

Childhood obesity prevalence has more than tripled since the 1970s and today, more than 1 in 5 children in the United States are obese. Epidemiologic studies and murine models suggest the microbiome plays a causal role in obesity. There has also been a dramatic rise in the use of Cesarean-section (C-section) delivery over the last 3 decades, making it one of the most common surgical procedures carried out in the United States. While C-section increases the chances of successful delivery and often protects the health of the mother and baby, C-section has been associated with an approximately 50% increased risk of childhood obesity, along with asthma and allergies. It is believed that the risk of diseases associated with C-section delivery owes to the lack of mother-to-newborn transfer of vaginal microbes at birth, which is interrupted in scheduled C-section.

Given this evidence, randomized trials are now needed to determine if mother-to-newborn transfer of microbiota at birth alters the development of the infant microbiome and prevents the metabolic and immune-mediated diseases associated with C-section delivery. While randomizing to delivery mode is not ethical, it is ethical and feasible to expose C-section infants to their own mothers' vaginal microbiota at birth. In a pilot study by our collaborator Dr. Dominguez-Bello, "vaginal seeding", the transfer of vaginal microbiota from mother to baby, of C-section delivered newborns was associated with increased abundance of bacteria typically missing or reduced in C-section infants. However, this study was not randomized and too small to determine robust effects on measures of infant obesity or allergy risk. After this study however, many Mothers having a scheduled C-section are asking for vaginal seeding to be performed although the health benefits and risks are unknown.

Inova Translational Medicine Institute has been approved to conduct the first randomized controlled trial of vaginal seeding for infants born by scheduled C-section. Starting in the New Year, Mothers undergoing planned C-sections at the Inova Fairfax Hospital will be enrolled; Mothers will be rigorously screened for any ailments or infections to ensure only healthy mothers are included. Their babies will be randomized to receive either their Mother's vaginal flora swabbed over their skin or a saline placebo shortly after birth. This trial will explore how vaginal seeding affects the development of the infant microbiome. Moreover, these babies will be followed until they are three years of age to investigate whether vaginal seeding actually improves long term health outcomes including obesity, allergies and asthma.

The study will directly inform whether there are health benefits from the vaginal seeding of C-section delivered newborns. This evidence could change the practice of obstetrics as we know it.

Principal Investigator: Suchitra Hourigan, MD

Director of Microbiome Research, Inova Translational Medicine Institute

Pediatric Gastroenterologist, Pediatric Specialists of Virginia

Co-Principal Investigator: Maria Gloria Dominguez-Bello, PhD

NYU School of Medicine, Human Microbiome Program

Co-Principal Investigator: Noel T. Mueller, PhD, MPH

Welch Center for Prevention, Epidemiology and Clinical Research, Johns Hopkins School of Medicine