All research should challenge existing paradigms and beliefs, and the article by Flaherman and colleagues on early limited formula as a strategy to promote exclusive breastfeeding does just that.\(^1\) The authors are respected contributors to the literature on breastfeeding. However, there are critical limitations to study design that bring their conclusion into question and restrict the generalizability of their results. All elements of the protocol, from inclusion and exclusion criteria to intervention content and timing, should receive careful evaluation before we accept the authors’ conclusions.

Mothers agreeing to enroll as participants had to be receptive to either exclusive breastfeeding or to formula supplementation as described in an informed consent form. This inclusion criterion supports the study design yet unintentionally normalizes and endorses formula feeding for breastfeeding infants and selects for a group of participants who do not intend to breastfeed exclusively. In fact only 62% of participating mothers intended to breastfeed exclusively; because maternal intent is a strong predictor of short-term breastfeeding outcomes,\(^2\) the primary study outcome and any secondary outcomes related to exclusive breastfeeding may be affected by this bias.

The study enrolls full-term infants who are not in need of intervention. The inclusion criterion for infants of “\(\geq 5\%\) below birth weight at \(\leq 36\) hours of age” is justified by reference to the authors’ retrospective cohort study showing that breastfeeding infants \(\geq 4.5\%\) below birth weight at \(< 24\) hours of age are at risk for \(> 10\%\) weight loss during hospital stay.\(^3\) However, evidence-based and expert consensus guidelines do not consider such infants (5% below birth weight) “dehydrated” or at risk for adverse outcomes.\(^4\)

The Centers for Disease Control and Prevention, American Academy of Pediatrics, United Nations International Children’s Emergency Fund, and other professional bodies describe best practices for support of breastfeeding mothers, and the protocol references but does not explicitly incorporate these.\(^5\)–\(^7\) The described level of breastfeeding support and education is not aligned with these standards. A single intervention is noted (“all study mothers breastfed their infants with advice and support from a study doctor or nurse”), without discussion of optimization of maternal milk supply by usual and best practices, such as involvement of certified lactation consultants, skin-to-skin care, support for latch by knowledgeable staff, milk expression by hand or by a hospital grade breast pump, and use of supplemental nursing systems. There is no report of teaching mothers to identify feeding cues (eg, rooting, sucking on fist) that would prompt breastfeeding, as recommended and scored on the Centers for Disease Control and Prevention National Survey on Maternity Practices in Infant Care and Nutrition (“how many breastfeeding patients are taught to recognize and respond to infant feeding cues instead of feeding on a set schedule,” with \(\geq 90\%\) the optimal response).\(^8\) In fact,
“soothing techniques” were taught to mothers in the control group as a placebo, whereas intervention mothers learned to give formula. Teaching soothing as an alternative to feeding is not optimal guidance because it may serve to decrease infant breast milk intake and increase maternal milk supply anxiety, creating additional potential bias.

The authors report that intervention infants received a small volume of formula, “so that infants would not be satiated and would maintain demand for breastfeeding,” but no data, such as number of feeds per day or volume of breast milk per feed, support this assertion. The amount of formula provided appears close to the total volume of colostrum in early lactogenesis II, which limits the value and impact of the formula intervention.9

The control group outcomes actually provide the most meaningful implications for practice and the richest food for thought. Mothers in the control group knew from the informed consent document that their infants might be randomized to receive early formula. We might thus postulate that mothers who are given the expectation that early formula feeding by syringe is “normal,” and who in addition do not receive specific support in establishing their milk supply and identifying infant hunger cues, are at risk for not achieving exclusive breastfeeding goals.

On the basis of this study, a reasonable reader could conclude that early limited formula is not an evidence-based strategy for full-term infants. Whether early limited formula would be appropriate for preterm or late preterm infants whose mothers receive optimal lactation support is not known; the intervention should not be extrapolated to other populations without a well-designed prospective study. It is hard not to wonder whether financial ties to the formula industry of a coauthor, who participated in study design and participant enrollment, created unintended bias. Nonetheless, the authors are to be commended for tackling an important clinical problem, that of optimizing exclusive breastfeeding outcomes. However, to evaluate early limited formula objectively, we need protocols that explicitly optimize lactation and enroll mother-infant dyads clearly at risk for poor breastfeeding outcomes; any early limited formula strategy should await these data.

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