Abstracts 1-9

1 Randomized Trial of Maternal Hyperimmune Globulin to Prevent Congenital Cytomegalovirus (CMV): 2 year outcomes
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OBJECTIVE: To evaluate whether CMV hyperimmune globulin (HIG) administered to women with primary CMV during pregnancy reduces adverse childhood outcomes at age 2 years.

STUDY DESIGN: Multicenter randomized double-masked trial of women with a singleton gestation < 24 weeks with primary maternal CMV infection defined by the presence of either CMV IgM and IgG with low avidity, or IgG seroconversion, as assessed by a central reference laboratory, without evidence of fetal infection. Monthly infusions of CMV HIG (100 units/kilogram) or placebo were given until delivery. At the time of delivery, congenital CMV infection or death did not differ between the HIG and placebo groups (22.7% vs. 19.4%). The primary composite 2-year child outcome included: death, sensorineural hearing loss (unilateral and bilateral), choriorrhatitis, seizure disorder, or developmental delay (defined as cognitive score < 70 or motor score < 70 on the Bayley III).

RESULTS: At 17 centers from 2012 to 2018, 206,111 pregnant women were screened; 712 had primary CMV infection (0.35%), of whom 399 (56%) were enrolled and 78 infants (19.5%) had congenital CMV. 90% of children had data collected for the 24-month visit and 75% had complete 2-year outcomes available. The rate of the child primary composite outcome in the CMV HIG group was 13.4% compared with 10.1% in the placebo group (Relative Risk 1.3; 95% confidence interval (0.7, 2.5)). The proportion of children with CMV infection and severe disability was similar between the groups (4.1% vs. 4.7%, p=0.69) and there was no improvement in neurodevelopmental outcomes or in the percentage of children whose weight was < 10th percentile at 2 years (Table).

CONCLUSION: CMV HIG did not decrease adverse two year outcomes among children born to women with primary CMV infection in early pregnancy.

2 Randomized Clinical Trial Comparing Group vs. Traditional Prenatal Care for Improving Equity in Birth Outcomes
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OBJECTIVE: The traditional model of individual prenatal care (IPNC) has not appreciably changed in more than a century and is associated with high rates of preterm birth (PTB) and low birthweight (LBW), the burden of which disproportionately affects Black women and infants. Innovative group prenatal care (GPNC) models may reduce the risk of PTB, especially for Black women. We sought to test whether GPNC compared to IPNC reduced rates of PTB and LBW, and if GPNC reduced the racial disparity among Black, White and Hispanic women.

STUDY DESIGN: This was a randomized clinical trial in which medically low-risk pregnant women were allocated 1:1 between GPNC and IPNC stratified by self-identified race/ethnicity at a single study site. Primary outcomes were PTB (< 37 weeks gestational age) and LBW (< 2500 grams). Comparisons were made using three analytic approaches: intent-to-treat (ITT) including all randomized participants, modified intent-to-treat (mITT) including participants attending at