Influenza and Tdap Immunizations in Pregnancy

A curriculum for health care providers
Vulnerable Populations Project

• This curriculum was produced through a cooperative agreement from the Association of State and Territorial Health Officers (ASTHO) and the Centers for Disease Control and Prevention (CDC). ACNM also produced a suite of material on immunizations available at their website: http://www.midwife.org/Immunization-Resources-for-Midwives
Objectives

• At the end of this presentation, a participant will be able to:
  • Address the safety of vaccines with a woman;
  • Recommend flu and Tdap vaccines in pregnancy;
  • Advise women on vaccines safe while breastfeeding.
Vaccines

**Vaccine** - A product that interacts with the immune system to produce active immunity against a disease without the risk of the disease and its potential complications.

### Inactivated
- Toxoids (DTaP, Td, Tdap)
- Whole (Hepatitis A, IPV)
- Split (Influenza - IIV)
- Recombinant vaccines (Hepatitis B, HPV4, HPV2)
- Polysaccharide vaccines (PPSV23, MPSV4)
- Conjugated vaccines (Hib, PCV13, MCV4)

### Live, Attenuated
- Measles, Mumps & Rubella (MMR)
- Varicella
- LAIV
- Rotavirus
- Herpes Zoster

Advisory Committee on Immunization Practices (ACIP)

• ACIP consists of 15 members - experts in immunization practices and public health;
• ACIP develops immunization schedules;
  and recommendations for the use of licensed vaccines
• New schedule is published every winter;
• ACIP immunization schedules and recommendations are approved by CDC, AAP, ACOG, AAFP, ACP, ACNM.
Influenza
Influenza and Pregnancy

• Influenza infection during pregnancy increases risk of
  • Severe illness, complications and hospitalizations, even death
  • preterm labor and birth and SGA
  • Febrile illnesses in pregnancy may be linked to neurological injury, including Parkinson Disease, schizophrenia, and autism spectrum disorder

• New mom can give the infection to newborn
Influenza and Pregnancy, References


Seasonal Influenza Vaccine

• Each year the World Health Organization the Food and Drug Administration identify the strains they consider most likely to circulate the following year.
• CDC contributes surveillance data on circulating strains
• Vaccines are developed by the manufacturers against those strains and then approved by the FDA

Recommended for all people age 6 months and older.
Influenza vaccine in pregnancy

- Influenza vaccine protects the woman, fetus and newborn for up to 6 months from serious illness and complications from the flu.
- Maternal transfer of antibodies to fetus and baby.
- CDC, ACOG, ACNM and AAP have recommended influenza vaccine for women who will be pregnant during influenza season.
Maternal Vaccination and Influenza in Infants: A NEJM Study

Inactivated influenza vaccine given to pregnant women reduced influenza by 63% in infants up to 6 months of age.
Administer by Injection:

Fluzone Quadrivalent Sanofi-Pasteur - 6 months of age and older IIIV4

Fluzone Sanofi-Pasteur – (Multidose vial) 6 months of age and older IIIV3

Fluarix Quadrivalent GSK - 3 years of age and older IIIV4

FluLaval Quadrivalent GSK - 3 years of age and older IIIV4

Fluvirin Novartis - 4 years of age and older IIIV3

Afluria bioCSL - 9 years of age and older IIIV3

Flucelvax Novartis - 18 years of age and older (ccIIIV3)*

Flublok Protein Sciences - 18 years of age and older (RIV3)**

Fluzone Intradermal Quadrivalent Sanofi-Pasteur - 18 through 64 years IIIV4

Fluzone High-Dose Sanofi-Pasteur - 65 years and older IIIV3

*ccIIIV3 = cell culture based trivalent inactivated influenza vaccine

**RIV3 = recombinant hemagglutinin influenza vaccine
Live, Attenuated Influenza Vaccine (LAIV4)

**Administer by Nasal spray:**

**FluMist® Medimmune**

- Appropriate for healthy persons 2 - 49 years of age.

- **LAIV4 is NOT intended for pregnant women**

Ref: Prevention and Control of Influenza with Vaccines: Interim Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2013 MMWR/May 10, 2013/ Vol. 62/No. 18
Safety of flu vaccine in pregnancy

• Influenza vaccine is safe during any trimester of pregnancy
• Influenza vaccine has been given to women in pregnancy for decades
• No adverse events have been reported for women who received the influenza vaccine in pregnancy
References
Safety of Flu vaccine in pregnancy

• Kharbanda, E; Olshen; Vazquez-Benitez; Lipkind, H; Naleway, A; Lee, G; Nordin. Inactivated Influenza Vaccine During Pregnancy and Risks for Adverse Obstetric Events. Obstetrics & Gynecology. 122(3):659-667, September 2013. DOI: 10.1097/AOG.0b013e3182a1118a


Pertussis (Whooping Cough)
Pertussis (whooping cough)

- Whooping cough is a highly contagious bacterial infection that has seen a recent resurgence in the United States.
- Cases are increasing mostly due to limited duration of protection offered by the vaccine, making it critical for pregnant women to get the vaccine during each pregnancy.
- In 2012, 48,277 cases were reported, which demonstrates a marked increase from the low of 1,000 in the 1970s.
- The death toll in 2012 was 20;
  - 15 of these cases occurred in babies less than 3 months of age.
  - The current recommendation for immunization of children begins at 2 months of age, but most deaths occur before this.
Pertussis is on the rise

- In the first 6 months of life, babies are at high risk for complications from whooping cough – even if they are healthy – because their immune systems are still developing.
- About half of babies who get whooping cough end up in the hospital.
- The younger the baby is when he gets whooping cough, the more likely it is that he will need to be treated in the hospital.
- Of those babies who are hospitalized with whooping cough, about 1 out of 4 will get pneumonia, and 1 or 2 out of 100 will die.
- Other complications include violent, uncontrolled shaking, life-threatening pauses in breathing, and brain disease.
Tetanus, Diphtheria, and Acellular Pertussis

- Tdap is for adults and adolescents
- Dtap is for children
Tdap Vaccines

• **Boostrix**™ 10 years and older
• **ADACEL**™ 11 through 64 years

Both are licensed for one dose.
Both are safe for pregnant women.
Tdap in each pregnancy

• Provides protection to the mother.
• Provides protection to the fetus and newborn with antibodies passed via the placenta;
  • Most deaths in newborns occur before 3 months of age.
• Should be given between 27 and 36 weeks:
  • Give irrespective of the number of prior Tdap vaccinations
  • Give irrespective of interval from Td

MMWR, February 22, 2013 / 62(07);131-135
Safety of Tdap Vaccine in Pregnancy

• No live bacteria
• No severe side effects linked to closely spaced revaccinations
• no safety signals have been found among pregnant women or their babies after Tdap vaccination per CDC and FDA
References: Safety of Tdap in Pregnancy


- Talbota, EA, Brown, KA, Kirkland, KB, Baughman, AL, Halperind, SA, and Broder, KR. The safety of immunizing with tetanus–diphtheria–acellular pertussis vaccine (Tdap) less than 2 years following previous tetanus vaccination: Experience during a mass vaccination campaign of healthcare personnel during a respiratory illness outbreak. Vaccine, November 2010, 28 (50) 23, 8001–8007. doi:10.1016/j.vaccine.2010.09.034

Tdap postpartum

• If Tdap is not given during pregnancy, and has not been given previously, administer Tdap immediately postpartum

• Cocooning is a strategy of vaccinating the family and friends the newborn will be exposed to
  • It is less effective at preventing newborn pertussis than vaccinating during pregnancy to allow transfer of protective antibody to the infant

• However, close contacts of newborns should be up to date on their vaccines, including Tdap
Cocooning Strategy

Child Care Provider

Parents

Siblings

Healthcare Worker

Grandparents

Parents
Immunize Adults with Tdap

• All adults aged 19 years and older, who have not previously received Tdap, should receive a single dose of Tdap regardless of the interval since the last dose of tetanus or diphtheria (Td).\(^1\)

• For adults 65 years and older Boostrix should be used, when feasible; however, either vaccine product provides protection and is considered valid.\(^2\)

1. MMWR January 14, 2011; 60 (1); 13-15
2. MMWR June 29, 2012; 61(25); 468-470
Safety of Thimerosal

• Many medications and vaccines contain preservatives to prolong shelf life.
• Thimerosal is used in the multi-dose vial of the adult influenza vaccine.
  • Researchers have conducted extensive research and have found no link between the mercury previously used in vaccines and the risk of side effects, especially in pregnant women.
  • exposure to thimerosal during pregnancy and in young children was not associated with an increased risk of ASD.
Vaccines safe while pregnant

• Recommended
  • Flu
  • Tdap

• If indicated
  • Hepatitis A
  • Hepatitis B
  • Meningococcal
  • Pneumococcal
Vaccines safe while breastfeeding

- Tdap
- Hepatitis A
- Hepatitis B
- Influenza
- MMR
- Varicella
- Meningococcal
- Pneumococcal
- Inactivated polio

http://www.cdc.gov/breastfeeding/recommendations/vaccinations.htm
Tips for Improving Vaccination Rates in Women

• Every woman needs to hear your commitment to the evidence on the benefits of vaccines. You are a valued and trusted source of health information for your patients. Research shows that a provider recommendation is the top predictor of patients getting vaccinated. Vaccination rates are low when the clinician hesitates to recommend vaccination.

Tips for Improving Vaccination Rates in Women

• Review each woman’s vaccine history at each visit.
• Recommend that women be vaccinated at each visit if they are not up to date on their vaccines.
• Use a screening form to create a reminder in the woman’s paper health record.
• Create a hard stop in the woman’s electronic health record to confirm an annual influenza vaccine, a pertussis vaccine in each pregnancy, and other vaccines for completion of series.
SHARE a strong recommendation

• **Share** the reasons why the recommended vaccine is right for each woman based on her health status and risk factors.

• **Highlight** positive personal experiences with vaccination.

• **Address** the woman’s questions and any concerns about adult vaccines, including safety and effectiveness, in plain and understandable language.

• **Remind** the woman that vaccine-preventable diseases still exist in the United States and can be serious for her, her baby, and her friends and family members.

• **Explain** the potential costs of getting disease, including serious health effects, time lost (missing work, activities, and family events), and financial costs.

Most women underestimate the severity of the disease and the safety of the vaccine.

• These are the first areas with which to begin the discussion.

• Key points to address
  • Consequences of not being vaccinated, including disease symptoms and potential severity
  • Safety and efficacy of the vaccine
  • Possible side effects
  • Benefits of the vaccine
  • How the vaccine works
  • How cold and influenza symptoms differ
  • How long each vaccine will provide protection
Addressing Women’s Concerns about Vaccines

• The following slides address myths and truths about immunizations and vaccine preventable diseases.
Appealing messaging concepts. Try the following language:

• *Protect your family*: “The best protection for your family is for everyone to be up to date on vaccines, especially you, the mother. Not only will you and your unborn child be protected, but once born, your infant will have some short-term protection until he is old enough to receive his own vaccines. Your children are most likely to get whooping cough or the flu from you or another household member. Make sure everyone coming in contact with your baby is up-to-date with their whooping cough and flu vaccines.”
The vaccine does not give you the disease.

Vaccines contain either dead or live proteins called antigens. Live attenuated vaccines have living microbes that are weakened but could make someone sick and should not be given to people with certain conditions. These vaccines include live influenza, measles, mumps, and rubella. Inactivated or “dead” vaccines cannot make you sick. If someone is exposed to the infection before the vaccine has triggered an immune response, the person could come down with the illness after being vaccinated.
Scientific studies and reviews continue to show no relationship between vaccines and autism

- The science does not support a link between vaccines and any developmental delays. The March of Dimes, Food and Drug Administration, Centers for Disease Control and Prevention (CDC), National Institutes of Health, American Academy of Pediatrics, Institute of Medicine, and World Health Organization all confirm the safety of vaccines. The original article reporting a link between the measles, mumps and rubella (MMR) vaccine and autism was fraudulent, and the author later lost his medical license.
Vaccines are very safe.

• Each vaccine is tested rigorously in clinical trials before it can be approved by the Food and Drug Administration.
• Once it is approved for use in humans, the research is reviewed by the Advisory Committee on Immunization Practices, a group of experts who advise the CDC on immunizations.
  • This group spends months or years reviewing the data before making recommendations about which vaccines are recommended for children and adults. They meet 3 times per year and review reports on adverse events, current disease trends, and recently published data on vaccines.
Vaccine side effects are usually mild and temporary.

- As with any medication or procedure, there are risks with vaccines, and the side effects vary by vaccine. Most side effects are mild or moderate, meaning they do not affect daily activities. They also get better on their own in a few days. The most common side effects from whooping cough vaccine (Tdap) include redness, swelling, pain, and tenderness where the shot is given, body-ache, fatigue, or fever.
The main side effects of being vaccinated are:

- Soreness at the site of injection;
- Headache and upper respiratory infection;
- Fever, joint pain, sore throat;
- Nausea, vomiting, diarrhea; more common in childhood vaccines.
Severe side effects are extremely rare and are less common than the complications from the disease.
Vaccine preventable diseases can be very serious.

- Complications from the flu include worsening of chronic conditions, hospitalization, and even death
- Examples of complications from getting a vaccine-preventable infection include pneumonia (e.g. chicken pox and whooping cough), birth defects (rubella), liver cancer (hepatitis B), and death (measles and whooping cough).
- 53,000 people died in the US in 2010 from the flu
  - [http://www.cdc.gov/nchs/fastats/deaths.htm](http://www.cdc.gov/nchs/fastats/deaths.htm)
- The World Health Organization estimates that 1.5 million children less than 5 years of age died worldwide in 2008 from vaccine-preventable deaths.
These diseases still occur in the United States.

- Thanks to immunizations, we have seen a reduction in vaccine-preventable illness and have eliminated some diseases in the United States, but in recent years the reported cases of many infections, especially whooping cough and measles have increased.
- Currently, unvaccinated international travelers are key sources of infection.14
- Also, some parents choose to not vaccinate their children, which creates new generations of children who are not immune to diseases such as measles and polio.
- If we were to stop vaccinating, cases would increase even more
Vaccines recommended during pregnancy are safe and can protect both you and your child

• Clinical trials demonstrating the safety of vaccines in pregnancy began decades ago with women who were vaccinated not knowing they were pregnant. The results of these studies demonstrated that no adverse events to pregnancy can be attributed to the influenza or Tdap vaccines.\textsuperscript{15}

• The benefit of vaccinating during pregnancy is that the woman is protected from disease; therefore, her fetus is protected from potential complications of that maternal disease. If a woman is vaccinated during pregnancy, she passes immunity to her baby, who is protected in the first few months of life. Breastfeeding also passes immunity to the newborn for those diseases to which the mother has developed antibodies.\textsuperscript{15}
The flu shot prevents the flu:

• “The flu vaccine can prevent the flu – it cannot give you the flu. Once you receive your vaccine, it takes about 2 weeks for your body to build immunity. Occasionally, someone will be exposed to the flu before her vaccine begins to take effect. Sometimes cold symptoms are mistaken for the flu. In either case, it was not the vaccine itself that caused the illness.”
Whooping cough vaccine (Tdap)

- Public health professionals expect that vaccinating women with Tdap during the prenatal period will prevent more infant hospitalizations and deaths due to Pertussis as compared with post partum Tdap vaccination.²
The whooping cough vaccine helps protect your baby:

• “The whooping cough vaccine helps prevent whooping cough – it cannot give you or your baby this disease. Whooping cough is a very contagious disease that can be deadly for babies. After receiving this vaccine, your body will create protective antibodies and pass some of them to your baby before birth. These antibodies provide your baby some short-term protection against whooping cough in early life. These antibodies can also protect your baby from some of the more serious complications that come along with whooping cough. Your protective antibodies are at their highest about 2 weeks after getting the vaccine. So you should get the vaccine late in your pregnancy, preferably during your 27th to 36th week, to give your baby the most protection when he is born. The amount of antibodies in your body decreases over time. When you get the vaccine during one pregnancy, your antibody levels will not stay high enough to provide enough protection for future pregnancies. It is important for you to get a whooping cough vaccine during each pregnancy so high levels of protective antibodies are transferred to each of your babies.”
You can safely get a whooping cough and flu vaccine at the same time.

You can get a whooping cough and flu vaccine at the same time during your pregnancy. You can also get them at different visits. If you are pregnant during flu season, you should get the flu vaccine as early as possible. You do not have to wait until later in your pregnancy for the flu shot, like is recommended for the whooping cough vaccine. 19
Prenatal Tdap vaccination is preferable to postpartum Tdap vaccination.

- Whooping cough vaccination during pregnancy will give your baby short-term protection as soon as he is born.
  - This early protection is important because the baby will not get the whooping cough vaccines until he is 2 months old.
- These first few months of life are when the baby is at greatest risk for catching whooping cough and having severe, potentially life-threatening complications from the infection. To avoid that gap in protection, it is best to get a whooping cough vaccine during pregnancy.  

\(^2\)
Healthcare Personnel (HCP) Need These Immunizations

• Annual influenza vaccine
  • http://www.cdc.gov/flu/healthcareworkers.htm
• Tdap or Td
• Hepatitis B (exposure risk)

Validate immune status of:
• Varicella
• Measles, Mumps & Rubella (MMR)

Are **YOU** up to date?
Acknowledgements

- American Academy of Pediatrics
Resources

• American College of Nurse Midwives
  • Talking points, position statements
  • “Super mom” education materials for women and their families
  • http://www.midwife.org/Immunization-Resources-for-Providers
Resources

• American College of Obstetricians and Gynecologist
  • Position statements, patient information
  • http://immunizationforwomen.org/default.php
• App http://www.acog.org/About-ACOG/News-Room/ACOG-and-GBS-App
• Influenza assessment and treatment in pregnant women
  • http://immunizationforwomen.org/providers/resources/acog-resources/algorithim.php
CDC Resources

• http://www.cdc.gov/pertussis/pregnant/
• http://www.cdc.gov/flu/protect/vaccine/pregnant.htm
• http://www.cdc.gov/vaccinesafety/concerns/vaccines-during-pregnancy.html
Maternal Immunizations in IHS

Amy V. Groom, MPH
IHS Immunization Program Manager
Lower respiratory tract Infections (LRTI)

- Significantly higher rates of hospitalizations and deaths from lower respiratory tract infections for AI/AN people and especially infants $^1-^3$
  - Pneumonia a common cause of LRTI
  - Influenza is a leading cause of pneumonia

Influenza

American Indian and Alaska Native people are at high risk for influenza-related complications.

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<th>Al/AN Rate</th>
<th>White Rate</th>
<th>Al/AN:White Rate Ratio</th>
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<td>19.1</td>
<td>1.90*</td>
<td>1.82-1.97</td>
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</tbody>
</table>

Maternal Influenza Vaccination Studies

- Pregnant women pass on protection to their newborn

- Studies conducted in AI/AN communities have shown babies born to moms who receive flu vaccine
  - Are less likely to get admitted to the hospital for flu than babies of unvaccinated mothers
  - Have a lower chance of catching the flu and getting admitted to the hospital for Influenza-Like-Illness

Pertussis

• On-going outbreaks across the US
  • Ramona’s story


• Historically, disparities for AI/AN infants compared to white infants
  • Mortality rates 4 times higher ¹
  • Significantly higher hospitalization rates ²

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RPMS Immunization Reminders

• Influenza for everyone 6 months and older
  • All adults, including pregnant women

• Tdap for adolescents

• Tdap for adults with no previous Tdap
  • Pregnant women already vaccinated with Tdap will NOT be forecast to receive additional doses
Monitoring Coverage

• Influenza and Tdap for pregnant women
  • Developmental measures in Clinical Reporting Software (CRS) v2016

• Denominator:
  • All pregnant female Active Clinical patients with no documented miscarriage or abortion.

• Numerators:
  • Patients who have received 1 dose of Tdap in the past 20 months, including contraindications.
    • 1, 2, and 3rd trimester
  • Patients with influenza vaccine documented during the Report Period or with a contraindication documented at any time before the end of the Report Period
The Future?

• Immunization reminder for Tdap for pregnant women?

• New GPRA Measure for flu and Tdap for pregnant women?

• Inclusion of pregnant women in RPMS Adult Immunization Coverage Report?