Best Practi	ices to	Improve
Maternal	Immu	nization





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Windows



Processor: SSOMHz 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 Friefox 1.5
Adobe Fash Pipers (lor 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)
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Adobe Flash Player 8 (or higher)

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

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Learn	ing O	bjectives
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- Emphasize the importance of maternal immunizations
- Update on current recommendations for maternal immunization and the future of maternal immunization
- Discuss practical tips to incorporate immunizations into your practice
- Identify and locate resources for providers and patients regarding immunizations

patients regarding	
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- Maternal vaccination saves lives!
- Routine adult vaccine recommendations are based on recommendations from the <u>Advisory Committee on Immunization Practices (ACIP)</u>
- Visit ACOG's http://immunizationforwomen.org/ for Adult, Maternal, and Childhood/Adolescent Immunization Schedules

Advancing Maternal Vaccination

- Maternal vaccination is an important strategy to protect against diseases that disproportionately threaten newborns and young infants, as well as the mother
 - Tetanus
 - Influenza
 - Partuccic
- \bullet New vaccines are in development for administration during pregnancy to protect mothers and infants
 - Group B Streptococcus (GBS)
 - Respiratory Syncytial Virus (RSV)

Benefits of Vaccinating Mothers During Pregnancy Maternal vaccination enhances immunity for both mother and baby Maternal antibodies will protect the mother from infection Maternal antibodies will cross the placenta and also protect newborns and young infants Transplacental antibodies provide protection during a vulnerable period before a baby's immune system matures and can adequately respond to a vaccine Breast milk antibodies could also contribute to infant protection	
Recommended Vaccines in Pregnancy: Influenza	
Influenza and Pregnancy • 1918: Mortality associated with infection during latter part of pregnancy ~50-61% (pneumonia) • 1957: 50% of women of childbearing age who died of influenza were pregnant; 10% of all influenza deaths that season were in pregnant women (most in latter half of pregnancy) • Since 2005 – H5N1: • Six affected pregnant women, 4 did not survive, 2 survivors had spontaneous abortions • Post-mortem studies suggest possible mother to fetus transmission via placenta • Interpandemic case reports of complications since 1950's – mostly healthy women in later stages of pregnancy	
Harris, JAM 3195;14:978 / 2. Freeman and Barno, Am J Ob Gyn 1959;78:1172 / 3. Abdel Ghafer et al., NEJM 2000;358: 261 / 4. Gu et al., Lancet 2007;370:1137 / 5. Ng and To, Lancet 2007;370:1106 / 6. Result et al all for Gu in N.Am 2000;15:123	

2009 Influenza A H1N1 and Pregnancy

- Pregnant women were at high risk to be hospitalized, admitted to the ICU
 (4x), require mechanical ventilation, and die* from influenza, particularly
 if in 2nd-3rd trimester of gestation or with underlying conditions (asthma)
- 5% of all reported 2009 H1N1 influenza deaths in the U.S. were pregnant women, while only approximately 1% of the population was estimated to be pregnant
- The median age of mothers who died: 25 years (14-43 years old)
- Severe illness in the postpartum period and increased rate of premature birth (30.2%) also documented
- Delayed diagnosis and treatment increased risk of death

Louie, JK, et al. NEJM 2010, 362:27-35; Newsome K, et al. MMWR, 2011;60(35):1193-96
*All cause maternal mortality California 19.3/100,000; USA 13.3/100,000 – most related to obstetrical factors influenza associated mortality 4.3/100,000

Newborn/Infant Benefits of Maternal Influenza Vaccination

- Decreased risk of acquiring influenza in the first 6 months of life (up to 70%, various prospective and obstetric studies)
- Decreased risk of influenza related hospitalizations in the first 6 months of life (up to 60%)
- Improved pregnancy outcomes also reported, including decrease in preterm birth (OR 0.87) and low birth weight (OR 0.88) (variable effect on SGA)

Steinhoff, Antenatal Influenza Immunization Am J Obstet Gynecol 2012

Influenza Vaccination Recommendations: Pregnant Women

ACOG Committee Opinion 608

- Influenza vaccination is an essential part of prenatal and prepregnancy care
 - Pregnant women have increased morbidity and mortality from influenza
 - Neonates also have increased morbidity and mortality from influenza and cannot be vaccinated until 6 months
 - Keeping mom healthy during pregnancy protects fetus from early delivery

Influenza Vaccination Durin	g Pregnancy
Influenza Vaccination Durin	g Pregnancy
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Influenza Vaccination Recommendations: Pregnant Women

Influenza vaccination is recommended for all pregnant women regardless of trimester

- Pregnant women should receive the inactivated vaccine and NOT the nasal spray, which is a live vaccine
- Pregnant women can receive the trivalent or the quadrivalent vaccine
- The Flu shot is OK to get while breastfeeding
- The Flu shot has been shown to protect both the mother and her baby (up to 6 months old) from flu

Influenza Vaccination Recommendations: Pregnant Women

Children younger than 6 months old $\underline{\text{cannot}}$ receive the flu vaccine – protecting mom helps protect baby:

- Maternal antibodies cross the placenta and protect newborns
- Vulnerable newborns/young infants are protected by vaccinating family members and caretakers
- Everyone (e.g. siblings, grandparents and babysitters) who will be around the baby should be vaccinated, ideally, before the baby is born
- Encourage extended family members and friends to get vaccinated
- Ensure anyone holding the baby washes their hands first

Inactivated Influenza Vaccine: Effectiveness in Mother and Child

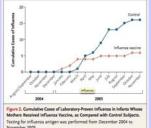
Infants

- Maternal influenza vaccine reduced proven influenza illness in infants by 65%
- 29% reduction in any respiratory illness
- 42% reduction in clinic visits

Mothers

- Maternal influenza vaccine reduced respiratory illness with fever by 36%
- Fewer clinic visits

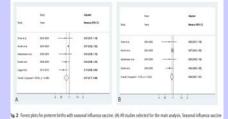
Zaman, NEJM, 200



Maternal Inactivated Influenza Vaccine: Effectiveness in Infants

Author	Site	Design	Vaccine	Control	Effect in infant*
Zaman et al, 2008 ⁴	Bangladesh, 2004-2005	Randomized controlled trial of vaccine	172	168	36% EJ 69% rapid test influenza iliness
Benowitz et al, 2010°	Connecticut, 2000-2009	Case-control	91	156	91.5% DFA or PCR influenza hospitalization
Poehling et al, 2011 ^a	Tennessee, Ohio, New York, 2002-2009	Case-control	151	1359	45-48% viral culture or PCR in influenza hospitalization
Eick et al, 2011 ⁷	Apache, Navajo, 2002-2005	Observational prospective cohort	573	587	41% serologically defined influenza episode

Effect of Maternal Influenza Vaccination on Preterm Birth

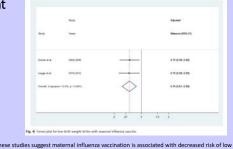


ompacon with or without A(H I H) pomors strain; (a) only suppes, including seasonal emuental section on concaring the A(H I H) pomors strain.

Studies of maternal influenza vaccination generally demonstrate either no association or modest decreased risks preterm birth, especially during the 2009/2010 pandemic season.

Nunes MC, Madhi S. Human Vaccines and Immunotherapeutics, 2015; 11: 2538-25

Effect of Maternal Influenza Vaccination on Low Birth Weight

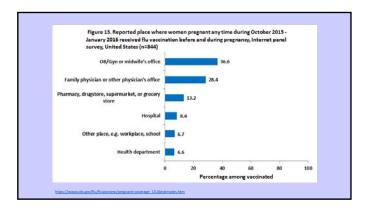


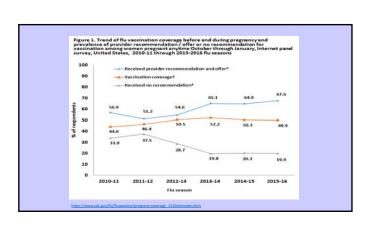
hese studies suggest maternal influenza vaccination is associated with decreased risk of low birthweight.

The Ob-Gyn's Role

- Studies continue to show a provider recommendation is the most influential factor in a patient's decision to receive an immunization
- Ob-Gyns have a long-standing role of providing primary and preventive care to women and are a major source of ambulatory care for women, accounting for 44% of preventive care visits for women over age 18
- Pregnant women see their ob-gyn regularly throughout the course of their prenatal and postpartum care allowing for multiple opportunities to vaccinate

<u>http://www.cds.gov/mmwr/preview/mmwr/html/mm633733.htm?s.cid=mm633733.etflig</u>
Stormo AR, Saraiya M, Hing E, Henderson IT, Sawaya GF. Women's Clinical Preventive Services in the United States: Who is Doing What?. JAMA Intern Med. Published online July 07, 2014. doi:10.1001/jamainternmed.2014.3003.





time during October 2015 - January (n=844), Internet panel survey, Uni					or during	pregnancy	
To protect my baby from flu				38.7			
To protect myself from flu			26.2				
My doctor, nurse, or other medical professional recommended the flu vaccination to me		14.4					
To protect my friends or family from flu	7.0						
It was easy/convenient to get the flu vaccination	5.8						
To avoid missing work or because I had to for work	5.0						
Because the flu might be bad this season	2.8						
	0	20	3552	so tage amor	60 ng vaccinate	80 d	10

Health Care Personnel: Be the Example

- Make sure all staff members are vaccinated
 - 79% coverage rate for Health Care Personnel for 2015-16 season
 - Coverage was highest among Health Care Personnel working in settings with flu vaccination requirements 96.5%
- Make sure you and your family are vaccinated
- Educate entire staff

Safety of influenza vaccine

How is it monitored?

- Vaccine Adverse Event Report System (VAERS) is a national program, jointly managed by CDC and FDA, which monitors the safety of all vaccines licensed in the United States. Anyone can file a VAERS report.
- Vaccine Safety Datalink (VSD) is a vaccine safety system used to both monitor and assess adverse events following vaccination
- Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) study

Influenza Vaccine Safety in Recent Studies	
Observational studies:	
VAERS ~ 2 million pregnant women vaccinated 2000-03 ¹	
VAERS ~11.8 million vaccinated from 1990 to 2009 ² VAESS VALUE — 1 2000 40 ² VAESS VALUE — 2000 40 ² VAESS VALU	
VAERS H1N1 vaccinations 2009-10 ²	
ALL: No increased risk of adverse events or pregnancy	
outcomes vs. background rates	
	-
Pool V and islander J. Am J Obstet Gynecol 2006;194:1200; 2. Moro et al. Am J Obstet Gynecol 2010; 203:1.e1-e7 3. Moro et al. Am J Obstet Gynecol 2011; 205-43e1-7	
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Vaccination is Safer than Influenza During Pregnancy	
Norwegian National Registries study	
• 113,331 pregnancies in 2009-2010	
• 54% of women were vaccinated (2 nd -3 rd trimester Pandemrix ASO3)	
 492 Fetal deaths – 4.3 per 1000 births (outside pandemic 4.1) Vaccination during pregnancy substantially reduced (70%) the risk of an 	
influenza diagnosis in pregnant women (Adjusted hazard ratio 0.30; 95% CI, 0.25-0.34)	
 Among pregnant women with influenza, the risk of fetal death was increased (Adjusted hazard ratio, 1.91; 95% CI 1.07-3.41) 	
 The risk of fetal death was reduced with vaccination during pregnancy (not significant: Adjusted hazard ratio, 0.88; 95% CI 0.66-1.17) 	
 Among live births: no association with preterm delivery, low birth weight, low Apgar 	
Haberg et al NEJM (2013)	
	1
	-
Recommended Vaccines in Pregnancy:	
Tetanus/Pertussis	

What is Tdap?

Tetanus, Diphtheria, and Pertussis

There are four combination vaccines used:

DTaP Tdap DT, Td

- DTaP and DT are given to children younger than 7 years of age
- Tdap and Td are given to older children and adults
 - Upper-case letters in abbreviations = pediatric strength doses of Diphtheria (D), Tetanus (T) toxoids and Pertussis (P) vaccine
 - Lower-case letters in abbreviations = adult strength doses of Diphtheria (d) and Pertussis (p) used in the adolescent/adult-formulations

For Maternal Immunization use Tdap

Pertussis (aka whooping cough)

- Causative organism:
 - Bordetella pertussis, a gram-negative bacterium
 - Uniquely human pathogen
- Incubation 7-10 days, catarrhal stage followed by paroxysm of coughing that can continue for 4-6 weeks
- Clinical case definition: Cough illness lasting at least 2 weeks with one of the following: paroxysms of coughing, inspiratory "whoop," or post-tussive vomiting, apnea, without other apparent cause (as reported by a health professional)
- Can lead to: rib fractures, weight loss, pneumonia, seizures, brain damage, incontinence and death

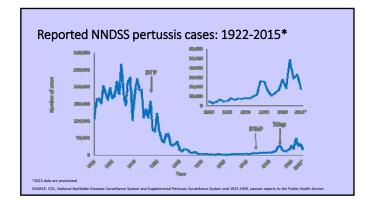
Burden of Disease: Pertussis

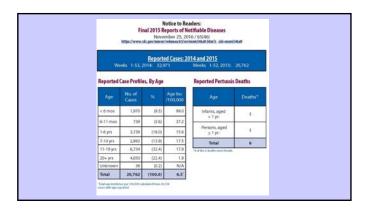
- One of the leading causes of vaccine preventable deaths world-wide
- Up to 2 in 100 adolescents and 5 in 100 adults are hospitalized or have complications such as pneumonia or death
- Pertussis remains a serious infection in young infants. Most deaths occur in the first 3 months of life, before the infant can be protected by their own vaccine series

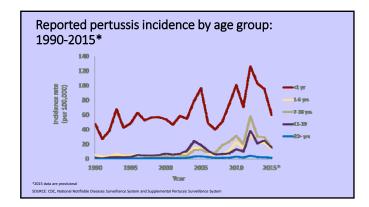
Newborn/Infant Benefits of Maternal Tdap Vaccination

- Significant impact on maternal-neonatal tetanus
- Decreased risk of acquiring neonatal pertussis (protection up to 90% reported in UK)
- Efficacy in decreasing severity of pertussis
- Efficacy in decreasing pertussis associated hospitalization and deaths

Amirthalingam G et al. The Lancet, 2014 Baxter R et al. Pediatrics 2017:e20164091







Continuing Epidemic: Increased Pertussis Cases

- During 2012, 48,277 cases of pertussis (most since 1955). The majority of deaths: infants younger than 3 months of age
- In 2012, 49 states and Washington, D.C. reported increases in disease compared with the same time period in 2011



As shown in prior slide, pertussis declined during 2013 with 28,639 reported cases. (Though 13 states and Washington, D.C. did report an increase in pertussis cases compared with 2012)

Tdap Vaccination Recommendations During Pregnancy

ACOG Committee Opinion 566

 A dose of Tdap vaccine should be given to all pregnant women preferably between 27-36 weeks gestation during every pregnancy.

The American College of Observations and Connectingues American American	
COMMIT	TEE OPINION
Number 196 • June 2013 September 2015	Physics No. 571, March 2012
Constitue or Statetic Practice	
	alvance of City has insert each subject to days. The information deads attack or placebox is the follows:
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Mother-Fetus Antibody Response, Every Pregnancy, **Every Infant**

- Transplacental transfer of antibodies from mother to infant provides some protection against pertussis in early life
- Immune response to vaccine peaks about 2 weeks after administration,

Tdap vaccine is recommended preferably between 27 and 36 weeks gestation, to optimize antibody transfer and protection at birth

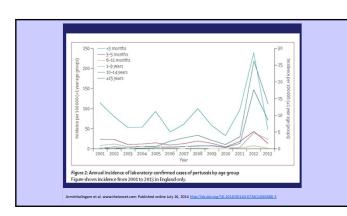
• The level of pertussis antibodies decreases over time, hence:

Tdap vaccine should be administered during every pregnancy so that each infant receives high levels of protective antibodies

Immunizing Pregnant Women DOES Protect Infants

- Pertussis outbreak in England in 2011-2012, with deaths in newborns less than three months
- Program initiated to immunize all pregnant women at 28-37 weeks of gestation
- \bullet 92% effective in preventing infant pertussis if mother received the vaccine at least seven days before birth
- No safety issues for the 23,000 infants whose mothers received Tdap in

Donegan et al. BMJ 2014;349:g4219 doi: 10.1136/bmj.g4219 (Published 11 July 2014)



Tdap Vaccine Safety Data	
New Study Finds Tdap Vaccine During Pregnancy Not Associated With Increased Risk of Preterm Delivery or Small Birth Size	
Safety of Tdap vaccine during pregnancy Applying a design texture and electronic health record data from two	
 Analyzed administrative and electronic health record data from two California <u>Vaccine Safety Datalink</u> sites to assess risk of maternal Tdap vaccination during pregnancy for mother or baby 	
 The study found that Tdap vaccination during pregnancy was not associated with increased risk for hypertensive disorders of pregnancy, preterm birth, or having a baby who is small for his or her gestational age. 	
Sharbanda EO, Vazquez-Benitez G, Lipkind KS, et al. Evaluation of the Association of Maternal Perturals Vaccination With Obstetric Events and Birth Outcomes. JAMA. 2014;31(18):1897-1994. doi:10.1001/jama.2014;14855. http://www.samunetwok.com/price-association-association-190812	
Maternal pertussis vaccination safety data collected in the United States continue to be reassuring	
Pattern of adverse events observed in VAERS in pregnant women receiving	
Tdap and their infants is consistent with expectations • Studies of >50,000 women receiving Tdap during pregnancy in the VSD show no increased risk for adverse maternal or infant health outcomes*	
 Clinical study in the CISA Project shows Tdap was well tolerated in both pregnant and non-pregnant women, including pregnant women receiving 	
a repeated Tdap dose	
*Garbands EO et al. JAMA. 2014;312/18;1897-904; Sulumaran I., et al. JAMA. 2015 314(15):1583-7; Sulumaran I., et al. Ob6/m. 2015;126(5): 1069-1074;	
Rharhands 10 et al. Vaccine 2016; 34: 969-73. Courtery of the CDC Immunization Safety Office	
Tdap Vaccine Safety Monitoring: We are looking	
Vaccine Adverse Event Report System (VAERS) National program	
 Jointly managed by CDC and FDA Monitors the safety of all vaccines licensed in the United States. 	

Vaccine Safety Datalink (VSD)

Vaccine safety system
 Monitors and assesses adverse events following vaccination

Effectiveness of maternal	Tdap on	pertussis	severity
in infants			

Infants born to vaccinated mothers

- Older when developed pertussis
 - Median: 45 days vs. 35 days; p=0.03
- Less likely have classic pertussis symptoms
- Significantly lower risk of hospitalization and ICU admission
 - Hospitalization: RR 0.5; p<0.001
 - ICU: RR 0.8; p=0.012
- No deaths due to pertussis

Winter K, et al. Effectiveness of prenatal Tdap vaccination on pertussis severity in infants. Clin Infect Dis. 2016 Sep 13. [Epub ahead of print

The Ob-Gyn's Role

Studies show the provider recommendation is the $\underline{\text{MOST}}$ influential factor in a patient's decision to receive an immunization.

- Ob-Gyns:
 - long-standing role of providing primary and preventive care to women
 - major source of ambulatory care for women
 - account for 44% of preventive care visits for women over age 18 years
- Pregnant women see their ob-gyn regularly throughout the course of their prenatal and postpartum care allowing for multiple opportunities to vaccinate

http://www.cdc.gov/immur/proview/mmwrhtml/mm6337a3.htm?s.cde/mm6337a3.effig Stormo AR, Saraiya NI, Hing E, Henderson T, Sawaya GF, Women's Clinical Preventive Services in the United States: Who is Doing What?. JAMAA Intern Med. Published online July 07, 2014. doi:10.1011/jamainermed 2014.3033.

Cocooning (protecting infants by vaccinating those in close contact with them)

- 2005 ACIP recommendation: cocooning with Tdap vaccine for all those with expected close contact with infants younger than 1 year of age
- Cocooning + maternal Tdap vaccination + childhood DTaP series on schedule best protection to the infant
- Providers should educate pregnant women about encouraging others (dads, grandparents and other caregivers) to be up-to-date with pertussis vaccination
- Family members & caregivers who aren't current with Tdap vaccine: get vaccinated at least two weeks before coming into contact with the infant

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Tips f	or	Incorporati	ing I	lmmuni	zati	ions l	Into
Ob-G	iyn	Practice					

- Offer an **educational seminar** on value of vaccines to cultural case workers and clinic staff
- Every August/September Dr. Eckert gives an in-service to nursing and clinic staff over lunch highlighting the importance of flu vaccines
- Identify a "vaccine champion" in your office
- Staff have to "opt out" of flu vaccine and Tdap vaccine. Those who opt out have to watch an educational video and sign a paper
- Using standing orders for flu vaccine

Tips for Incorporating Immunizations Into Ob-Gyn Practice

- Post a sign on the front desk when people check in that reads: "Flu vaccine available and strongly recommended"
- Educate patients
- Hanging **signs in bathroom**: "Help prevent your baby from getting the flu or whooping cough"
- Send out EHR reminder through patient portal such as MyChart, early October to all users reminding the patient to receive their flu vaccine.
 - Link this reminder to your flu clinics webpage

Questions?

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