

September 6, 2017

Dr. Matthew Gilman
Director, Environmental Influences on Child Health Outcomes (ECHO)
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Gilman,

On behalf of the March of Dimes, a unique collaboration of scientists, clinicians, parents, members of the business community, and other volunteers representing every state, the District of Columbia and Puerto Rico, I would like to thank you for the opportunity to respond to a the request for information, "Inviting Comments on the Environmental Influences on Child Health Outcomes (ECHO)-wide Cohort Data Collection Period" (Notice Number: NOT-OD-17-090). We are hopeful that ECHO's research will enhance the health of children for generations to come and are proud to participate in such a significant project. Our recommendations focus on issues related to pregnancy, neonatal and infant care.

- **Unnecessary data elements.** Some data measures currently included in the protocol may be unnecessary, duplicative or unclear. Currently, in pregnancy-related data elements, the protocol requires information on the first full feed and first full *per os*, or PO, feeding. However, determining a full feed may be difficult, especially if this measure is reported by a parent, and may not be relevant to any research question.

Several measures in the NICU section require clarification. First, the protocol appears to require the duration of an infant's NICU stay to be measured prenatally. As this is impossible, we suggest it be measured in the perinatal period. Additionally, the NICU Network Neurobehavioral Scale (NNNS) is not standardized across all NICUs, and including it without standardization could lead to inaccurate conclusions. Some data elements may be covered in other measures, including infant cerebrospinal fluid (CSF) culture results, which is covered by the infant meningitis measure, and Patent Ductus Arteriosus (PDA) surgery, which is included in the larger infant surgery measure.

Finally, we suggest replacing ambiguous NICU pain/withdrawal measurements with a report of the medications used to treat these symptoms, as well as replacing infant temperature at birth for all infants with temperature at admission for NICU patients only.

- **Critical data elements.** We suggest the addition of several important data elements, such as the interval between pregnancies, maternal caffeine consumption, and whether or not a mother breastfeeds. We also suggest expanding the parental incarceration measure to include previous incarceration or other involvement with the criminal justice system. Maternal foreign travel/infections should be an essential, rather than a recommended, data element, especially given the urgency and timeliness of infectious diseases like Zika.

In regard to NICU measures, the primary admission diagnosis must be included in order to fully understand postnatal outcomes. Finally, “child neurodevelopmental health” should include specific measures like motor dysfunction or cerebral palsy.

- **Essential biospecimens.** We are pleased to see that the placenta is included as an essential biospecimen. However, given the large size of a whole placenta, storage could quickly become an issue. In order to resolve this issue, we suggest additional clarification that placenta samples are acceptable to meet this requirement.

The March of Dimes thanks you for the opportunity to provide feedback on this important research. We look forward to working with you to increase knowledge of early childhood environmental influences on long term health. For more information, please contact Jaimie Vickery, Director of Federal Affairs, at jvickery@marchofdimes.org or 202-292-2752.

Sincerely,



Paul Jarris, MD MBA
Chief Medical Officer