



EPIC® Immunization Update
Education for Women's Health Care Providers

Making a Strong Recommendation for Vaccines in your Practice

Clinical, Operational, & Financial Issues

March 2021

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Acknowledgements

EPIC® is presented by:

Georgia OB/Gyn Society

Georgia Chapter – American Academy of Pediatrics

Ga. Dept. of Public Health/Immunization Program

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Faculty Disclosure Information

- In accordance with ACCME* and ANCC-COA* Standards, all faculty members are required to disclose to the program audience any real or apparent conflict of interest to the content of their presentation.
- This presentation will include the most current ACIP recommendations for frequently used vaccines but is not a comprehensive review of all available vaccines.
- Some ACIP recommendations for the use of vaccines have not currently been approved by the FDA.
- Detailed information regarding all ACIP Recommendations is available at www.cdc.gov/vaccines/acip/recs/index.html

*Accreditation Council for Continuing Medical Education
*American Nurses Credentialing Center Commission on Accreditation

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Objectives

At the end of this presentation, attendees will be able to:

- Discuss three reasons why it is important to provide vaccines at OB/Gyn practices
- Interpret the Adult Immunization Schedule
- Make a strong recommendation for vaccines in pregnant women
- Summarize the most recent CDC recommendations for storage and handling of vaccines
- State a plan to incorporate vaccines into the workflow of the practice
- Assess an immunization financial analysis

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Why is it important for an OB/GYN practice to provide vaccines?

- ACOG recommends assessments of immunization status as part of the routine screening recommendations*
- Your practice may be the **only** source of health care for many of your patients
- You have an opportunity to decrease the likelihood of influenza during pregnancy (**Influenza vaccine**)
- You can protect pregnant women and newborns against pertussis (**Tdap vaccine**)
- You can offer a vaccine to prevent infection with 9 types of HPV for women and men through 45 years of age (**HPV vaccine**)**
- You can protect women at risk for hepatitis B infection (**Hepatitis B vaccine**)

*ACOG Committee Opinion 558 April 2013 **https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf

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Advisory Committee on Immunization Practices (ACIP)

- 15 voting members with expertise in one or more of the following:
 - Vaccinology
 - Immunology
 - Infectious diseases
 - Pediatrics
 - Internal Medicine
 - Preventive medicine
 - Public health
 - Consumer perspectives and/or social and community aspects of immunization programs
- ACIP develops recommendations and schedules for the use of licensed vaccines



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2021 Recommended Immunization Schedule for Adults Aged ≥19 Years*

- Recommended adult schedule by age group
- Recommended immunization schedule for adults aged 19 years or older by medical condition and other indications

Changes

- Clarification of the charts
- Additional information in the Notes section

READ THE FOOTNOTES TO ACCESS SPECIFIC VACCINE ADMINISTRATION DETAILS!

*<https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>

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Influenza

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Influenza*

- Influenza affects about 10-20% of the population every year (spreads easily).
- Responsible for significant illness, hospitalizations and deaths every year.
- In the United States, the influenza season typically occurs from October through May with peak activity occurring December to March.

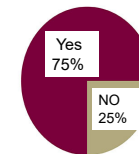


*ACOG Committee Opinion number 608: Influenza Vaccination During Pregnancy, September 2014
*ACOG Committee Opinion number 558: Integrating Immunizations into Practice, April 2013

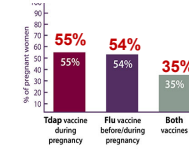
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Vaccines often offered, but many pregnant women and babies left unprotected

Women who report provider offer or referral for flu and Tdap vaccine



Flu and Tdap vaccination coverage for pregnant women



SOURCE: CDC Internet Panel Survey 2019

VitalSigns™



<https://www.cdc.gov/media/releases/2019/p1008-vaccination-moms-babies-unprotected.html>

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Influenza*

- Influenza begins with the abrupt onset of fever, headache, myalgia, and malaise accompanied by non-productive cough, sore throat, and nasal discharge.
- Pregnant women disproportionately experience severe sequelae including pneumonia, cardiopulmonary complications, preterm birth and death.
- This risk increases with each trimester.
- ACIP recommends that all persons 6 months and older, including pregnant women, receive the influenza vaccine starting in the fall of each year.
- Only about 54% of pregnant women receive the influenza vaccine.**



*ACOG Committee Opinion 558 April 2013

**<https://www.cdc.gov/media/releases/2019/p1008-vaccination-moms-babies-unprotected.html>

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Reasons why pregnant women do not receive influenza vaccine*

- Lack of knowledge about seriousness of influenza
- Never have received influenza vaccine in the past
- Safety concerns about the vaccine
- Fear of needles
- Lack of insurance or access to care
- General mistrust of medical profession
- **Medical provider did not recommend influenza vaccine**

*American Journal of Obstetrics & Gynecology – Supplement 2012

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Effects of Influenza Vaccination during Pregnancy*

- Reduces influenza related complications in pregnant women and their infants
- Vaccinating the mother protects newborns against influenza. This is the only way of providing antibody to the newborn.
- No evidence of teratogenicity
- No evidence of harm to pregnant women or their infants even with vaccines containing thimerosal



* ACOG Committee Opinion number 558: Integrating Immunizations into Practice. April 2013.

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Frequently Asked Questions About Influenza Vaccine During Pregnancy*

Why should pregnant women get a flu shot?

Changes in the immune system, heart, and lungs during pregnancy make pregnant women more prone to severe illness from flu and raises the risk for complications.

Is it safe for pregnant women and their unborn babies to get a flu shot?

YES

What side effects have pregnant women experienced from flu shots?

The most common side effects are the same as other vaccine recipients (soreness, redness, swelling at injection site), fainting, headache, fever, muscle aches, nausea, fatigue.

Can pregnant women with egg allergies get vaccinated?*

YES

*https://www.immunize.org/askexperts/experts_inf.asp

**MMWR Recommendations and Reports / Vol. 67 / No. 3 August 24, 2018

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More Frequently Asked Questions About Influenza Vaccine During Pregnancy*

How is the safety of influenza vaccination of pregnant women monitored?

The CDC and FDA conduct ongoing safety monitoring of all vaccines licensed for use in the United States using two monitoring systems:

- The Vaccine Adverse Event Reporting System (**VAERS**) monitors reported problems following vaccination.
- Vaccine Safety Data Link (**VSD**) is a collaboration between CDC and nine healthcare organizations that allows ongoing monitoring and proactive searches of vaccine related data.

The Vaccine and Medications in Pregnancy System (VAMPSS):

This is a national surveillance system designed to monitor the use and safety of vaccines and asthma medications during pregnancy, and uses two data collection approaches to get information about how vaccines and medications might affect your baby.

*https://www.cdc.gov/flu/highrisk/qa_vacpregnant.html

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FDA Recommended Influenza Antigens for 2020-2021 Season in the U.S.*

Trivalent Vaccines (IIV3):

A /Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like virus
A/Hong Kong/2671/2019 (H3N2)-like virus
B/Washington/02/2019 (Victoria lineage)-like virus

Cell-cultured and Recombinant vaccines contain
A/Hawaii/70/2019 (H1N1)pdm09-like virus

Quadrivalent Vaccines

(IIV4 & LAIV4) also include: B/Phuket/3073/2013-like virus

ACIP recommends annual influenza vaccine for all persons 6 months of age and older who do not have contraindications.

*https://www.cdc.gov/mmwr/volumes/69/rr/rr6908a1.htm?ts_cid=rr6908a1_w

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Influenza Vaccines for 2020-2021 Season*

≥ 6 months	≥ 4 years	≥ 18 years	≥ 65 years
Fluzone (IIV4)* 0.5 ml (≥ 6 mos.)	Flucelvax** (ccIIV4) 0.5 ml	FluBlok*** (RIV4) 0.5 ml	Fluzone High-Dose* (HD-IIV4) 0.7 ml
Afluria (IIV4) * 0.25 ml (≥ 6 thru 35 mos.) 0.5 ml (≥ 3 years)			Fluad (aIIV3)* 0.5 ml
FluLaval (IIV4) * 0.5 ml dose (≥ 6 mos.)			
Fluarix (IIV4) * 0.5 ml. dose (≥ 6 mos.)			

Egg allergy is no longer a contraindication to receiving flu vaccine

* Egg-based
** Cell-cultured
*** Recombinant

*<https://www.cdc.gov/flu/professionals/acip/2020-2021/acip-table.htm>

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Live, Attenuated Influenza Vaccine (LAIV4)*

FluMist® MedImmune (Nasal Spray)

Licensed for healthy persons 2 through 49 years of age but not to be given to pregnant women

LAIV4 MAY be used in the 2020-2021 season.

Contraindications to LAIV:

- Children 2-4 yrs. of age with a diagnosis of asthma
- Persons receiving aspirin-containing medications
- Persons who are immunocompromised, by medication or disease, have a CSF leak or cochlear implant, or asplenia
- Close contacts and caregivers of severely immunosuppressed persons
- Persons who have received influenza antiviral medications within the previous 48 hrs.

*MMWR Recommendations & Reports/Vol. 67/No. 3 August 24, 2018

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Making a strong recommendation

- Making a Strong Flu Vaccine Recommendation (SHARE)
- **S- SHARE**
- **H- HIGHLIGHT**
- **A- ADDRESS**
- **R- REMIND**
- **E- EXPLAIN**



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S- Share

- **S- SHARE the reasons** why the influenza vaccine is right for the patient given his or her age, health status, lifestyle, occupation, or other risk factors.
- “This vaccine can protect you and your family from getting sick from flu. By getting the shot today, you’ll be protecting yourself and the people around you who are more vulnerable to serious flu illness, like your children and parents.”

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H- Highlight

- **H - HIGHLIGHT positive experiences** with influenza vaccines (personal or in your practice), as appropriate, to reinforce the benefits and strengthen confidence in flu vaccination.
- Tell your patients that CDC and **you** recommend they get the influenza vaccine each year.

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A- Address

- **A - ADDRESS** patient questions and any concerns about the influenza vaccine, including side effects, safety, and vaccine effectiveness in plain and understandable language.
- “A flu shot cannot cause flu illness. Flu shots are made either with flu vaccine viruses that have been ‘inactivated’, making them not infectious or with no flu vaccine viruses at all. The most common side effects of an influenza vaccine are mild, like redness, swelling, or pain in your arm where the shot was given. This should go away within a few days.”

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R-Remind

- **R - REMIND** patients that influenza vaccines protect them and their loved **ones** from serious flu illness and flu-related complications.
- “Flu activity is going to start to pick up, and CDC says to expect more cases in the coming months. That is why I want to make sure I help protect you and your loved ones.”

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E- Explain

- **E - EXPLAIN** the potential costs of getting the flu, including serious health effects, time lost (such as missing work or family obligations), and financial costs.
- “It’s important to get vaccinated this season because flu vaccination can reduce potential flu illnesses, doctor visits, and missed work and school due to flu.”

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Tetanus, Diphtheria and Acellular Pertussis

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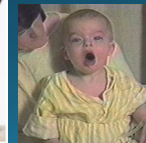
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Diphtheria



Tetanus

Pertussis
Whooping Cough

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Tdap Vaccines

- **Boostrix**® 10 years and older
- **ADACEL**® 10 through 64 years

Tdap may be used for decennial booster or
for wound prophylaxis

Both safe for pregnant women

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Tdap for Pregnant Women*

ACIP recommends:

One dose of Tdap during each pregnancy, regardless of a prior history of receiving Tdap.

Optimal timing:

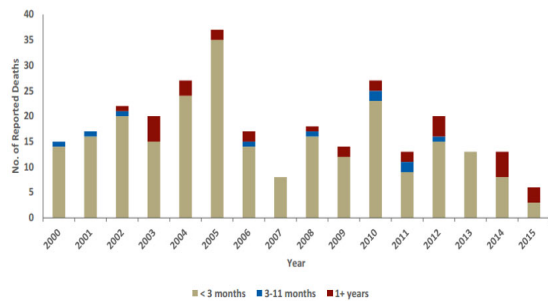
- Between 27 and 36 weeks gestation.
- Vaccinating earlier in the 27 through 36 week window will maximize passive antibody transfer to the infant.
- This has been shown to be 80%-91% effective.
- If Tdap is not given during pregnancy, administer Tdap immediately postpartum.

*MMWR, January 24, 2020/ Vol.69/No. 3

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Pertussis deaths by age group, 2000-2015*

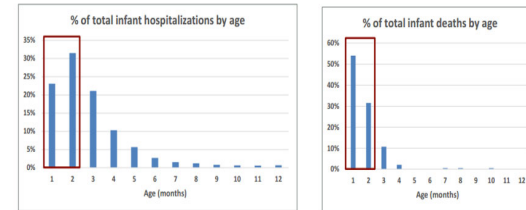


*2015 data are provisional

SOURCE: CDC, National Notifiable Diseases Surveillance System, 2015

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Hospitalizations and deaths in infants <12 months of age, % of total pertussis cases, 2004-2015*



*2015 data are provisional

SOURCE: CDC, National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System

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Making the Referral for Tdap

- Begin each referral with a vaccine recommendation that includes information on why the vaccine is beneficial and safe for mother and baby.
 - Tailor your message with scientific data or personal anecdotes
 - Convey the vaccine's importance to individual patients.
- Always write a patient-specific prescription. This will help your patients obtain the vaccine at another location where a prescription may be required.
- Anticipate questions on why patients cannot get vaccinated in your office.
- Plan to answer questions from other immunization providers who are concerned with vaccinating your pregnant patients. <https://www.cdc.gov/pertussis/downloads/fs-hcp-tdap-vaccine-referral.pdf>

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Vaccines in Pregnancy

- CDC and ACOG recommend that pregnant women are vaccinated against flu and pertussis in **each** pregnancy
- If you do not stock them
 - Provide information on where patients can get the vaccine(s) you recommend.
 - Re-emphasize the fact that just because you do not stock a specific vaccine in your office does not mean it is not important, is less important than other vaccines you do stock, or that you have concerns about its safety.
- For help locating vaccines in your area, the HealthMap Vaccine Finder is available at: <http://vaccine.healthmap.org>

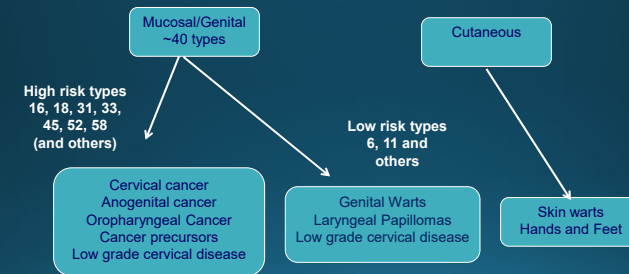
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Human Papillomavirus (HPV)

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Types of Human Papilloma Virus (HPV)*

(More Than 200 Types Identified)



*Epidemiology and Prevention of Vaccine Preventable Diseases 13th Edition, 2015

*Red Book – AAP 2018 Report of the Committee on Infectious Diseases

*MMWR, August 29, 2014, RR Vol. 63, No. 5

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HPV Vaccine*

Gardasil 9® (9vHPV) HPV types 6, 11, 16, 18, 31, 33, 45, 52, 58

ACIP recommends HPV vaccine starting at age 11 or 12 years for:

- All males and females through 26 years of age
- Catch-up vaccination for persons through age 26 who are not adequately vaccinated

Gardasil 9 is now also licensed for all persons 9 through 45 yrs. of age**

- Use the 3-dose schedule for persons 15-45 years of age
- Based on shared clinical decision making, the series may be given to persons ages 27-45.

*https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf

* MMWR, August 29, 2014, RR Vol. 63, No. 5

**MMWR, August 16, 2019, Vo1 68, No. 32

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ACIP Recommendations and Schedule*

3 Dose Schedule:

HPV vaccine initiated after the 15th birthday or certain immunocompromising conditions should be vaccinated with the 3 dose schedule: 0, 1-2, 6 months

Dose 2 should be given at least 1 to 2 months after first dose (1 month minimum); Dose 3 should be given at least 6 months after the first dose (minimum of 3 months between dose 2 and 3)

*MMWR, December 16, 2016, Vol 65, No. 49

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ACOG Recommendations*

- Sexually active women and women with previous abnormal cervical cytology or genital warts can receive the HPV vaccine
- These women should be counseled that the vaccine may be less effective in women who have been exposed to HPV before vaccination than in women who were HPV naive at the time of vaccination
- Women with previous HPV infection will benefit from protection against disease caused by the HPV vaccine types with which they have not been infected

*ACOG Committee Opinion 641 September 2015
American College of Obstetricians and Gynecologists (ACOG). *Obstet Gynecol.* 2015;126:e38-43.

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Hepatitis B

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Hepatitis B Virus*

- Acute hepatitis B can lead to chronic hepatitis B or rarely to liver failure
- Chronic hepatitis B can lead to:
 - Cirrhosis
 - Hepatic decompensation
 - Hepatocellular carcinoma
 - Extra-hepatic manifestations and death
- Transmission:
 - Percutaneous or mucosal exposure to blood or body fluids of infected person including contaminated surfaces
 - Perinatal infection from HBsAg + mother to fetus

*Lok AS. Clinical manifestations and natural history of hepatitis B virus infection. Post TW (Ed), UpToDate, Waltham, MA. (Accessed on March 6, 2014.)

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Hepatitis B

Hepatitis B is an infectious liver disease caused by the hepatitis B virus (HBV) that can lead to cirrhosis, liver cancer, and premature death.

Transmission: percutaneous or mucosal exposure to infectious blood or body fluids (e.g., skin puncture, sexual contact, contaminated surfaces)

- Vertical transmission from a HBsAg-positive mother to her newborn at birth
 - Infected infants have a 90% risk of developing chronic infection if not given HepB vaccine and HBIG at birth*

ACIP Recommendations for Hepatitis B Vaccination

- Administer hepatitis B vaccine to all newborns within **24 hours** of birth; Dose 2 at 1-2 months of age and Dose 3 at 6-18 months of age
- Unvaccinated children aged <19 years
- Persons at risk for infection by sexual exposure (e.g., HBV-infected partner, seeking evaluation or treatment for a sexually transmitted infection, men who have sex with men)**
- Persons at risk for infection by percutaneous or mucosal exposure to blood**
- Current or recent injection-drug users**

*MMWR, December 23, 2005, Vol 54, #RR16,

** MMWR, December 9, 2006, Vol 55, #RR16 , **MMWR, December 22, 2011 Vol 60 , #50

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Hepatitis B Vaccine Recommendations (cont'd)*

- Household contacts of HBsAg-positive persons
- Residents and staff of facilities for developmentally disabled persons
- Health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids
- Hemodialysis patients and pre-dialysis, peritoneal dialysis, and home dialysis patients
- Persons with diabetes aged 19–59 years; persons with diabetes aged ≥60 years at the discretion of the treating clinician
- International travelers to countries with high or intermediate levels of endemic hepatitis B virus (HBV) infection
- Persons with hepatitis C virus infection or chronic liver disease
- Persons with HIV infection
- Incarcerated persons
- All other persons seeking protection from HBV infection

* MMWR, December 8, 2006, Vol 55, #RR16, MMWR, December 22, 2011 Vol 60, #50

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Procedures to Prevent Perinatal Hepatitis B Virus Transmission at Delivery*

Woman presents for delivery - HBsAg Positive

- Alert Pediatric Primary Care Provider
- Give infant single antigen Hepatitis B vaccine and HBIG within 12 hours of birth

Woman presents for delivery – HBsAg Negative during prenatal care

- If she has risk factors for Hepatitis B – Retest for HBsAg at time of delivery

Woman presents for delivery - HBsAg Unknown

- Obtain HBsAg on mother
- Alert Pediatric Primary Care Provider
- Give infant single antigen Hepatitis B vaccine within 12 hours of birth
- If mother is HBsAg positive give infant HBIG as soon as possible – no later than 7 days after birth
- If infant weighs less than 2000 grams – give Hep B vaccine and HBIG within 12 hours of birth or as soon as possible thereafter

*<http://www.cdc.gov/hepatitis/hbv/pdfs/deliveryhospitalpreventperinatalhbvtransmission.pdf>

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Key Messages to Promote During Pregnancy about Immunizations*

- Promote protection for the expectant mothers and improves the chances of having a healthy delivery and providing essential protection to babies during the first few months of life.
- The protective antibodies that babies receive from their mothers can be life-saving.
- Talking with the patient directly about the recommended vaccines during pregnancy could promote a positive foundation for the vaccine series recommended for the infant.
- Will help the transition from obstetrical to pediatric care and the acceptance of essential vaccines.

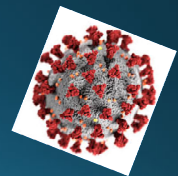
*Call to Action: Improving Vaccination Rates in Pregnant Women: Timely Intervention-Lasting Benefits. National Foundation for Infectious Diseases, March 2014.

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SARS-CoV-2 (COVID-19)*

- Virus affects the respiratory system primarily but other organ systems may also be impacted
- Transmission is through droplet and respiratory spread but may also include indirect contact with contaminated objects
- Symptoms can be mild to severe
 - 2-14 days after exposure
 - Fever or chills
 - Cough
 - Shortness of breath
 - Fatigue
 - Myalgia
 - Headache
 - Loss of taste or smell
 - Sore throat
 - G-I symptoms



Access current data on COVID-19 cases and deaths in Georgia** and nationally***

*<https://www.fda.gov/media/144413/download> **<https://usafacts.org/visualizations/coronavirus-covid-19-spread-map/state/Georgia>
 ***https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days

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COVID-19 mRNA Vaccines*

	Pfizer-BioNTech	Moderna
Vaccine Type	mRNA (messenger RNA) Efficacy ≈ 92%	mRNA (messenger RNA) Efficacy ≈ 94%
Age Indication	≥ 16 years of age	≥ 18 years of age
Recipient EUA (Emergency Use Authorization) factsheet	http://labeling.pfizer.com/ShowLabeling.aspx?id=14472	https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf
Vaccine Presentation	<ul style="list-style-type: none"> Frozen liquid concentrate Multi-dose vial, at least 5 doses per vial 	<ul style="list-style-type: none"> Frozen liquid Multi-dose vial, at least 10 doses per vial
Packaging	195 vials/tray (975 doses)	10 vials/carton (100 doses)
Dose	0.3 mL (IM)	0.5 mL (IM)
Dosing Regimen	2 doses, separated by 21 days	2 doses, separated by 28 days

*<https://www.immunize.org/catg.d/p3210.pdf>

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COVID-19 Vaccine Administration Guidelines*



- Vaccines are NOT interchangeable
- Do not administer other vaccines at the same visit; CDC recommends a 14 day interval between COVID-19 vaccine and any other vaccine
- There is no maximum interval to a required 2nd dose of vaccine, though CDC currently states up to an interval of 6 weeks
- Before vaccination, counsel patients about expected local and systemic reactions and the availability of the v-safe program
- No CDC VIS is yet available
- Give appropriate EUA to vaccine recipients

*<https://www.fda.gov/media/144413/download> / *<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html> ** <https://www.cdc.gov/vaccinesafety/concerns/fainting.html>

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VACCINE CONTRAINDICATIONS AND PRECAUTIONS*



Contraindications

- Persons with severe allergic reactions to a previous dose of COVID-19 vaccine or to any vaccine component
- Immediate allergic reaction of any severity to previous dose of the vaccine or any of its components, including polyethylene glycol (PEG)
- Immediate allergic reaction of any severity to polysorbate (found in foods, cosmetics, vitamins, vaccines, and medicines.) Could react with some of vaccine ingredients.

Precaution

- Persons with severe allergic reactions to any other vaccine or injection therapy

*<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

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VACCINE CONTRAINDICATIONS AND PRECAUTIONS*



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Precaution

- Persons with severe allergic reactions to any other vaccine or injection therapy

*<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

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Possible Vaccine Side Effects*

Characteristic	Immediate Allergic Reax.	Vasovagal Reax.	Vaccine Side Effects
Timing after vaccine	Most within 15-30 min.	Most within 15 min.	Median of 1-3 days later, mostly the day after vaccine
Cutaneous	Skin symptoms present in ≈ 90 % of people	Pallor, sweating	Pain, redness/swelling at injection site
Neurologic	Confusion, dizziness	Syncope, weakness	Headache
Respiratory	Shortness of breath, wheezing, hypoxia	Variable, possibly hypotension	N/A
Cardiovascular	Hypotension, tachycardia	Variable, possible hypotension	N/A
Gastrointestinal	Nausea, vomiting, diarrhea	Nausea, vomiting	Vomiting or diarrhea
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Receive 2 nd dose?	No	Yes	Yes

*<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

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Other Vaccine Side Effects Characteristics*



- These local and/or systemic reactions usually appear in the first two days and then resolve within a week after vaccination**
- Side effects may be more pronounced after the 2nd dose of vaccine and after prior COVID19 infection**
- Syncope risk after vaccination
 - Before vaccination, counsel patients about expected local and systemic reactions, especially syncope
 - Have patient sit or lie down to receive vaccine
 - Observe for 15 minutes under medical supervision
 - Wait 30 minutes if history of allergic reaction

*<https://www.fda.gov/media/144413/download/> *<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>

** <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html#:~:text=COVID-19%20vaccination%20will%20help,away%20in%20a%20few%20days>

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Considerations re: COVID-19 Vaccination of Pregnant or Lactating Women*



- CDC cites growing evidence that pregnancy is a factor that leads to increased risk for severe COVID-19 disease and adverse pregnancy outcomes.
- ACOG recommends COVID-19 vaccine should not be withheld from pregnant women who meet the ACIP criteria for vaccinating persons in specific priority groups.
- Prior conversation with a clinician may be helpful but should not be required .
- A pregnancy registry is looking at safety data and is ongoing.
- Pregnancy testing should not be required prior to receiving an approved COVID-19 vaccine.
- mRNA vaccines cannot cause any genetic changes.
- ACOG recommends vaccination of persons who are actively trying to become pregnant.

*<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html>

*www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

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FAQS*



What is mRNA?

Messenger RNA—found in all living cells; teaches cells to make a protein to help trigger an immune response. Cannot alter our DNA.

How do we know the vaccines are safe?

All vaccines must undergo extensive safety testing, which is reviewed by the FDA before the vaccine is licensed for widespread use.

Can a person receive the vaccine if they are taking antibiotics?

Yes, there is no interaction between the two.

Can you get the disease from the vaccine?

No, but it may take a few weeks for the body to develop immunity so if exposed during that period of time, the person could become infected.

Should someone who has had COVID-19 disease get the vaccine?

Yes, the CDC recommends this, after a 3 month waiting period.

Will persons be required to show proof of vaccination at work or school?

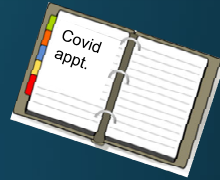
Some employers may require this.

*<https://www.nfid.org/infectious-diseases/frequently-asked-questions-about-covid-19-vaccines/>

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Where to Find Vaccination Location Sites



GA Department of Public Health at:
www.dph.Georgia.gov/covid-vaccine

- Participating vaccine sites
- Link to the Vaccine Dashboard for interactive search
- FAQs re: safety of COVID-19 vaccines
- Other covid-19 related information for Georgia residents

Planyourvaccine.org---select your age, occupation and other applicable factors to see if you are eligible now.

Pharmacy websites-----contact specific pharmacy or their website

* <https://www.mayoclinic.org/diseases-conditions/coronavirus/diagnosis-treatment/drc-20479976> **<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19>

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Critical Elements for Immunization Services



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Recommended Healthcare Personnel Vaccinations

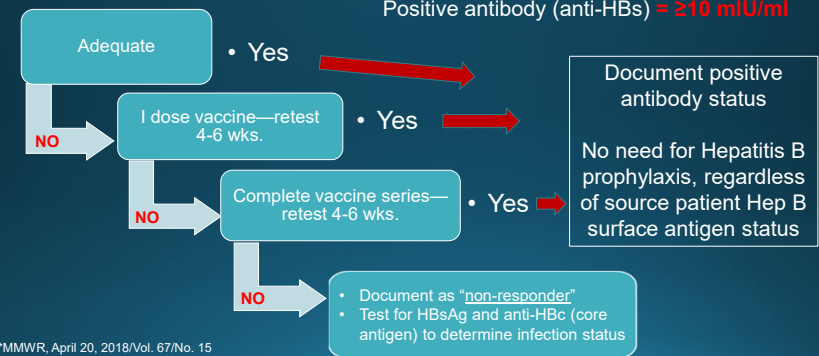
- Hepatitis B (exposure risk) check immunity
- Influenza (annual)
- Measles, Mumps, Rubella (MMR)
- Varicella (Chickenpox)
- Tetanus, Diphtheria, Pertussis (Tdap)
- Meningococcal (recommended for microbiologists who are routinely exposed to isolates of *N. meningitidis*).
- COVID-19 vaccine

Are YOU up to date?

Available at www.immunize.org, P#2017

Hepatitis B Immunization Status for Previously Vaccinated HCP with No Post-vaccination Testing*

Positive antibody (anti-HBs) = ≥ 10 mIU/ml



*MMWR, April 20, 2018/Vol. 67/No. 15

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Updated Vaccine Storage and Handling Recommendations*

- Use stand-alone refrigerator and stand-alone freezer units. If combined, use only refrigerator part.
- Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit.
- Use a bio-safe glycol-encased probe or a similar temperature buffered probe
- Probes should be calibrated every 1-2 yrs. or according to manufacturers' guidelines
- Use digital data loggers.
- Do not store ANYTHING ELSE in refrigerator.
- Review vaccine expiration dates and rotate vaccine stock weekly.



*Vaccine Storage and Handling Toolkit, January, 2020

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Maintaining Appropriate Vaccine Storage & Handling*

- Assign a primary and alternate vaccine coordinator.
- Store all vaccines as recommended by manufacturer and IN ORIGINAL PACKAGING, WITH THE LID CLOSED.
- Monitor and record temperatures of refrigerator and freezer twice daily.
- Correct ranges: refrigerator 36° F to 46° F; freezer -58° F to +5° F
- Maintain temperature log records for 3 years.
- Take immediate action for all out-of-range temps.
- Implement a vaccine emergency system.
- If it is necessary to transport vaccine, do NOT use dry ice. See Vaccine Storage and Handling Toolkit, Section 6 for Transport System Recommendations.
- **For COVID-19 vaccine, see specific vaccine guidelines.**

*Vaccine Storage and Handling Toolkit, January 2020

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Improper Immunization Administration Practices with Any Vaccine*

DO NOT re-use needles or syringes, due to the possibility of:

- Transmission of blood-borne viruses (HCV, HBV, HIV)
- Referral of providers to licensing boards for disciplinary action
- Malpractice suits filed by patients

Never use partial doses from 2 or more vials to obtain a dose of vaccine.**

Per OSHA and the CDC, you MAY use the same needle to withdraw a diluent, inject this into a lyophilized vaccine vial, and then administer to a patient, providing the needle or syringe has not otherwise been contaminated.**

*CDC, NCEIZ, DHQP. Injection Safety Information for Providers: www.cdc.gov/injectionsafety/providers.html
 **<http://www.immunize.org/askexperts/administering-vaccines.asp>

**Vaccine Storage and Handling Toolkit, January, 2020

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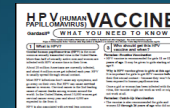
Always Document...

Accept only written documentation of prior immunizations

Provide VIS prior to administration of vaccine

After administering a vaccine, document:

- Publication date of VIS & Date VIS given
- Date, site, route, antigen(s), manufacturer, lot #
- Person administering vaccine, practice name and address



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A 'Birth to Death' Immunization Registry

- Providers administering vaccines in Georgia must provide appropriate information to GRITS.
- GRITS personnel can work with your EHR/EMR vendor to create an interface between your system and GRITS.
- Use GRITS to generate reminders on medical records and/or notify patients when vaccines are needed.
- Assess your immunization rates using GRITS to improve patient care, HEDIS scores, and identify problem areas.

Call the GRITS Training Coordinator (404) 463-0807 or e-mail : <https://dph.georgia.gov/georgia-immunization-registry-grits>

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Monitoring Vaccine Safety



• VAERS—Vaccine Adverse Event Reporting System

Option 1 - Report Online to VAERS (Preferred)

Submit a VAERS report online. The report must be completed online and submitted in one sitting and cannot be saved and returned to at a later time. Your information will be erased if you are inactive for 20 minutes; you will receive a warning after 15 minutes.

Option 2 - Report using a Writable PDF Form

Download the Writable PDF Form to a computer. Complete the VAERS report offline if you do not have time to complete it all at once. Return to this page to upload the completed Writable PDF form by clicking here.

If you need further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967.

• FDA and Vaccine Data Link Safety Project

• VERP: VACCINE ERROR REPORTING SYSTEM

- On line reporting at <http://verp.ismp.org/>
- Report even if no adverse events associated with incident
- Will help identify sources of errors to help develop prevention strategies

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Setting Up Your Office For Immunization Services

Operational & Financial



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Setting Up Your Office for Immunization Services

- Planning
- Purchasing supplies
- Storing vaccines
- Administering vaccines

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Setting Up Your Office for Immunization Service

• Planning

- Conduct an Immunization Financial Analysis (Resource Kit)
- Obtain staff support
- Identify a vaccine coordinator
- Make a list of vaccines to be offered
- Obtain vaccination forms and reference materials
- Create standing orders
- Plan workflow and workspace
- Conduct staff training
- Inform patients about availability of vaccines (posters, fact sheets)
- Identify community resources

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Consider these vaccines

- Annual influenza vaccine for all patients (consider immunizing other family members)
- Tdap for pregnant women or anyone planning to have a child (consider household members)
- HPV vaccine for women through age 45 years
- Hepatitis B vaccine for women at risk

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Additional Steps

- Revise assessment forms to include an immunization record.
- Estimate the percent of individuals you are likely to immunize.
- Estimate the total number of doses of vaccine required (Remember that some vaccines have a series of shots).

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Setting Up Your Office for Immunization Service

• Purchasing

- Set up vaccine purchasing spreadsheet showing prices, terms, discounts, rebates, etc. (see resource kit)
- Purchase:
 - Storage equipment and certified thermometers
 - Administration supplies
 - Emergency response supplies
 - Vaccines (Most vaccines can be ordered on line and arrive at the practice within 5 days)

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Immunizations as a Profit Center?

- Choose the vaccines you will provide to your patients
- Determine the top third party payers for your practice
- Calculate average reimbursement for each vaccine
- Calculate average reimbursement for administration fees
- Calculate the net revenue using the weighted average

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Code Immunizations Properly!

- Keep up with changes
- Code for vaccine administration
- Code for diagnosis

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Stay Current!

- Sign up for listserv sites which provide timely information pertinent to your practice
www.immunize.org/resources/emailnews.asp
- CDC immunization websites (32 in all)
- CHOP Parents Pack Newsletter
- IAC Express, Needle Tips and Vaccinate Adults
- Websites specific to particular vaccines



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**YOU ARE ALL PART OF THE TEAM THAT CAN
MAKE SURE YOUR PATIENTS RECEIVE THE
IMMUNIZATIONS THEY NEED!**

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Online Resources*

Current Childhood and Adult Immunization Schedules –
www.cdc.gov/vaccines/schedules/index.html

Parent's Guide to Childhood Immunizations –
www.cdc.gov/vaccines/parents/tools/parents-guide/index.html

Order Information for Free CDC Immunization Materials for Providers and Patients – wwwn.cdc.gov/pubs/CDCInfoOnDemand.aspx

Vaccine Labels to Organize a Storage Unit –
www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf

*Course Resource—Epidemiology & Prevention of Vaccine-Preventable Diseases—C296544-E

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Vaccine Information Statements (VISs) –
www.cdc.gov/vaccines/hcp/vis/current-vis.html

Refusal to Vaccinate Form –
https://www.aap.org/en-us/documents/immunization_refusaltovaccinate.pdf

Standing Orders (Explanation and Templates) –
www.immunize.org/standing-orders/

Ask the Experts – www.immunize.org/askexperts/

General Best Practice Guidelines for Immunization –
<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>

*Course Resource—Epidemiology & Prevention of Vaccine-Preventable Diseases—C296544-E

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Questions?

Contacts for more immunization information and resources!

National Center for Immunization and Respiratory Diseases, CDC

E-mail ► NIPInfo@cdc.gov

Hotline 800.CDC.INFO

Website <http://www.cdc.gov/vaccines>

Georgia Immunization Program

E-mail DPH-Immunization@dph.ga.gov

Hotline 404-657-3158

Website <http://dph.georgia.gov/immunization-section>

Immunization Action Coalition

E-mail admin@immunize.org

Phone 651.647.9009

Website www.immunize.org

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Thank You!!

- Additional EPIC Training Opportunity
- ## Breastfeeding Education



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Questions?

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