

## **Influenza vaccination of pregnant women and protection of their infants.**

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### **BACKGROUND:**

There are limited data on the efficacy of vaccination against confirmed influenza in pregnant women with and those without human immunodeficiency virus (HIV) infection and protection of their infants.

### **METHODS:**

We conducted two double-blind, randomized, placebo-controlled trials of trivalent inactivated influenza vaccine (IIV3) in South Africa during 2011 in pregnant women infected with HIV and during 2011 and 2012 in pregnant women who were not infected. The immunogenicity, safety, and efficacy of IIV3 in pregnant women and their infants were evaluated until 24 weeks after birth. Immune responses were measured with a hemagglutination inhibition (HAI) assay, and influenza was diagnosed by means of reverse-transcriptase-polymerase-chain-reaction (RT-PCR) assays of respiratory samples.

### **RESULTS:**

The study cohorts included 2116 pregnant women who were not infected with HIV and 194 pregnant women who were infected with HIV. At 1 month after vaccination, seroconversion rates and the proportion of participants with HAI titers of 1:40 or more were higher among IIV3 recipients than among placebo recipients in both cohorts. Newborns of IIV3 recipients also had higher HAI titers than newborns of placebo recipients. The attack rate for RT-PCR-confirmed influenza among both HIV-uninfected placebo recipients and their infants was 3.6%. The attack rates among HIV-uninfected IIV3 recipients and their infants were 1.8% and 1.9%, respectively, and the respective vaccine-efficacy rates were 50.4% (95% confidence interval [CI], 14.5 to 71.2) and 48.8% (95% CI, 11.6 to 70.4). Among HIV-infected women, the attack rate for placebo recipients was 17.0% and the rate for IIV3 recipients was 7.0%; the vaccine-efficacy rate for these IIV3 recipients was 57.7% (95% CI, 0.2 to 82.1).

### **CONCLUSIONS:**

Influenza vaccine was immunogenic in HIV-uninfected and HIV-infected pregnant women and provided partial protection against confirmed influenza in both groups of women and in infants who were not exposed to HIV. (Funded by the Bill and Melinda Gates Foundation and others; ClinicalTrials.gov numbers, [NCT01306669](#) and [NCT01306682](#)).

### **Comment in**

- [ACP Journal Club: IIV3 reduced flu in HIV- pregnant women and infants, and in HIV+ pregnant women but not their infants.](#) [Ann Intern Med. 2015]
- [Influenza vaccination of pregnant women and protection of their infants.](#) [N Engl J Med. 2014]
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