

Maternal Respiratory Syncytial Virus (RSV)

Vaccine Health System Readiness Package

INTRODUCTION

Obstetrician–gynecologists and other obstetric care providers are crucial in ensuring pregnant women receive recommended vaccines, with studies showing that when they directly recommend and offer a vaccine, the acceptance rate increases five-fold to 50-fold.¹ Immunization rates are notably higher when providers offer a vaccine during the same visit, rather than referring patients elsewhere, underscoring the importance of immediate availability in vaccine acceptance.²

The *Maternal RSV Vaccine Health System Readiness Package* is designed to enhance maternal RSV vaccination programs, providing health systems and providers with essential tools, pathways, educational materials and best practices. This package includes the following tools:

Maternal Vaccination Care Journey Roadmap 3 >

Maternal RSV Vaccine Readiness Checklist for Health Systems 8 >

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Links to Additional Maternal Vaccination Resources 14 >



INDICATION

ABRYSVO is a vaccine indicated for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.

IMPORTANT SAFETY INFORMATION

- Do not administer ABRYSVO to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of ABRYSVO
- A numerical imbalance in preterm births was observed compared to placebo in 2 clinical studies. Data are
 insufficient to establish or exclude a causal relationship between preterm birth and ABRYSVO. To avoid
 potential risk of preterm birth with use of ABRYSVO before 32 weeks of gestation, administer to pregnant
 individuals at 32 through 36 weeks gestational age
- Appropriate medical treatment must be available in case of an anaphylactic reaction
- Syncope (fainting) may occur in association with administration of injectable vaccines, including ABRYSVO.

 Procedures should be in place to avoid injury from fainting
- Immunocompromised individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to ABRYSVO
- Vaccination with ABRYSVO may not protect all vaccine recipients
- In clinical trials with pregnant individuals, the most commonly reported (≥10%) adverse reactions were pain at the injection site (40.6%), headache (31.0%), muscle pain (26.5%), and nausea (20.0%)
- In clinical trials with infants born to pregnant individuals, low birth weight (5.1% ABRYSVO versus 4.4% placebo) and neonatal jaundice (7.2% ABRYSVO versus 6.7% placebo) were observed

Individuals who received ABRYSVO during pregnancy are encouraged to contact 1-800-616-3791 to enroll in a Pregnancy Exposure Registry.

Please see full Prescribing Information for ABRYSVO.

< Cover References

1. The American College of Obstetricians and Gynecologists. Maternal Immunization. 2021. Accessed August 19, 2024. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/06/maternal-immunization 2. The American College of Obstetricians and Gynecologists. Immunization Implementation Strategies for Obstetrician Gynecologists. 2022. Accessed August 19, 2024. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/03/immunization-implementation-strategies-for-obstetrician-gynecologists#:~:text=Vaccine%20Purchasing&text=in%20their%20offices.-,Studies%20show%20that%20immunization%20rates%20are%20 higher%20when%20a%20health,to%20receive%20the%20vaccine%2011.





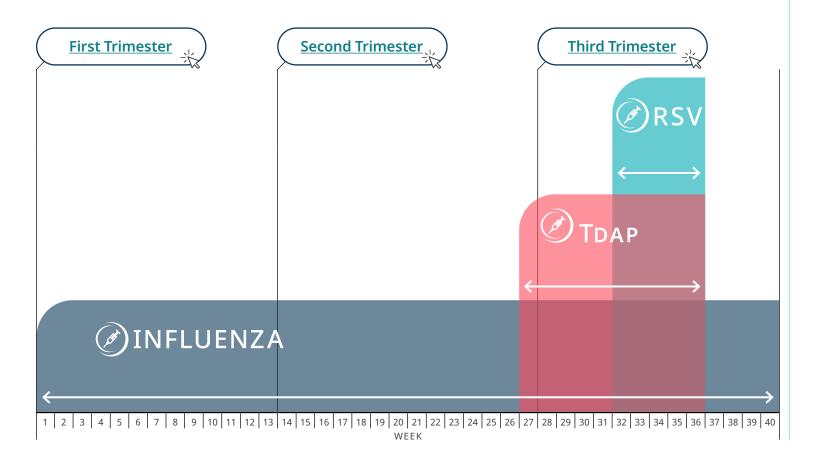


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Maternal Vaccination Care Journey Roadmap

INTRODUCTION

The *Maternal Vaccination Care Journey Roadmap* offers a structured approach to maternal vaccinations during pregnancy. It outlines the critical steps and considerations for immunizations across the three trimesters, helping to ensure both mother and/or baby are protected from vaccine-preventable diseases. The Roadmap includes key decision points and action points for three recommended maternal vaccines; it does not cover special situations like travel vaccines or vaccines for pregnant mothers who require catch-up vaccines.



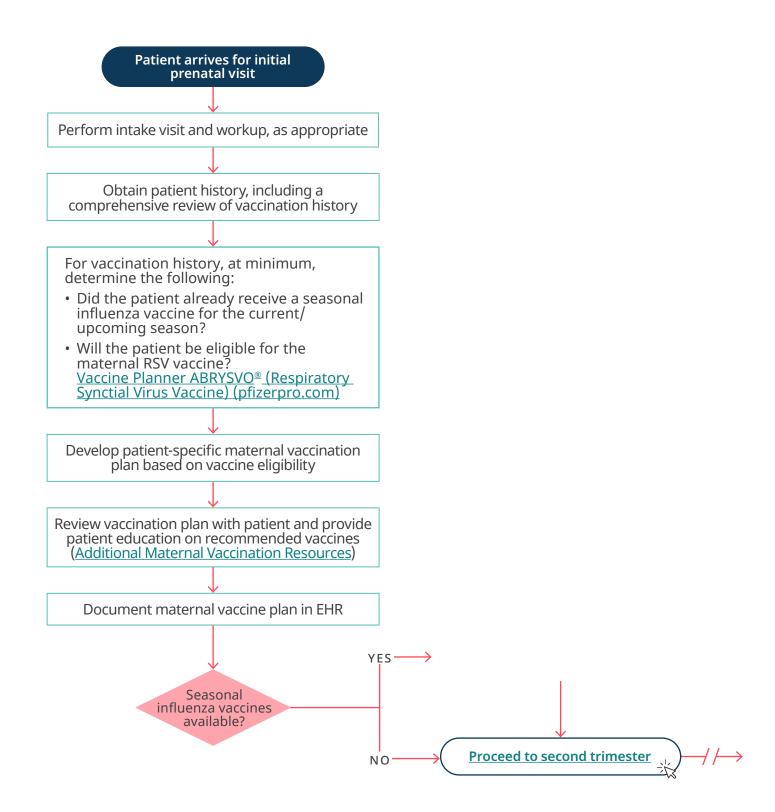
Note: Vaccination timelines may be affected by seasonal administration.







First Trimester: Weeks 1-13



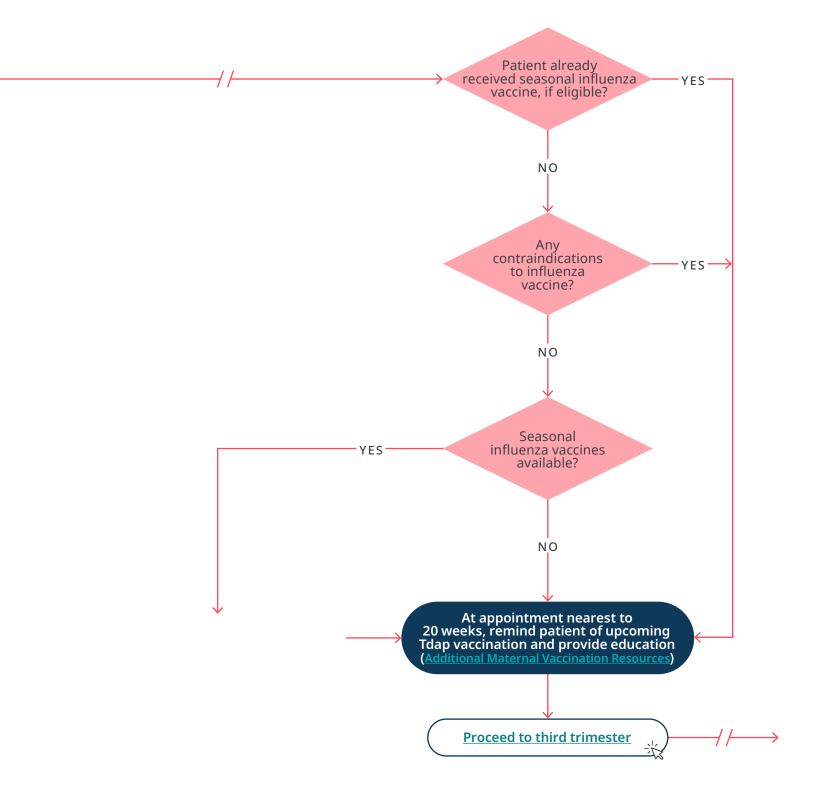
^{*} Refer to CDC or Health System policies/guidance on optimal timing of influenza vaccines for pregnant patients







Second Trimester: Weeks 14-27



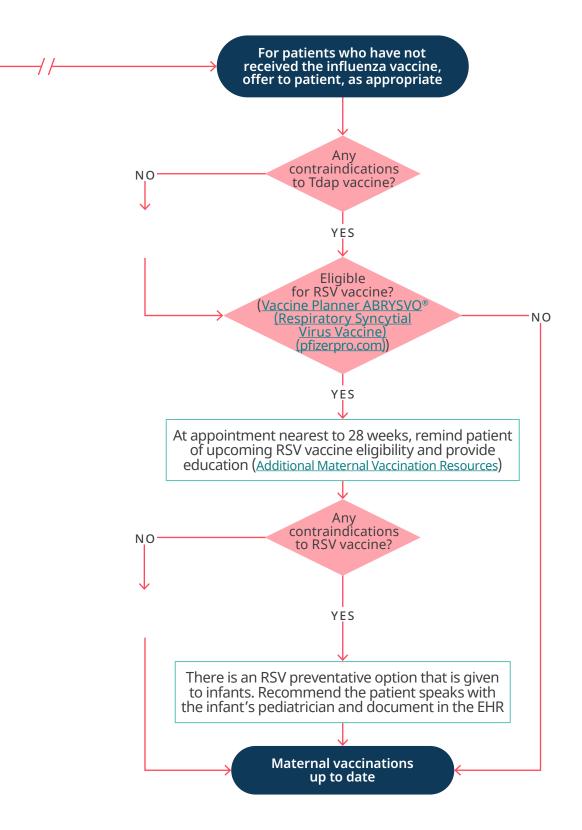
^{*} Refer to CDC or Health System policies/guidance on optimal timing of influenza vaccines for pregnant patients







Third Trimester: Weeks 28-40



^{*} Pregnant people should get a dose of Tdap during every pregnancy, preferably during the early part of the third trimester







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- 1. Premier Inc. Information on file. 2024
- 2. Immunize.org. Suggestions to Improve Your Immunization Services. 2023. Accessed August 18, 2024. https://www.immunize.org/wp-content/uploads/catq.d/p2045.pdf
- 3. The American College of Obstetricians and Gynecologists. Immunization for Pregnant Women: A call to Action. 2020. Accessed August 18, 2024. https://www.acog.org/programs/immunization-for-women/activities-initiatives/immunization-for-pregnant-women-a-call-to-action
- 4. The American College of Obstetricians and Gynecologists Influenza in Pregnancy: Prevention and Treatment. 2020. Accessed August 19, 2024. https://www.acog.org/clinical/clinical-guidance/committee-statement/articles/2024/02/influenza-in-pregnancy-prevention-and-treatment#:~:text=The%20inactivated%20influenza%20vaccine%20can,vaccine%20during%20a%20previous%20pregnancy.
- 5. Pfizer. Maternal RSV Vaccine Planner. 2024. Accessed August 18, 2024. https://abrysvomaternal.pfizerpro.com/resources/maternal-rsv-vaccine-planner
- 6. Centers for Disease Contol and Prevention. About Vaccines and Pregnancy. 2024. Accessed August 20, 2024. https://www.cdc.gov/vaccines-pregnancy/about/index.html
- 7. Centers for Disease Control and Prevention. Vaccine Information Statement (Tdap). 2021. Accessed August 19, 2024. https://www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.pdf
- 8. Centers for Disease Control and Prevention. Immunizations to Protect Infants. 2024. Accessed August 19, 2024. https://www.cdc.gov/rsv/immunizations-protect-infants/index.html





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Vaccine Readiness Checklist for Health Systems

In subsequent seasons, revisit this checklist to confirm the following are in place.

Leadership (Recommended timing: Q1)		Best practices ¹
	If not already identified, appoint a system-wide maternal vaccine champion ¹⁻³	 Implement a mate vaccine pathway a to increase vaccin Schedule quarterl readiness meeting prepare for this senext season
	Ensure standing orders are in place, if applicable (<u>Standing Orders for Administering Pfizer's ABRYSVO® (Respiratory Syncytial Virus (RSV) Vaccine</u>) During Pregnancy (immunize.org)) ^{4,5}	
	Implement a system-level initiative to offer all recommended vaccines to every pregnant patient ^{1,6}	
	Design and establish a clear communication structure to effectively distribute RSV vaccine information and updates from the leadership level directly to the clinics ⁷	 Consider implement patient reminders code to link to eduresources, providi
	Confirm payer coverage and requirements ^{1,8}	educational resou
	Develop system wide inventory management plan ⁴	materials and usir grade reading leve patient facing mat
	coring and Continuous Improvement mmended timing: Q1)	 Work with IT to lin to mother's chart
	Determine QA metrics to monitor and track ^{1,7}	provide maternal cards
	Develop benchmarks or vaccination goals for maternal RSV vaccinations ^{1,7}	 Provide equitable and opportunity – clinics outside larg systems and state
	Determine cadence of reporting metrics to providers and vaccinating clinics ^{1,3}	
	If applicable, perform end of season review and debrief to disseminate clinic performance, successes, barriers, lessons learned and strategies for improvement ^{1,3}	departments
Techn	ology (Recommended timing: Q1-Q2)	
	Create pre-populated order sets including the maternal RSV vaccine ¹	
	Create best practice alerts (BPAs) or clinical decisions support (CDS) alerts ^{1,9}	
	Develop and activate patient care gap alerts and educational materials in the patient portal ^{1,9,10}	

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Outre	ach (Recommended timing: Q2)
	Develop community outreach plan including community education and engagement strategies (patient portal and message notifications, if applicable) ^{10,11}
	Develop a maternal RSV vaccine marketing plan including social media strategy ^{10,11}
Staff a	and Patient Education (Recommended timing: Q2-Q3)
	Develop comprehensive training for all staff on the burden of RSV, importance of RSV vaccination and communication strategies for vaccine discussions with pregnant patients and their family ^{3,6,12}
	Identify appropriate settings/venues for RSV vaccine information dissemination (grand rounds, physician meetings, etc.) ^{1,12}
	Ensure vaccinating clinics receive and implement the Maternal RSV Vaccine Readiness Checklist for Clinics
	Provide training on early vaccine conversations and evidence-based communication strategies for trust building and overcoming vaccine hesitancy ^{1,6}
	Ensure vaccinating clinics receive and implement patient education resources (<u>Additional Maternal Vaccination Resources</u>) ^{3,11}

- 1. Premier Inc. Information on file. 2024
- 2. American Medical Group Association. Assemble your Rise to Immunize Team. 2021. Accessed August 18, 2024. https://www.amga.org/getmedia/9e502d7c-bc3c-42a5-9cac-80ac49a2d081/Core-Team-Members-Chart_READY-FOR-WEB_Registered-Trademark.pdf
- 3. Immunize.org. Suggestions to Improve Your Immunization Services. 2023. Accessed August 18, 2024. https://www.immunize.org/wp-content/uploads/catg.d/p2045.pdf
- 4. Immunization Action Coalition. Vaccinating Adults: A Step-by-Step Guide. 2017. Accessed August 18, 2024. https://www.immunize.org/wp-content/uploads/guide/pdfs/vacc-adults-entire.pdf
- 5. Immunize.org. Standing Orders for Administering Pfizer Respiratory Syncytial Virus (RSV) Vaccine (Abrysvo) During Pregnancy. 2024. Accessed August 18, 2024. https://www.immunize.org/wp-content/uploads/catq.d/p3096.pdf
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- 8. National Adult and Influenza Immunization Summit. Insurance Coverage of Adult Immunizations. 2023. Accessed August 18, 2024. https://www.amga.org/getmedia/d4325bff-2353-4825-a8c8-4230a082f0ea/NAIIS_Insurance-Coverage-of-Adult-Immunizations.pdf
- 9. American Medical Group Association. IT/Documentation: Level 2. 2022. Accessed August 18, 2024. https://www.amga.org/Rise-To-Immunize/Campaign-Toolkit/campaign-planks/IT-Documentation/Level-2
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- 11. American Medical Group Association. Patient Education: Level 1. 2022. Accessed August 18, 2024. https://www.amga.org/Rise-To-Immunize/Campaign-Toolkit/campaign-planks/Patient-Education/Level-1
- 12. American Medical Group Association. Provider & Staff Education: Level 1. 2022. Accessed August 18, 2024. https://www.amga.org/Rise-To-Immunize/Campaign-Toolkit/campaign-planks/Provider-Staff-Education/Level-11





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Vaccine Readiness Checklist for Clinics

Roles	and Responsibilities (Recommended timing: Jan-Feb* Jun-Jui')	
	Assign a clinic-level vaccine manager/educator*1	
	Assign a clinic-level maternal vaccine champion*2-4	-
	Identify staff involved in vaccinations ^{3,5}	
Workf	flow and Planning (Recommended timing: Jan-Feb* Jun-Jul†)	\
	Establish a formal clinic workflow (Maternal Vaccination Care Journey Roadmap)*1	
	Ensure standing orders are in place, if applicable (<u>Standing Orders for Administering Pfizer's ABRYSVO®</u> (<u>Respiratory Syncytial Virus (RSV) Vaccine</u>) <u>During Pregnancy (immunize.org)</u>) ^{1,6}	•
	Ensure vaccine storage requirements are met: Refrigerated at 2°C to 8°C (36°F to 46°F) ⁷	_
	Implement digital tools to assist in identification of eligible patients <u>Vaccine Planner ABRYSVO® (Respiratory Syncytial Virus Vaccine) (pfizerpro.com)</u> ^{2,8}	-
	Run reports of last year's maternal RSV vaccination volumes (if applicable) to forecast demand ^{2,9}	_
	Run report of established patient due dates to identify estimated number of eligible patients to forecast demand ²	
	Training and Education (Recommended timing: Jun-Aug* Mid Jul-Aug†) training delivered to staff including training on:	
	Clinic vaccination protocol/workflow ^{1,4,9-10}	_
	Clinic staff roles and responsibilities ⁹	_
	Abrysvo (the only approved maternal RSV vaccine) product details, indications and eligibility requirements ⁷	_
	Side effects, adverse events and contraindications ^{7,11}	_
	Product information on an RSV preventative monoclonal antibody for infants ¹²	_
	Health equity and vaccine access (Link to Health Equity Resource) ^{2,13}	_
	How to make strong vaccine recommendations and address vaccine hesitancy/concerns ^{4,14}	_
	Vaccine reconstitution instructions ⁷	
Clinic	Preparation (Recommended timing: Early Aug* Early Aug¹)	
	Ensure vaccine information statements are available in every room (physical or electronic) ^{1,4}	
	Verify approved or standardized patient education resources are available in the clinic ¹⁵ (<u>Additional Maternal Vaccination Resources</u>)	
	Verify maternal RSV vaccine promotional or educational materials placed throughout clinic (banners on sign in screens, pamphlets, posters or flyers on walls, badge buddies, etc.) ¹⁵	
Techn	ology (Recommended timing: Late Aug* Late Aug¹) ————————————————————————————————————	
	Verify functionality of BPAs or other clinical decision support tools, if applicable ¹⁶	
	Ensure functionality of patient alerts and care gap notifications in patient portals, if applicable ¹⁶⁻¹⁷	_
	Ensure patient educational materials are uploaded and up to date on patient portals and clinic website, if applicable ¹⁷	





MATERNAL RSV VACCINE READINESS CHECKLIST FOR CLINICS

- 1. Immunization Action Coalition. Vaccinating Adults: A Step-by-Step Guide. 2017. Accessed August 18, 2024. https://www.immunize.org/wp-content/uploads/guide/pdfs/vacc-adults-entire.pdf
- 2. Premier Inc. Information on file. 2024
- 3. American Medical Group Association. Assemble your Rise to Immunize Team. 2021. Accessed August 18, 2024. https://www.amga.org/getmedia/9e502d7c-bc3c-42a5-9cac-80ac49a2d081/Core-Team-Members-Chart_READY-FOR-WEB_Registered-Trademark.pdf
- 4. Immunize.org. Suggestions to Improve Your Immunization Services. 2023. Accessed August 18, 2024. https://www.immunize.org/wp-content/uploads/catg.d/p2045.pdf
- 5. Immunize.org. Steps to Implementing Standing Orders for Immunization in Your Practice Setting. 2023. Accessed August 18, 2024. https://www.immunize.org/wp-content/uploads/catg.d/p3067.pdf
- 6. Immunize.org. Standing Orders for Administering Pfizer Respiratory Syncytial Virus (RSV) Vaccine (Abrysvo) During Pregnancy. 2024. Accessed August 18, 2024. https://www.immunize.org/wp-content/uploads/catg.d/p3096.pdf
- 7. ABRYSVO (Respiratory Syncytial Virus Vaccine) for injection (prescribing information). Pfizer. 2023. Accessed August 18, 2024. https://labeling.pfizer.com/ShowLabeling.aspx?id=19589
- 8. Pfizer. Maternal RSV Vaccine Planner. 2024. Accessed August 18, 2024. https://abrysvomaternal.pfizerpro.com/resources/maternal-rsv-vaccine-planner
- 9. American Medical Group Association. Getting Started Checklist. 2022. Accessed August 18, 2024. https://www.amga.org/rise-to-immunize/campaign-toolkit/getting-started/
- 10. American Medical Group Association. Provider & Staff Education: Level 1. 2022. Accessed August 18, 2024. https://www.amga.org/Rise-To-Immunize/Campaign-Toolkit/campaign-planks/Provider-Staff-Education/Level-11
- 11. Immunize.org. Medical Management of Vaccine Reactions in Adults in a Community Setting. 2023. Accessed August 18, 2024. https://www.immunize.org/wp-content/uploads/catg.d/p3082.pdf
- 12. Centers for Disease Control and Prevention. Immunizations to Protect Infants. 2024. Accessed August 18, 2024. https://www.cdc.gov/rsv/immunizations-protect-infants/index.html
- 13. American Medical Group Association. Promoting Health Equity in Adult Immunizations. 2022. Accessed August 18, 2024. https://www.amga.org/rise-to-immunize/campaign-toolkit/health-equity/
- 14. American Academy of Pediatrics. Checklist for Planning and Implementing a Flu Vaccination Clinic. 2023. Accessed August 18, 2024. https://downloads.aap.org/AAP/PDF/InfluenzaVaccinationClinic ChecklistForm UPDATED.pdf
- 15. American Medical Group Association. Patient Education: Level 1. 2022. Accessed August 18, 2024. https://www.amga.org/Rise-To-Immunize/Campaign-Toolkit/campaign-planks/Patient-Education/Level-1
- 16. American Medical Group Association. IT/Documentation: Level 2. 2022. Accessed August 18, 2024. https://www.amga.org/Rise-To-Immunize/Campaign-Toolkit/campaign-planks/IT-Documentation/Level-2
- 17. American Medical Group Association. Patient Education: Level 2. 2022. Accessed August 18, 2024. https://www.amga.org/Rise-To-Immunize/Campaign-Toolkit/campaign-planks/Patient-Education/Level-2





Health Equity in Maternal Vaccinations

IMPROVING VACCINE ACCESS AND UPTAKE FOR PREGNANT INDIVIDUALS

Health equity issues may affect vaccination during pregnancy

Patients may encounter barriers and challenges accessing vaccinations which may affect receiving them in a timely manner. Issues may include distrusting vaccines or medical care, health literacy, costs, transportation and English proficiency.

Patients may have had previous negative experiences related to vaccines or related to medical care which may make them distrustful.¹⁻³ These experiences may include adverse events after immunization, medical dismissal due to vaccine hesitancy or other adverse healthcare experiences.

- Learn about and use <u>cultural intelligence</u> to develop a conscious awareness of personal feelings, assess knowledge gaps and gauge readiness to effectively interact with patients from marginalized populations.²
- Use tools such as "Ask, Acknowledge, Ascend." Ask
 the patient questions in a respectful tone to try
 to understand the cause of distrust. Acknowledge
 the patient's concerns and experience. Ascend the
 distrust, establish rapport and begin to address the
 problem.³

Patients may have concerns about vaccine safety or may not understand the need for vaccines.

- Use <u>"Patient-Oriented Evidence that Matters"</u>
 (<u>POEMs</u>) tools^{4,5} to focus on outcomes patients care
 about and can relate to, such as health during and
 after pregnancy and the health of their babies.
- Use <u>motivational interviewing</u> to align with patient values and needs⁶ which is an evidence-based, culturally sensitive way to talk to patients and help them adopt healthy behavior change.
- Use plain language and teach-back to ensure patients understand vaccine information. Plain language uses everyday words to explain concepts.⁷ (Vaccine Information Statements from immunize. org are written in plain language.) The teach-back method asks patients to explain information presented to them in their own words to make sure they understand it, and the provider can address anything that isn't clear.⁸
- Ensure all staff have resources and education to answer questions about vaccines that can be customized to the patient population. (See Resources)

Patients may think they can't afford vaccines.

- Most health insurance plans cover recommended vaccines for little or no cost to patients.⁹
- Beginning October 1, 2023, state Medicaid and <u>CHIP programs must cover FDA-approved, ACIP-recommended vaccines for adults.</u>¹⁰

Patients may have difficulty getting to and from prenatal appointments.

- Expand clinic hours and location options with dropin vaccination sites¹¹ and walk-in and scheduled express vaccination appointments.¹²
- Refer patients to local pharmacies, health centers or state health department resources that may have more convenient locations and hours.⁹

Patients may not be proficient in English and may have trouble understanding information.

- Pre-natal vaccination education is available in multiple languages from the <u>Society for Maternal-</u> Fetal Medicine.
- Vaccine information statements are available in multiple languages from <u>immunize.org</u>

RESOURCES

Centers for Disease Control and Prevention – Vaccine Safety https://www.cdc.gov/vaccine-safety/about/pregnancy.
https://www.cdc.gov/vaccinesafety/concerns/vaccines-during-pregnancy.html

American College of Obstetricians and Gynecologists – Vaccine Safety During Pregnancy https://www.acog.org/womens-health/faqs/vaccine-safety-during-pregnancy

Pediatric Infectious Disease Society Comprehensive Vaccine Education Program—From Training to Practice https://pids.org/education-training/vaccine-education-program/

Children's Hospital of Philadelphia Vaccine Education Center https://www.chop.edu/centers-programs/vaccine-education-center







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- 2. Richard-Eaglin A, McFarland ML. Applying Cultural Intelligence to Improve Vaccine Hesitancy Among Black, Indigenous, and People of Color. *Nurs Clin North Am.* Sep 2022;57(3):421-431. doi:10.1016/j.cnur.2022.04.008
- 3. Barksdale A. Overcoming Barriers of Distrust. Fam Pract Manag. Mar-Apr 2022;29(2):40.
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- 12. Klusaritz H, Paterson E, Summers C, et al. Community-Based COVID-19 Vaccine Clinics in Medically Underserved Neighborhoods to Improve Access and Equity, Philadelphia, 2021-2022. *Am J Public Health*. Dec 2022;112(12):1721-1725. doi:10.2105/AJPH.2022.307030





ADDITIONAL MATERNAL VACCINATION RESOURCES

This list of resources provides additional information to help providers and patients understand the importance of maternal vaccines and to help make informed decisions for better health outcomes.

CDC

- Pregnancy and Vaccination | https://www.cdc.gov/vaccines-pregnancy/index.html
- Why Maternal Vaccines Are Important | https://www.cdc.gov/vaccines-pregnancy/hcp/maternal-vaccines/index.html
- Guidelines for Vaccinating Pregnant Persons | https://www.cdc.gov/vaccines-pregnancy/hcp/vaccination-quidelines/index.html
- Immunization and Pregnancy Research | https://www.cdc.gov/vaccines-pregnancy/hcp/research/ index.html
- From Me, To You | https://www.cdc.gov/vaccines/events/from-me-to-you.html#for-healthcare-providers

ACOG

- Increasing Maternal Immunization Rates | https://www.acog.org/programs/immunization-for-women/activities-initiatives/increasing-maternal-immunization-rates
- Maternal Immunization Practice Advisory | https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2022/10/maternal-immunization

PATIENT EDUCATION:

ACOG

• Vaccines During Pregnancy | https://www.acog.org/-/media/project/acog/acogorg/womens-health/files/infographics/vaccines-during-pregnancy.pdf

CDC

- About vaccines and pregnancy | https://www.cdc.gov/vaccines-pregnancy/about/index.html
- Vaccine Recommendations Before, During, and After Pregnancy | https://www.cdc.gov/vaccines-pregnancy/recommended-vaccines/index.html
- Vaccine Safety for Moms-to-Be | https://www.cdc.gov/vaccines-pregnancy/vaccine-safety/index.
 https://www.cdc.gov/vaccines-pregnancy/vaccine-safety/index.
- Vaccine Resources for Pregnant Women | https://www.cdc.gov/vaccines-pregnancy/resources/ index.html
- From Me, To You | https://www.cdc.gov/vaccines/events/from-me-to-you.html#pregnant-people-support-networks



