Respiratory Vaccines Update

Webinar 2

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- **You must complete the Evaluation Survey following this webinar.**
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  - **DEADLINE: Midnight on Friday, January 24th.**
    - No late evaluations will be accepted. Please complete the survey ASAP.
  - The survey link will also be sent out tomorrow afternoon in a follow-up email.

- **Certificates of Completion for attending this course will be available after you complete the Evaluation Survey.**
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Webinar

- If you have a question during or after the webinar, please ask your question in the chat.
  - I will do my best to answer all questions before the end of the webinar.

- If you have a question after the webinar, please email Allie Staton.
  - Email: allie@immunizear.org

Objectives

- Interpret current guidelines for respiratory vaccines.
- Recommend appropriate respiratory vaccines to patients and community members.
- Discuss current respiratory vaccine guidelines and recommendations.

Topics

- Discuss current RSV vaccine recommendations for patients ages 60 years and older
- Review RSV vaccine recommendations for pregnant patients
- Review RSV immunization recommendations for infants and young children

IMPORTANT NOTE…

Insurance plans are **not required** to pay for vaccines if they are administered outside of the ACIP/CDC guidelines.

NOTE: FDA approval and package inserts may not be the same as ACIP/CDC guidelines.

If you prescribe and/or administer an immunization outside of ACIP/CDC guidelines…

- Please document the clinical reason for prescribing outside of guidelines
- Counsel the patient on why you recommend it
- Counsel the patient that they may have to pay out of pocket

DON'T FORGET!

A strong recommendation from a healthcare provider is important!

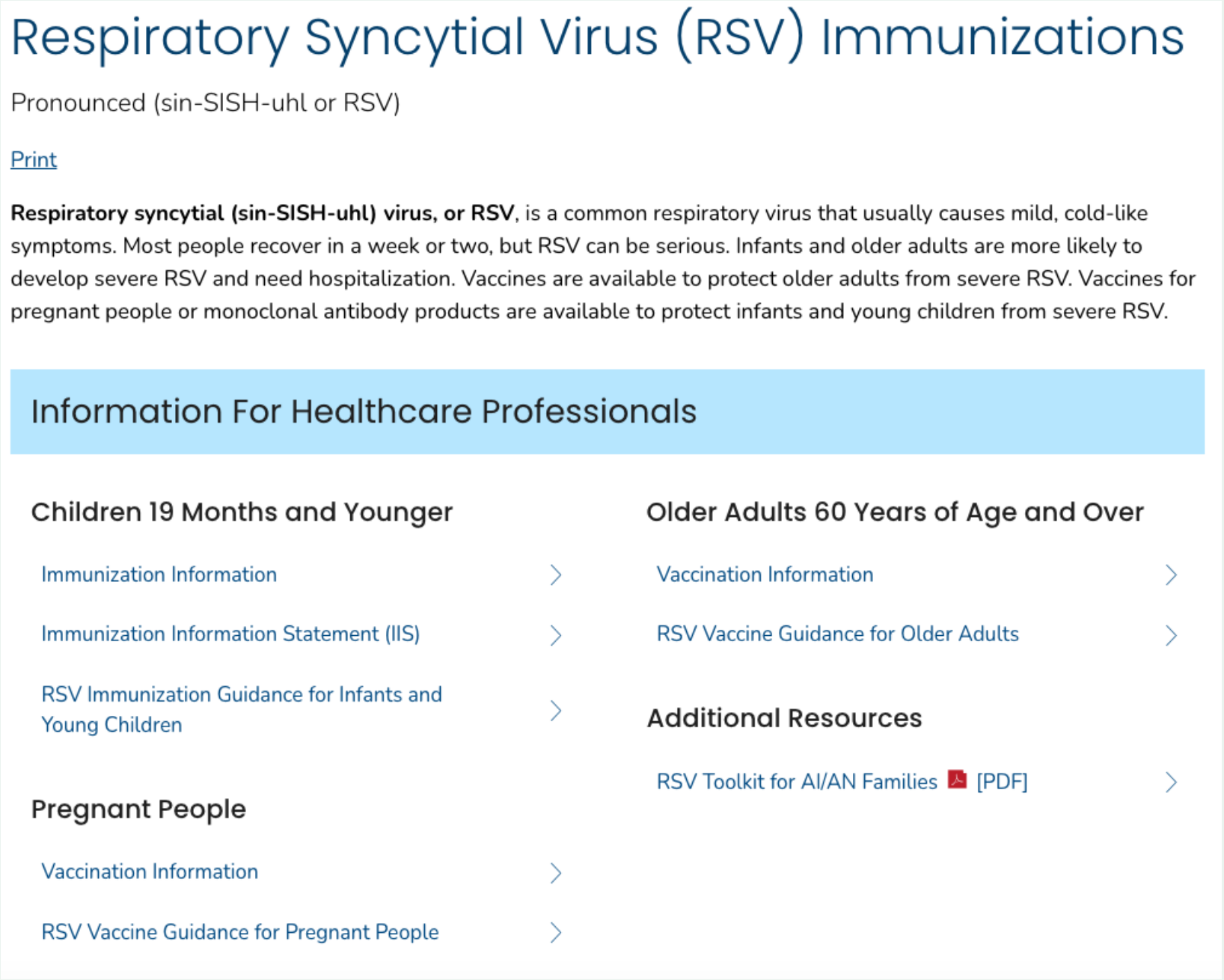
Patients are more likely to choose to vaccinate if their healthcare providers make a **strong** recommendation for vaccination.

RSV

Immunizations

2024 - 2025

Where to find information about RSV and guidelines…



Respiratory Syncytial Virus (RSV) Immunizations

Pronounced (sin-SISH-uhl or RSV)

Print

Respiratory syncytial (sin-SISH-uhl) virus, or RSV, is a common respiratory virus that usually causes mild, cold-like symptoms. Most people recover in a week or two, but RSV can be serious. Infants and older adults are more likely to develop severe RSV and need hospitalization. Vaccines are available to protect older adults from severe RSV. Vaccines for pregnant people or monoclonal antibody products are available to protect infants and young children from severe RSV.

Information For Healthcare Professionals

Children 19 Months and Younger

- Immunization Information
- Immunization Information Statement (IIS)
- RSV Immunization Guidance for Infants and Young Children

Pregnant People

- Vaccination Information
- RSV Vaccine Guidance for Pregnant People

Older Adults 60 Years of Age and Over

- Vaccination Information
- RSV Vaccine Guidance for Older Adults

Additional Resources

- RSV Toolkit for AI/AN Families [PDF]

https://www.cdc.gov/vaccines/vpd/rsv/index.html

RSV

Immunization Products

	Abrysvo *Pfizer*	Arexvy *GSK*	mRESVIA *Moderna*	Beyfortus (nirsevimab) *Sanofi and AstraZeneca*
FDA approved for: • Ages 60 and older	✓	✓	✓	X
ACIP/CDC recommended for: • Ages 60-74 with risk factors • Everyone ages 75 and older	✓	✓	✓	X
FDA approved for: • Ages 50-59 with increased risk of severe RSV	✓	✓	X	X
ACIP/CDC recommended for: • Ages 50-59 with increased risk of severe RSV	X	X	X	X
FDA approved for: • Ages 18-59 with increased risk of severe RSV	✓	X	X	X
ACIP/CDC recommended for: • Ages 18-59 with increased risk of severe RSV	X	X	X	X
FDA approved for: • Use in pregnancy	✓	X	X	X
ACIP/CDC recommended for: • Use in pregnancy	✓	X	X	X
FDA approved for: • Use in infants and young children	X	X	X	✓
ACIP/CDC recommended for: • Use in infants and young children	X	X	X	✓

RSV

Immunizations for Older Adults

RSV Vaccines *(older adults)*

Three RSV vaccines approved and recommended for adults ages 60 years and older.

	Abrysvo ***Pfizer***	**Arexvy** ***GSK***	**mRESVIA** ***Moderna***
FDA-approved use (for older adults)	• Ages 60 years and older • Ages 19-59 years who are at increased risk of LRTD caused by RSV	• Ages 60 years and older • Ages 50-59 years who are at increased risk of LRTD caused by RSV	• Ages 60 years and older

ACIP/CDC Recommendations (for older adults)	• One single dose for:
	  • Adults ages 75 years and older
	  • Adults ages 60-74 years who are at increased risk for severe RSV disease
		• One single dose for:
		  • Adults ages 75 years and older
		  • Adults ages 60-74 years who are at increased risk for severe RSV disease
			• One single dose for:
			  • Adults ages 75 years and older
			  • Adults ages 60-74 years who are at increased risk for severe RSV disease

NOTE: These vaccines are NOT recommended by ACIP/CDC for use in older adults under the age of 60 years.

Risk factors for severe RSV disease

- Cardiovascular diseases
  - Heart failure, CAD, congenital heart disease (excluding isolated hypertension)
- Lung disease
  - COPD, emphysema, asthma, interstitial lung disease, cystic fibrosis
- Advanced chronic kidney disease
  - Stages 4-5, dependence on hemodialysis or other renal replacement therapy
- Diabetes mellitus with end-organ damage
  - Diabetic nephropathy, neuropathy, retinopathy, or cardiovascular disease
- Severe obesity (BMI >/= 40kg/m2)
- Liver disorders
  - Cirrhosis
- Neurologic or neuromuscular conditions
  - Neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness, excluding history of stroke without impaired airway clearance
- Hematologic disorders
  - Sickle cell disease, thalassemia
- Moderate or severe immunocompromise
  - Either due to medical condition or receipt of immunosuppressive medications or treatment

Risk factors for severe RSV disease, continued.

- People who are frail*
- People who reside in nursing homes or other long-term care facilities providing assistance with activities of daily living**
- People with other chronic medical conditions or risk factors that a healthcare provider determines might increase the risk of severe disease due to a respiratory infection

*Frailty is multidimensional geriatric syndrome and reflects a state of increased vulnerability to adverse health outcomes. Although there is no consensus definition, one frequently used tool is the Fried frailty phenotype in which frailty is defined as a clinical syndrome with three or more of the following symptoms present: unintentional weight loss (10lbs in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity.

** Retirement communities and independent living communities for seniors are not considered long-term care facilities. Adults ages 60-74 living in these facilities may still be recommended to receive RSV vaccination if they have certain medical conditions (listed above and on previous slide.)

RSV Vaccines *(older adults)*

- **Abrysvo, Arexvy, and mRESVIA recommended for:**
  - **All adults ages 75 years and older**
  - **Adults ages 60 - 74 years who are at increased risk of severe RSV disease**

- **Currently, only one dose is recommended.**
  - Administer prior to RSV season, if possible.
    - RSV season is typically October through March.
    - Eligible adults may receive an RSV vaccine at any time, but the best time to vaccinate patients is late summer and early fall, before RSV starts to spread.
  - **This is NOT a yearly recommendation. It is currently a ”one and done” recommendation.**

- **Coadministration with other vaccines is acceptable.**
  - Efficacy of coadministration is not expected to be an issue.
    - Studies are ongoing.
  - Patients *may* experience more side effects when Abrysvo, Arexvy, or mRESVIA are administered with other vaccines.
    - Counsel appropriately.
  - Use your clinical judgment when deciding to coadminister.
    - Will the patient return for other vaccines?

RSV Vaccines Warnings and Precautions *(older adults)*

Abrysvo and Arexvy

Warnings and Precautions:

- **Guillian-Barre Syndrome (GBS)**
  - The results of a postmarketing observational study suggest an increased risk of GBS during the 42 days following vaccination with Abrysvo and Arexvy.

RSV

Immunizations to Protect Infants

RSV Immunizations *(to protect infants)*

There are two immunizations recommended to prevent RSV lower respiratory tract infection in infants.

1. **Abrysvo (RSVpreF):** ***maternal vaccination***
    - Administered to pregnant patient during 32 – 36 weeks gestation (during the months of September through January)
    - **It is NOT currently recommended to administer a dose for each pregnancy**

2. **Beyfortus (nirsevimab):** ***long-lasting monoclonal antibody***
    - Administered to infant after birth

- **<u>Either</u>** maternal vaccination ***or*** monoclonal antibody is recommended, in most situations, for newborns.
- **Administration of both is not needed for most infants.**

https://www.cdc.gov/rsv/clinical/index.html

RSV Immunizations *(to protect infants)*

Reason for Seasonal Administration

Babies will be born 1–2 months after the mother is vaccinated and will have immediate protection against RSV. Protection provided by a maternal vaccine wanes over time.

CDC does not currently recommend maternal vaccination outside of this period in most of the U.S. because vaccinating a pregnant woman in February or March for an infant born in April or May will provide that infant limited protection during the RSV season (typically fall and winter). That infant would be better protected by receiving nirsevimab just before or at the start of the RSV season. Because administration happens before the baby is born, it is difficult to adjust vaccination timing based on year-to-year variations in RSV circulation.

https://www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/pregnant-people.html

RSV

Immunizations for Pregnant Patients

RSV Vaccine *(pregnancy)*

One RSV vaccine approved for pregnant patients.

	Abrysvo **(RSVpreF)** ***Pfizer***
FDA-approved use	• Pregnant patients 32 – 36 weeks gestational age

ACIP/CDC Recommendations	• Administer one dose to pregnant patients during weeks 32 – 36 weeks of pregnancy during ***September through January***
	  • **It is not currently recommended to administer a dose during each pregnancy.**
	  • Only one dose is currently recommended.

https://www.fda.gov/vaccines-blood-biologics/abrysvo

RSV

Immunizations for

Infants and Young Children

RSV Immunization *(infants and young children)*

One RSV immunization approved for infants and young children.

	Beyfortus **(nirsevimab)** ***Sanofi and AstraZeneca***
FDA-approved use	• Neonates and infants born during or entering their first RSV season • Children up to 24 months who remain vulnerable to severe RSV disease through their second RSV season

ACIP/CDC Recommendations	• One dose for infants younger than 8 months, born during or entering their first RSV season if:
	  • The mother did not receive RSV vaccine during pregnancy
	  • The mother's RSV vaccination status is unknown
	  • The infant was born within 14 days of maternal vaccination
	• A second dose, shortly before or during their second RSV season, is recommended for some children ages 8 – 19 months who are at increased risk for severe RSV disease

https://www.cdc.gov/rsv/clinical/index.html

https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

RSV Immunization *(infants and young children)*

Infants and children aged 8 – 19 months with increased risk for severe disease who are recommended to receive nirsevimab when entering their second RSV season:

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season
- Children with severe immunocompromise
- Children with cystic fibrosis who have severe disease
- American Indian or Alaskan Native children

https://www.cdc.gov/rsv/clinical/index.html

https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

RSV Immunization *(infants and young children)*

Administration Guidance

- Administer shortly before RSV season, if possible.
    - This is optimal.
- Infants born shortly before or during RSV season should receive nirsevimab within 1 week of birth.
- Nirsevimab may be administered either during the birth hospitalization or in the outpatient setting.
- Nirsevimab may be administered to eligible infants or children who have not yet received a dose at any time during the season.
    - Only one dose is recommended for an RSV season.
- Infants with prolonged birth hospitalizations related to prematurity or other causes should receive nirsevimab shortly before or promptly after hospital discharge.
- Coadministration with other age-appropriate vaccines is recommended.

https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Thank you!

Questions?

References

- RSV Information
  - https://www.cdc.gov/vaccines/vpd/rsv/index.html
- RSV Vaccines in Older Adults – MMWR
  - https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm
- Use of Pfizer RSV vaccine during pregnancy – MMWR
  - https://www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm
- Use of nirsevimab for prevention of RSV in infants and young children – MMWR
  - https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm
- Abrysvo Package Insert
  - https://www.fda.gov/media/168889/download
- Arexvy Package Insert
  - https://www.fda.gov/media/167805/download
- mRESVIA Package Insert
  - https://www.fda.gov/media/179005/download