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Publishing Title: Effectiveness of Influenza Vaccine Given to Pregnant Women in Preventing Hospitalization in their Infants

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Abstract Body: **Background:** Influenza (flu) is a major cause of serious respiratory disease in pregnant women and of hospitalization in infants. Although flu vaccine is recommended for pregnant women and children, it is not approved for infants < 6 months of age. Placental transfer of antibodies to the fetus has been demonstrated in the past, but the few studies having examined the effectiveness of flu vaccination during pregnancy have had inconsistent findings. This study assesses the effectiveness of flu vaccine when given to mothers during pregnancy in preventing hospitalization due to laboratory-confirmed flu in their infants.

Methods: This is an ongoing matched case-control study. Cases are infants (0-12 months of age) hospitalized at Yale New Haven Hospital due to laboratory confirmed flu. Controls are flu-negative infants matched to cases by age and date of hospitalization. Parents are interviewed to determine risk factors for flu. Medical records of infants and mothers are reviewed to determine prior vaccination against flu. Respiratory samples will be tested by RT-PCR to compare subject flu strains to those included in the vaccine.

Results: From 2000-present, we have enrolled 157 cases and 195 matched controls. Cases vs. controls are comparable in most demographic characteristics, with differences in race (11% vs. 22% African American; $p=0.013$) and breastfeeding (55% vs. 67%; $p = 0.031$). Of subjects with complete medical record data, 5/118 (4%) cases and 23/139 (17%) controls had mothers who received flu vaccine during pregnancy ($p=0.002$). The effectiveness of flu vaccine given to mothers during pregnancy in preventing hospitalization in their infants is 78.9% (95% CI: 24.7%-94.1%; $p = 0.017$) for all non-vaccinated infants (0-12 months) and 85.3% (95% CI: 34.0%-96.7%; $p = 0.012$) for infants 6 months of age.

Conclusion: Flu vaccine given to women during pregnancy is 85% effective in preventing hospitalization in their infants < 6 months of age.

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