



Advancing High Performance Health

Maternal RSV Vaccine Preparedness

Quality and Innovation Collective (QuIC)

Phase 1 Meeting Summary





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Up to 80,000 children younger than age 5 are hospitalized each year due to maternal respiratory syncytial virus (RSV).¹ In August 2023, the Food and Drug Administration approved ABRYSSVO™ (Respiratory Syncytial Virus Vaccine) for use against RSV, given to pregnant patients weeks 32 through 36 of pregnancy to protect infants from birth through 6 months of age.²

Recommendations by the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP),³ and the American College of Obstetrician and Gynecologists (ACOG)⁴ soon followed. Because RSV is a seasonal disease, the vaccine is recommended for administration during September through January in most parts of the United States.⁵

How can healthcare organizations use this vaccine to improve care for infants at risk for RSV? How can they work together, within their organizations, and within their communities to raise awareness of the burden of RSV disease?

Ten healthcare organizations are exploring these questions and more in AMGA's Maternal RSV Vaccine Preparedness Quality and Innovation Collective(QuIC).

"This is a chance for groups to learn from each other about shared barriers and possible solutions," said Senait Temesgen, senior program manager of population health initiatives with AMGA.

The three-phase QuIC will use interactive workshops, quality improvement tools, and qualitative methodology to engage participants in thoughtful discussions to collect insights and share best practices on creating and implementing successful immunization strategies.



Maternal RSV QuIC Participants

- Advocate Aurora Medical Group
- The Everett Clinic and The Polyclinic, Part of Optum
- Inova
- Lehigh Valley Physician Group
- Northwell Health
- Olmstead Medical Center
- Oregon Health & Science University, School of Medicine
- Shannon Health System
- Valley Health System
- Vanderbilt University Medical Center

QuIC Framework





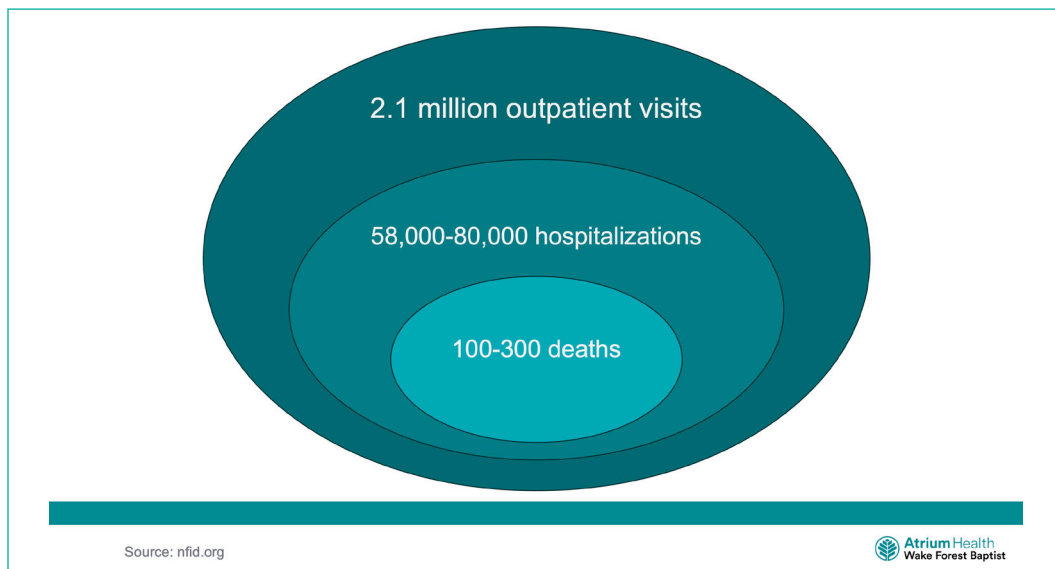
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November 15: Educational Webinar

Temesgen began the session with the educational webinar's purpose: "to level set everyone on their knowledge of the maternal RSV vaccine." She then acknowledged the QuIC Advisory Committee, "the experts behind the content and curriculum development," and introduced the educational session's two speakers: Elisabeth M. Stambaugh, MD, MMM, chief medical officer with Wake Forest Health Network, and Sarah Pugh, PhD, senior director of US Medical Affairs, Vaccines, Pfizer.

Stambaugh began with a brief overview of what RSV is: a negative sense-single-stranded RNA virus with a typical seasonal onset in October with peaks in most parts of the United States between December and January. "It affects mostly the nose, throat, and lungs," she explained. "It's transmitted by respiratory droplets or contaminated surfaces such as tables and rib rails, and it can actually survive for many hours on those hard surfaces. After the symptoms disappear in a patient, they can still spread the virus for up to four weeks after their symptoms stop."

With many children, symptoms are mild, but 15%–50% can develop more severe lower respiratory tract disease. "The burden on the healthcare system is significant," Stambaugh said.



"The peak hospitalization rate for infants comes within the first two months of life," Pugh said.

She explained how maternal immunization protects infants at birth and in the first few months of life through the natural process of transplacental antibody transfer, then walked through the clinical guidance for the RSV vaccine, including:

- The vaccine is seasonally administered during weeks 32 through 36 of pregnancy.
- It can be simultaneously administered with other vaccines, including those for tetanus, diphtheria, and pertussis (Tdap), influenza, and COVID.
- Additional research is needed to determine whether subsequent pregnancies require additional seasonal doses.



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While two RSV vaccines are currently approved and recommended for use in adults age 60 and older, only the Pfizer RSV vaccine, ABRYOVO, should be administered to pregnant individuals, Pugh noted, emphasizing that it's critical to educate providers on this point and implement systems to avoid potential medication errors.

Pugh then walked through results from MATISSE (Maternal Immunization Study for Safety and Efficacy) phase 3 clinical trial,⁶ including data for determining vaccine efficacy in infants and an overview of the serious adverse events that were reported: neonatal jaundice, low birth weight, and preterm birth. Local reactions and systemic events for pregnant participants were mostly mild to moderate. The most common local reaction was pain at the injection site.

Pugh concluded by walking through preparation and storage and handling information for the RSV vaccine, emphasizing that it should be refrigerated at 2–8° Celsius, never frozen, and either administered immediately or stored at room temperature and used within four hours. Immunization teams should not store or freeze reconstituted vaccine.

For the last part of the session, Temesgen moderated questions from participants, starting with an inquiry about research on vaccine efficacy for pregnant patients.

Stambaugh noted the rise in vaccine hesitancy in recent years. “We are really going to have to think about the best way to educate our patients so that they’re willing to take the vaccine.”

During the initial roll out of this vaccine in the fall of 2023, an immediate challenge was getting the vaccine to the patients who want and need it.

In certain cases, if the provider had not yet established standing orders, pregnant individuals have required a prescription for the vaccine from their obstetrician.

Here, the maternal RSV vaccine’s ACIP recommendation will be an advantage, one participant said. There’s an impetus for health systems and OBGYNs to vaccinate eligible individuals.

Then there’s the issue of payments and reimbursement by commercial and government payers that imposed barriers to administration during the first year of implementation as well.

Finally, participants discussed the geographical and seasonal nuances of maternal RSV vaccine administration. One big challenge: getting the seasonality window of the vaccine to align with a patient’s gestational window. For example, will patients who reach 32 weeks in March or who are scheduled to deliver in April have access to the vaccine for themselves or their child?

“We have patients get flu shots in May or June,” Stambaugh noted about influenza’s similar seasonality. “I think time will tell. That’s a great issue for us to talk about as a collaborative.”

Additional information about the maternal RSV vaccine

- [Pfizerpro.com](https://www.pfizerpro.com)
- [Pfizermedinfo.com](https://www.pfizermedinfo.com)
- [abryovo.com](https://www.abryovo.com)
- [cdc.gov/rsv/clinical](https://www.cdc.gov/rsv/clinical)
- [acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/09/maternal-respiratory-syncytial-virus-vaccination](https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/09/maternal-respiratory-syncytial-virus-vaccination)
- [vaers.hhs.gov/index.html](https://www.vaers.hhs.gov/index.html)



AMGA Quality and Innovation Collective (QulC) Maternal RSV Vaccine Preparedness

December 12: Virtual Discussion Forum

Danielle Casanova, MBA, vice president of population health initiatives and health equity at AMGA, welcomed participants to the second part of Phase 1, the virtual discussion forum.

“We’re in the midst of RSV season right now,” she noted. “It’s a very exciting time, because there are a lot of prevention options this year. But there are also a lot of missing parts. Here, we’ll have the opportunity to discuss the development of vaccine programs in your organizations, challenges and strategies, and gaps and opportunities to guide future work in Phases 2 and 3.

A survey of current plans and practices

Before the session, participants completed a detailed survey of questions, such as:

- Has their organization developed a vaccine administration strategy?
- Have they added the RSV vaccine to their electronic health record (EHR)?
- Is there a documentation process in place for vaccine receipt and declination?
- Do they plan on using choice-based, shared decision-making with their patients for navigating vaccine options?
- Is there a process in place for assessing patient education needs?
- Does the organization currently have an RSV vaccine physician champion?

Participants were also asked to rank the top challenges and barriers to maternal RSV administration in their organizations. This ranking guided the day’s discussion.

Barrier 1: Vaccine hesitancy

Several organizations ranked hesitancy among their top challenges.

Moderator Christopher Russo, MD, director of pediatrics and medical director for quality and innovation with WellSpan Health, asked participants what they had been seeing and hearing from providers, staff, and pregnant women specific to maternal RSV and where people were getting their information.

Along with established sources like the CDC, “a lot” of information comes from social media, participants responded.

“With vaccines, there’s going to be a lot of misinformation out there,” one declared. Their organization’s strategy has been to “get out in front of patient education as much as possible” with evidence-based information: when a pregnant patient is enrolled, during weekly updates, in MyChart blasts, and more, offering information about the vaccine, why it’s recommended, and links to valid resources to learn more.

“Patients appreciate hearing this directly from their provider,” another participant remarked. “It’s validating the information they’ve received, and I think that’s what usually pushes them over” into receiving the vaccine.

Another strategy: reminding patients of nirsevimab shortages and that there might not be a supply if they forgo maternal vaccination.



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Patients want to know how the vaccine works. Does it go through the placenta? Does it change a person's DNA? How many vaccines should a patient be getting at once? "If I'm not supposed to be eating lunch meat while I'm pregnant, is it the best idea to get four vaccines at one time?"

Many patients asked about the duration of the RSV season. How long would the vaccine be available? Some weren't even aware of the vaccine's launch. "I think more advertising for it would be helpful," one participant suggested, noting that the nurses at their organization "do a lot of teaching" during patient visits.

As a whole, however, participants reported that most patients have been knowledgeable about the vaccine and its effects, saying, "They have family members, sisters, and there's so much RSV right now, so I think they're very in tune with it."

Russo then asked about vaccine hesitancy within the healthcare organizations themselves. Were those frontline staff greeting and rooming patients and answering calls buying in?

Staff generally want to give the vaccine because they know it's going to help, participants said. "The biggest feedback has been, 'Ugh, one more vaccine.' They're inundated with flu, Tdap, COVID."

"There's not a lot of staff discussion with patients, because we don't have a protocol like with flu and Tdap," was another observation. "Visits are short, and there are a lot of things to cover."

What do participants recommend? Adding best practice advisories to Epic and maintaining good lines of communication between obstetricians and pediatric clinicians regarding vaccine supply were two suggestions.

Barrier 2: Cost to the patient

The plan is that eligible patients are able to receive a recommended RSV vaccine at zero cost. But reality has been rockier for many patients and care teams navigating the system.

Russo asked if patients were able to get the vaccine covered through their regular pharmacies, or if they had to schedule a visit with another facility. Was prior authorization needed?

"For a while, confusion reigned," one participant commented.

"We know what the law is, but insurers take time, especially public funding like Medicaid," another remarked. "They eventually get there, but it's not instantaneous."

When maternal RSV vaccinations started at the end of September, "the biggest barrier and fear was patient would get stuck with a large out-of-pocket cost," one participant said. "Patients cancel their appointment when they find out there's a cost," another shared.

"If a patient says they want the vaccine today, what do you tell them?" Russo asked.

"We recommend they check with insurance first, call during their visit, and schedule later or at their next visit if it falls within the vaccination window," was one reply.

For some patients, recent approval and MMWR publication in November 2023 created an insurance coverage gap with denials.



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In short, this situation is resulting in vaccination gaps on the patient side. “Patients are waiting for it all to be sorted out.” On the provider side, it’s impacting supply and procurement. “My team is afraid to buy in bulk because they might get stuck with the vaccine,” one participant said. “There’s just a fear there’ll be a gap or lag in how the payment evolves.”

Organizations should be aware that insurers may not cover the costs if providers opt to utilize clinician judgment and administer maternal RSV vaccines outside of the recommended September–January window.

Barrier 3: Cost to the organization

The cost of storage, and equipment and the vaccine itself are just the beginning of the expenses for a clinic rolling out a new vaccine. There’s staff education to consider as well, one participant noted. “We need to make sure our OB nurses have the competency and the training.”

Have the ordering processes for maternal RSV been different than those for influenza and Tdap?

Some organizations are “stocking the vaccine at every obstetrics office” while others are “working toward a centralized location.” Many started out with minimum quantities, then reordered as needed.

Russo asked participants if they had any advice for forecasting demand.

“I’m smiling because I don’t know the answer,” was one participant’s reply. “I think that’s the challenge, and we’d be open to any suggestions.”

Barrier 4: Patient awareness and education

Russo circled back to the earlier discussion about patient education. What channels are participants using to drive awareness of the maternal RSV vaccine?

Answers were plentiful and varied: communicating directly to patients through social media and direct mail, sending out a “plain language version” of a letter for providers, enlisting public affairs teams and providers to spread the word, and leveraging opportunities for education at grand rounds and staff meetings.

Russo asked if participants were seeing any provider pushback.

One participant cited “a lot of thank yous because they were getting calls from patients, and they were grateful for the guidance.”

Russo asked if organizations were equipping providers with resources like talking points.

For one participant, a presentation at the monthly practice meeting served this purpose: “We used it as talking points, and the PowerPoint gets sent out to everyone. Then at the end of September, before we actually had the vaccine, we started giving the presentation here in the office as reinforcement.”

Russo concluded the discussion with the subject of health equity.

“How are you making sure there’s real equitable allocation of this vaccine?” he asked. “We know cost can be prohibitive for some families. How are you addressing known disparities in your population?”



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“Right now, we’re just trying to get anyone and everyone who’s eligible to get the vaccine,” one participant said. Another added that they’ve made a special effort for patients who are bedridden in the hospital on pregnancy watch, who can’t get to a clinic or pharmacy.

Next Steps

For next steps, participants will submit their thoughts on what is required to implement an maternal RSV vaccine program in their organization.

The Phase 2 virtual meeting May 22 from 11:00 am to 3:00 pm ET will be an interactive virtual learning featuring discussion questions developed from a post-meeting survey. After the session, participants will submit their organizations’ current practices of bringing a new vaccine into organizations, including workflows and barriers, and plans for the implementation of tailored interventions.

Finally, in October, participants will meet in person in Alexandria, VA, to talk about their work to date and share best practices, lessons learned, and next steps for their maternal RSV immunization strategies.

Initial Considerations for the Development of a Maternal RSV Program

- Develop provider, staff, and patient education to provide evidence-based information about the maternal RSV vaccine.
- Leverage opportunities to provide patient education (social media, direct mail, MyChart, etc.).
- Ensure all patients who are eligible have access to the vaccine.
- Develop staff competency training for administering the maternal RSV vaccine.
- Incorporate timing, administering, documentation, and tracking the RSV vaccine into the current clinical workflow.
- Work with IT department to include RSV information and documentation into the EHR.
- Identify cost and procurement process for the organization.
- Consider storage and handling of the new vaccine (i.e., centralized location or in each clinic).
- Develop a process of communication between obstetricians and pediatricians to identify patients receiving the maternal RSV vaccine.

References

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2. [fda.gov/news-events/press-announcements/fda-approves-first-vaccine-pregnant-individuals-prevent-rsv-infants#:~:text=Today%2C%20the%20U.S.%20Food%20and,through%206%20months%20of%20age](https://www.fda.gov/news-events/press-announcements/fda-approves-first-vaccine-pregnant-individuals-prevent-rsv-infants#:~:text=Today%2C%20the%20U.S.%20Food%20and,through%206%20months%20of%20age)
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