INFORMATION PAPER

DHA-IHD

8 Feb 2024

SUBJECT: Respiratory Syncytial Virus (RSV)

1. Purpose. To describe Respiratory Syncytial Virus (RSV) disease and the vaccines to prevent it.

2. Facts.

   a. Microbiology. RSV disease is caused by the Respiratory Syncytial Virus. RSV is a single-stranded RNA virus. The virus causes cells to fuse with neighboring cells, creating multinucleated (single cells containing multiple nuclei). This can lead to severe respiratory illness, including RSV- associated lower respiratory tract disease (LRTD).

   b. Disease. RSV in adults generally produces mild or no symptoms. Symptoms are generally consistent with an upper respiratory infection which can include rhinorrhea, pharyngitis, cough, headache, fatigue, and fever. It generally lasts about 5 days. Some adults, however, may have more severe symptoms consistent with a lower respiratory tract infection, such as pneumonia. People 60 and older with certain chronic conditions are at the highest risk of severe RSV disease. Most children get an RSV infection by 2 years old. Usually it will cause a mild, cold-like illness but can also cause severe illnesses such as bronchiolitis and pneumonia. Some children are at increased risk for severe RSV because of premature birth, chronic heart or lung disease or a weakened immune system. Very young infants almost always show symptoms of RSV infection. They may include irritability, decreased activity, eating/drinking less and/or apnea.

   c. Epidemiology. The virus that causes RSV is usually transmitted by direct contact with contaminated secretions. This may occur by exposure to droplets from an infected person when they cough or sneeze in close proximity, generally < 6 feet. Transmission is also possible through contact with secretions on surfaces and then touching the eyes, nose, or mouth. RSV can remain on hard surfaces for several hours and on surfaces for a shorter amount of time. Transmission can occur 1 to 2 days prior to symptoms until about 8 days after showing signs of illness. The incubation period ranges from 2 to 8 days but 4 to 6 days is most common.

   d. Immunization. In 2023, several new immunization products received U.S. Federal Drug Administration (FDA) approval for prevention of RSV. Immunization against RSV is recommended based on age group. The Centers for Disease Control and Prevention (CDC) recommends RSV vaccines to protect adults ages 60 and older from severe RSV. To protect infants from severe RSV, CDC recommends an RSV vaccine for people who are 32 to 36 weeks pregnant or a monoclonal antibody given to the baby after birth.
      (1) There are two FDA-approved RSV vaccines for adults age 60 years and older.
         - ABRYSVO™ (Pfizer) is a bivalent, recombinant protein subunit vaccine.
         - Arexvy™ (GlaxoSmithKline) is an adjuvanted, monovalent, recombinant subunit vaccine.
         - Both RSV vaccines are recommended as a single dose.

      (2) Only one RSV vaccine (ABRYSVO™ by Pfizer) has been FDA-approved for

pregnant people.
- A single dose of ABRYSVO™ vaccine is recommended between 32 and 36 weeks of gestation.

(3) There are two FDA-approved RSV monoclonal antibody products for the prevention of severe RSV infection in infants and young children.
- A single dose of nirsevimab (Beyfortus™ by Sanofi) is recommended for all infants aged <8 months born during or entering their first RSV season and a single dose of nirsevimab (Beyfortus™) is recommended for certain infants and children aged 8–19 months who are at increased risk for severe RSV disease and entering their second RSV season.
- Palivizumab (SYNAGIS® by Sobi) is only recommended in certain high-risk children. Patients should receive monthly doses (15mg/kg of body weight) throughout the RSV season, with the first dose administered prior to the commencement of RSV season.

e. Clinical Guidance: Recommendations for immunization against RSV is based on the age group of the patient.

(1) Adults aged 60 years and older. The CDC's Advisory Committee on Immunization Practices (ACIP) recommends that individuals 60 years may receive a single dose of RSV vaccine using shared clinical decision- making based on discussions between the patient and their health care provider, to help prevent LRTD caused by RSV.
- Persons aged 60 years and older who are at highest risk for severe RSV disease and who might be most likely to benefit from vaccination include persons who are frail, persons of advanced age, and persons who reside in nursing homes or other long-term care facilities, as well as those with chronic medical conditions such as:
  - Cardiopulmonary disease,
  - Kidney disorders,
  - Liver disorders,
  - Neurologic or neuromuscular conditions,
  - Hematologic disorders,
  - Diabetes mellitus, and
  - Moderate or severe immune compromise

(2) Pregnant persons at 32 to 36 weeks gestation. Only the RSV vaccine ABRYSVO™ by Pfizer is recommended for pregnant people who are 32 to 36 weeks pregnant with seasonal administration during September–January in most of the continental U.S. In geographic areas with seasonality that differs from most of the continental U.S., state, local, or territorial guidance on timing of administration should be followed.
- This vaccine works by producing antibodies that are passed through the placenta and provides protection against severe RSV illness to the recipient's infant for up to 6 months of age.
- Either parental RSV vaccination during pregnancy or administration of infant monoclonal antibody product can be used for RSV prevention. Prenatal care providers should discuss both options with pregnant patients and consider patient preference when determining if the RSV vaccine should be given to the pregnant patient.

(3) Infants and young children. There are two ways to protect infants from severe RSV infection; one is maternal RSV vaccine during pregnancy and the other is RSV immunization to the infant after birth.

- Nirsevimab (Beyfortus™) is recommended for:
  - All infants younger than 8 months of age born during RSV season or entering their first RSV season.
  - Except in rare circumstances, most infants younger than 8 months of age do not need nirsevimab (Beyfortus™) if they were born 14 or more days after their mother got vaccinated against RSV with ABRYSVO™.
  - Some children aged 8 through 19 months who are at increased risk for severe RSV disease and entering their second RSV season.
- Palivizumab (SYNAGIS® by Sofi) use is limited to the prevention of severe RSV infection among high-risk children. Indications for palivizumab (SYNAGIS®) include:
  - Infants born at 35 weeks of gestation or less who are less than six months of age at the onset of RSV season.
  - Children less than two years of age and requiring treatment for bronchopulmonary dysplasia within the last six months.
  - Children less than two years of age and with hemodynamically significant congenital heart disease

f. Precautions and Contraindications: Adult RSV vaccination should be delayed for persons experiencing moderate to severe illness with or without fever. The RSV vaccine is contraindicated and should not be administered to individuals with a history of severe allergic reaction, such as anaphylaxis, to any component of the vaccine. RSV preventive antibodies should not be given to children 8 months or older who are not at increased risk of RSV disease. Most infants less than 8 months do not need to receive the antibodies if their mother received RSV vaccination with ABRYSVO™ at least 14 days prior to delivery. Children who have a moderate or severe acute illness usually should wait until they recover before getting the antibodies.

g. Adverse Reactions/Events: The most common side effects of the immunization are local reactions: injection site pain, redness, and swelling and systemic reactions: fatigue, fever, headache, nausea, diarrhea, muscle pain and/or joint pain. Rarely, serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported. The most common side effects with RSV antibodies include pain, redness, or swelling where the injection was given, and a rash. No serious allergic reactions occurred in the clinical trials.

h. DoD Policy. The DoD follows the Advisory Committee for Immunization Practices (ACIP) for routine, age, or condition-specific vaccine recommendations.

3. References.

i. Centers for Disease Control and Prevention (CDC), Recommendations of the Advisory Committee on Immunization Practices for Use of Respiratory Syncytial Virus Vaccines in Older Adults. MMWR, July 21, 2023/72(29); 793-801. https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7229a4-H.pdf

j. Centers for Disease Control and Prevention (CDC) Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices. MMWR, August 25, 2023, 72(34);920–925. http://www.cdc.gov/vaccines/vpd-vac/rotavirus/default.htm#clinical

k. American Society for Microbiology. Respiratory Syncytial Virus (RSV), Tis the Season. December 6, 2022. https://asm.org/Articles/2022/December/Respiratory-Syncytial-Virus-RSV- Tis-the-Season

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m. Centers for Disease Control and Prevention (CDC). Health Alert Network, Limited Availability of Nirsevimab in the United States—Interim CDC recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season. October 23, 2023. https://emergency.cdc.gov/han/2023/han00499.asp

n. American Academy of Pediatrics (AAP). Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection. Volume 152, Issue 1, July 2023. https://publications.aap.org/pediatrics/article/152/1/e2023061803/192153/Palivizumab-Prophylaxis-in-Infants-and-Young

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