COVID-19 VACCINATION DURING PREGNANCY: WHAT YOU NEED TO KNOW

OCTOBER 28, 2021



LEARNING OBJECTIVES

By the end of this webinar, attendees will be able to:

- Summarize current CDC & ACOG findings and recommendations regarding the use of COVID-19 vaccines during pregnancy
- Explain the process of becoming a COVID-19 vaccine provider
- Illustrate the role clinicians can play in increasing vaccine confidence and demand



HOUSEKEEPING

- This webinar is being recorded and will be posted on ACOG's website. All registered attendees will receive a link once it is posted.
- This session is closed captioned using Zoom's artificial intelligence. Click the button at the bottom of the Zoom screen to view or hide closed captioning and subtitles.
- All participants are muted on the line and the chat is disabled.
- To submit questions, please send a message via Q&A button in Zoom at any time during the presentation. If it for a specific speaker, please note that in your question. We will have a moderated Q&A session at the end of the webinar.
- If you have any questions after this presentation, please email immunization@acog.org.



OPENING REMARKS

J. Martin Tucker MD, FACOG
President
American College of Obstetricians and Gynecologists





CDC PRESENTATION

Lead, Maternal COVID-19 Immunization, Vaccine Task Force, COVID-19 Response

Chief, Prevention Research and Translation,
National Center for Birth Defects and Developmental
Disabilities

Centers for Disease Control and Prevention





CDC Coronavirus Disease 2019 Response

Pregnant During a Pandemic:
Updates on COVID-19 and Vaccination
During Pregnancy

Dana Meaney-Delman, MD MPH
Maternal Immunization Lead, COVID-19 Response

ACOG Townhall October 28, 2021





cdc.gov/coronavirus

Disclosure

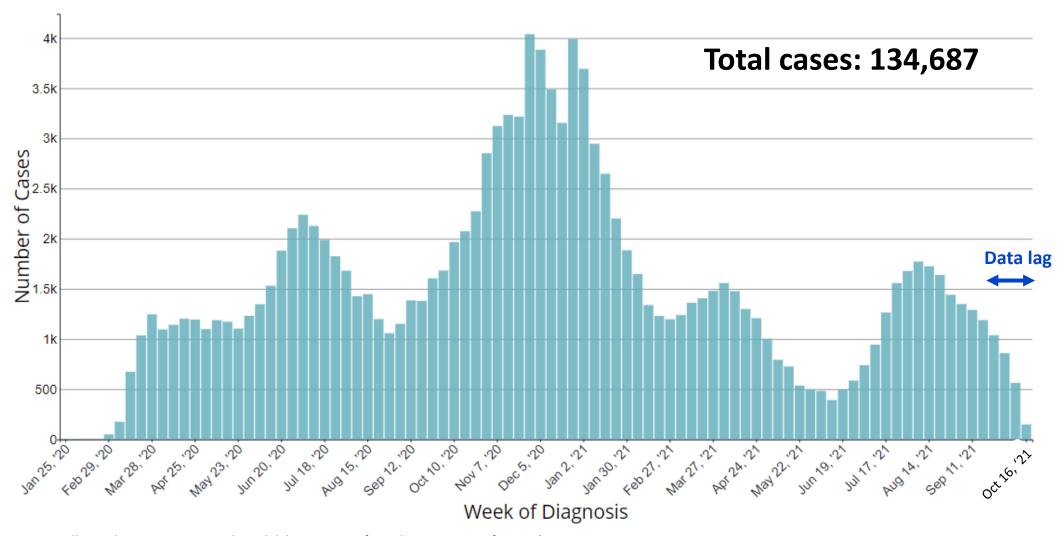
- I have no potential conflicts of interest to disclose.
- The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention (CDC).



Epidemiology of COVID-19 in Pregnancy



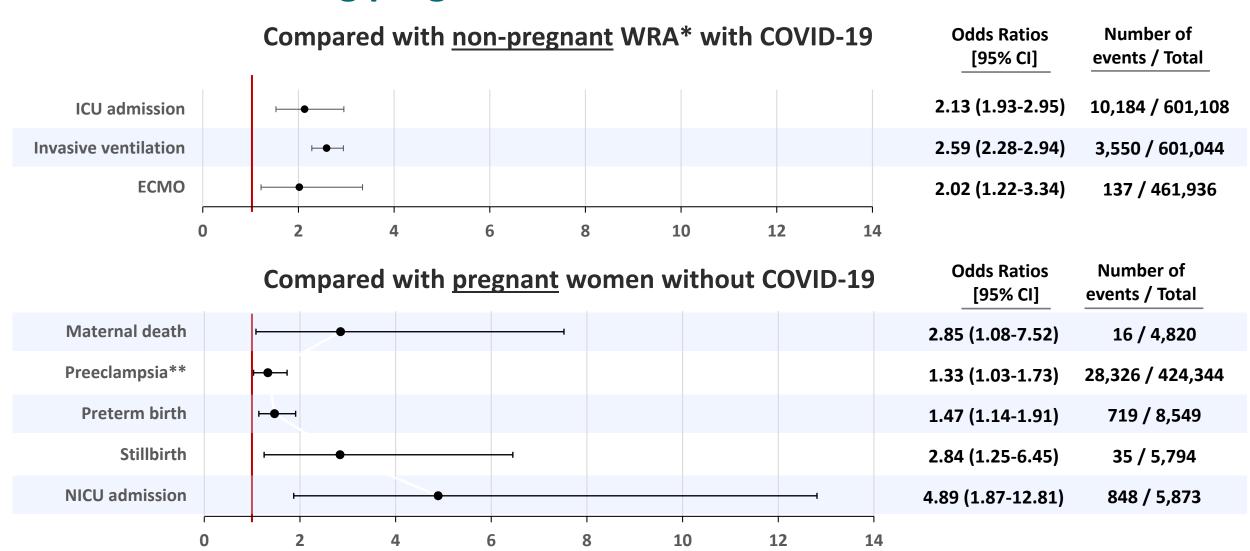
Pregnant people with laboratory-confirmed SARS-CoV-2 infection (National COVID-19 Case Surveillance Data)*



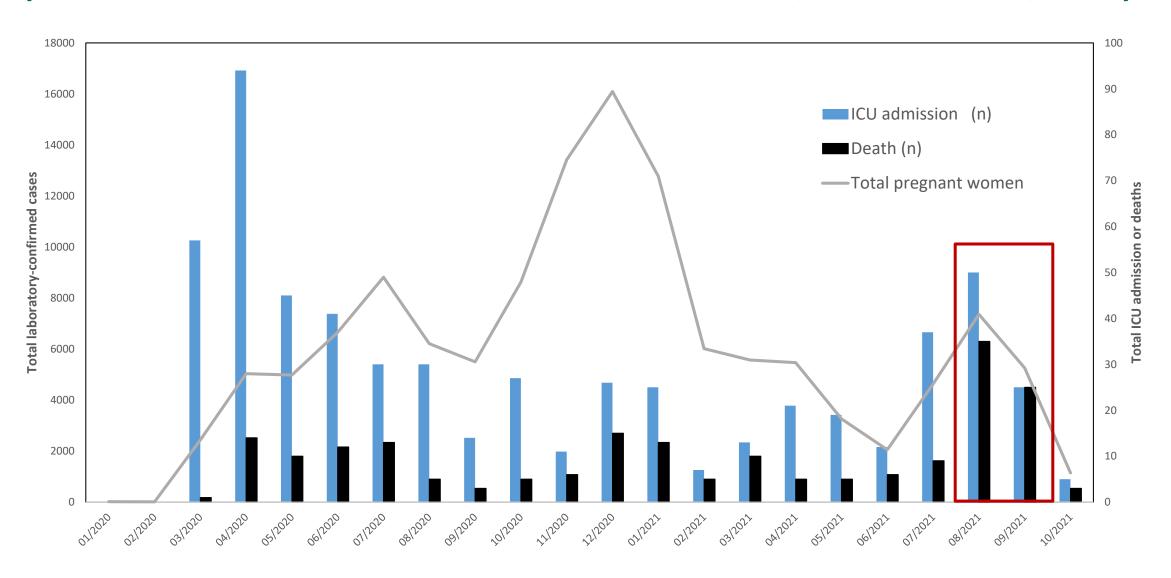
National COVID-19 case surveillance data: Pregnant people with laboratory-confirmed SARS-CoV-2 infection,* Jan 22, 2020–Oct 25, 2021

^{*} Based on detection of SARS-CoV-2 in a clinical specimen by molecular amplification techniques

Severe illness and adverse maternal, pregnancy, and neonatal outcomes among pregnant women with COVID-19



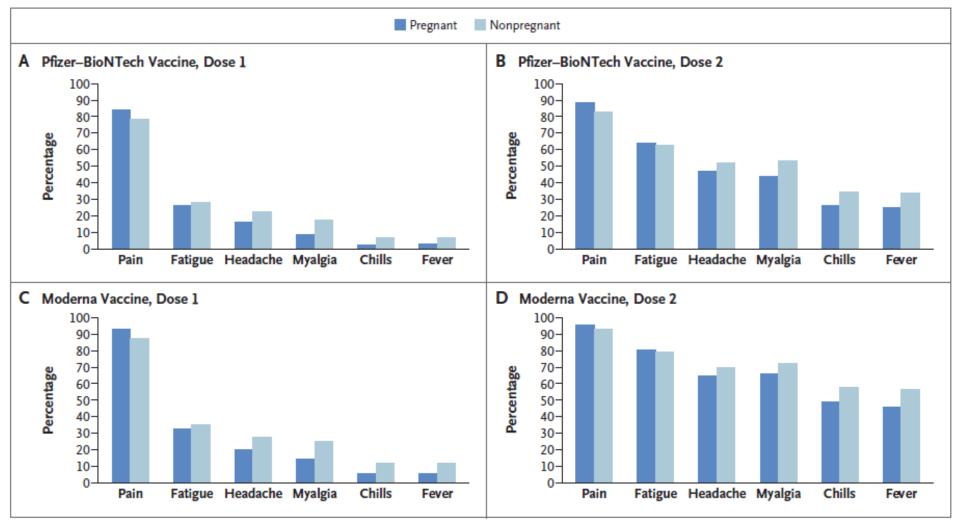
COVID-19 cases, ICU admission and death among pregnant people (National COVID-19 Case Surveillance Data; Jan 22, 2020 – Oct 18, 2021)



COVID-19 Vaccine in Pregnancy



Similar reactogenicity among pregnant people and non-pregnant women after mRNA Covid-19 vaccination



Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons, April 2021. https://www.nejm.org/doi/10.1056/NEJMoa2104983

Reactogenicity similar after 3rd dose among v-safe participants (data not specific to pregnant people; collected Aug 12–Oct 10, 2021)

- No unexpected patterns of adverse events were identified
- ≥92% of VAERS reports following dose 3 of COVID-19 vaccination were nonserious
 - Vaccination errors and systemic symptoms were most commonly reported
- Over 270,000 v-safe registrants reported an additional dose
 - Most reported a primary mRNA vaccine series followed by dose 3 from the same manufacturer
 - For Pfizer-BioNTech, local and systemic reactions were reported less frequently following dose 3 than dose 2
 - For Moderna, local reactions were reported slightly more frequently and systemic reactions slightly less frequently following dose 3 than dose 2

COVID-19 vaccination: Safety and effectiveness during pregnancy

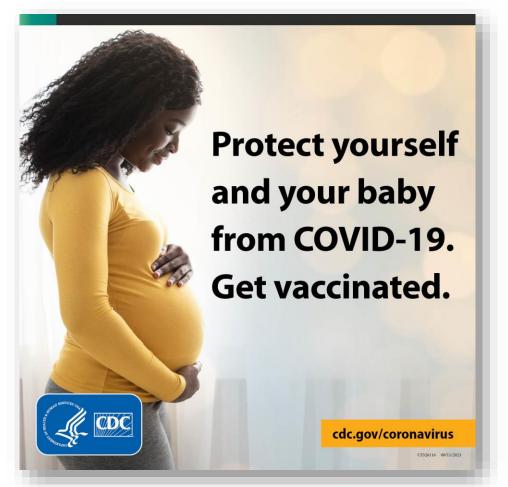
- Evidence on safety of COVID-19 vaccine is reassuring
 - Early data did not find any vaccine-related safety concerns for pregnant people vaccinated in the third trimester or for their babies.
 - No increased risk of miscarriage among pregnant people vaccinated before 20 weeks
- Early data suggest mRNA COVID-19 vaccines during pregnancy are effective
- Maternal antibodies following COVID-19 vaccination during pregnancy were present in umbilical cord blood



https://www.nejm.org/doi/full/10.1056/NEJMoa2104983 https://www.nejm.org/doi/full/10.1056/NEJMc2113891 https://jamanetwork.com/journals/jama/fullarticle/2784193 https://jamanetwork.com/journals/jama/fullarticle/2782047 https://www.nature.com/articles/s41591-021-01490-8 https://www.ajog.org/article/S0002-9378(21)00187-3/fulltext

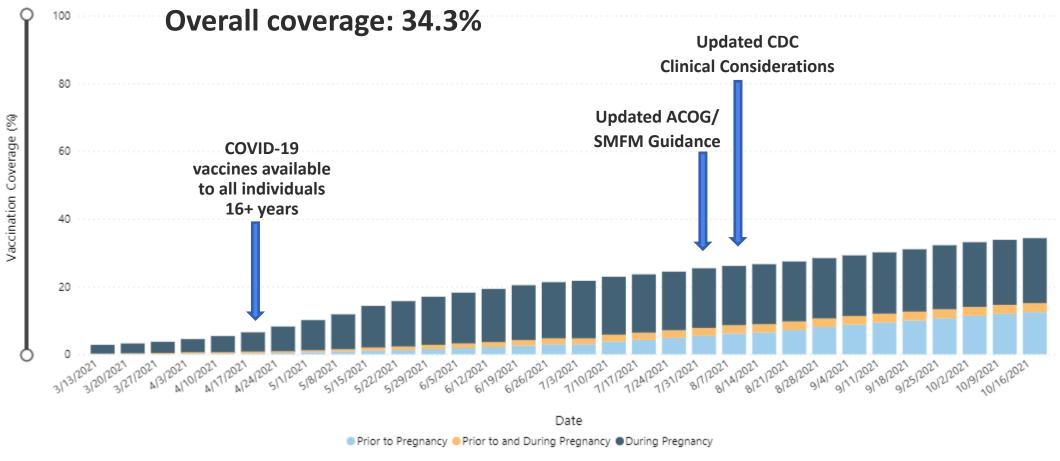
Updated clinical considerations: COVID-19 vaccination during pregnancy and lactation

- COVID-19 vaccination is recommended for all people aged 12 years and older, including people who are pregnant, breastfeeding, or who trying to get pregnant now or might become pregnant in the future.
- Consistent with recommendations from numerous professional medical organizations



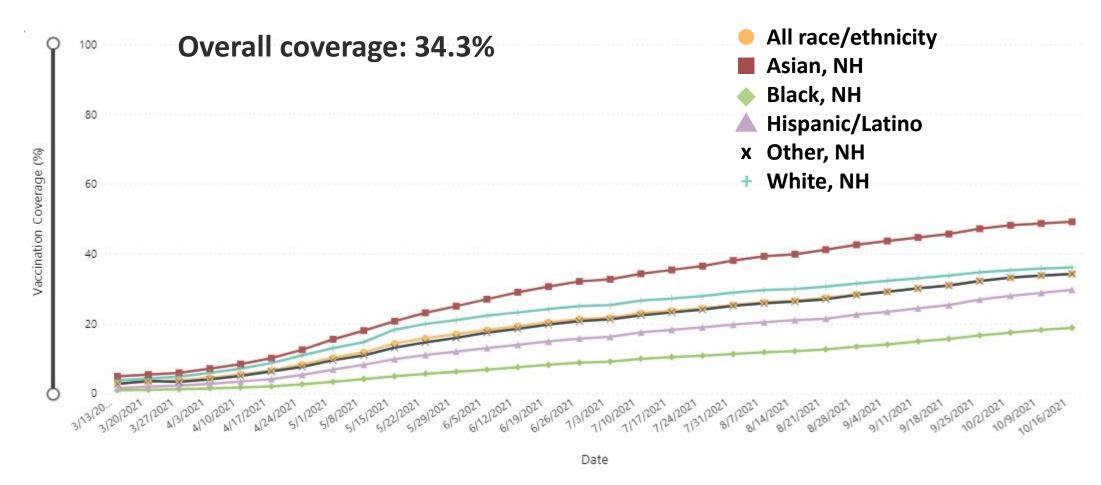
COVID-19 vaccination coverage among pregnant people

Percent of pregnant people aged 18–49 years fully vaccinated with COVID-19 vaccine prior to and during pregnancy, by timing of vaccination and date reported to CDC—Vaccine Safety Datalink, United States, December 14, 2020–October 16, 2021



COVID-19 vaccination coverage among pregnant people

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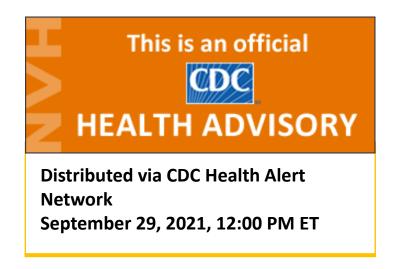
CDC efforts to improve vaccination coverage for pregnant people

Patients

- Disseminate information and updates
- Assess reasons for vaccine hesitancy
- Share personal stories
- Recruit vaccine champions of diverse backgrounds
- Providers and Health Systems
 - Encourage clinicians to become a vaccine providers in different clinic settings*
 - Provide resources to assist with vaccine discussions
 - Work with hospitals to encourage vaccine availability in triage and postpartum



Health Alert Notice Urging Vaccination among Pregnant People

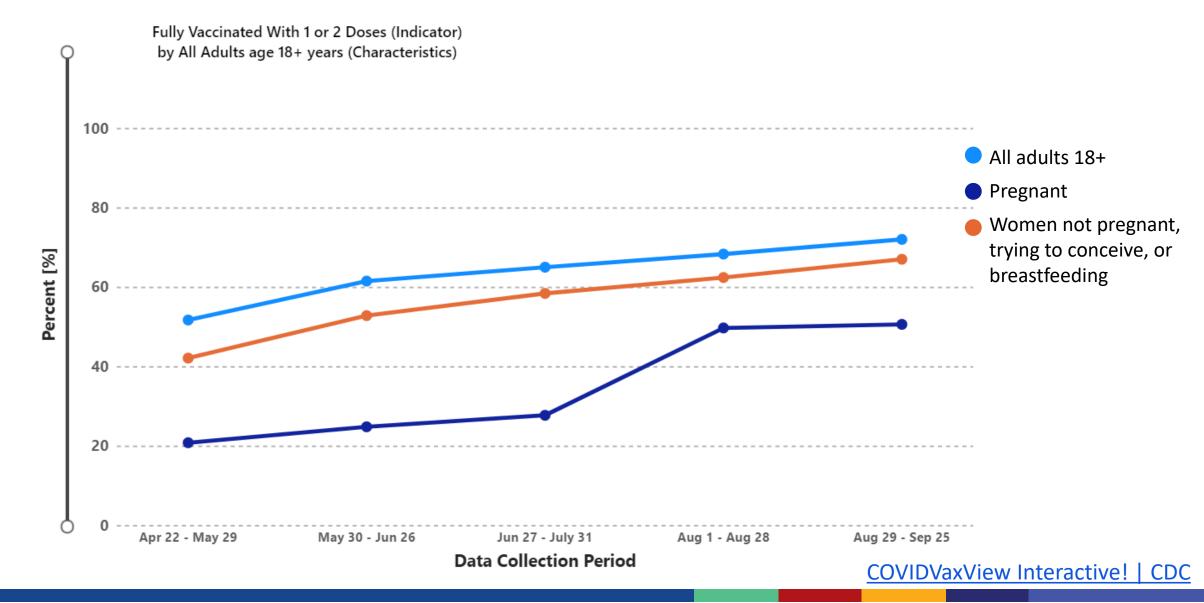


COVID-19 Vaccination for Pregnant People to Prevent Serious Illness, Deaths, and Adverse Pregnancy Outcomes from COVID-19

The Centers for Disease Control and Prevention (CDC) recommends urgent action to increase Coronavirus Disease 2019 (COVID-19) vaccination among people who are pregnant, recently pregnant (including those who are lactating), who are trying to become pregnant now, or who might become pregnant in the future. CDC <u>strongly recommends</u> COVID-19 vaccination either before or during pregnancy because the benefits of vaccination outweigh known or potential risks.

^{*}Resources to enroll as a vaccine provider: https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html

Promising upward trend in COVID-19 vaccination during pregnancy after strong recommendations issued



Updated clinical considerations: COVID-19 vaccination boosters

- COVID-19 Vaccine booster shots are available for certain populations
 - Certain groups of people who received
 Pfizer-BioNTech or Moderna COVID-19
 vaccine and completed their initial series at least 6 months ago
 - People who received Johnson & Johnson's Janssen COVID-19 vaccine 2 or more months ago
- Pregnant and recently pregnant people should be considered in the same group as people with underlying medical conditions



Vaccine Conversations



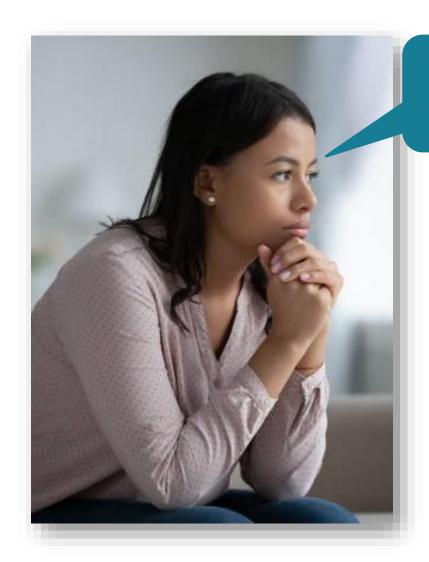
Talking with Patients about COVID-19 Vaccination

- Lead with listening
- Use patient-centered techniques
- Respond with empathy
- Address misinformation about COVID-19 vaccination by sharing key facts
- Help individuals find their motivation for getting vaccinated
- Wrap up the conversation by encouraging your patients to take at least one action
- Re-engage in conversations during follow up visits





Strategies to improve COVID-19 vaccination coverage: Combatting misinformation



Does getting a COVID-19 vaccine affect my chances of getting pregnant in the future?

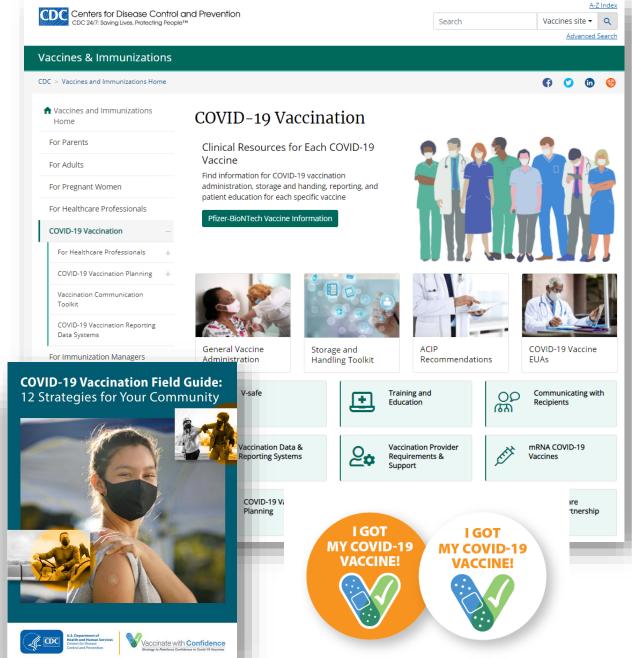
- There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems.
- Professional medical organizations serving people of reproductive age, including adolescents, emphasize that there is no evidence that COVID-19 vaccination causes a loss of fertility.
- Many people have become pregnant after COVID-19 vaccination.
- COVID-19 vaccination is recommended for all people aged 12 years and older, including people who are trying to get pregnant now or who might become pregnant in the future.

CDC Resources

CDC's COVID-19 vaccine tools and resources.

- COVID-19 Vaccination: <u>https://www.cdc.gov/vaccines/covid-19/index.html</u>
- For Healthcare Professionals: https://www.cdc.gov/vaccines/covid-19/hcp/index.html

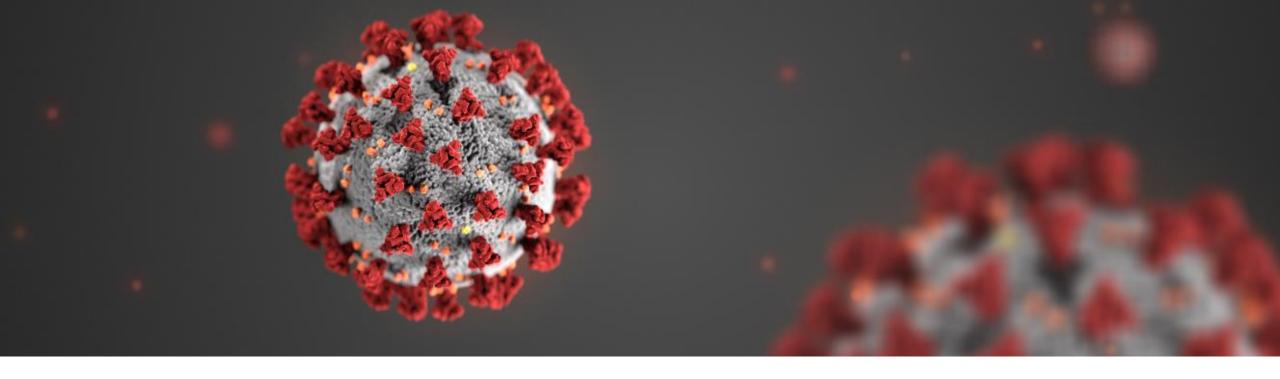




Acknowledgments

- CDC's COVID-19 Response:
 - Maternal Immunization Team
 - Pregnancy and Infant Linked Outcomes Team
 - Vaccine Task Force
- Advisory Committee on Immunization Practices
- CDC's National Center on Birth Defects and Developmental Disabilities
- CDC's Division of Reproductive Health
- CDC's National Center on Immunization and Respiratory Diseases
- State and Local Jurisdictions
- Clinical and Public Health Partners
- Healthcare Providers and Pregnant Persons





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

TTY: 1-888-232-6348 www.cdc.gov

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.



AIM PRESENTATION

Claire Hannan, MPH
Executive Director
Association of Immunization Managers





COVID-19 Provider Enrollment

American College of Obstetricians and Gynecologists

Claire Hannan
Association of Immunization Managers (AIM)
October 28, 2021



About AIM

- The Association of Immunization Managers (AIM) represents immunization programs (jurisdictions) that receive funding from CDC's National Center for Immunization and Respiratory Diseases (NCIRD)
- Jurisdiction state, territory, pacific island, or individual city receiving federal-funding for implementation and oversight of the Vaccines for Children (VFC) Program and other federally-funded vaccination programs.
- 50 states, 6 major cities, 8 territories/federated states

A 3:

COVID Vaccination Program

- Modeled after the Vaccines for Children Program
- Enrolled providers receive vaccine and ancillary supplies provided by federal government
- Program administered at state/awardee level
- Liability protection covered by Public Readiness and Emergency Preparedness (PREP) Act
- Providers cannot charge \$\$ for vaccine, but can receive administration fee reimbursement

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COVID Vaccination Program Key Elements

- Providers must enroll in COVID vaccine programs to order and receive vaccine
- Providers must have reporting capacity
- Providers must commit to proper storage and administration of COVID vaccine

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Provider Enrollment

- Provider agreement must be signed (legal agreement)
 - Chief Medical Officer (CMO), Chief Financial Officer (CFO), and the primary contact for each facility's vaccination program.
- Providers responsible for adhering to all requirements outlined in agreement
- Enrollment process varies by jurisdiction (Red Cap, Microsoft forms, etc)
 - COVID-19 Vaccination Program Provider Agreement is the same for all jurisdictions
- Average time to complete varies depending on the site's readiness for implementation of the Program.
 - For example, a site that meets all CDC recommendations for proper storage and handling of vaccine may be able to complete the process in less time than a site that does not have the infrastructure in place yet.

Requirements can be found on CDC's Provider Enrollment webpage

Reporting Requirements

- Enrolled providers must report all administered doses of COVID-19 vaccine to the jurisdiction's Immunization Information System (IIS) within 24-72 hours of administration.
- Inventory must be maintained in the jurisdiction's IIS and reported to vaccine finder daily (some jurisdictions report to vaccine finder for the provider)
- Adverse events reported to VAERS

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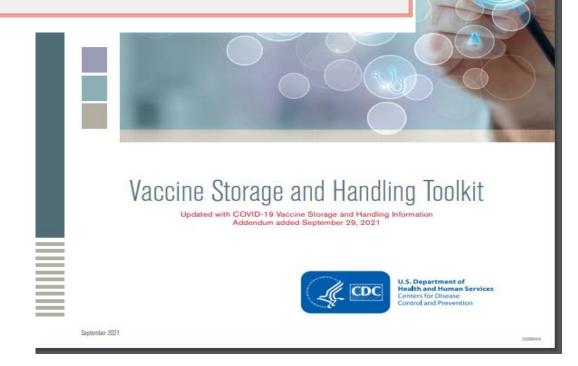
COVID Vaccine Storage and Administration

- Providers must meet all CDC recommendations for proper storage and handling of vaccine
 - S&H toolkit. <u>Vaccines Storage and Handling Toolkit | CDC</u>
- Administer in accordance with ACIP guidance and recommendations
- CDC trainings: COVID-19 vaccine management, administration, reporting, storage & handling
 - [CHECK WITH JURISDICTION FOR TRAINING REQUIREMENTS]

Online Training Resources

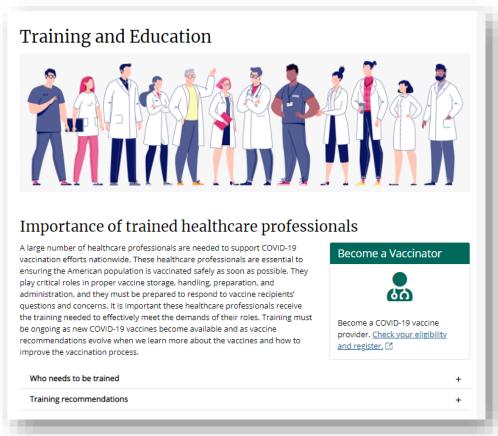
CDC's <u>You Call the Shots: Vaccine Storage and Handling</u>[†] is a free, online training module focused on storage and handling requirements.

Check with your <u>immunization program</u>* and professional organizations to see what vaccine storage and handling training resources they offer.



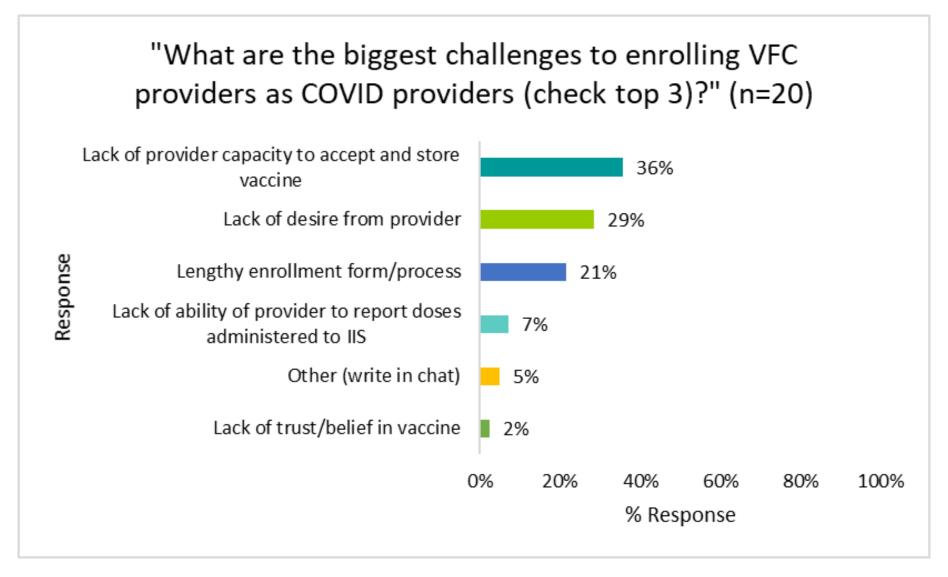
Training and Resources

- The COVID-19 Provider Agreement requires the completion of the <u>CDC's COVID-19</u> <u>training for healthcare professionals</u>.
 - Additional training may be required by the jurisdiction.
- CDC has extensive <u>training for vaccination</u> <u>providers</u>
- CDC Vaccine Storage and Handling Toolkit
 provides a comprehensive guide for storage
 of vaccine as required by sites receiving
 and/or administering COVID vaccine.



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Poll Results: Provider Enrollment Challenge



Common Questions and Concerns

Myth: The vaccine requires ultra cold storage.

Fact: The vaccine does NOT REQUIRE ultra cold storage.

- Pfizer: Freezer for up to 2 weeks. Refrigerator for up to 5 days. New packaging will be refrigerator stable for 10 weeks.
- Moderna: Freezer until expiration date. Refrigerator up to 30 days.
- JnJ: Refrigerator until expiration date.

Myth: I can only order large quantities.

<u>Fact:</u> Most jurisdictions have some kind of redistribution model and will work with providers who need to order smaller amounts. Pfizer is moving to smaller packaging soon. Moderna and JnJ have 100 dose minimum.

Myth: Enrollment is a lot of red tape.

<u>Fact:</u> Yes and no. It's a federally-funded vaccination program, so there are requirements. Jurisdictions will work with providers to help them navigate the process. Tens of thousands of providers have successfully enrolled.

Myth: Our site can't meet the reporting requirements.

<u>Fact:</u> there are multiple ways to report doses administered and vaccine inventory to the IIS. Electronic data exchanges can be used for automatic reporting to the IIS from the EHR. Jurisdictions may also allow direct access to the IIS for reporting purposes until an interface can be established. Reporting is critical for tracking the level of populations protection and identifying areas of low coverage/high risk.

Myth: No one wants the vaccine.

<u>Fact</u>: Some people are vaccine hesitant, not necessarily anti-vax. Pregnant women are especially concerned about the health of their baby. Individuals are more likely to receive the vaccine if it is recommended or offered by their trusted healthcare provider.

Check with your jurisdiction to enroll!

CDC - How to Enroll as a COVID-19

Vaccination Provider





Thank you!



ACOG PRESENTATION

Alison G. Cahill, MD, FACOG Committee Chair, Obstetric Clinical Consensus (formerly Obstetric Practice) American College of Obstetricians and Gynecologists







COMMUNICATING WITH PATIENTS ABOUT COVID-19 VACCINES

Alison G. Cahill, MD, FACOG I October 28, 2021

ACOG RECOMMENDATIONS

• ACOG recommends that all eligible persons greater than age 12 years, including pregnant and lactating individuals, receive a COVID-19 vaccine or vaccine series.

 Any of the currently authorized COVID-19 vaccines can be administered to pregnant, recently pregnant or lactating people



COVID-19 VACCINES: COMMUNICATING WITH PATIENTS



COMMUNICATING WITH PATIENTS

COVID-19 vaccines are new; it's expected that people have questions about them.

- Empathy
- Open-ended questions
- Share information
- Find their own reason to get vaccinated



ADDRESSING PATIENT QUESTIONS & CONCERNS

Will COVID-19 vaccines affect my fertility?

Are COVID-19 vaccines safe during pregnancy?

I already had COVID-19, why do I need to get vaccinated?

I'm nervous because COVID-19 vaccines are so new and were developed so quickly

I'm young and healthy, why should I get vaccinated?



WILL COVID-19 VACCINES AFFECT MY FERTILITY?

COVID-19 vaccines do not cause infertility



ARE COVID-19 VACCINES SAFE DURING PREGNANCY?

Key Messages:

- There is no evidence of adverse maternal or fetal effects from vaccinating pregnant individuals with the COVID-19 vaccine, and a growing body of data demonstrates safety.
- None of the COVID-19 vaccines available for use under emergency use authorization or FDA license causes infertility or spontaneous abortion.



I ALREADY HAD COVID-19, WHY DO I NEED TO GET VACCINATED?

Vaccination is recommended for everyone age 12 years and older, regardless of if you previously had COVID-19 illness

- Research has not yet shown how long people are protected from getting COVID-19 again after recovery from COVID-19.
- Vaccination helps protect people from severe illness if they have already had COVID-19.



I'M NERVOUS BECAUSE COVID-19 VACCINES ARE SO NEW AND WERE DEVELOPED SO QUICKLY

While COVID-19 vaccines were developed rapidly, all steps were taken to make sure they are safe and effective.

COVID-19 Vaccines:

- Were developed using existing vaccine platforms or platforms already in development, which sped up the development process
- Completed all three required phases of clinical trials before EUA
- Met FDA's safety and effectiveness standards required for EUA
- Have safety monitoring systems that are the most intense and comprehensive in U.S. history.



I'M YOUNG AND HEALTHY, WHY SHOULD I GET VACCINATED?

- Physiological changes to the immune response increase the risk of getting infected
- As more people are vaccinated, community transmission will go down
- Risk of severe COVID-19



COVID-19 VACCINATION AMONG HIGH-RISK

- Large Federally Qualified Health Care system CommUnityCare
- Serves >120,000 patients annually
- 4,000 new OB patients
- 77% Medicaid, 15% uninsured
- 89% live at or below the poverty level



IMPLEMENTING A COVID-19 VACCINATION PROGRAM

- System leadership charge themselves with becoming vaccine providers
- Integrated into care
- Opt out approach
- Critical window to provide factual counseling
 - Wait and see would not be enough
 - Take on mis/disinformation
- Create more bandwidth
 - Schedule changes
 - Drive up testing sites pivoting to vaccine sites



IMPLEMENTING A COVID-19 VACCINATION PROGRAM

- Knowing your community
- Staffing is critical
- Champions
 - Nicholas Yagoda, MD CMO
 - Ashley Choucroun, MD OB/GYN Medical Director



QUESTIONS & ANSWERS



CDC RESOURCES

- CDC COVID Data Tracker
- Clinical Care Considerations for COVID-19 Vaccination
- Clinical Resources for Each COVID-19 Vaccine
- COVID-19 Vaccine Finder
- COVID-19 Vaccines for People Who Would Like to Have a Baby
- HAN COVID-19 Vaccination for Pregnant People to Prevent Serious Illness, Deaths, and Adverse Pregnancy Outcomes from COVID-19
- Talking with Patients about COVID-19 Vaccination
- V-safe COVID-19 Vaccine Pregnancy Registry
- Vaccine Recipient Education



AIM RESOURCES

- CDC's Provider Enrollment webpage
- CDC's COVID-19 training for healthcare professionals
- Frequently Asked Vaccine Questions and Answers
- Vaccine Confidence Toolkit
- Vaccine Confidence Toolkit Webinar Series
- Vaccines Storage and Handling Toolkit | CDC



ACOG RESOURCES

- COVID-19 Vaccination, Pregnancy, and Medical Misinformation: How You Can Help | ACOG
- Practice Advisory: COVID-19 Vaccine Considerations for Obstetric-Gynecologic Care
- COVID-19 Physician FAQs
- COVID-19 Vaccines and Pregnancy: <u>Conversation Guide</u> for Clinicians
- Vaccinating Pregnant Individuals: Eight Key Recommendations for COVID-19 Vaccination Sites
- COVID-19 Vaccines: Tools for Your Practice and Your Patients
 - Infographic on COVID-19 and pregnancy to share with patients
 - Flier on COVID-19 vaccination to give to your patients
 - Flier on COVID-19 vaccination to give to your patients who are pregnant
 - Flier on COVID-19 vaccination to give to your patients who are breastfeeding
 - How to become a COVID Vaccinator <u>Guide</u>
 - Conversation <u>prompts</u> for offices
- Resources for You | ACOG



CLOSING REMARKS

- Please answer a few brief questions posted in the chat.
- A follow-up email will be sent out with additional resources and a brief survey.
- Answering these survey questions will help us to continue to provide you with valuable content.
- Contact immunization@acog.org for further questions.





Thank you!