

PRACTICE INSIGHTS



PHARMACY PERSPECTIVES ON MATERNAL RSV VACCINATION

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This report was developed by the American Pharmacists Association (APhA) with support from Pfizer, Inc.

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Background

The 2024 adult immunization schedule from the Centers for Disease Control and Prevention (CDC) recommends that pregnant people receive vaccines to help prevent COVID-19, influenza, respiratory syncytial virus (RSV), tetanus-diphtheria-pertussis (Tdap), and hepatitis B infections.¹ (Meningococcal and mpox vaccines may also be appropriate during pregnancy in specific situations.) Among these vaccines, Tdap and RSV vaccines are specifically tar-

geted to people who are pregnant; the goal is to generate passive immunity, which occurs when maternal antibodies are passed to the infant and provide protection. Both Tdap and RSV vaccines should be administered during specific gestational windows, which poses additional challenges for appropriate vaccine delivery. Tdap vaccines should be administered once during each pregnancy regardless of maternal prior history of receiving Tdap.



Although Tdap may be given at any time during pregnancy, the optimal timing for Tdap administration is between 27 and 36 weeks of gestation.²

RSV vaccine is the most recently approved vaccine for use in pregnancy (see sidebar). RSV is the cause of substantial morbidity and mortality among infants in the United States, and it is the leading cause of hospitalization among infants in this country. Remarkably, between 2% and 3% of all infants in the United States will be hospitalized for RSV infection. The highest hospitalization rates occur during the first month of life and decline with increasing age. Each year, RSV in infants results in 100 to 300 deaths, 58,000 to 80,000 hospitalizations, and more than 500,000 emergency department visits.³

A RSV vaccine should be administered between 32 and 36 weeks of gestation from September through January in most areas of the continental United States. In geographic regions with seasonality that differs from most of the continental United States (e.g., Alaska, areas with tropical

Maternal RSV Vaccination Approval

On August 21, 2023, the U.S. Food and Drug Administration (FDA) approved the RSVpreF (Abrysvo) vaccine for use in pregnant individuals for the prevention of RSV lower respiratory tract disease and severe lower respiratory tract disease in infants from birth to 6 months of age based on the following information:

- In phase 2b and 3 trials, vaccination was given to pregnant individuals during 24 through 36 weeks of gestation.⁶
 - A numerical imbalance in preterm births was observed in RSVpreF vaccine compared with placebo recipients in two clinical studies.
 - Available data are insufficient to establish or exclude a causal relationship between preterm birth and RSVpreF.
 - Additionally, a numerical imbalance in hypertensive disorders of pregnancy was observed in RSVpreF vaccine recipients compared with placebo recipients.
- Starting dosing at 32 weeks of gestation can reduce the potential risk of and complications from preterm birth.⁷
 - It avoids the risk of extremely preterm births and very preterm births, which are associated with higher morbidity and mortality.
 - Similar vaccine efficacy in 32 through 36 weeks of gestation was observed compared with the overall study population.

Few data are currently available on uptake and usage of RSVpreF since its August 2023 FDA approval as a single dose to be given at 32 through 36 weeks of gestation. FDA has required the manufacturer to conduct postmarketing studies to assess preterm birth and hypertensive disorders of pregnancy, including pre-eclampsia.^{3,8}

climates), providers should follow state, local, or territorial guidance on timing of administration. (Two RSV vaccines are available as of the time of publication: RSVPreF3 (Arexvy—GSK) and RSVpreF (Abrysvo—Pfizer) are indicated for adults aged 60 years and older, but only RSVpreF is currently indicated for pregnant patients.³)

Although vaccination during pregnancy is important for prevention of illness in infants, available data indicate that vaccination rates with Tdap during pregnancy are suboptimal. A retrospective analysis of electronic health records from 2017 through 2021 identified 1,021,260 deliveries among 886,660 individuals.⁴ Among these individuals, 55.1% received a Tdap vaccination

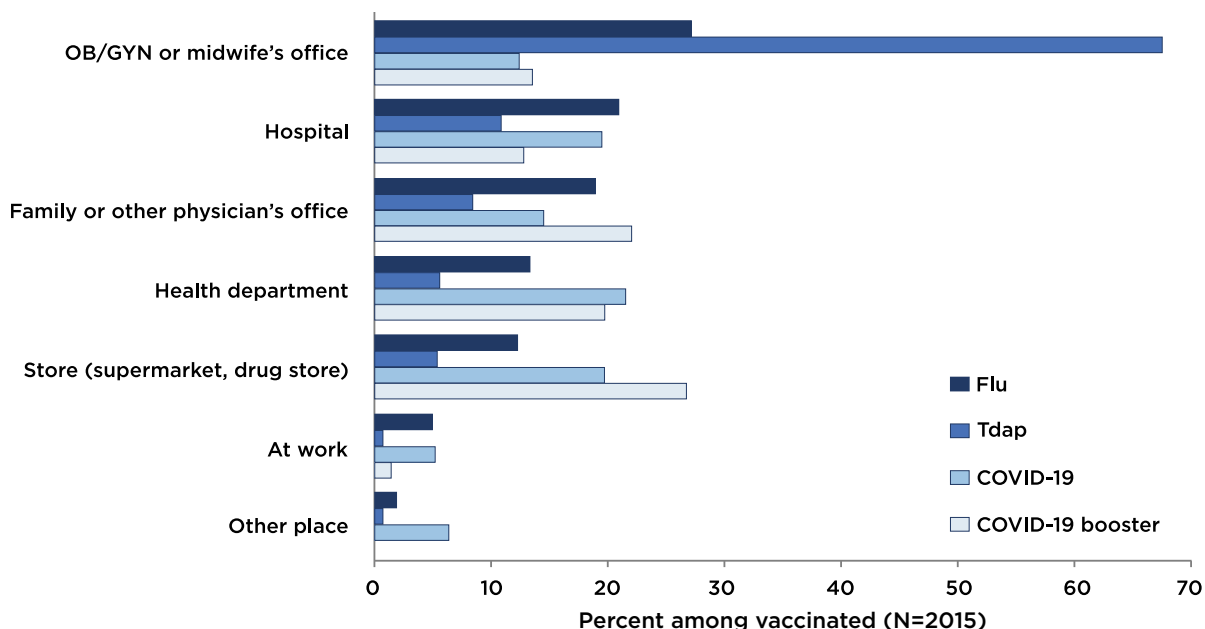
during pregnancy; 79.5% of these vaccinations occurred during the recommended vaccination window.⁴ Rates were highest in 2017 (56.5%) and lowest in 2021 (52.1%).⁴ Survey data from an internet panel of 2,015 pregnant people found that they frequently have vaccinations administered at their obstetrician or midwife's office; this was the most common setting for administration of Tdap and influenza vaccines, although vaccines are also often obtained from health professionals at other locations such as pharmacies (Figure 1).⁵

On December 11, 2023, the American Pharmacists Association (APhA) convened a roundtable to gather information and insights about current practices for mater-

nal immunization in pharmacy settings, explore pharmacists' knowledge and perspectives about RSV disease burden in infants and the maternal RSV vaccine, and identify gaps and opportunities to support the role of pharmacists in maternal immunization for the prevention of RSV in infants.

Roundtable participants included representatives from chain and independent community pharmacy practices as well as individuals who worked in an obstetrics/gynecology clinic and specialty pharmacy. In addition, APhA conducted a national survey of practicing pharmacists to gather their insights and perspectives on maternal vaccination practices.

Figure 1. Place of Flu, Tdap, COVID-19 Vaccination Among Pregnant women, United States, Internet Panel Survey April 2022



"Other place" includes other medical or non-medical place, including school or special site for COVID-19 vaccination

OB/GYN=obstetrician/gynecologist; Tdap=tetanus-diphtheria-pertussis.

Maternal RSV Vaccination Survey Results

A total of 163 pharmacists responded to the APhA survey on maternal vaccination practices. Respondents were well-distributed geographically, and most respondents practiced in independent pharmacy (34%), chain pharmacy (29%), or supermarket pharmacies (23%) (Table 1).⁹ⁱ The overwhelming majority of respondents administered vaccines (90%), including to pregnant patients (79%) (Figure 2). Respondents who did not administer any vaccines (n=16) did not participate in the rest of the survey. The remaining respondents were very supportive of vaccinating pregnant patients (Figure 3).⁹ They “agreed” or “strongly agreed” that vaccines recommended during pregnancy are beneficial (99%) and that pregnant individuals should receive the influenza vaccine (99%) and the Tdap vaccine (98%). Support for the COVID-19 vaccine and the RSV vaccine was also high; however, more respondents “agreed” rather than “strongly agreed” that they supported the use of these vaccines during pregnancy.⁹ Respondents reported the vaccines that they most commonly recommend for pregnant individuals were for influenza (97%), Tdap (87%), COVID-19 (83%), and RSV (61%). Only 2% of respondents did not administer vaccines to pregnant patients. Most respondents reported that they regularly approach pregnant individuals to discuss the importance of receiving

Table 1. *Demographics of Respondents to the APhA Survey on Maternal Vaccination Practices*

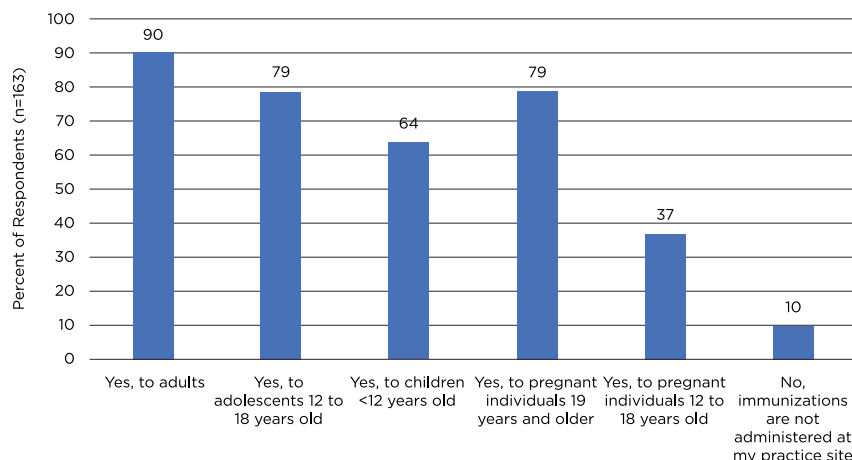
Parameter	Percent of Respondents (%)
Pharmacy practice setting	
Chain pharmacy	29
Supermarket pharmacy	23
Mass-merchant pharmacy	3
Independent pharmacy (1–3 units)	34
Clinic (outpatient) pharmacy	5
Managed care pharmacy	0
Physician office-based practice	0
Academia	0
Ambulatory care clinic	3
Federal/military/Department of Defense	0
Other*	3
Year of entry-level pharmacy degree	
1987 or before	15
1989 to 1997	16
1998 to 2007	19
2008 to 2012	11
2013 to 2018	27
2019 or later	13
Pharmacy practice region	
Northeast	11
Midwest	29
South	40
West	18
Puerto Rico/Outside U.S.	2

*Other included vaccine coordinator for a tribal health clinic, hospital (outpatient pharmacy), and health system.
Source: Reference 9.

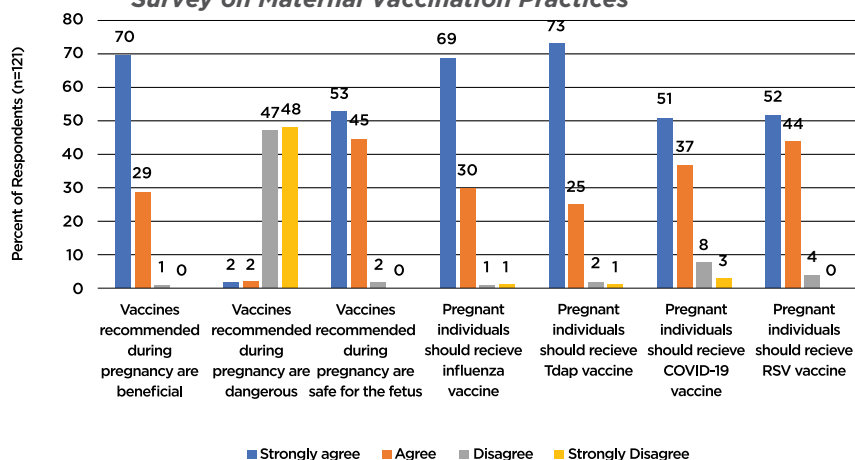
vaccines. Respondents who indicated that they are unlikely to recommend RSV vaccine to pregnant patients reported concerns about wanting to see additional evidence regarding the risk for atrial fibrillation, wanting to wait for the vaccine to be out longer so that long-term data are available, and concerns

about risks versus benefit.⁹ Patterns for vaccine administration to pregnant patients were similar to those for vaccine recommendations (Figure 4). Other vaccines that respondents reported administering to pregnant patients included those for hepatitis A and hepatitis B.

i Percentages for survey responses may not add to 100% due to rounding.

Figure 2. Vaccine Administration by Pharmacists Responding to the Survey on Maternal Vaccination Practices

Source: Reference 9.

Figure 3. Pharmacist Support for Vaccinating Pregnant Patients in the Survey on Maternal Vaccination Practices

RSV=respiratory syncytial virus; Tdap=tetanus-diphtheria-pertussis.

Source: Reference 9.

Barriers reported that impacted respondents' ability to vaccinate pregnant individuals included:⁹

- Pregnant individuals usually receiving vaccines elsewhere (58%)
- Difficulty identifying gestational age of pregnant individuals (48%)
- Difficulty identifying pregnant individuals (45%)
- Patient refusal due to safety concerns (36%)
- Difficulty tracking immunization status for appropriate vaccines (24%)
- Patient refusal due to cost or lack of insurance (24%)
- Patient refusal due to efficacy concerns (17%)
- Comfort level vaccinating pregnant patients (10%)
- Restrictions per state laws and regulations (4%)
- Employer policies (2%)
- Other (6%)

The majority of respondents reported that they were “very knowledgeable,” “knowledgeable,” or “somewhat knowledgeable” about topics related to RSV disease and maternal immunization with a RSV vaccine. However, few considered themselves to be at the “very knowledgeable” level about various topics as follows:⁹

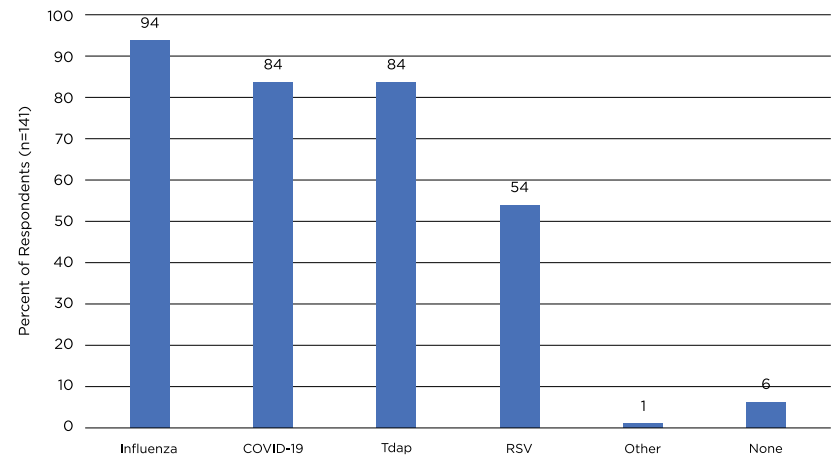
- RSV disease burden in infants (14%)
- RSV seasonality (14%)
- RSV indication for patients who are pregnant (19%)
- Approved gestational time frame for administering RSV vaccine (18%)
- Selection of appropriate RSV vaccine and dosage for pregnant patients (20%)
- Appropriateness of coadministration of RSV vaccine with other vaccines in pregnant patients (14%)

Further, respondents were more likely that they felt “not too knowledgeable” or “not at all knowledgeable” about certain topics:

- Approved gestational time frame for administering RSV vaccine (48%)
- Selection of appropriate RSV vaccine and dosage for pregnant patients (45%)
- The appropriateness of coadministration of RSV vaccine with other vaccines in pregnant patients (45%)

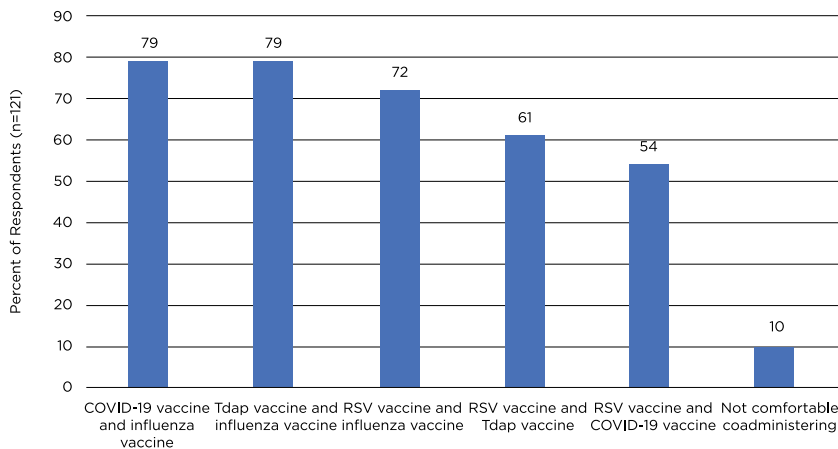
Although the majority of respondents (82%) reported stocking RSVpreF for pregnant patients, some pharmacists reported stocking RSVPreF3 (7%) or both RSVpreF and RSVPreF3 (12%) for pregnant patients, even though RSVPreF3 is not currently indicated for pregnant patients. Additionally, 82% correctly reported that RSVpreF is FDA-approved for

Figure 4. Vaccines Administered to Pregnant Patients by Pharmacists Responding to the Survey on Maternal Vaccination Practices



RSV=respiratory syncytial virus; Tdap=tetanus-diphtheria-pertussis.
Source: Reference 9.

Figure 5. Pharmacist Comfort with Coadministering Vaccines to Pregnant Patients in the Survey on Maternal Vaccination Practices



RSV=respiratory syncytial virus; Tdap=tetanus-diphtheria-pertussis.
Source: Reference 9.

administration to pregnant individuals during 32 through 36 weeks of gestation.⁹ The majority of respondents reported feeling comfortable

coadministering multiple vaccines to pregnant patients, although comfort levels were higher for certain vaccine combinations compared with others (Figure 5).⁹

The most common strategy for identifying pregnant patients who are eligible for receiving vaccines is through the patient’s request, which was reported by 83% of respondents. Referrals were the second most common strategy, with 59% reporting receiving referrals from obstetricians and/or midwives, and 40% reporting referrals from other health care providers. Less common strategies included interviewing patients directly (34%), proactive review of prescription records (29%), clinical alerts from pharmacy software (22%), and collaboration with third-party payers and/or integrated care providers (6%).⁹ Recommendations from the Advisory Committee on Immunization Practices (ACIP) were reported to be the most important factor for determining which vaccines to prioritize for pregnant patients, followed by the patient’s gestational status and the patient’s comorbid conditions. Respondents reported a high level of interest in receiving continuing education, with the overwhelming majority being very interested or interested in education on topics including:⁹

- Safety and efficacy of RSV vaccine in pregnant patients for the prevention of RSV in infants (96%)
- Appropriate RSV vaccine selection and best practices for coadministration (95%)
- Vaccine safety for pregnant patients (95%)
- RSV disease burden (88%)
- RSV seasonality (85%)

Perspectives on Pharmacy-Based Maternal RSV Immunization

During the roundtable, participants discussed their perspectives regarding the use of RSV vaccines and opportunities for improving practices for vaccinating pregnant patients. Even though national data and survey responses indicated that pregnant patients often receive vaccines in nonpharmacy locations, pharmacy has many strengths that support the delivery of maternal vaccination services.^{4,5} Pharmacists are experienced vaccine providers with established infrastructure for payment, inventory, storage, and documentation. They are also highly qualified and trusted providers who have improved accessibility and convenience compared with many other providers.

The ability to improve patient and population health through improving vaccination rates was seen by roundtable participants as a key benefit for implementing maternal immunization services in pharmacy practice. Participants felt that pharmacies were a logical location for the delivery of maternal immunization services and were in favor of supporting pharmacies that implement these services. Participants felt that implementing maternal immunization services in pharmacies could increase access to care for patients, particularly in areas with limited prenatal care services. Participants believed that the implementation of maternal immunization services could lead to improved communication with patients throughout the pregnancy along with opportunities to build trust, identify and address barriers the patients are experiencing, and provide patient education. Provision

of maternal vaccinations also could foster greater collaboration with community partners that provide services to pregnant patients.

Participant Approaches to Incorporating New Vaccines in Pharmacy

Survey respondents were much less likely to administer RSV vaccines than influenza, COVID-19, or Tdap vaccines, even though most agreed that pregnant patients should receive the vaccine (Figures 3 and 4).⁹ Because RSV vaccines were only recently approved in 2023, practices for uptake of new vaccines in a pharmacy practice can influence the integration of new services.

Roundtable participants discussed their approaches to offering new vaccines when they become available. Most reported that their pharmacy waits until the CDC publishes recommendations for the vaccine before it is offered to patients. They reported often being aware of the vaccines following review during ACIP meetings, but third-party payers will not pay for the vaccines until CDC publishes their report in Morbidity and Mortality Weekly Report. Some participants noted that decisions regarding which vaccines to offer are often made at a corporate level and may be influenced by state laws and regulations. Roundtable participants noted that pharmacies provide educational opportunities to their staff in preparation for offering the vaccine as soon as the recommendations are published so that the vaccine may be available promptly to interested patients. However, importantly, many survey respondents reported remaining

knowledge gaps regarding RSV vaccines, suggesting a need for additional educational interventions.

Participants suggested pharmacy entities that collaborate closely with prescribers could also offer education about upcoming vaccines to prescribers in an effort to present consistent messaging to patients about new vaccines. They felt this would be an effective strategy for informing prescribers about the availability of the vaccine at the pharmacy so that referrals can be made.

Survey responses indicated some pharmacists require additional education to ensure that RSVPreF3 is administered only to older adults (i.e., aligned with its current indication). Roundtable participants discussed how to prevent errors in administration when multiple vaccines are offered in the pharmacy with distinct indications, such as RSVpreF and RSVPreF3. They reported having dedicated quality teams that aim to systematically and proactively prevent the occurrence of errors. These teams meet regularly to assess practices and determine whether any interventions are appropriate. If an error occurs with the administration of a vaccine, it is reported immediately through centralized reporting systems to support the work of quality teams. Proactive systems used to prevent administration errors for RSV vaccines include adding blocks in computer systems (e.g., to prevent someone younger than 60 years of age from receiving RSVPreF3), barcode scanning, and ensuring clear labeling.

Challenges for Pharmacy-Based Vaccine Services in Pregnancy

Roundtable participants identified several challenges facing the delivery of pharmacy-based vaccine services to pregnant patients. As noted in the survey, identifying patients who are pregnant and at the correct gestational age for services was considered a key challenge. Furthermore, a need to increase patient awareness of the availability of RSV vaccine in pharmacies was cited as a challenge. Some participants indicated a need to increase pharmacists' confidence

States, the vaccine should be administered from September through January, which coincides with influenza vaccination season, adding to increased demand for vaccination services during this time period. In geographical regions with seasonality that differs (including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands), providers should follow state, local, or territorial guidance on timing of administration.

and gestational age is generally not available while filling prescriptions in community pharmacy settings, and it is generally socially inappropriate or awkward to ask people whether they are pregnant. Participants noted that prenatal vitamins could potentially be used as a marker for pregnancy, but these supplements may also be used by individuals who are trying to get pregnant. Further, they cautioned of the need to be sensitive to people who might be struggling with infertility or pregnancy loss.

Marketing to Patients

Marketing the availability of vaccines for pregnant patients along with the benefits of those vaccines was seen as a key strategy to overcoming awareness barriers and increasing patient requests for the vaccines. Instead of directly asking individual patients about pregnancy, participants recommended having informational materials in the pharmacy regarding the availability of RSV vaccine for pregnant people to prompt awareness and patient questions. Recommended materials and strategies included overhead announcements, posters, tear sheets, and brochures on display. These educational offerings should be available to the general public so that all people are aware of the availability of RSV vaccine in addition to the appropriate administration window and therefore know to ask for it when pregnant. Participants observed that most patients who should receive maternal RSV vaccine also receive other vaccines, especially influenza and COVID-19 vaccines, and that these patients should also be offered



and comfort level answering pregnant patients' questions about vaccines during pregnancy. Gaps in third-party payer coverage and affordability for patients were also considered challenges. Additionally, participants reported challenges related to the seasonality of maternal RSV vaccine. In most of the continental United

Strategies for Identifying Patients During the Appropriate Gestational Window

Participants indicated that identifying patients who are appropriate for maternal RSV vaccination is a challenge. They noted that information about pregnancy status



Provider Collaboration and Care Coordination

Roundtable participants recommended marketing initiatives directed to other providers who care for pregnant patients. Specifically, they recommended collaboration with obstetricians in their service areas to trigger referrals. They observed that most obstetricians do not stock and administer RSV vaccines themselves but prefer to be able to refer patients. Of paramount importance is that obstetricians need to know the correct gestational age during which to refer. Participants recommended encouraging obstetricians to incorporate RSV vaccines into their checklists for patients based on gestational age. They also suggested asking obstetricians to write the patient's gestational age on a prescription so that the pharmacy has the information. (They stated that a prescription is not necessarily required; however, this can be used as a communication strategy.)

Additionally, participants observed that many people in the United States lack access to adequate prenatal care and that it is important to have other strategies for reaching pregnant people. They shared that pharmacies can take on roles for getting pregnant patients connected to prenatal care and that maternal vaccinations can be one pathway for making connections with these patients.

Participants recommended involving other groups in communicating with patients, including professional organizations representing family practitioners and obstetricians. They also recommended involving community health workers to assist with education. Finally, immunization coalitions were identified as important entities for collaborative efforts.

RSV vaccination. Participants noted that there is a lack of data and recommendations regarding coadministration at this time; however, CDC guidance does allow for coadministration, and none of the participants worked in pharmacies that had a policy that prevented coadministration.² Importantly, non-RSV vaccines may be administered at times that do not match the gestational age window for RSV vaccination. For example, pregnant patients may request influenza vaccination prior to the gestational window for a RSV vaccine. In these cases, patients will require education about the appropriate timeline for RSV vaccine administration and should be prompted to return to the pharmacy during the appropriate gestational age. Additionally, participants suggested educating patients who receive a Tdap vaccine during pregnancy about the benefits of RSV vaccines and encouraging them to receive a RSV vaccine or return later for it if

they receive the Tdap vaccine at an earlier gestational age.

Word-of-mouth communication was noted by participants as being particularly powerful among pregnant people, who often share information about their pregnancy experiences with each other. Participants recommended asking patients who receive RSV vaccine to share information about the vaccine with other pregnant people in their social networks.

Other Tools

Participants proposed the development of tools to target patients who are pregnant and at the correct gestational age, such as smartphone apps or printed calendars that are distributed by prenatal care providers and that include information about when recommended vaccines should be administered. They also proposed adding notations about pregnancy and gestational age in electronic health records.

Providing Patients with Information About RSV and the RSV Vaccine

Roundtable participants recommended a multifaceted approach to educating the public about RSV and the RSV vaccine. Educational efforts could include direct-to-consumer advertising through mass media as well as education provided by health care providers.

Based on personal reports from many of their patients, participants noted that there is a general awareness of RSV and its potential for severe impacts, particularly if the patient knows someone who has been hospitalized due to RSV infection. However, not all of their patients had the same level of awareness, and patient education was seen as an important need. Participants also noted that well-informed patients may have specific concerns about preterm birth along with concerns that the FDA-approved indication for gestational age differs from the age range studied in clinical trials. They reported that there may be increased concerns about preterm birth in patients with a history of preterm birth.

Participants reported that there is increasing public awareness about the availability of RSV vaccine for pregnant people, but noted encountering confusion and hesitancy. (These roundtable responses aligned with data from the survey.) Roundtable participants indicated that the relatively recent launch of RSV vaccines for older adults further complicates perceptions regarding vaccinations for pregnant

individuals and emphasized a need for additional efforts to educate the public about RSV and prevention efforts.

Educating patients that “RSV vaccination is an action you can take to protect your baby” is an impactful message, according to the participants. They also reported that many pregnant patients were receptive to information about RSV vaccination but wanted to discuss it with their obstetricians before making their decisions. Participants observed that patients often have to hear about a vaccine multiple times before they are willing to be vaccinated. Pharmacists who are knowledgeable about current vaccination recommendations and can provide accurate information in a confident manner can help patients make informed decisions about vaccinations.

Participants observed that pregnant people are highly motivated to protect their babies and that when they hear consistent messaging from their pharmacist and their obstetrician, their confidence in the vaccine improves. Therefore, partnerships and collaboration with obstetricians is important for encouraging patient acceptance of vaccines.

Addressing Misinformation

Roundtable participants reported that patient acceptance of vaccines is variable; therefore, it is beneficial to assess for the presence of vac-

cine hesitancy and tailor educational interventions to the patient’s level of understanding.

Participants noted that pharmacists can play an important role in combating misinformation about vaccines. Although misinformation on social media was noted as an enormous challenge, participants felt that pharmacists and others could counter this obstacle by providing accurate information about vaccines through effective use of social media.

As a consequence of misinformation that was shared about COVID-19 vaccines, there has been an increase in general misperceptions about vaccines and increased vaccine hesitance, participants observed. They referred to principles of motivational interviewing to avoid arguments with patients about vaccines.¹⁰ Instead, they emphasized the importance of validating patient experiences and autonomy to make their own choices. Participants shared using statements such as “It is my job to give you the information so that you have all the facts to make a choice for your baby,” and asking for permission to share information so that patients will be more receptive as potential strategies. Among the other phrases that participants reported using was “You have a chance to protect your baby.”

Other Approaches for Supporting Pharmacy-Based Maternal Immunizations

Workflow and staffing issues were noted to be challenges for implementing additional vaccination services. To address workflow challenges for pharmacists, roundtable participants proposed increasing staffing as appropriate to meet seasonal needs. Other tools that participants thought would be helpful for pharmacists included additional education and resources such as “cheat sheets” and conversation guides with relevant information to help recommend the correct vaccine for the patient at the right time.

Participants indicated that APhA could support pharmacy-based maternal immunization services through the provision of additional education and resources for pharmacists and other providers who care for pregnant patients. Pharmacists also recommended that APhA collaborate with a diverse array of partners, including Lamaze childbirth educators and doulas as well as community health care workers. They also recommended the creation of universal messaging along with patient education materials that could be shared with all partners to help

ensure patients receive consistent messaging.

Training for pharmacy staff to support the identification of patients who are eligible for maternal vaccination services was another of the participants' recommendations. They noted that pharmacy technicians often are the first staff members to interact with patients regarding vaccines. Therefore, it is important that pharmacy technicians are also aware of information regarding appropriate patients for RSV vaccination and that their conversations with patients about the vaccine support the pharmacy's messaging.



Summary

The RSVpreF RSV vaccine is the most recent vaccine recommended for use in pregnancy to protect infants from disease for the first months after birth. There is an opportunity for pharmacists who offer RSV vaccines to pregnant patients to contribute to public health efforts by increasing immunization rates. Pharmacists have begun offering RSV vaccines in their practices and recommending

it to patients. However, pharmacists face many challenges with offering these services. Challenges specific to providing maternal RSV vaccine include identifying patients who are pregnant and in the appropriate gestational window for vaccination. Recommendations for addressing this challenge focus on increasing awareness about RSV vaccination among the general public and other health care providers who manage pregnant

patients so that patients are aware of its availability and benefits. Strategies that support consistent universal messaging about vaccines can help to address misperceptions and help address vaccine hesitancy. Overall, pharmacists are highly qualified, trusted, and accessible providers with proven abilities to collaborate with other providers and educate patients to increase vaccination rates.



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