

Comments in response to the Federal Register Notice

A 60-day Notice was published in the Federal Register on July 5, 2022, Vol. 87, No. 127, pp. 39838-39839 with the title “Pregnancy Risk Assessment Monitoring System (PRAMS)” (Attachment 3a). CDC received two comments related to this notice (Attachment 3b). CDC did not provide a response to one comment because it fell outside the scope of this information collection. The other comment was submitted by The National Lactation Consultant Alliance (NLCA), an organization outside of the CDC. NLCA commented on the importance of including additional survey questions to PRAMS on lactation support and care and formula supplementation of breastfed infants, which CDC has addressed in response, along with additional comments related to utility, accuracy, quality, burden and additional areas of concern related to this information collection request (Attachment 3b).

Standard Area/Topic	Description	Comments	Date Received by CDC	CDC’s Response
<p>1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.</p>	<p>To collect jurisdiction-specific, population-based data on maternal behaviors and experiences before, during, and short after pregnancy</p>	<p>A comment from Jean Publiee suggests that CDC, as an agency before more transparent with providing health data to the public.</p>	<p>07/14/2022</p>	<p>No reply (outside scope of project)</p>
	<p>To collect jurisdiction-specific, population-based data on maternal behaviors and experiences before, during, and shortly after pregnancy</p>	<p>The National Lactation Consultant Alliance (NLCA) suggests that PRAMS add two questions on which sources mothers used for lactation support and care and two questions around formula supplementation among breastfed infants.</p>	<p>07/05/2022</p>	<p>CDC appreciates the work that NLCA does to provide proper support and care for breastfeeding families and the recommendations made for questions to be added to the PRAMS survey.</p> <p>The Phase 9 Core survey reflects a balance between the need to address competing health research priorities (at CDC and among 50 PRAMS jurisdictions) and to limit survey length to minimize respondents’ burden. The Core survey covers a variety of topics, which includes but is not limited to preconception, prenatal, and postpartum care, access and barriers to care, chronic health conditions, mental health, experiences of racism and discrimination, intimate partner violence, contraception use, and breastfeeding initiation and duration.</p> <p>In addition to the Core survey, PRAMS jurisdictions also have the option to expand on the breastfeeding topic by selecting questions from the Standard breastfeeding module. The PRAMS breastfeeding module includes 14 questions. Questions on sources for breastfeeding planning before pregnancy (B9), sources for breastfeeding information and support during and after pregnancy (B17), baby-friendly hospital breastfeeding practices (B3), the kinds of breastfeeding help mothers needed after delivery (B14) and on timing of</p>

Attachment 3b – Program Response to Comments to 60 Day FRN

				<p>formula introduction (B10) and timing of solid foods (B11) are very similar to the questions that NLCA is proposing. Additionally, the breastfeeding module includes questions on barriers to starting and continuing breastfeeding, and the use of and sources for obtaining a breast pump.</p> <p>Because of limited space on the PRAMS survey and the proposed questions overlap substantially with the planned Phase 9 breastfeeding module which has completed cognitive and field testing, the CDC will retain the current questions around breastfeeding without adding additional ones.</p> <p>CDC has added NLCA to our PRAMS partners list and will contact NLCA to provide an opportunity for input and question recommendations as part of the next PRAMS questionnaire revision process.</p>
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Comment from publiee, jean

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General Comment

it is vitally important that we have accurate stats for vaccinated mothers and babies and the outcome of the pregnancy. can we trust the cdc to provide such - probably not. i am not in favor of this agency taking this kind of information and do not believe it will be honest or available to the us public for 76 years. the accuracy of information from this lying corrupt agency cannot be trusted so we should really get an outside firm to do this investigation. we get tainted stats from this agency. we are not getting honesty or truth. i am not in favor of cdc getting tax dollars any more for this project. cdc lies to the american public. get a new outside agency to keep stats. cdc standards are too loose and negligent. this agency deserves a grade of f minus for its work



Comments on Docket No. CDC–2022– 0080]

The National Lactation Consultant Alliance (NLCA) is pleased to submit these comments in response to the Notice from the CDC regarding the proposed information collection for the Pregnancy Risk Assessment Monitoring System (PRAMS). As a trusted healthcare advocate, NLCA routinely provides comments on policies that impact public health through breastfeeding and the provision of human milk. NLCA is the advocacy organization for the International Board Certified Lactation Consultant (IBCLC).¹ The Women’s Preventive Services Initiative (a cooperative agreement between the American College of Obstetricians and Gynecologists (ACOG) and the Health Resources and Services Administration (HRSA) defines the IBCLC as a clinical lactation professional along with nurses, physicians, and midwives, as contrasted with lactation personnel that provide counseling, education, or peer support.²

The American Academy of Pediatrics (AAP) identify breastfeeding and human milk as the normative standards for infant feeding and nutrition.³ The enhanced short- and long-term medical and neurodevelopmental outcomes from breastfeeding and the provision of human milk, the reduction in disease burden for both mothers and infants, and the considerable cost savings to the US healthcare system, make breastfeeding a public health imperative. It is therefore important that breastfeeding families receive the level of lactation care they need if they are to breastfeed exclusively for 6 months and with appropriate complementary foods up to 2 years thereafter. It has been found that women who received IBCLC care and services were more than 4 times as likely to exclusively breastfeed their infant at 1 month and nearly 3 times more likely to do so at 3 months compared with a control group.⁴ However, breastfeeding families and mothers may not be able to distinguish from whom they receive lactation help. There exists a bewildering array of lactation certificates that may be confused with the lactation certification of an IBCLC.⁵ Families and clinicians need to be able to access and refer to the appropriate lactation personnel for the level of expertise needed. Breastfeeding counselors and educators provide basic support and education while the IBCLC handles acute and complex

¹ www.nlca.us

² Women’s Preventive Services Initiative. (2022). *Breastfeeding services and supplies updated January 2022*. <https://www.womenspreventivehealth.org/recommendations/breastfeeding-services-and-supplies/>

³ Meek, J.Y., Noble, L.; Section on Breastfeeding. (2022). Policy statement: Breastfeeding and the use of human milk. *Pediatrics*, 150(1), e2022057988. <https://doi.org/10.1542/peds.2022-057988>.

⁴ Bonuck, K., Stuebe, A., Barnett, J., Labbok, M.H., Fletcher, J., & Bernstein, P.S. (2014). Effect of primary care intervention on breastfeeding duration and intensity. *American Journal of Public Health*, 104, S119-S127. <https://doi.org/10.2105/AJPH.2013.301360>

⁵ Dodgson, J.E. (2020). Lactation-specific certifications: A comparison of independently accredited credentials. *Journal of Human Lactation*, 36(1), 119-125. <https://doi.org/10.1177/0890334419888217>

breastfeeding scenarios. It is important that breastfeeding mothers know who to access for basic help and who to contact with more acute or complex challenges. Receiving support from lactation personnel who are not trained, equipped, or skilled in assessment of complex situations place mothers and infants at risk of poor health outcomes.

We therefore feel it is important to include questions within the PRAMS surveys that help determine if mothers know from whom they receive lactation support and care. Such data would assist policy makers in the identification of populations at high risk for health problems and provide data for planning programs and policies that would enhance breastfeeding outcomes. Questions could include the following:

Did you see or talk about breastfeeding with any of the following

- doctor
- nurse
- midwife
- International Board Certified Lactation Consultant (IBCLC)
- doula
- peer counselor
- breastfeeding educator or breastfeeding counselor
- dietitian
- don't know

If you talked with or saw any of the following for a breastfeeding problem, indicate who you saw or spoke with and if your problem was resolved

- doctor
- nurse
- midwife
- International Board Certified Lactation Consultant (IBCLC)
- doula
- peer counselor
- breastfeeding educator or breastfeeding counselor
- dietitian
- yes
- no

The term “lactation specialist” used in the current PRAMS questions is too vague to allow clarification of who is delivering care and if it is effective.

Infant formula supplementation of breastfed infants

Up to 25% of breastfed infants receive formula before 2 days of age.⁶ Such an intervention can result in perturbations of the infant gut microbiome, altered infant health outcomes, and early abandonment of breastfeeding. In a breastfed infant, consumption of one bottle of formula per day for the first week of life is enough to shift the gastrointestinal microbiology toward proinflammatory taxa.⁷ Avoiding cow's

⁶ Centers for Disease Control and Prevention. (2022). *Breastfeeding report card United States, 2022*. <https://www.cdc.gov/breastfeeding/pdf/2022-Breastfeeding-Report-Card-H.pdf>

⁷ O'Sullivan, A., Farver, M., & Smilowitz, J. T. (2015). The influence of early infant-feeding practices on the intestinal microbiome and body composition in infants. *Nutrition and Metabolic Insights*, 8 (Suppl 1), 1–9.

milk formula supplementation in the first three days of life has the potential to reduce the risk of asthma or recurrent wheeze in young children.⁸ Avoiding exposure to cow's milk formula for at least three days of life decreased the risk of sensitization to cow's milk and cow's milk allergy compared with supplementing with cow's milk formula from the first day of life.⁹ In-hospital formula supplementation halved the likelihood of following a breastfeeding trajectory characterized by sustained exclusive breastfeeding, it decreased the likelihood of breastfeeding initiation with a subsequent child by >66%, and reduced the average duration of breastfeeding any subsequent children by >6 weeks.¹⁰ Infants exposed to in-hospital formula supplementation are at a 2.5 to 6 times higher risk of early weaning than infants exclusively breastfed.¹¹ In-hospital formula supplementation often leads to continued supplementation after discharge.¹²

Questions regarding formula supplementation of breastfed infants would yield data on the extent of the practice and aid policy makers in planning for the reduction of a practice that can result in poor breastfeeding and health outcomes. Questions such as:

If your breastfed baby was supplemented with formula while in the hospital or early days at home, did you feel pressured to give your baby bottles of formula? If so, by whom were you so advised?

- Family
- Friends
- Nurse
- Pediatrician
- Midwife
- Doula
- WIC
- Social media
- Yes
- No

Were you offered any other options to using infant formula?

- Yes
- More intense breastfeeding support
- Referral to an International Board Certified Lactation Consultant (IBCLC)
- Pumping or hand expressing colostrum/milk
- Banked donor human milk
- No

⁸ Tachimoto, H., Imanari, E., Mezawa, H., Okuyama, M., Urashima, T., Hirano, D., Gocho, N., & Urashima, M. (2020). Effect of avoiding cow's milk formula at birth on prevention of asthma or recurrent wheeze among young children: Extended follow-up from the ABC Randomized Clinical Trial. *JAMA Network Open*, 3(10), e2018534.

⁹ Urashima, M., Mezawa, H., Okuyama, M., Urashima, T., Hirano, D., Gocho, N., & Tachimoto, H. (2019). Primary prevention of cow's milk sensitization and food allergy by avoiding supplementation with cow's milk formula at birth: A randomized clinical trial. *JAMA Pediatrics*, 173(12), 1137–1145.

¹⁰ Whipps, M.D.M., Yoshikawa, H., Demirci, J.R., & Hill, J. (2021). Estimating the impact of in-hospital infant formula supplementation on breastfeeding success. *Breastfeeding Medicine*, 16(7), 530-538.

¹¹ McCoy, M.B., & Heggie, P. (2020). In-hospital formula feeding and breastfeeding duration. *Pediatrics*, 146, e20192946.

¹² Pérez-Escamilla, R., Buccini, G.S., Segura-Pérez, S., & Piwoz, E. (2019). Perspective: Should exclusive breastfeeding still be recommended for 6 months? *Advances in Nutrition*, 10, 931–943.

We thank you for the opportunity to comment. Please feel free to contact us with any questions or if we may be of further help.