because of the real-world consequences that inaccurate results may cause (Chertok & Haile, 2018; Moher et al., 2009). "Systematic reviews and meta-analyses are essential tools for summarizing evidence accurately and reliably. They help clinicians keep up to date; provide evidence for policy makers to judge risks, benefits, and harms of health care behaviors and interventions" (Liberati et al., 2009, p. 1). In this case, the safety and effectiveness of ingested substances (herbs and prescribed medication) to improve milk production has been long a

debated topic in lactation; the editorial team at *JHL* has the responsibility to operate within the highest international ethical standards, which has led us to this decision.

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Editor in Chief

Declaration of Conflicting Interests

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