

# Maternal immunization: understanding safety and efficacy and making a strong recommendation

Lakshmi Sukumaran, MD, MPH

Medical Officer, Immunization Safety Office

**Ashley Brooks, MPH** 

Health Communication Specialist National Center for Immunization and Respiratory Diseases

ACOG/ACNM Maternal Immunization Webinar March 1, 2018



#### **ACCME** Accreditation

The American College of Obstetricians and Gynecologists is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

#### AMA PRA Category 1 Credit(s)™

The American College of Obstetricians and Gynecologists designates this **enduring material** for a maximum of 1 *AMA PRA Category 1 Credit* TMPhysicians should claim only the credit commensurate with the extent of their participation in the activity.

#### College Cognate Credit(s)

The American College of Obstetricians and Gynecologists designates this **enduring material** for a maximum of 1 Category 1 College Cognate Credit. The College has a reciprocity agreement with the AMA that allows *AMA PRA Category* 1 *Credits*<sup>TM</sup> to be equivalent to College Cognate Credits.

#### Disclosure of Faculty and Industry Relationships

In accordance with the College policy, all faculty and planning committee members have signed a conflict of interest statement in which they have disclosed any financial interests or other relationships with industry relative to topics they will discuss at this program. At the beginning of the program, faculty members are expected to disclose any such information to participants. Such disclosure allows you to evaluate better the objectivity of the information presented in lectures. Please report on your evaluation form any undisclosed conflict of interest you perceive. Thank you!

represent the official views of CDC or ASTHO.

This webinar was made possible by cooperative agreement number 6.5

contents are solely the responsibility of ACOG and do not necessarily

NU38OT000161-05-00 from the Centers for Disease Control and Prevention

(CDC) and the Association of State and Territorial Health Officials (ASTHO). Its

#### Our recommended software and hardware configuration is the following:

#### Windows



Processor: 850MHz or faster processor (or

above)

Operating System: Windows XP/2000/98

Memory: 512MB of RAM (or above)

Screen Resolution: 1024 x 768 (or above) Microsoft Internet Explorer 5.5 (or higher)

or Mozilla Firefox 1.5

Adobe Flash Player 8 (or higher)

Adobe Acrobat 6 (or higher)

Macintosh



Processor: G3 500MHz or faster processor (or above)

Operating System: OS 10.3 (or above)

Memory: 512MB of RAM (or above)

Screen Resolution: 1024 x 768 (or above) Mozilla Firefox 1.5 or Safari 1.2.2 browser

supported for Mac OS X 10.3 or higher

Adobe Flash Player 8 (or higher)

Adobe Acrobat 6 (or higher)

## Conflict of Interest Disclosure: Faculty/Planning Committee/Reviewer/Staff

#### CONFLICT OF INTEREST DISCLOSURE: FACULTY/PLANNING COMMITTEE/REVIEWER/STAFF

Kevin A. Ault, MD – Research: Inovio and NIH; Consultant: ACI Clinical, Moderna Therapeutics, NIH, CDC, and ACOG; Data and Safety Monitoring Board: NIH, CDC and Novartis

Brenna L. Hughes, MD – Royalties from UpToDate for authorship; Scientific Advisory: Merck

Flor Munoz, MD – Author and Editorial Board: UpToDate; DSMB Member: Moderna, NIH, Propel study, Thrasher; Research (CTA trough Baylor College of Medicine): Biocryst, Alios, Regeneron, Novavax, CDC respiratory and GI viral surveillance, The National Institutes of Health, BMGF - GAIA project - Vaccine safety; Advisory board: WHO - maternal immunization with influenza/GBS projects

Laura E. Riley, MD – Author: UpToDate; Published Author: Wiley Publishing

Geeta K. Swamy, MD – Research: GSK, Novavax, Regeneron; Independent Data Monitoring Committee: GSK; Chairperson, External Data Monitoring Committee: Pfizer

All other faculty, planning committee members, reviewers and staff have no conflict of interest to disclose relative to the content of the presentation.

#### **Course Faculty**

#### Lakshmi Sukumaran, MD, MPH

Medical Officer, Immunization Safety Office Centers for Disease Control and Prevention

#### Ashley Brooks, MPH

**Health Communication Specialist** 

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

#### **Learning Objectives**

- Discuss the scientific evidence supporting maternal flu vaccination safety and monitoring.
- Educate pregnant patients about the importance of an annual flu vaccine.
- Name three components of a strong recommendation.
- Use CDC ACOG, ACNM and messaging and resources to address patient questions and concerns regarding flu immunization.

#### **Disclaimer**

 The findings and conclusions in this presentation are those of the author and do not necessarily represent the official position of the CDC

#### BOME > NEWS > HEALTH > HEALTH NEWS

#### Woman dies of swine flu days after giving birth

A woman who contracted swine flu died just weeks after giving birth to her first child.



56 deaths among US pregnant women



before death; delivered baby in coma







#### Family: Former Lincoln woman dies of swine flu during childbirth

A former mayor of Boys Town has died, apparently of swine flu. A paid obituary in the Lincoln Journal Star says 20-year-old Caitlin Anne Treat Huber died of swine flu a day after elving birt.

per cent of pregnant women vaccinated even though they are four times more at risk of swine flu



#### Swine flu alert for pregnant women and babies

LAMA DOMELY	burses to have foun patheting for
center considerates.	manufactured and of males
UNION were to show a total sense.	ing any solutions because their sources
in progness senses and now purcols	is engineered to come that their he
tedg is an attempt to first the spread of	show out reget their help:
the circu prices; the most referential.	Experie believe that most case of est
fragery and the stand to	the secure are have the motion
array assurances exercise and closely.	frame, he need court code foreign upon
with property magazining that they do not	Not believe at the entirings of course for
Stand on States and the bunden States	details. In facilitate, affects 21 capacits
ground at peak times.	ments with more to on in intend
Paraste will be advised to lamp believe	ners, progness? women have been experi step at home when progette, and to so
and from morels, while program	that it forms where projection and to so
poster will also be recognized to look	face receiver where their de-up-man,
the automore of their other challens, so	Make progress in the place of Bellijo
thing also and foreign the come feature.	strong terms in a dringly to be be
The surrough come send morning	to colour the aproad of charges at
counts flat progned women and provid-	consiste conferred agent to
differ an energ for groups mad at that from motor fix.	melal manages, such as regular has
ma man man to	The second secon
to the second time with people force from	Sobal's pobleson, to be published the Automat People Service
took or brighter with the room or bug-	the Appendix regards formed power
Code: Non-hor hors from tops over	factories, will adult parcelle and progress
Starty Steen older particular to be believe to	money in decompositions, that he
there has note persons to be taken to	been street up by the Broad College
Septid to September 10 people have been been been be beginning within it from	Military and the Republishing of Char
See beat of the Section Section & Section 1	the same of the same of the same
AND CORNEL TO SEE STATE OF THE PARTY OF THE PARTY.	biream and Geographysists.  Secure Spaces from South Angustiania.
Officials, there have been in frequir	and the other spectrum changes.

The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

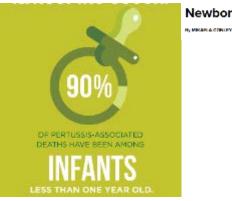
#### Severe 2009 H1N1 Influenza in Pregnant and Postpartum Women in California

Ianice K. Louie, M.D., M.P.H., Meileen Acosta, M.P.H., Denise J. Jamieson, M.D., M.P.H., and Margaret A. Honein, Ph.D., M.P.H., for the California Pandemic (H1N1) Working Group\*

#### 38-Day-Old Baby Dies After Persisting Cough

By LARA SALAHI . April 28, 2010





Newborn Nearly Dies Contracting Whooping Cough

Whooping Cough Back Again With A Vengeance In California



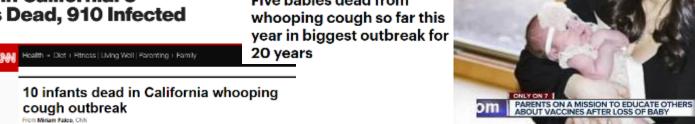
By MEE WATE / CHRISTING / JAMES SA, 2010, 2249 PM

Whooping Cough Epidemic Rages in California: 5 **Babies Dead, 910 Infected** 

October 20, 2010 10,10 p.m. ED1

Five babies dead from whooping cough so far this 20 years

Disease burden highest in infants during pertussis epidemic Share this



Third baby dies from whooping cough in California

#### **OVERVIEW**

- Infections and vaccinations during pregnancy
- CDC vaccine safety monitoring in pregnancy
- Results of inactivated influenza vaccine (IIV) and tetanus, diphtheria, and acellular pertussis (Tdap) safety studies in pregnancy
- Maternal vaccine safety recap



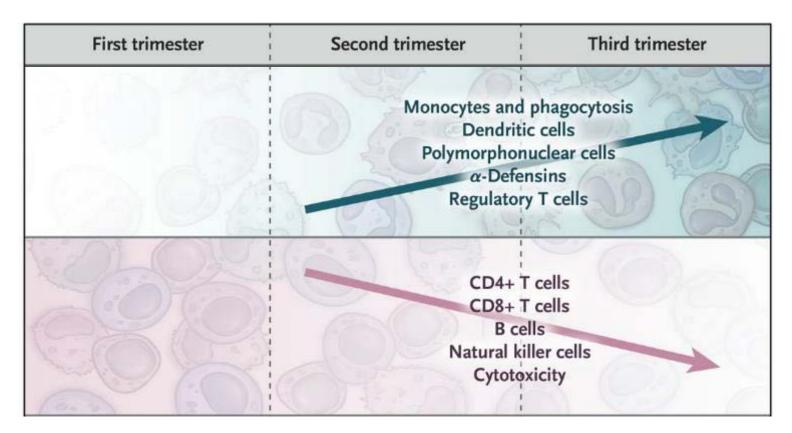
# Vaccination during pregnancy protects mom and baby

## Infections in pregnant women and neonates

- Maternal influenza
  - Physiologic changes during pregnancy → severe disease<sup>1</sup>
  - 5-fold increased risk of death in pregnant women (typically 2<sup>nd</sup>/3<sup>rd</sup> trimester)
- Neonatal influenza
  - No infant vaccine until 6 months of age
  - Infants at high risk of hospitalization and death from influenza<sup>2</sup>
- Neonatal pertussis
  - Primary immunization series complete at 6 months
  - Majority of pertussis deaths occur in infants < 3 months of age<sup>3</sup>

- Grohskopf L et al. MMWR (2016).
- 2. Epperson S et al. MMWR (2014).
- 3. 2016 provisional pertussis surveillance report: http://www.cdc.gov/pertussis/downloads/pertuss-surv-report-2014.pdf

## Increased susceptibility to severe influenza infection



## Potential impacts of exposures during pregnancy

Pre-implantation (0-2 weeks)

Embryonic period (2-9 weeks)

Fetal period (9 weeks - term)

Injury to a large number of cells → spontaneous abortion

Major defects and altered function of organs Small for gestational age, intrauterine growth restriction, fetal death, minor malformations, altered function of organs

# Recommendations for influenza vaccine during pregnancy

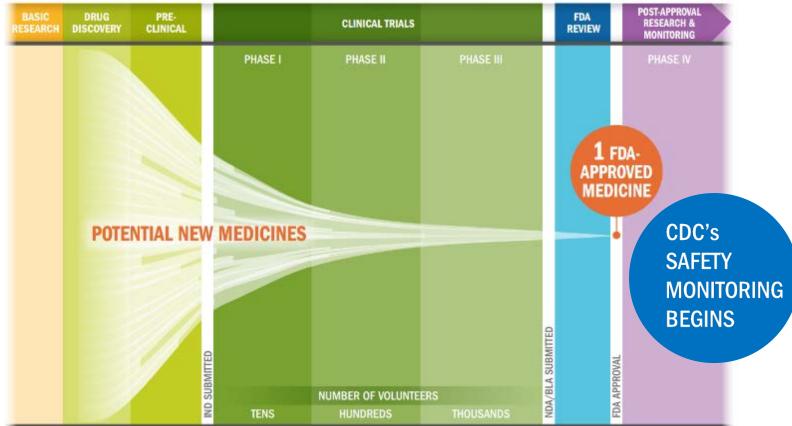
- Advisory Committee on Immunization Practices (ACIP) recommendations for pregnant women
  - 1960: Pregnant women noted to be at risk of severe illness and were recommended to receive influenza vaccine
  - since 1990s: Vaccination during 2<sup>nd</sup> and 3<sup>rd</sup> trimesters recommended
  - 2004: Influenza vaccine recommended for all pregnant women during any trimester of pregnancy
  - 2017: Any licensed, recommended and age-appropriate trivalent, quadrivalent, or recombinant inactivated influenza vaccine can be administered during pregnancy

# Recommendations for Tdap vaccine during pregnancy

- ACIP recommendations in pregnant women<sup>1</sup>
  - 2006: Tdap booster to post-partum mothers and family members (cocooning)
  - 2011: Tdap for unvaccinated pregnant women after 20 weeks gestation
  - 2012: Tdap for every pregnant woman at every pregnancy regardless of prior immunization status (optimally between 27-36 weeks gestation)

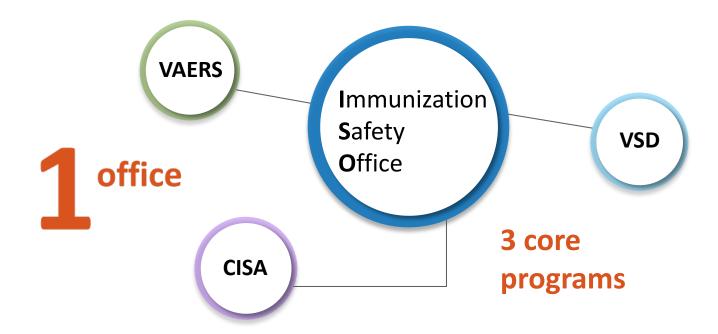
## CDC prioritizes maternal vaccine safety

## Vaccine licensure process in the United States



## Why post-licensure vaccine safety monitoring?

- Pregnant women often excluded from pre-licensure clinical trials
- Pre-licensure clinical trails may not detect rare events
- Safety standards for vaccines are high











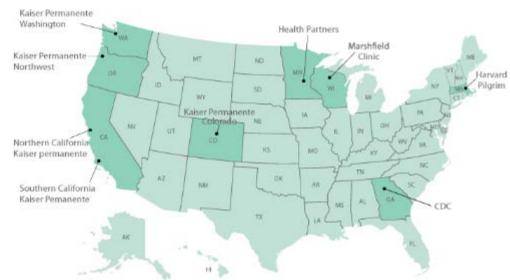
Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA









8 participating healthcare organizations



### Identifying pregnancies in the VSD

- VSD uses an validated algorithm<sup>1</sup> to identify pregnancy outcomes and start and end dates from electronic health records
- VSD data can be used to link pregnant women to their children
- VSD annual cohort ~3% of US population<sup>2</sup>
  - ~125,000 pregnancies per year
  - ~90,000 live births per year
- Additional pregnancy data: Height and weight, education, prior pregnancy history, smoking and alcohol use, plurality, delivery type, Apgars, last menstrual period, estimated due date

## **CISA**

Clinical Immunization Safety Assessment

7 participating healthcare organizations

vaccine safety experts

- assist U.S. healthcare providers with complex vaccine safety questions about their patients
- conduct clinical research



Influenza vaccine safety studies: mom, baby and pregnancy

## Maternal influenza studies – general safety

- IIV and live attenuated influenza vaccines during pregnancy in VAERS, 1990-2009<sup>1</sup>
  - No unusual patterns of pregnancy complications or fetal outcomes
- Influenza A (H1N1) 2009 monovalent vaccine during pregnancy in VAERS<sup>2</sup>
  - No concerning patterns of maternal or fetal outcomes
- IIV during pregnancy in VAERS, 2010-2016<sup>3</sup>
  - No vaccine safety concerns among pregnant women or their infants

3. Moro PL, et al. Drug Saf (2017).

Moro PL, et al. Am J Obstet Gynecol (2011).

Moro PL, et al. Am J Obstet Gynecol (2011).

#### Maternal influenza studies – maternal outcomes

- Medically attended maternal acute events in the VSD<sup>1,2</sup>
  - Outcomes included allergic reactions, local reactions, neurologic events
  - No increased risk following IIV or monovalent H1N1 vaccines
- Feasibility of text message influenza vaccine safety monitoring during pregnancy<sup>3,4</sup>
  - Prospective CISA study
  - Post-vaccination fever was infrequent and a typical pattern of maternal and neonatal health outcomes was observed

<sup>1.</sup> Nordin JD et al. Vaccine (2014)

<sup>2.</sup> Nordin JD et al. Obstet Gynecol (2013)

<sup>3.</sup> Stockwell M et al. AJPM (2017)

<sup>4.</sup> Registered at ClinicalTrials.gov www.clinicaltrials.gov (NCT01974050)

## Maternal influenza studies – pregnancy outcomes

- Spontaneous abortion (SAB) in the VSD<sup>1,2</sup>
  - No increased risk of SAB in the 28 days following IIV exposure during 2005-2007 influenza seasons<sup>1</sup>
  - Increased risk of SAB in the 28 days following IIV exposure during 2010-2012 influenza seasons<sup>2</sup>
    - Risk seen in women vaccinated in prior influenza season
  - Follow up study evaluating subsequent influenza seasons in progress

## Maternal influenza studies – pregnancy outcomes

- Medically attended adverse obstetric events in the VSD<sup>1,2</sup>
  - Outcomes included hyperemesis, gestational hypertension, gestational diabetes, proteinuria, urinary tract infection
  - No increased risk following IIV or monovalent H1N1 vaccines
- Adverse birth outcomes in the VSD<sup>3</sup>
  - No increased risk of preterm birth or small for gestational age following IIV

<sup>1.</sup> Kharbanda EO et al. Obstet Gynecol (2013)

<sup>2.</sup> Nordin JD et al. Vaccine (2014)

<sup>3.</sup> Nordin JD et al. J Pediatr (2014)

#### Maternal influenza studies – infant outcomes

- Major birth defects after vaccination in VAERS, 1990 to 2014<sup>1</sup>
  - Major birth defects were infrequently reported, with no condition reported disproportionally
- Major structural birth defects in the VSD<sup>2</sup>
  - No increased risk after first trimester IIV exposure
- Infant mortality and hospitalizations in the VSD<sup>3</sup>
  - No increased risk of infant death, hospitalization or hospitalizations from respiratory causes following maternal IIV exposure

<sup>2.</sup> Kharbanda EO et al. Journal of Pediatrics (2017).

<sup>3.</sup> Sukumaran L et al. Pediatrics [in press]

## Systematic reviews and meta-analyses

- Outcomes: fetal death, spontaneous abortion, congenital malformations<sup>1</sup>
  - In 19 studies, no increased risk of fetal death, spontaneous abortion, or congenital malformation following influenza vaccine
- Outcomes: stillbirth and spontaneous abortion<sup>2</sup>
  - In 7 studies, lower risk of stillbirth and no increased risk of spontaneous abortion following influenza vaccine
- Outcome: congenital malformations<sup>3</sup>
  - In 15 studies, no association was found between congenital defects and influenza vaccination at any trimester or at first trimester

McMillan M, et al. Vaccine (2015).

<sup>.</sup> Bratting KN, et al. Clinical Infectious Diseases (2015).

<sup>3.</sup> Polyzos KA, et al. Obstetrics and Gynecology (2015).

#### A word about thimerosal

- Currently only used in multi-dose vials of influenza vaccine
- Institute of Medicine: "Immunization safety review: vaccines and autism"
  - Scientific evidence does not support a causal association between thimerosal-containing vaccines and autism
- CDC study: "Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism" <sup>2</sup>
  - Case-control study in VSD found prenatal exposure to thimerosal containing immunizations did not increase the risk of autism

Tdap vaccine safety studies: mom, baby and pregnancy

## Maternal Tdap studies – general safety

- Adverse events after Tdap vaccines in pregnant women in VAERS, 2005-2010<sup>1</sup>
  - During a time when Tdap was not routinely recommended in pregnancy, no concerning patterns in maternal, infant, or fetal outcomes
- Enhanced surveillance of Tdap vaccines in pregnancy in VAERS, 2011-2015<sup>2</sup>
  - No new or unexpected adverse events were noted among vaccinated pregnant women after routine recommendations for maternal Tdap vaccination
  - Changes in reporting patterns expected, given the broader use of Tdap in pregnant women in the third trimester

### Maternal Tdap studies – maternal outcomes

- Medically attended maternal acute adverse events in the VSD<sup>1-3</sup>
  - Outcomes included local reactions, allergic reactions, neurologic events
  - No increased risk following Tdap vaccine, concomitant Tdap and IIV, or following repeated doses of tetanus-containing vaccines
- Clinical study of Tdap safety in pregnant women in CISA (in progress)<sup>4,5</sup>
  - Prospective observational study in pregnant and non-pregnant women
  - Preliminary findings: Tdap was well tolerated and immunogenic; proportion of reactions in pregnant women receiving repeat Tdap not higher than those receiving first Tdap

Kharbanda EO et al. Vaccine (2016)

<sup>2.</sup> Sukumaran L et al. Obstet Gynecol (2015)

<sup>3.</sup> Sukumaran L et al. JAMA (2015)

<sup>4.</sup> Presented to ACIP June 2016

Registered at ClinicalTrials.gov www.clinicaltrials.gov NCT02209623

#### Maternal Tdap studies – pregnancy outcomes

- Adverse obstetric events in the VSD<sup>1</sup>
  - Small statistically significant increased risk of chorioamnionitis
    - Follow-up study evaluating infant morbidity showed no signals (next slide)
    - No increased risk of hypertensive disorders of pregnancy
- Chorioamnionitis reports to VAERS<sup>2</sup>
  - Chorioamnionitis was infrequently reported (<1% of pregnancy reports) over a period of 24 years<sup>2</sup>
- Adverse birth outcomes in the VSD<sup>1,3,4</sup>
  - No increased risk of preterm delivery, small for gestational age following Tdap vaccine, concomitant Tdap and IIV, or following repeated doses of tetanus-containing vaccines

Kharbanda EO et al. JAMA (2014)

<sup>2.</sup> Datwani H, et al. Vaccine (2015).

<sup>.</sup> Sukumaran L et al. Obstet Gynecol (2015)

<sup>4.</sup> Sukumaran L et al. JAMA (2015)

#### Maternal Tdap studies – infant outcomes

- Birth defects in the VSD<sup>1</sup>
  - No increased risk of microcephaly or other structural birth defects
    - Response to concerns of increase in microcephaly in Brazil related to Zika
- Infant morbidity in the VSD<sup>2</sup>
  - No increased risk of tachypnea of newborn, neonatal sepsis, neonatal pneumonia, respiratory distress syndrome, newborn convulsions after maternal Tdap vaccine despite slight increase in diagnosed chorioamnionitis
- Infant mortality and hospitalizations in the VSD<sup>3</sup>
  - No increased risk for infant death, hospitalizations or respiratory hospitalizations after maternal Tdap
- DeSilva M et al. JAMA (2016)
- DeSilva M et al. Vaccine (2017)
- 3. Sukumaran L et al. Pediatrics [in press].

# Maternal vaccine safety recap

#### Recap

- Pregnant women and neonates at increased risk of complications from influenza and pertussis disease
  - Vaccination during pregnancy important tool to protect pregnant women and their infants
- Pregnant women often excluded from drug and vaccine pre-licensure trials
  - Post-licensure monitoring crucial
- The CDC has a comprehensive mechanism for monitoring vaccine safety
  - Studies support the use of influenza and Tdap vaccines in pregnancy and are consistent with larger body of evidence

#### Your recommendation matters

 Consistently shown in literature to be the most influential factor in a patient's decision to receive an immunization



#### **Centers for Disease Control and Prevention**

National Center for Immunization and Respiratory Diseases



# Maternal Immunization: Understanding Safety and Efficacy and Making a Strong Recommendation

**Maternal Vaccination Communication Strategies** 

Ashley Brooks, MPH
Health Communication Specialist
National Center for Immunization and Respiratory Diseases

#### **Overview**

- ACIP-recommended immunization schedule for pregnant women
- Research surrounding maternal immunization communication
- Role of health care provider
- Use of CDC, ACOG, and ACNM messaging and resources to address patient questions

## **ACIP** recommendations for pregnant women

#### **Maternal Vaccination**

Vaccine	Before pregnancy	During pregnancy	After pregnancy	Type of vaccine
Influenza	Yes	Yes, during flu season	Yes	Inactivated
Tdap	May be recommended; it is better to vaccinate during pregnancy when possible	Yes, during <b>each</b> pregnancy	Yes, immediately postpartum, if Tdap never received in lifetime; it is better to vaccinate during pregnancy	Toxoid/ Inactivated
Td	May be recommended	May be recommended, but Tdap is preferred	May be recommended	Toxoid
Hepatitis A	May be recommended	May be recommended	May be recommended	Inactivated
Hepatitis B	May be recommended	May be recommended	May be recommended	Inactivated
Meningococcal	May be recommended	Base decision on risk vs. benefit; inadequate data for specific recommendation	May be recommended	Inactivated
Pneumococcal	May be recommended	Base decision on risk vs. benefit; inadequate data for specific recommendation	May be recommended	Inactivated
HPV	May be recommended (through 26 years of age)	No	May be recommended (through 26 years of age)	Inactivated
MMR	May be recommended; once received, avoid conception for 4 weeks	No	May be recommended	Live
Varicella	May be recommended; once received, avoid conception for 4 weeks	No	May be recommended	Live

## Influenza and pregnant women

#### **Health and Economic Cost of Influenza**

- Millions of cases per year, varies year to year
- 226,000 hospitalizations per year, >75% among adults<sup>1</sup>
- 3,000–49,000 deaths per year, >90% among adults<sup>2</sup>
- Direct medical cost \$10.4 billion<sup>3</sup>
- With loss of work and life \$87 billion
- Estimates for 2015–2106<sup>4</sup>
  - 25 million illnesses
  - 11 million medical visits
  - 310,000 hospitalizations
  - 12,000 deaths



<sup>1.</sup> Thompson WW, et al. Influenza-Associated Hospitalizations in the United States. JAMA 2004;292:1333–1340

<sup>2.</sup> CDC. Estimates of deaths associated with seasonal influenza – United States, 1976–2007. MMWR 2010;59(33):1057–1062

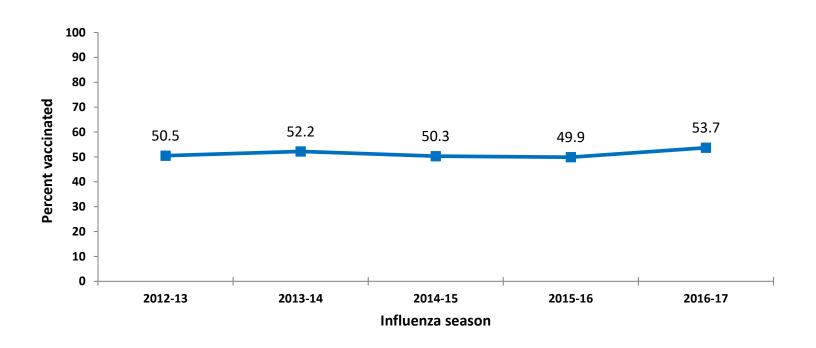
<sup>3.</sup> Molinari, et al. The annual impact of seasonal influenza in the US: Measuring disease burden and costs. Vaccine 2007;25:5086-5096

<sup>4.</sup> CDC. Estimated Influenza Illnesses, Medical Visits, Hospitalizations, and Deaths Averted by Vaccination in the United States, 2017. Available at: <a href="https://www.cdc.gov/flu/about/disease/2015-16.htm">www.cdc.gov/flu/about/disease/2015-16.htm</a>

#### Influenza and Pregnancy

- Influenza illness during pregnancy
  - Higher risk for severe illness and complications
  - Increase in delivery complications (fetal distress, preterm labor, cesarean delivery)
- Vaccinating pregnant women
  - Protective levels of anti-flu antibody for mom, passive transfer of antibody for baby
  - Reduced risk for influenza infection and hospitalizations among infants <6 mos age</li>
  - -36% in respiratory illness for mom, 29%  $\downarrow$  for infants <6 mos age
- Influenza vaccination recommended for women who are or will be pregnant
  - CDC, American College of Obstetricians and Gynecologists, American College of Nurse Midwives, American Academy of Family Physicians
  - Grohskopf LA et al. Prevention and control of seasonal influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices United States, 2013–2014. MMWR 2013;62(RR07);1–43
  - Eick AA et al. Maternal influenza vaccination and effect on influenza virus infection in young infants. Arch Pediatr Adolesc Med 2011;165:104–11

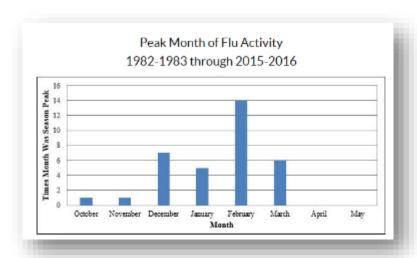
# Influenza Vaccination Coverage Among Pregnant Women, 2010–2011 through 2016–2017 Influenza Seasons



#### **Maternal Flu Vaccine Recommendation**

 CDC recommends that pregnant women get a flu shot during any trimester of their pregnancy to protect themselves and their newborn babies from flu.

 By the end of October, if possible, to help ensure protection before flu activity begins to increase



## Pertussis and pregnant women

#### **Burden of Pertussis**

- Notifiable disease based on clinical, lab, epi criteria
- 21,000 cases in 2015, 22% among adults (underdiagnosed and underreported)
- Transmission from adults to children
  - Disease most severe for infants
  - Among hospitalized, apnea (61%), pneumonia (23%), death (1%)





CDC. National Notifiable Disease Surveillance System <a href="www.cdc.gov/pertussis/surv-reporting.html">www.cdc.gov/pertussis/surv-reporting.html</a> CDC. MMWR 2017;66(11):1-28

#### **Pertussis Vaccination Recommendations**

#### Adults

- 1 dose Tdap if previously not received, except for pregnant women

#### Pregnant women

- Direct protection for mom, indirect protection for baby
- Infants of vaccinated moms were born with significantly higher anti-pertussis antibodies if
   Tdap given in pregnancy weeks 27–36
- Concentration of anti-pertussis antibodies in infant cord blood higher when mothers vaccinated earlier in this window
- Longer exposure to vaccine allows higher vaccine-induced antibody levels produced by mother and transferred to infant
- Vaccination is recommended for every pregnancy
- Cocooning alone may not be effective and it is difficult to implement

#### Pertussis Vaccination Recommendations

- Adults
  - 1 dose Tdap if previously not received, except for pregnant women
- Pregnant women
  - Direct protection for mom, indirect protection for
- Administer 1 dose of Tdap every pregnancy preferably during early part of gestational weeks 27–36 cussis antibodies if Infants of vaccinated moms were be Tdap given in pregnate
  - miniant cord blood higher when mothers
  - vaccine allows higher vaccine-induced antibody levels produced by mother and transferred to infant

# Bottom Lines

- Pregnant women should get influenza vaccine and Tdap (for every pregnancy)
- But vaccination coverage rates remain low

- We know that health care provider recommendations have big impact
- So, focus on effective messaging and communication strategies

What does communication research tell us?

CDC Maternal Research



#### **Summary of Findings from 2014 Mixed Methods Research**

#### Methodology:

- Surveys
- Focus groups
- In depth interviews

#### Pregnant Women

- Low disease and vaccine awareness
- Protection for their babies is very important
- Want to be assured of safety
- High information-seeking
- Want information from ob-gyn or midwife

#### Ob-gyns

- Are recommending vaccines to pregnant patients
- Understand importance of maternal vaccination
- Low perceived susceptibility
- Systems barriers to stocking vaccines

#### Additional Research: November – December 2016

- Online survey and message testing with pregnant women
  - -251 pregnant women aged 18-45 years in U.S. receiving prenatal care
  - Mixed household income, age, and experience with pregnancy
  - Range of intention for flu and Tdap vaccines
- In-depth interviews with HCPs
  - 16 OB-GYNs and 8 certified nurse midwives (CNM)
  - Across all regions of U.S.
  - Included those that provide Tdap onsite + those that refer

#### **Key Findings: Pregnant Women**

#### Vaccine Recommendations

- 69% received flu vaccine recommendation and 41% received Tdap vaccine recommendation
- About 60% who received recommendations (for flu or Tdap vaccine) were told the vaccine was "extremely or very important"

#### Vaccine Acceptance

- More respondents had gotten or intended to get flu vaccine (59%) than Tdap (42%)
- 28% had decided not to get each of the vaccines

#### Vaccine Decision-making

- Pregnant women get vaccines because their prenatal care providers recommend them or because they heard the illnesses could harm their baby.
- They want information about safety of individual vaccines, side effects, and
   PRELIMINARY CINE INGRESION

#### **How HCPs Talk about Maternal Vaccines**

- Most use similar Tdap and flu vaccine messages with patients
- Most discuss Tdap and flu vaccination concurrently, during initial intake visit
  - Use printed materials to help educate patients about vaccines
- Key message themes to facilitate vaccine conversations:
  - Disease susceptibility and severity
  - Vaccination benefits (protection, passive immunity)
  - Vaccine safety
- CNMs were more likely than OB-GYNs to feel uncomfortable making a strong recommendation for either vaccine, as they view it as a patient decision

#### **Best Ways to Reach Pregnant Women**

- Pregnant women get maternal vaccination formation from 3 main sources:
  - 80% HCPs (most important source for 60%)
  - 50% Internet health resources
  - 33% Family
- However, most are not actively looking for information about pregnancy vaccines
- Some pregnant women would be prompted by messages they see online to ask their HCP about maternal vaccination



**Role of Health Care Provider** 

# We know pregnant women have questions once they realize they need vaccines...



Are these diseases really dangerous?

Is it safe for me and my baby?

Can't I just get it after my baby is born (like my last pregnancy)?

Why every pregnancy?

Why hasn't my doctor talked to me about this?

Is it enough to just make sure everyone around my baby is vaccinated (or if we stay away from sick people)?

# They may look to many sources for pregnancy-related information















#### **Standards for Adult Immunization Practice**

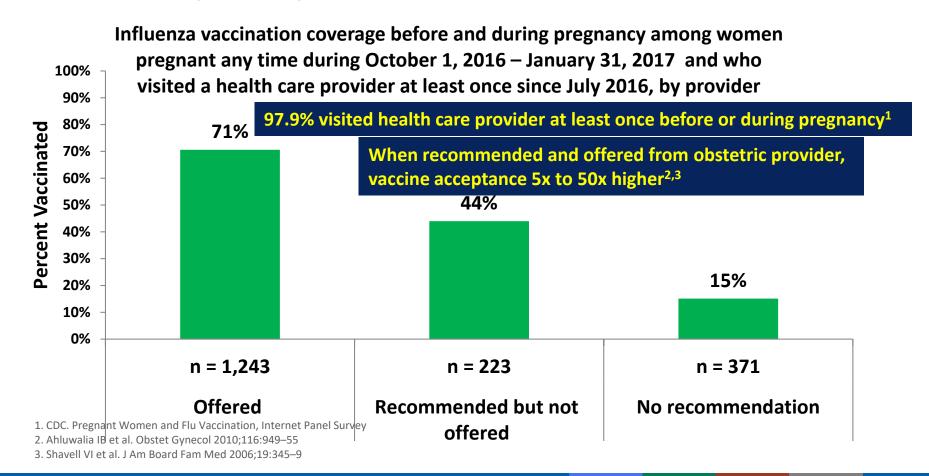
- All health care providers, including those who do not provide vaccine services, have role in ensuring adult patients up-todate on vaccines
- Call to action for adult health care providers to
  - ASSESS vaccination status of all patients at every clinical encounter
  - Strongly RECOMMEND vaccines that patients need
  - ADMINISTER needed vaccines or REFER to a vaccine service provider
  - DOCUMENT vaccines received by patients in state vaccine registries

#### **Present Vaccination as a Standard Part of Obstetric Care**

- Provide your patients with information and resources about maternal vaccines during her first prenatal visit, and be sure to mention the timeframe for each vaccine when discussing her pregnancy
- Ensure your staff deliver consistent messaging about the importance of maternal vaccines
- Normalize vaccination as part of your patients' pregnancy care

# Making a strong recommendation

#### Vaccination Uptake by Provider Recommendation and Offer



#### A Strong Recommendation Makes a Difference

- Providers should talk to pregnant patients about the importance of on-time vaccination
  - Pregnant patients need to be vaccinated to protect them and their babies
  - Pregnant patients may not be aware of the recommendations
  - Healthcare providers are patients most trusted sources of health information during their pregnancies.



#### **Strong Vaccine Recommendation**

- CDC's research indicates that some pregnant women do not feel their healthcare providers strongly recommend vaccines
- Providers should state clearly that they would like her to get vaccinated

"Today, I strongly recommend two vaccines to help protect you and your baby against the flu and whooping cough."

#### **HCPs** can **SHARE** information with patients

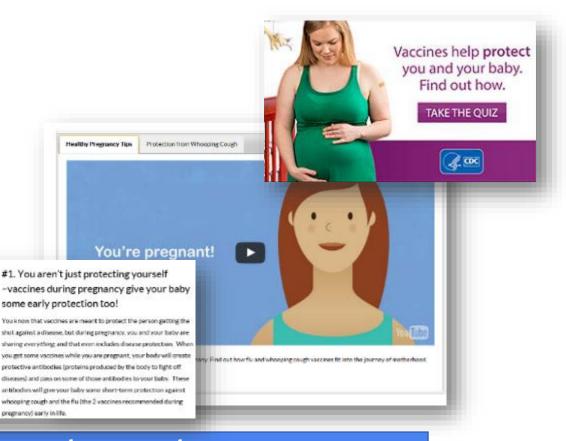
- SHARE tailored reasons why the recommended vaccine is right for the patient
- HIGHLIGHT positive experiences with vaccines to reinforce the benefits and strengthen confidence in vaccination
- ADDRESS patient questions and any concerns about the vaccines
- REMIND patients about the protection vaccines can help provide from serious diseases
- **EXPLAIN** the potential costs of getting the disease

## **Resources and Tools**

#### **Digital Resources**

- Website
- Quiz
- Motion graphic
- Listicle
- Digital Toolkit





www.cdc.gov/vaccines/pregnancy

#### **Print Resources**

#### Making a strong vaccine referral to pregnant women





Students of the product of the students of the

property and instant a many series

THE PERSON NAMED IN COLUMN

The region of the County of th

Michies Easthern Record mon A COMMENT OF HIS TOUR COMPANIES. the post-record logic, at an inte

• It dis become a protection of the model of the state of The set and an edition of the being the or a service of the constraint of the con-

WHEN THE RESIDENCE

Making the Referral

at and some officer was a second that he administration on which is made. to be solved a surface from a softent matteritie.
Their regions are stronger and a constitution are so parts on the a solved decrease polymer and that report to the programme of productions.

tookin lake carbo or olare carbon record the an obligar man and fail a rating vacuum is according to a contract the according to a failer and the contract to the contr

#### Maternal Vaccination

eres for band throw probations in

Vaccines help keep your pregnant patients and their growing families healthy.

Cast Discussed Decreamings (2015)

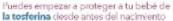
Vector	Before	Dering	Affect programmy	Transit
ofises-	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	to simply seen	B	morney
18p	Myle represented. Included and strongers programmers position	technological and	to, emolitely colpeten. / Tilgs 1 opt moted in Military Colorer (contract-follographer)	Total mineral
#1	May be recovered as	deplementation.	angle-recorded	1 met
dayarri-4	Mytemoralistical	by necessari	Mylennesses	land balant
Insulat	May be incompressed.	Agranamati	Aglantesia	Section
Margard.	May be recognished	http://doi.org/10.100/sc. ton:00.nooling.cite.bior.bio- syndis.economication	dylomeradic	-
Philosoph	May be recommended	Andrews of the banks of the ban	dyleromenai	menus
100	Autonomical Bright-year Figs		Meta-sunmedia (North April France)	-
-	May be recommended.		-	-
tenana	Market access and other source, average cross area for his source		Approximatel	like :

For more information, visits www.odc.gov/rescince/programcy Cut an answer to your specific question by a maring crimming old gree or calling tops CDC-INFO (222-4636)









A temperative para les regires notacionates.



DESCRIPTION OF THE PARTY OF THE

situatio briscopy transatus da babel beautiful straight community reformated

The distribution of the control of t all many principles was not come with her

Control of the Contro

You can start protecting your baby from whooping cough before birth Information for program waters Arrivate & tealer to



Weapprovide and residence of

Sensor our John to relate here are much by 2 years for

all lean regularity people for observe.

the arm is principle to parking the principles.

suggestation belongs belief by the first part to DESCRIPTION AND ADDRESS OF SECTION

the state of the states, surfacely between your

It's now the same or engaging to get the man street, you will compare be in the your balls.

singly is bare with balanching sins of package

Million you get the whoeping oxigh vaccing sharing year 2" intransitive your Lody of the boot of the potentials equinat schooping cough.

We do t well to be a refusions great which we

Why do I made logal a filtra play deligh reliable width Long programs?

The class and a single color and an extended the anguest plant and the anguest plant anguest plant

In this vaccine teles for me-and my heary?

To the compression of the compression of a com-late for the common district and the first and modern and common district about the com-OUR FOR EAR HAVE A THE AUTHORS HAVE AND ADDRESS OF THE

Early and more of specific and a support of the second of

El constituy at the second order of the effected

the accordance type to be all the place? And the principle of the state of the state

Are belies was quiting relanguage ough segmen.

And belief with a start of the first of the desired belief.

The first halds are one of the start of the star

managers, produting ingroups



tomortom from 6

www.cdc.gov/vaccines/pregnancy

#### **ACOG Resources**



- Immunization for Women website
- Patient & Provider Resources:
  - Clinical Guidance
  - FAQs
  - Recommendations
  - Safety
  - Coding and Reimbursement
  - Practice Management





#### **ACNM Resources**

- Talking Points
- Position statements
- FAQ
- Posters, coloring books
- Curriculum
- Other resources
- http://midwife.org/Immunization-Resources-for-Providers

SuperMom

 http://ourmomentoftruth.co m/your-health/importanceof-vaccines/



#### What Can YOU Do?

- GET VACCINATED
- TALK to pregnant patients about maternal vaccines
  - Tell them way it's important for them and their babies
  - Make the conversation and recommendation memorable and compelling
- ADMINISTER indicated vaccines in your office if possible and FOLLOW UP to ensure receipt
- USE and PROMOTE resources available and encourage others to do the same
  - Include maternal vaccine resources in prenatal information packets
  - Promote resources and products through social media channels
- EDUCATE your staff about maternal vaccines
  - Identify or serve as a Vaccine Champion in your practice
- ENCOURAGE pregnant women to ask questions
- TELL US what else you need to help you communicate about vaccines

www.cdc.gov/vaccines/pregnancy

#### **Contact Information**

**ACOG** 

**ACNM** 

Debra Hawks, MPH dhawks@acog.org

Sarah Carroll, MPH scarroll@acog.org

Sarah Wright, MPH <a href="mailto:Swright@acog.org">Swright@acog.org</a>

Lindsey Regallis lregallis@acog.org Elaine Germano, CNM, DrPH, FACNM eagermano@acnm.org

Carol Hayes, CNM, MN, MPH carolhayescnm@gmail.com

#### **Questions?**

For more information, contact CDC 1-800-CDC-INFO (232-4636)

TTY: 1-888-232-6348 <u>www.cdc.gov</u>



The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Photographs and images included in this presentation are licensed solely for CDC/NCIRD online and presentation use. No rights are implied or extended for use in printing or any use by other CDC CIOs or any external audiences.



## **Extra Slides**

#### Spontaneous abortion (SAB) and influenza vaccine

- Background rates of SAB range from 10-22%
- Miscarriages following (not attributed to) influenza vaccine are expected
- Limited data on first trimester influenza vaccine exposure
  - In a 2015 systematic review, 7 studies evaluating SAB found no risk
- Observational studies have limitations
  - Cannot prove flu vaccine was cause of miscarriage
- Original VSD study evaluating 2005-2007 seasons found no risk
  - Follow up study results expected 2019

#### How to talk to patients about SAB

- Health care decisions should be an ongoing discussion between provider and patient
- Providers should use clinical judgement, based on factors including the patient's health status, local influenza activity, and then benefits versus potential risks from flu vaccination when deciding whether and/or when to immunize their patient against influenza