Maternal Immunization: Two for One

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Disclosures

• Laura Hammitt has the following financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this CME activity
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Agenda

1. Introduction and overview maternal immunization
   Laura Hammitt, MD, Assistant Professor, Center for American Indian Health, Johns Hopkins Bloomberg School of Public Health

2. Antenatal influenza and pertussis uptake among Aboriginal mothers in Australia
   Annette Regan, PhD, MPH, Research Fellow, Curtin University School of Public Health

3. Validation of an algorithm to measure maternal vaccine uptake
   Cheyenne Jim, MS, Indian Health Service Immunization Program Analyst

4. Facilitators and barriers to maternal vaccine uptake among Navajo and White Mountain Apache women
   Jessica Atwell, PhD, MPH, Assistant Scientist, Center for American Indian Health, Johns Hopkins Bloomberg School of Public Health

5. Discussion/Questions
   All
Why vaccinate pregnant women

- Neonates uniquely at risk for infections that cause death and disability
- Immune system of neonates is immature
- Active immunization of newborns is rarely successful

- High risk for exposure of pregnant women to disease
- Infection poses a special risk to the mother
- Infection poses a special risk to the fetus
Vaccination during pregnancy – “Nature’s Gift”

Period of highest severity of early childhood infections

Maternal antibody

Child’s antibody

Infant immunization starts
## Figure 2. Recommended Immunization Schedule for Adults Aged 19 Years or Older by Medical Condition and Other Indications, United States, 2017

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Pregnancy</th>
<th>Immuno-compromised (including HIV infection)</th>
<th>HIV infection CD4+ cell count (cells/µL)</th>
<th>Asplenia, persistent complement deficiencies</th>
<th>Kidney failure, end-stage renal disease, on hemodialysis</th>
<th>Heart or lung disease, chronic alcoholism</th>
<th>Chronic liver disease</th>
<th>Diabetes</th>
<th>Healthcare personnel</th>
<th>Men who have sex with men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td>1 dose annually</td>
<td>Substitute Tdap forTd once, then Td booster every 10 yrs</td>
<td>1 dose annually</td>
<td>1 dose annually</td>
<td>1 or 2 doses depending on indication</td>
<td>2 doses</td>
<td>1 or more doses depending on indication</td>
<td>3 doses through age 26 yrs</td>
<td>3 doses through age 26 yrs</td>
<td>3 doses through age 26 yrs</td>
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<tr>
<td>Td/Tdap</td>
<td>1 dose Tdap each pregnancy</td>
<td>1 dose Tdap each pregnancy</td>
<td>1 dose Tdap each pregnancy</td>
<td>1 dose Tdap each pregnancy</td>
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<td>1 dose Tdap each pregnancy</td>
<td>1 dose Tdap each pregnancy</td>
<td>1 dose Tdap each pregnancy</td>
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<tr>
<td>MMR³</td>
<td>contraindicated</td>
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<td>VAR⁴</td>
<td>contraindicated</td>
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<td>HZV³</td>
<td>contraindicated</td>
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<tr>
<td>HPV-Female⁴</td>
<td>3 doses through age 26 yrs</td>
<td>3 doses through age 26 yrs</td>
<td>3 doses through age 26 yrs</td>
<td>3 doses through age 26 yrs</td>
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<tr>
<td>HPV-Male⁵</td>
<td>3 doses through age 26 yrs</td>
<td>3 doses through age 26 yrs</td>
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<tr>
<td>PCV13⁷</td>
<td>1 dose</td>
<td>1 dose</td>
<td>1 dose</td>
<td>1 dose</td>
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<td>1 dose</td>
<td>1 dose</td>
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<tr>
<td>PPSV23⁷</td>
<td>1, 2, or 3 doses depending on indication</td>
<td>1, 2, or 3 doses depending on indication</td>
<td>1, 2, or 3 doses depending on indication</td>
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<td>HepA⁷</td>
<td>2 or 3 doses depending on vaccine</td>
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<td>2 or 3 doses depending on vaccine</td>
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<td>HepB⁹</td>
<td>3 doses</td>
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<tr>
<td>MenACWY or MPSV4¹⁰</td>
<td>1 or more doses depending on indication</td>
<td>1 or more doses depending on indication</td>
<td>1 or more doses depending on indication</td>
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<td>MenB¹⁹</td>
<td>2 or 3 doses depending on vaccine</td>
<td>2 or 3 doses depending on vaccine</td>
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<td>2 or 3 doses depending on vaccine</td>
<td>2 or 3 doses depending on vaccine</td>
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<tr>
<td>Hib¹¹</td>
<td>3 doses post-HSCT recipients only</td>
<td>3 doses post-HSCT recipients only</td>
<td>3 doses post-HSCT recipients only</td>
<td>3 doses post-HSCT recipients only</td>
<td>3 doses post-HSCT recipients only</td>
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<td>3 doses post-HSCT recipients only</td>
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</tbody>
</table>

- **Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection**
- **Recommended for adults with additional medical conditions or other indications**
- **Contraindicated**
- **No recommendation**

Clinical presentation and burden of influenza

- Sudden onset of fever, cough, sore throat, body aches, headaches, fatigue
- Spread by respiratory droplets
- Complications: pneumonia, myocarditis, encephalitis, death
- Highest risk in young children, adults ≥65 years, pregnant women and people with chronic conditions
- 7,000-26,000 pediatric hospitalizations per year
- Child deaths
  - 148 in 2014-2015
  - 61 so far this season

Pneumonia and Influenza Death Rate, 1999-2009

CDC recommendations for influenza vaccination

All persons ≥ 6 months should be vaccinated annually

When vaccine supply is limited, focus should be on:

- Children ages 6 months-4 years
- Adults ≥ 50 years
- Those with chronic heart, lung, kidney or metabolic disease
- Those who are immunosuppressed or on aspirin therapy
- Those who are or will be pregnant during flu season
- Residents or nursing homes or chronic care facilities
- American Indian/Alaska Native populations
- Morbidly obese
- HCW and household contacts/caregivers for high risk patients

http://www.cdc.gov/flu/professionals/acip/flu_vax1011.htm#box1
Pregnancy and influenza

- Seasonal influenza (non-pH1N1) in pregnancy
  - 5-fold increase in perinatal mortality including miscarriages, stillbirths, early neonatal disease and death
  - 3-fold increase in preterm birth

- 2009 pH1N1
  - Pregnant women ~1% of the population BUT
  - 6% of influenza-associated hospitalizations
  - 6% of ICU admissions (stronger risk factor than cardiac failure, diabetes or obesity)
  - 6% of deaths
Maternal influenza vaccination protects infants

Vaccine Efficacy: 63% (95%CI: 5, 85)

Maternal influenza vaccine study in Navajo and White Mountain Apache mothers

- Nonrandomized, observational, open label, cohort study

- Three influenza seasons
  - 2002-2005

- N = 1160 pregnant women
  - 573 received influenza vaccine
  - 587 did not receive influenza vaccine

Relative risk of influenza in the infant, by maternal vaccination status

- **Lab-Confirmed Influenza**
  - Vaccinated: 1.0
  - Unvaccinated: 0.61 (0.45, 0.84)
  - 41% reduction
  - RR=0.59 (0.37, 0.93)

- **ILI**
  - Vaccinated: 7.0
  - Unvaccinated: 0.92 (0.73, 1.16)
  - 39% reduction

- **Hospitalized ILI**
  - Vaccinated: 1.0
  - Unvaccinated: 0.61 (0.45, 0.84)

Half of pregnant women protect their babies against the flu. Time to bump it up!

With only half of pregnant moms getting their flu vaccine, too many remain unprotected

Flu shots help protect pregnant women and their babies from potentially serious illness during and after pregnancy.

During the 2015-16 flu season, an estimated 50%* of pregnant women in the U.S. protected themselves and their babies from flu by getting a flu shot. While this is a significant improvement since the years before the 2009 pandemic, about half of pregnant women, and their babies, still remain unprotected from influenza.

We can do better. All pregnant women need flu shots to protect themselves and their babies.

Get vaccinated to protect yourself and your baby.

www.cdc.gov/flu/protect/vaccine/pregnant.htm

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Protect the Circle of Life

Your Flu Vaccine Protects Me
My Flu Vaccine Protects You

- The flu vaccine is safe. You can't get the flu from a flu vaccine.
- Pneumonia and flu are a leading cause of death among Native elders.
- Please get a flu vaccine each year to protect you and your family.

Learn more at https://www.cdc.gov/flu or call 1-800-CDC-INFO

https://www.cdc.gov/flu/pdf/freeresources/native/protect_circle_life_poster_8.5.pdf
Clinical presentation and burden of pertussis

- Cough illness lasts 2-10 weeks, with paroxysms, “whooping”, post-tussive vomiting, apnea
- Complications: rib fractures, malnutrition, pneumonia, seizures, death
- 10,000-50,000 pediatric cases per year
- 10-20 child deaths per year (most in 1st 3 months of life)

*Per 100,000 population.
Maternal Tdap vaccination protects infants

- Tdap during each pregnancy
  - Preferably at 27-36 weeks gestation
- Retrospective analysis of hospitalized infants born to vaccinated and unvaccinated mothers in California
  - Infants born to vaccinated mothers had LOWER risk of
    - Hospitalization (RR 0.5; 95% CI: 0.4, 0.6)
    - ICU admission (RR 0.6; 95% CI: 0.7, 0.9)
    - And had shorter hospital stays (median 3 vs 6 days)
  - Adjusted vaccine effectiveness: 58% (95% CI 15, 80)
- Vaccine effectiveness of maternal Tdap vaccination in the United Kingdom
  - 91% for infants <3 months of age

### Vaccines for women during pregnancy

<table>
<thead>
<tr>
<th>Licensed and recommended</th>
<th>Timing</th>
<th>Benefit to the mother</th>
<th>Benefit to the infant</th>
<th>Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetanus</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt; trimester</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Acellular pertussis</td>
<td>27-36 weeks</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Inactivated influenza</td>
<td>Anytime</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>

**Under development**

<table>
<thead>
<tr>
<th></th>
<th>Timing</th>
<th>Benefit to the mother</th>
<th>Benefit to the infant</th>
<th>Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group B Strep</td>
<td>No data</td>
<td>✔️</td>
<td>No data</td>
<td>No data</td>
</tr>
<tr>
<td>RSV</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
<td>No data</td>
</tr>
</tbody>
</table>

Adapted from Kachikis et al, J Infection; Vol 5 July 2016, Pages S83–S90
Strategies for improving maternal vaccination

- Understand facilitators and barriers
- Promote provider recommendation
  - Education
  - Reminders
  - Establish who is responsible
- Ensure access
- Develop evidence-based interventions
  - Emphasize safety
  - Mention disease severity in infancy
  - Are culturally congruent
- Identify and use effective channels of communication
Vaccination of Pregnant Women Saves Lives

- Changes in immune function during pregnancy still allow for **good response to inactivated vaccines**
- Maternally-derived IgG can **prevent morbidity and mortality**
  - Maternal
  - Fetal
  - Neonatal
  - Young infant
- Inactivated vaccines are **safe**
- We should not exclude pregnant women or their offspring from vaccine-derived benefits **(equity)**
References on safety of maternal vaccination

- Pasternak et al. Risk of adverse fetal outcomes following administration of a pandemic influenza A (H1N1) vaccine during pregnancy, JAMA 2012 Jul 11;308(2):165-74
- Sukarman et al. Safety of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis and influenza vaccinations in pregnancy, Obstet Gynecol. 2015 Nov; 126(5): 1069-74
- Donegan et al. Safety of pertussis vaccination in pregnant women in UK: Observational study. BMJ. 2014;349:g4219.
## Agenda

1. **Introduction and overview maternal immunization**
   - Laura Hammitt, MD, Assistant Professor, Center for American Indian Health, Johns Hopkins Bloomberg School of Public Health

2. **Antenatal influenza and pertussis uptake among Aboriginal mothers in Australia**
   - Annette Regan, PhD, MPH, Research Fellow, Curtin University School of Public Health

3. **Validation of an algorithm to measure maternal vaccine uptake**
   - Cheyenne Jim, MS, Indian Health Service Immunization Program Analyst

4. **Facilitators and barriers to maternal vaccine uptake among Navajo and White Mountain Apache women**
   - Jessica Atwell, PhD, MPH, Assistant Scientist, Center for American Indian Health, Johns Hopkins Bloomberg School of Public Health

5. **Discussion/Questions**
   - All
pregnant women are at risk for serious complications from flu

- Severe illness
- Hospitalization
- Pneumonia
- Preterm and emergency cesarean delivery
- Death

Ask your doctor about the flu vaccine today!

Vaccination can protect both pregnant mothers and their babies from flu and flu-related complications.

LEARN MORE AT http://www.cdc.gov/flu or 1-800-CDC-INFO

The most effective tool in the world only works if you use it

Smallpox vaccination in Nigeria

Photo courtesy of Stan Foster
Receipt of Tdap during pregnancy by trimester, 2007-2013, Vaccine Safety Datalink Data

Reprinted from Vaccine Vol 34(7), Kharbanda et al., Maternal Tdap vaccination: Coverage and acute safety outcomes in the vaccine safety datalink, 2007–2013, with permission from Elsevier
Maternal vaccination - easier said than done

- Debate about risk/benefit → poor-moderate uptake
- Lack of data (until recently) to assure safety and efficacy
- Thalidomide → profound changes to regulatory environment
  - FDA excluded pregnant women from clinical trials
  - Pharma concerned about liability
  - Providers perceive unwillingness of pregnant women to receive recommended vaccines
- Perceived that potential risk trumped benefit

UNTIL 2009 pandemic H1N1 and resurgence of infant pertussis cases
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I understand that I have a right to revoke this authorization at any time. I can do so by submitting my revocation in writing to the Field Administrator at knorton@jhsph.edu or by mail at 20 E. White Mountain Blvd. Suite A5 PMB #327 Lakeside, AZ 85929.

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Printed Name: [name]
Date: [date]

For more information please contact:
Kathleen Norton, Administrative Director
20 E. White Mountain Blvd. Suite A5 PMB #327
Lakeside, AZ 85929
(928)205-5822 cell
knorton@jhsph.edu
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- presenting JHU programs at meetings and conferences, and,
- making posters and brochures which provide information about JHU programs.

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By signing this form, I am consenting to be photographed and am also allowing my family member(s), and I give permission for my and/or family member(s) photograph(s) to be used for the purposes stated above. In addition, this consent has been verbally administered to me in its entirety and I have also read the consent.

Signature: [Signature] Date: [Date]
Name of child: [Name of Child]
Address: [Address] Phone: [Phone]
Directions to Home: [Directions]

Johns Hopkins Program PO Box 3779 Shiprock, New Mexico 87426 Phone: 505-365-4676 FAX: 505-365-4673
CONSENT FOR PHOTOGRAPHING

[Signature]

I, [Name], hereby give permission to [Name] of the Johns Hopkins University (JHU) Center for American Indian Health to photograph me (and [Name], who is a member of my family). I understand that the photographs (made from print- and/or slide-film) will be used to promote the work of JHU among Indian families. Promotion of the work of JHU will include any or all of the following:

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[Signature]

Date: 5/1/85

[Name]

[Date]

Address: 

[Phone]

[Name]

[Phone]

[Address]

Johns Hopkins Study Co. PG Box 3770 Shiprock, New Mexico 87476 Tel 505-558-6000 FAX 505-558-6899
Maternal immunization is NOT a new concept

- 1879: Maternal immunization with cowpox virus protected mothers and infants from smallpox

- 1938: Maternal immunization with whole cell pertussis vaccine protected infants from complications of pertussis

- 1961: Maternal immunization with tetanus toxoid vaccine in New Guinea protected infants → millions of maternal and neonatal deaths prevented worldwide since then

- 1964: Inactivated influenza vaccine recommended
Acknowledgements

- Ruth Karron
- Shabir Madhi
- Carol Baker
- Kate O’Brien
Reasons for flu immunization during pregnancy

- Influenza 5x more likely to cause severe illness in pregnant women
- Increased risk of preterm labor and birth in pregnant women with influenza
- Influenza hospitalization rates in infants <6 mos are 10x greater than in older children but there are no licensed vaccines for children <6 mos
- Vaccination during pregnancy has been shown to protect both the mother and her infant from influenza illness, influenza hospitalization and influenza-related preterm birth
  - Babies whose mother have a flu shot in pregnancy are ~50% less likely to be diagnosed with flu in their first flu season
Neonatal tetanus

WHO 2015 Data
- 34,019 NT deaths
- 96% reduction from 1988

ubiquitous spores – majority cases birth-associated

Image: https://www.cdc.gov/tetanus/about/photos.html
AI/AN vs non-AI/AN rates of death related to 2009 pH1N1, 12 states

MMWR Dec 11, 2009
Maternal influenza vaccination study, 2002-2005

1160 Mother-infant pairs

573 Given the flu shot

- 31 Lab-confirmed flu cases
- 293 Flu-like Symptoms
  - 76 Hospitalized for flu like symptoms

587 Not given the flu shot

- 52 Lab-confirmed flu cases
- 312 Flu-like Symptoms
  - 117 Hospitalized for flu like symptoms
Main reason for receiving vaccination

Figure 9. Reported main reason for receiving flu vaccination among women pregnant anytime August 1 – November 10, 2016, who were vaccinated before or during pregnancy (n=1,031), Internet panel survey, United States

- To protect my baby from flu: 33.8%
- To protect myself from flu: 22.5%
- My doctor, nurse, or other medical professional recommended the flu vaccination to me: 17.6%
- To protect my friends or family from flu: 7.3%
- Because the flu might be bad this season: 6.9%
- It was easy/convenient to get the flu vaccination: 6.3%

https://www.cdc.gov/flu/fluvoxview/pregnant-women-nov2016.htm
Main reason for NOT receiving vaccination

Figure 10. Reported main reason for not receiving flu vaccination among women pregnant anytime August 1 – November 10, 2016, who do not intend to receive flu vaccination for the rest of the flu season, Internet panel survey, United States (n=446)

- I do not think the vaccination is effective in preventing flu: 18.2%
- I am concerned about possible safety risks to my baby if I got vaccinated: 17.2%
- I get sick when I get the vaccination or I’m concerned I might get sick: 15.5%
- I am not concerned about getting the flu: 12.2%
- I do not need the vaccination: 11.0%
- I am concerned about possible safety risks to myself if I got vaccinated: 10.1%