Tdap in Pregnancy: What the New Guidelines Say

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The Centers for Disease Control recently updated their recommendations for tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccination (Tdap) in pregnant women. But what do the recommendations say and what do you as a clinician need to know? A physician recently inquired about these recommendations on the OBGYN.net forum.

The CDC’s Advisory Committee on Immunization Practices (ACIP) made the recommendation to move administration to the late second trimester or third trimester rather than immediately after delivery in women who have not been previously vaccinated. The ACIP originally recommended in 2008 that the maternal dose be given in the immediate postpartum period. However, by moving the administration to the end of the pregnancy (after 20 weeks gestation), the fetus is protected against pertussis indirectly through transplacental antibodies and the mother receives the protection directly and sooner. Infants younger than 12 months of age have substantially higher rates of pertussis and the largest burden of pertussis-related deaths.

Although the CDC recommends all adults who anticipate close contact with children younger than 12 months receive the vaccination as part of cocooning strategy, it has been found to be not sufficient.

At the time of the ACIP recommendations, committee member Dr Mark Sawyer, of the University of California San Diego, noted it is difficult to immunize all of an infant’s potential contacts and, therefore, there is a suboptimal national cocooning strategy.

“The reason we’re continuing to pursue this is we feel that [existing guidance] is inadequate and is not doing the job to protect infants adequately from pertussis,” he explained.

Before making their recommendation, the ACIP reviewed data, both published and unpublished, from the pregnancy registries of manufacturers of the vaccine (ie, VAERS, Sanofi Pasteur, and GlaxoSmithKline) as well as small studies. Based on their review, the ACIP concluded, “Available data from these studies did not suggest any elevated frequency or unusual patterns of adverse events in pregnant women who received Tdap and that the few serious adverse events reported were unlikely to have been caused by the vaccine.” Moreover, the worldwide use of tetanus and diphtheria toxoids in pregnant women has been shown to not be teratogenic. By administering the vaccine after 20 weeks gestation, ACIP believes any low-frequency adverse event will be minimized. Furthermore, it will also help reduce the possibility that any spurious association might appear causative.

In addition to recommending Tdap vaccination programs for women in the third or late second trimester, ACIP continues to recommend a single dose of Tdap vaccination for adults who have not previously received Tdap and will be in close contact with an infant. Furthermore, ACIP now recommends that adolescents who anticipate close contact should also receive vaccination. It is preferred for adolescents and adults to receive the vaccination at least 2 weeks before anticipated contact with an infant.

The ACIP and CDC shared some tips for some special situations. For instance, they noted that if a woman has never received Tdap (or it has been more than 10 years since previousTd) and a tetanus and diphtheria booster is indicated, then Tdap should be administered during pregnancy, preferably during late second or third trimester. Similarly, as part of a wound management program aiming to prevent tetanus, Tdap should be administered when the patient previously has not received Tdap. For women with unknown or incomplete tetanus vaccination, clinicians should administer three vaccinations containing tetanus and reduced diphtheria toxoids. A schedule of 0, 4 weeks, and 6 to 12 months should be followed, with Tdap should replacing one dose ofTd, preferably in the end of the second trimester or in the third trimester of pregnancy.

Recent research supports maternal immunization as a means to protect the fetus. In a study published in the American Journal of Obstetrics and Gynecology, researchers compared antitoxin levels in newborns whose mothers received Tdap with those whose mothers did not. They found that newborns who had been exposed to Tdap during pregnancy had significantly higher
concentrations of diphtheria antitoxin, tetanus antitoxin, and antibodies to pertussis toxin, filamentous hemagglutinin, pertactin, and fimbriae 2/3 as compared to those newborns whose mothers did not receive Tdap. “Administering Tdap during pregnancy increases antibody titers against diphtheria and pertussis antigens,” the researchers concluded. “Maternal Tdap may prevent neonatal pertussis infection.”

While some critics remain concerned about the safety of the vaccine, research points to its relative safety. For instance, researchers from the Netherlands discussed the benefits, importance, and issues associated with maternal pertussis vaccination. They wrote, “Maternal vaccination studies with whole-cell pertussis vaccines have not shown serious adverse effects in mother and child.” With minimal safety data in humans available, there is currently a US study looking specifically at this issue. The National Institute of Allergy and Infectious Diseases is supporting a study examining the safety and immunogenicity of Tdap. Nonetheless, the US Food and Drug Administration has classified Tdap as a Class C drug. Such drugs lack adequate and well-controlled studies in humans but have been associated with an adverse effect on the fetus in animal reproduction studies. In reviewing the available literature, researchers have noted that “potential benefits may warrant use of the vaccine in pregnant women despite potential risks.”

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References:

2. Updated recommendations for use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) in pregnant women and persons who have or anticipate having close contact with an infant aged <12 months --- advisory committee on immunization practices (ACIP), 2011. MMWR. 2011;60(41):1424-1426.


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