

U.S. Department of Health and Human Services

Task Force on Research Specific to Pregnant and Lactating Women

[Agency Activities: National Vaccine Program Office, Office of the Assistant Secretary for Health, HHS](#)

Research

The National Vaccine Program Office (NVPO) provides strategic leadership to further the five goals of the [National Vaccine Plan \(NVP\)](#) and ensure collaborative, coordinated immunization activities are carried out in an efficient, consistent and timely manner. To meet the statutory goals outlined for the National Vaccine Program, administered by the Assistant Secretary for Health, NVPO works with both federal and non-federal stakeholders to develop and implement strategies to prevent human infectious diseases through immunization, prevent adverse events following vaccination, and overcome barriers in the planning of immunization activities. NVPO also supports the National Vaccine Advisory Committee and the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. (<https://www.hhs.gov/nvpo/about/index.html>).

The first two objectives of the National Vaccine Plan – (1) to develop new and improved vaccines; and (2) to enhance the vaccine safety system – depend crucially on research. NVPO supports research projects specifically related to immunization of women during pregnancy. Key examples include:

- Clinical study of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular pertussis vaccine (Tdap) Safety in Pregnant Women: This is an observational study of both pregnant and non-pregnant women. Detailed data will be collected from study participants on prior Tdap/Td/TT receipt. With Day 0 serving as the day of vaccination, participants will be followed through Day 7 for reaction symptoms, and data will be analyzed to see if there is a difference in reaction symptoms between pregnant and non-pregnant women. Pregnant women will be followed through delivery for collection of pregnancy outcome data. In addition, follow-up will be conducted for infants born to mothers who received Tdap during pregnancy to assess health outcomes and growth through 6 months of life.
- Clinical Study of the Safety of Simultaneous Administration of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) and Inactivated Influenza Vaccine in Pregnant Women: This is a pilot, prospective, randomized, open-label clinical trial. During the study, pregnant women will be randomized (1:1) to receive co-administration of a single dose of influenza vaccine and a single dose of Tdap, or sequential administration of the vaccines – first influenza, followed by Tdap ~ 21 days later. Researchers will analyze whether reaction symptoms, antibody levels, and adverse maternal and infant outcomes vary across the study groups.
- NVPO is also currently supporting a research study in collaboration with BARDA and FDA to analyze possible associations between infections, vaccinations, and medications during pregnancy with possible birth defects outcomes. Tdap, HPV, and influenza vaccines are the vaccines being researched. NVPO is also trying to identify possible causal associations with crucial birth outcomes such as microcephaly (other than Zika virus).

NVPO also supports efforts to improve research methods and infrastructure to benefit the field of maternal immunization research. For example:

- NVPO funded the creation of a maternal-neonatal vaccine safety database and analysis of outcomes using the database. The first analysis compares the likelihood of fever in babies born to vaccinated versus unvaccinated mothers after receiving their first pertussis vaccination. The second analysis compares alternative benefits to influenza vaccination during pregnancy. (<https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html>)
- NVPO has supported the development of a study to improve the algorithms used to identify miscarriages and stillbirths in post-licensure immunization safety surveillance databases (www.cdc.gov/vaccinesafety).
- NVPO is currently supporting research to validate vaccine safety definitions in studies that include pregnant women and newborns (www.hhs.gov/nvpo/featured-priorities/vaccine-safety/index.html; <https://www.hhs.gov/nvpo/national-vaccine-plan/funding-opportunity-vaccine-safety-research/index.html>).

Clinical Practice Information and Recommendations

NVPO is responsible for staffing the National Vaccine Advisory Committee. The Committee serves an advisory role, providing peer review, consultation, advice, and recommendations to the Assistant Secretary for Health in his capacity as the Director of the National Vaccine Program, on matters related to the Program's responsibilities. Specifically, the Committee studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccination products in the United States; recommends research priorities and other measures to enhance the safety and efficacy of vaccines; advises the Assistant Secretary for Health in the implementation of Sections 2102 and 2103 of the PHS Act; and identifies annually the most important areas of government and non-government cooperation that should be considered in implementing Sections 2102 and 2103 of the PHS Act.

In 2014 and 2016, the Committee issued two reports with recommendations regarding maternal immunizations. These reports addressed the charge issued by the Assistant Secretary for Health to i) review the current state of maternal immunization and existing best practices, and identify programmatic barriers to the implementation of current recommendations related to maternal immunization and make recommendations to overcome these barriers; and ii) identify barriers to and opportunities for developing vaccines for pregnant women and make recommendations to overcome these barriers

(https://www.hhs.gov/sites/default/files/nvpo/nvac/reports/nvac_reducing_patient_barriers_maternal_immunizations.pdf ; <http://journals.sagepub.com/doi/full/10.1177/0033354917698118>).

Communications

NVPO administers the www.vaccines.gov website, which provides extensive information about vaccines generally. The website includes specific materials about vaccinations administered during pregnancy (www.vaccines.gov/who_and_when/pregnant/index.htm). NVPO also held a webinar in 2016 about vaccine safety in pregnancy; and supports social media efforts to connect NVPO with stakeholders and the public.

Other Collaborative Efforts

NVPO works in close collaboration with CDC and FDA on vaccine safety related issues in general. NVPO also supports the Immunization Safety Task Force, an interagency effort involving CDC, NIH, DoD, IHS, VA, FDA, and DoD (<https://www.hhs.gov/nvpo/featured-priorities/vaccine-safety/index.html>). The NVPO has contracted with the National Committee for Quality Assurance to incorporate maternal immunization composite measures (including Tdap and influenza) into the Healthcare Effectiveness Data and Information Set (HEDIS).