**PREVAIL (Pediatric Respiratory & Enteric Virus Acquisition and Immunogenesis Longitudinal) study: A U.S. birth cohort of children 0-2 years**

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**Background**: Acute gastroenteritis (AGE) and acute respiratory infection (ARI) remain major causes of morbidity and mortality in young children. Birth cohort studies are needed in the U.S. to understand natural immunity to vaccine-preventable viruses, and those with vaccines under development. PREVAIL is an academic-CDC collaborative birth cohort underway in Cincinnati, OH that follows subjects from pregnancy to the 2nd birthday. The goal is to document the natural history of infection and immunity to improve existing vaccines (rotavirus, influenza) and optimize vaccines under development (norovirus, RSV).

**Methods**: After maternal enrollment in the 3rd trimester, healthy mother-infant pairs achieved final eligibility at postnatal week 2. Immunity and infections are documented by collection of maternal, cord, and infant blood samples at 6 weeks and 6, 12, 18 and 24 months, and infant stool and mid-turbinate nasal swabs collected weekly by mothers. Saliva and mother’s milk samples are also collected. ARI and AGE cases are documented by weekly cell phone surveys to mothers via automated text messaging and by medical records. Immunization records are obtained from registries and providers. Infection is defined by a positive sample or 4-fold rise in serum antibody. ARI is defined by cough or fever (≥38.0°C, rectal), and AGE is defined by >3 loose or watery stools and/or >1 vomiting episodes within 24 hours, at any time in the previous week. Weekly stool and nasal samples are being tested by multiplex pathogen panels and viral confirmatory PCR.

**Results**: As of 12/1/2018, enrollment is complete. Data collection is ongoing. Enrolled mothers (n=245) were 52% white, 43% black; and 56% publicly-insured. Breastfeeding initiation was 87%. Infants contributed 10,638 weeks of follow-up; only 23 (9%) were lost to follow-up. In retained subjects, a median of 87% per week had stool and nasal swabs collected; blood collection was 100% for mothers, 83% for cord, 90% and 89% for infants aged 6 weeks and 6 months. Median maternal response to text message surveys was 97% of weeks. To date, ARI incidence is 2.99 cases/child-yr (median duration 4 d), and AGE incidence is 1.03 cases/child-yr (median duration 3 d).

**Conclusions**: To date, PREVAIL demonstrates the ability to conduct logistically challenging, intensive mother-infant follow-up in the U.S. to document the natural history of infection and immunity. ***Funded by CDC***

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