



May 7, 2018

Lisa Kaeser, JD
Executive Secretary, NICHD

RE: Task Force on Research Specific to Pregnant Women and Lactating Women

Dear Dr. Kaeser,

This letter of intent is being submitted to confirm the participation of PATH at the May 14–15 meeting of the Task Force on Research Related to Pregnant Women and Lactating Women (PRGLAC). PATH is a global health non-profit organization dedicated to the health of women and children and focused on driving transformative innovation to save lives. PATH has headquarters in Seattle, WA and an office in Washington D.C., as well as presence in over 50 countries around the world. One PATH representative, Carrie Hubbell Melgarejo, will attend this PRGLAC meeting in person to present oral comments.

Ms. Melgarejo's oral presentation will include requests for enhanced research in the following areas:

- **To identify lactating women's barriers to optimal breastfeeding of children.**

Optimal breastfeeding, including early initiation of breastfeeding within one hour of birth, exclusive breastfeeding through six months, and continued breastfeeding until the infant is two years old and beyond, has been shown to be one of the most effective interventions to save children's lives.¹ However, barriers to these optimal practices—whether at the facility, at work, at home, or in the community—are not well understood; further research to identify practices that break down these barriers is greatly needed.

- **To determine feasible and effective mechanisms of support for pregnant and lactating women to ensure optimal infant feeding.**

Innovation and research are needed to identify effective mechanisms of support for all pregnant and lactating women. This includes improvements in counseling and skill building among pregnant women in preparation for lactation and identifying innovative ways to reach all mothers, not just those that seek support during pregnancy. Further research is needed to understand barriers to seeking skilled support for lactation, especially in the first weeks of life while lactation is being established. This research will also provide insight on effective initiatives to ensure all women have access to cost-effective, skilled support for any issues that arise in lactation and infant feeding. When feeding at the breast is not an option, further research and design is needed to understand optimal lactation processes to ensure adequate supply, and equally important, optimal infant feeding mechanisms for providing mother's own milk for growth, development, and optimal health, with the eventual goal of advancing to feeding at the breast.

- **To identify and address determinants of inequity for pregnant and lactating women to receive counseling and support for optimal infant feeding.**

Given the disparities found in the use of human milk in the neonatal intensive care units in the United States,² further research is needed to identify determinants of optimal use of human milk for all infants. Additionally, formative research is needed to determine facilitators and barriers to accessing community resources for

¹ Black RE, Victora CG, Walker SP, et al. Maternal and child undernutrition and overweight in low-income and middle-income countries. *The Lancet*. 382;(9890):427–451. doi: 10.1016/S0140-6736(13)60937-X.

² Boundy EO, Perrine, CG, Nelson, JM, Hamner HC. Disparities in hospital-reported breast milk use in neonatal intensive care unit—United States, 2015. *Morbidity and Mortality Weekly Report*. 2017; 66(48). Available at: <https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6648a1-H.pdf>.

human milk, in rare cases where the mother is unable to provide her own milk to her child. In general, formative research is needed to identify socio-cultural factors linking optimal care-seeking behaviors and research to identify solutions for such inequities.

- **To assess the cost benefit of employers providing paid leave and workplace support for lactating mothers.**

A cost-benefit analysis of paid leave and support for lactation in the workplace provided to mothers is needed to assess the business-related and social benefits to providing optimal nutrition. Further research is needed to determine models that offset the costs to the employers to support mothers, as well as ways to mitigate these costs, given the benefits of optimum nutrition for infants and the impact on the whole of society. The United States is behind many other countries, including other wealthy and low- to middle-income countries, in terms of access and use of paid parental leave. The economic assessment of costs associated with not breastfeeding is needed to detail room for improvement in current workplace policies. Regulations requiring jobsite lactation facilities and accommodations are very important to this effort, and research is needed on how these can be even more effective. Additionally, further research is needed to design effective programs that incentivize employers to support such practices that benefit society.

- **To determine challenges and systems improvements for mothers, including the mothers of sick and small infants who may be in a neonatal intensive care unit, to receive counseling and support and appropriate logistics (i.e., rooming in) for providing their breast milk for their infant.**

The World Health Organization and the American Academy of Pediatrics identify that mother's own milk is optimal for the infant and should be prioritized, and that donor human milk is the next best alternative for premature, low-birthweight infants when mother's own milk is unavailable. Further research is needed to guide systems-strengthening approaches for ensuring all infants and mothers receive support to prioritize the provision of mother's own milk for their infants.

- **To determine equality of eligible neonates to access to donor human milk across socio-demographic, region, and ethnicity.**

Similarly, research is needed to determine factors that limit mothers of vulnerable infants from being able to supply adequate volumes of breast milk to their own infants and the optimal method of using donor human milk as a bridge, while continued lactation is supported to increase supply. It is unknown how many infants require donor human milk in the neonatal intensive care units in the United States, and what percentage of infants in need are receiving donor human milk during this critical time period. Further improvements in data collection during this period are essential to capture the ongoing need and the factors that ensure all infants receive optimal nutrition support.

- **To improve the quality of donor human milk provided from human milk banks through determination of optimal temperature thresholds for pasteurization of human milk, as well as established methods for safety and supply.**

Current methods of pasteurization for donor human milk performed by human milk banks ensure safety, while also ensuring the quality of the milk in terms of retaining immune and other biologically active substances in human milk. Research is needed to determine the optimal pasteurization temperature curve for human milk that maintains the destruction of potentially pathogenic viruses and bacteria, while maximizing the retention of immune components. Additionally, research is needed for improvements in the methods of supplying safe and quality donor human milk, through improved diagnostics, processing devices/systems, and tracking systems that are specialized for human milk. Furthermore, research is needed to better understand the importance of the properties found in human milk and optimal processing techniques to ensure safety in the supply of donor human milk.

- **To assess current feeding practices and health outcomes among vulnerable infants in neonatal intensive care unit settings.**

Current methods of infant feeding are not well understood in neonatal intensive care units around the United States, nor globally. Further data collection and improved methods for data collection are required, especially for better understanding the practices in current neonatal feeding of the most sick and vulnerable infants. Research is needed to understand best practices in supporting mothers of infants in the neonatal intensive care units to provide optimum human milk for their infants, characterizing diets of vulnerable neonates with associated health outcomes to know how best to feed low-birthweight and premature infants.

Please contact us if further information is required.

Sincerely,

/Kiersten Israel-Ballard/

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