visit. A diagnosis of trichomoniasis was defined as a positive nucleic acid amplification test (NAAT) and/or motile trichomonads on wet mount microscopy, urinalysis, or cervical cytology. Women with abnormal vaginal discharge at the time of testing were considered symptomatic. A chi-squared test of proportions was used to compare the percentage of cases that received treatment and that had a TOR by testing modality. The Mann Whitney U test was used to compare time to treatment and TOR by mode of diagnosis.

**RESULTS:** Among 3,349 women, 390 (11.6%) women were diagnosed with 541 unique cases of trichomoniasis (1 case: 289 women, 2 cases: 61, 3 cases: 32; 4 cases: 6, 5 cases: 2). Of the 541 cases, 177 women were diagnosed by wet mount microscopy, 360 by NAAT, 39 by cytology, and 14 by urinalysis. Nearly 10% of women had more than one mode of diagnosis. There were 1,779 women (53.1%) that had NAAT screening for trichomoniasis at some point during pregnancy. Among women with a positive NAAT, 103 (28.6%) had wet mount microscopy done on the same day. Of these 103 women, 75 (72.8%) tested negative on wet mount. Of the 541 cases, 123 (22.7%) had abnormal vaginal discharge at time of testing. A Time to treatment ranged from 0 to 210 days, with 62 women (12.2%) waiting more than four weeks for treatment. Days to treatment was shorter for those who had a positive wet mount compared to those who were diagnosed by other modalities (median wet mount= 0 days, median other= 8 days, $p < 0.0001$). Time to TOR ranged from 14 to 260 days. The proportion tested for reinfection and time to TOR did not differ significantly by mode of diagnosis (wet mount= 73.6%, all others= 71.1%, X2= 0.4, p= 0.54; median wet mount= 37 days, median other= 38.5 days, p= 0.71).

**CONCLUSION:** Our results highlight that delays in treatment are common when point of care testing is not performed. Given the low sensitivity of wet mount, higher sensitivity point-of-care testing approaches should be explored. The high percentage of asymptomatic cases underscores the need for more structured guidelines for trichomoniasis testing and treatment in pregnancy. This need is even greater in high-risk populations, given the association of trichomoniasis infection with preterm delivery and increased HIV acquisition risk.

**LEARNING OBJECTIVES:** Learners will be able to identify the different patterns of testing, tests of reinfection, and treatment for trichomoniasis in pregnancy.

## 9 A comparison of 2 g single-dose versus 7-day 500 mg twice daily metronidazole for the treatment trichomoniasis in women by selected clinical factors

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**OBJECTIVES:** Trichomonias is the most common non-viral sexually transmitted infection (STI) among women worldwide and is associated with serious reproductive morbidity, poor birth outcomes, and amplified HIV transmission. Single-dose (2 g) metronidazole (MTZ) is the first line of treatment recommended by the Centers for Disease Control and Prevention and the World Health Organization with multi-dose MTZ as an alternative. Two multi-centered randomized trials and a meta-analysis found that women receiving multi-dose MTZ were nearly half as likely to retest positive to T. vaginalis post-treatment compared to women receiving single-dose MTZ, indicating that multi-dose MTZ should be recommended over single-dose. The purpose of this study was to examine if this effect was similar by selected clinical factors to determine if treatment recommendations should be nuanced.

**METHODS:** This is a secondary analysis of a previously published randomized, parallel, multi-site, open-label trial of single-dose (2 g one-time) versus multi-dose (500 mg twice daily for 7 days) MTZ for the treatment of trichomoniasis. The primary outcome was T. vaginalis infection at test-of-cure (TOC) 4 weeks after completion of treatment measured by nucleic acid amplification test or culture. Analyses were stratified by reported T. vaginalis history, genital symptoms, and bacterial vaginosis (BV) at baseline.

**RESULTS:** Women who returned for their TOC visit (n=540) were included. At baseline, 53.1% had a history of trichomoniasis, 80.6% had genital symptoms, and 45.9% had BV. At TOC, 15.0% rested positive. Stratified rates of T. vaginalis at TOC are in Table 1. In women who received single dose MTZ, those who were symptomatic and had a history of trichomoniasis had the highest rate of infection at TOC (26.7%) whereas those with neither factor had the lowest rate (4.3%). Among women receiving multi-dose MTZ, TOC+ rates were similar by these factors (range 9.3%-13.0%). There was a high rate of concomitant BV.

**CONCLUSION:** Multi-dose metronidazole should be recommended over single dose for all women, but it is particularly imperative that women who are symptomatic and/or who have a history of trichomoniasis receive multi-dose.

**LEARNING OBJECTIVES:** Multi-dose MTZ should be recommended over single dose for all women, but it is particularly imperative that women who are symptomatic and/or who have a history of trichomoniasis receive multi-dose.

## 10 Immunoglobulin A, immunoglobulin G, and neutralizing antibodies to respiratory syncytial virus increase in human milk following immunization with an RSV F protein vaccine

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**OBJECTIVES:** Maternal immunization with respiratory syncytial virus (RSV) F nanoparticle vaccine during pregnancy increases serum RSV antibodies. Our objective was to determine the effect of maternal immunization on the levels of RSV F-specific antibody levels in human breast milk.

**METHODS:** Prepare is a randomized, observer-blind, placebo-controlled trial of RSV F vaccination during the third trimester of pregnancy. It was conducted in the Northern and Southern hemispheres. As a sub-study to the parent trial, we evaluated breast milk in vaccinees and placebo recipients from 3 study sites in Bangladesh, New Zealand, and the United States. Maternal breast milk samples were obtained following delivery, and at 14 days, 35 days, 60 days, 90 days, 120 days, and 180 days. Maternal serum samples were obtained at 14 days, 60 days, 90 days, 120 days, and 180 days. Milk and serum specimens from 145 subjects were assayed using an enzyme-linked immunosorbent assay (ELISA) for RSV F-specific IgA and IgG, and using an RSV/A-specific microneutralization assay.

**RESULTS:** RSV F protein-specific IgA and IgG levels in breast milk, but not total IgA and IgG or RSV G protein-specific antibodies, were significantly higher in women who received RSV F vaccine than in placebo recipients. Both background levels and vaccine-stimulated levels were markedly higher in colostrum, as expected, but RSV-specific antibodies also persisted in vaccine recipients for 180 days ($p \leq 0.0003$ for both RSV-specific IgA and IgG at all post-delivery time points). RSV/A-specific neutralizing antibodies were 3-fold higher in the colostrum of RSV F vaccine recipients relative to controls ($p=0.0333$); precision of the neutralization contrasts at later timepoints was limited by technical limitations and small sample size, although point estimates were higher for at least 35 days. Geometric mean concentrations in ELISA were 28 to 31 units/mL for specific IgA in vaccinees, versus 9 to 13 in controls. Geometric mean concentrations in ELISA were 227 to 360 $\mu$g/mL for specific IgG in vaccinees, versus 40 to 107 in controls.
**CONCLUSION:** Sustained high levels of specific anti-RSV antibodies in breast milk suggest that breastfeeding may provide local mucosal protection against RSV to the infant. Additional studies are needed to determine the immunologic impact of breast milk-mediated protection following maternal RSV immunization.
**LEARNING OBJECTIVES:** Learners will be able to identify the potential impact of anti-RSV antibodies in breast milk following maternal RSV immunization.

## 11 Safety of third trimester immunization with a respiratory syncytial virus F protein vaccine and protection of infants over the first 180 days of life against all-cause lower respiratory tract infection

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**OBJECTIVES:** The Pneumovirus family includes two human pathogens: human metapneumovirus (HMPV) and respiratory syncytial virus (RSV), that cause respiratory disease in infants. We studied the impact of maternal immunization with RSV F protein nanoparticle vaccine on pneumovirus and all-cause severe lower respiratory tract infection (LRTI) in the first 90 to 180 days of infant life.
**METHODS:** We recruited 4,636 women with low-risk singleton 3rd trimester pregnancies in 11 countries to receive RSV F vaccine or placebo (2:1 ratio) in a randomized, observer-blind trial. Women were followed for safety for 6 months post-delivery, and infants for 1 year. Surveillance of infants for LRTI, with virus detection by RT-PCR, physical examination, and pulse oximetry, was carried out for 180 days from delivery.
**RESULTS:** Results: The RSV F vaccine was well tolerated in women, with modest reactogenicity and no apparent negative impacts on pregnancy, delivery, or infant well-being. Vaccine-induced maternal antibodies were transferred efficiently, with enhanced transfer (1.29 to 1.92-fold, depending on the antibody specificity measured) when the interval from immunization to delivery was 30 days. Efficacy against severe LRTI through 90 days of life in infants was as follows: Table 1. HMPV added few severe cases, but including these did not dilute efficacy possibly due to cross-reactive F protein immunity between RSV and HMPV. With decay of maternal antibodies, efficacy estimates declined from day 90 through day 180 of life. Persistence of protective effects from 90 to 180 days remains to be better defined with larger case numbers.
**CONCLUSION:** RSV F vaccine was safe in the 3rd trimester and was associated with reduced rates of severe infant LRTI. Our data suggest that this strategy could reduce infant all-cause LRTI with severe hypoxemia by 13 cases, and all-cause LRTI hospitalization by 28.5 cases, per 1000 infants over the first 180 days of life.
**LEARNING OBJECTIVES:** To recognize the impact of the timing of maternal immunization on the efficiency of transplacental transfer of vaccine-induced antibodies. To recognize the potential impact of RSV prophylaxis in early infancy on pneumovirus and all-cause respiratory morbidity beyond the RSV season.

## 12 Randomized trial to prevent congenital cytomegalovirus

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**OBJECTIVES:** Primary CMV infection during pregnancy carries a high risk of transmission to the fetus with the potential for severe sequelae including fetal death, premature birth, hearing loss and developmental delay. There is no universally accepted method of preventing congenital CMV. Our objective was to evaluate whether CMV hyperimmune globulin (HIG) administered to women with primary CMV during pregnancy reduces congenital infection.
**METHODS:** Multicenter randomized double-masked trial of women with a singleton gestation $< 24$ weeks with primary CMV infection defined by the presence of either CMV IgM and IgG with low avidity or IgG seroconversion, as assessed at a central reference laboratory. Those with presumptive or confirmed evidence of fetal CMV were not eligible. Monthly infusions of HIG (100 units/kilogram) or placebo were given until delivery. The primary outcome was fetal loss or neonatal CMV infection defined as CMV by PCR or culture in urine or saliva within 3 weeks of birth, in amniotic fluid prior to delivery or in postmortem tissue. A sample size of 800 was planned to detect at least 30% reduction in the primary outcome with 90% power and type I error 5%.
**RESULTS:** From 2012 to 2018, 206,111 pregnant women were screened; 712 (0.35%) had primary CMV infection, of whom 399 (56%) were enrolled at 17 centers. The trial was stopped for futility at the recommendation of the Data and Safety Monitoring Committee due to a planned interim analysis that revealed complete enrollment was statistically very unlikely to demonstrate a significant difference between the groups. The mean gestational age at randomization was 16.2 and 15.6 weeks in the HIG and placebo groups, respectively. Primary outcome data were available for 394 participants (98.7%). The primary outcome rate was 22.7% in the HIG group and 19.4% in the placebo group (relative risk [RR], 1.17; 95% confidence interval [CI], 0.80 to 1.72; $p=0.42$). Overall there was no significant difference in the proportion of women with a side effect; however, those receiving HIG had a higher rate of headache ($P=0.05$) and shaking chills ($P=0.03$). The rate of preterm birth was 12.2% in the HIG group and 8.3% in the placebo group (RR, 1.47; CI 0.81 to 2.67; $P=0.2$). No statistical interactions were found in pre-specified subgroup analyses.
**CONCLUSION:** CMV HIG was not effective at decreasing the risk of congenital CMV infection or fetal death among women with primary CMV infection in early pregnancy.