Frequently Asked Questions
Regarding Use of Tdap Vaccine 9/2014

1. **I want to protect pregnant women and their unborn children from pertussis. Can I give Tdap to pregnant women?**
   Yes, you can give Tdap to pregnant women. Tdap is not contraindicated during pregnancy. According to ACIP recommendations (2/22/2013), pregnant women should receive a dose of Tdap vaccine during each pregnancy preferably between 27 and 36 weeks of gestation. If a woman was not previously vaccinated with Tdap and did not receive a dose during their pregnancy, a dose of Tdap should be administered immediately postpartum.

   - ACIP's Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) in Pregnant Women: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6207a4.htm?s_cid=mm6207a4_w

2. **Is administering a dose of Tdap to a pregnant woman considered "off-label use"?**
   No, it is not considered off-label use. "Off-label" use is when a vaccine or other pharmaceutical is used in a different way than is specified in the FDA-approved drug label or prescribing information. In terms of licensure by the Food and Drug Administration (FDA), Tdap is not, and has never been, contraindicated for pregnant women.

   Pregnant women are not included in clinical trials for vaccines, which is why the package insert for Tdap vaccine (and other vaccines like influenza) indicates that it belongs to Category C, where the vaccine/drug can be given if the benefits outweigh the potential risk and can be given if "clearly needed." After review of epidemiological and safety data, ACIP has made the recommendation that the vaccine is needed.

   Either Tdap brand, Boostrix (GSK) or Adacel (Sanofi) can be used to vaccinate pregnant women.

3. **What are the latest Tdap recommendations for people 65 years and older?**
   On 1/14/2011, ACIP officially recommended Tdap vaccination for adults 65 years and older who have not previously received Tdap, and who have or anticipate having contact with infants younger than 12 months. A one-time dose of Tdap in place of Td may also be given to adults 65 years and older who may not have infant contact. ACIP also made a recommendation that older adults could receive either Tdap product, Adacel (Sanofi Pasteur) or Boostrix (GlaxoSmithKline). Boostrix's license includes use in adults aged 65 years and older, based on FDA's 7/8/2011 approval. Currently, Boostrix is licensed for use in persons aged 10 years and older and Adacel is licensed for use in those 10 to 64 years.

   - Boostrix package insert: http://us.gsk.com/products/assets/us_boostrix.pdf
   - Adacel package insert: http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm142764.pdf

4. **What is the minimum interval between doses of Td and Tdap?**
   According to recommendations published 1/14/2011, there is no minimum interval between doses of Td and Tdap. ACIP recommends that "pertussis vaccination, when indicated, should not be delayed and that Tdap vaccine should be administered regardless of the interval since the last tetanus or diphtheria toxoid-containing vaccine."

   - ACIP's Updated Recommendations for Use of Tdap: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm?s_cid=mm6001a4_w

5. **What are the "off-label" recommendations for use of Tdap?**
   ACIP has recommended off-label use of Tdap products in order to expand Tdap vaccination and reduce pertussis disease. Off-label use includes:
   - Administering Tdap regardless of the interval since last Td dose;
   - Administering Boostrix or Adacel to persons age 7-10 years who either have not completed their DTaP primary series, or who have not received a primary series of tetanus, pertussis, and diphtheria, or if their vaccination status is unknown;
   - Administering Adacel to persons aged 65 years and older

   Note: Adacel (Sanofi Pasteur) is licensed for use in those 10 to 64 years and Boostrix (GSK) is licensed for use in persons 10 years and older.

6. If Tdap is used "off-label," is the vaccine provider covered by the National Vaccine Injury Compensation Program?

The National Vaccine Injury Compensation Program (VICP) was established by the National Childhood Vaccine Injury Act (NCVIA) of 1986. It is a no-fault system in which persons thought to have experienced an injury or to have died as a result of administration of a covered vaccine can seek compensation by filing a claim. The program is intended as an alternative to civil litigation under the traditional tort system in that negligence need not be proven.

Tdap, DTaP and Td are some of the many vaccines covered by the VICP. Claims may be filed on behalf of children, adolescents or by adults receiving VICP-covered vaccines. There are **no requirements** that the petitioner/claimant show that the vaccine was used pursuant to Food and Drug Administration (FDA) labeling or specific Advisory Committee on Immunization Practices (ACIP) administration recommendations or otherwise was administered pursuant to any standard of care.

To be compliant with the NCVIA, vaccine providers must comply with certain federal requirements: 1) Give the patient or parent/ guardian a copy of the relevant, federal "Vaccine Information Statement" (VIS) 2) Record certain pieces of information about the vaccine(s) administered in the patient's medical record and 3) Document and report any adverse event following vaccination to the Vaccine Adverse Event Reporting System (VAERS).

- FAQs for VICP: http://www.hrsa.gov/vaccinecompensation/faq.html

For more information, call the Virginia Department of Health's Immunization Division at 1-800-568-1929

Adapted from "Ask the Experts" at www.immunize.org, Information from the Minnesota Department of Health (http://www.health.state.mn.us/divs/idepc/diseases/pertussis/hcp/tdapvax.html), and Chesapeake Health Department's "Dear Chesapeake Physician" letter.