

Overview of RSV

0.25 CREDIT HOURS



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PHARMACIST OBJECTIVES

PHARMACY TECHNICIAN OBJECTIVES

- 1. Identify prevention strategies for RSV and what patients are at greatest risk of developing severe RSV
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OVERVIEW

Micro-learning opportunities were created in response to evidence that learning is maximized when delivered in short and focused 'bursts.' In this session, RSV and prevention using palivizumab are broadly explored, along with a summary of risk factors and pharmacologic and non-pharmacologic prevention strategies.

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TARGET AUDIENCE

Pharmacist, Pharmacy Technician

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All opinions expressed by the author(s) are strictly their own and not necessarily approved or endorsed by PharmCon. Consult full prescribing information on any drugs or devices discussed. PharmCon freeCE is a division of KnowFully Learning Group. 201 N. King of Prussia Rd, Suite 370, Radnor, PA 19807 All Rights Reserved. None of these materials may be reproduced in any form without the written permission of the publisher. Questions? info@freeCE.com or (843) 488-5550 My sister Mary is a top flight pediatric nurse with over 40 years of practice. She has staffed pediatric wards, pediatrician's offices, and served as a school nurse. Her entire career has been devoted to the care of the little ones. I spoke with her on the phone, and she was telling me that she has never seen so many RSV cases so early on.

She spent the last week helping family members deal with RSV cases. Good nursing care kept the little ones out of the hospital. She also noticed that the kids that had it all reacted differently, with the youngest having the most respiratory distress. Since not everyone has access to a private duty pediatric nurse like Mary, the hospital pediatric wards and ERs are busting at the seams. Like me, Mary cannot wait for the RSV vaccines to become widely available.

RSV (does it stand for REALLY SCARY VIRUS??)

In our corner of the world, respiratory syncytial virus, or RSV, rears its ugly head from October through April, with the peak occurring in January and February. RSV seems to have gotten an early start this year, as many of the pediatric hospitals are loaded with kids burdened with this disease. It is believed that this large resurgence is due to previous COVID precautions decreasing its spread. The number of cases in 2022 are DOUBLE of those in 2021.

Epidemiology

RSV is a single-stranded, large-enveloped, negative-sense ribonucleic acid (RNA) virus and a member of the Pneumoviridae family. These viruses are seen in mammalian species and are spread by respiratory droplets (coughing, sneezing, talking). The virus can survive on hard surfaces like crib rails, doorknobs, and tables for many hours.

Nearly all kids contract RSV by the time they reach the age of 5, with most kids having the disease before their second birthday. RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) and pneumonia (inflammation of the lungs) in kids under one in the US. RSV can also infect adults, but the cases are usually milder. According to the CDC, each year in the United States, RSV leads to approximately:

- 2.1 million outpatient (non-hospitalization) visits among children younger than 5 years old
- 58,000-80,000 hospitalizations among children younger than 5 years old
- 60,000-120,000 hospitalizations among adults 65 years and older
- 6,000-10,000 deaths among adults 65 years and older
- 100-300 deaths in children younger than 5 years old

Symptoms occur rapidly after infection occurs usually within 4-6 days of exposure. Symptoms of RSV infection may include:

- Runny nose
- Decrease in appetite
- Coughing
- Sneezing
- Fever
- Wheezing

Treatment

Pharmacological

Management of pain and fever with over-the-counter pain and fever reducers, such as acetaminophen or ibuprofen. Never give aspirin or naproxen to children, due to potential of developing Reyes syndrome.

- Ibuprofen:
 - Do not use ibuprofen in children less than 6 months of age
 - Dose is 4-10 mg/kg every six hours. Some sources say use 5mg/kg for mild fever and 10 mg/kg for high fever.
- Acetaminophen
 - Acetaminophen is usually dosed at 10-15mg/kg every 4-6 hours with a maximum of 5 doses per day. Some clinicians use the shortcut of 5 mg per pound.
- Hydration:
 - Drink lots of water to prevent dehydration
 - Pedialyte is also a good option to replace electrolytes
- Consult your doctor or pharmacist to select appropriate over the counter medications for management of symptoms

Vaccines

The RSV vaccine has been slow to come to market because of its history. In 1966, infants and toddlers immunized with a formalin-inactivated vaccine against respiratory syncytial virus (RSV) experienced an enhanced form of RSV disease characterized by high fever, bronchopneumonia, and wheezing when they became infected with wild-type virus in the community. 80% of the kids were hospitalized, and two immunized toddlers died upon infection with wild-type RSV. Now that we have a better understanding of the immune system, this tragedy should not be repeated.

- CodaVax[™]-RSV (by Codagenix)
 - CodaVax[™]-RSV, an intranasal, live-attenuated vaccine candidate, for the prevention of RSV
 - On November 7, 2022, the FDA announced the beginning of Phase-1 trials for an RSV vaccine by Codagenix. The trial will begin in 2023 after the RSV season. After Phase-1 trial, the Phase 2 dose confirming study will explore efficacy during the RSV season in 2023-2024.
 - The age group to be tested is age 6 months through 5 years
- RSVpreF[®] (by Pfizer)
 - Administered to a pregnant woman to protect the newborn and can synthesize antibodies and passively transfer them to the fetus via placenta. Pfizer's RSV vaccine candidate could be the first maternal vaccine available to help prevent this common and potentially life-threatening respiratory illness in young infants.
 - Vaccine efficacy of 81.8% was observed against severe medically attended lower respiratory tract illness due to RSV in infants from birth through the first 90 days of life with high efficacy of 69.4% demonstrated through the first six months of life

- The RSVpreF[®] investigational vaccine was well-tolerated with no safety concerns for both vaccinated individuals and their newborns
- On March 2, 2022, Pfizer announced that its vaccine candidate received Breakthrough Therapy Designation from the FDA for the prevention of RSVassociated lower respiratory tract disease in infants up to six months of age by active immunization of pregnant women
- Read the press release at: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-announces-positive-top-line-data-phase-3-global

RSV prevention

- Do not share cups or utensils (especially if they have mild cold symptoms)
- Do not touch your face (eyes nose and mouth) after touching potentially infected surfaces
- Wash hands often with antibacterial soap for at least 30 seconds
- Frequently disinfect "high touch" surfaces like doorknobs, table surfaces and toys

The understanding we will have, thanks to Dr. Kendsersky, is most appreciated by the readers of this column.

Palivizumab for RSV prevention

RSV was discovered in 1956 but took until 1998 to get a monoclonal antibody to prevent the disease.

Palivizumab (SYNAGIS [®]) injection

- Approved in 1997 and available in 50 mg and 100 mg for intramuscular injection
- Designed to help prevent a serious lung disease caused by respiratory syncytial virus (RSV) in children who:
 - $\circ~$ are born prematurely (at or before 35 weeks) and who are 6 months of age or less at the beginning of RSV season
 - have a chronic lung condition, called bronchopulmonary dysplasia (BPD), that needed medical treatment within the last 6 months, and who are 24 months of age or less at the beginning of RSV season
 - are born with certain types of heart disease and who are 24 months of age or less at the beginning of RSV season
- Dose:
 - o Administered 15 mg/kg at first visit and given monthly thereafter
 - The first dose should be given prior to the commencement of RSV season and given monthly throughout

Non-pharmacological prevention strategies

- Hand washing in all settings, particularly when high-risk infants are at risk for exposure to respiratory infections from older siblings
- Practicing cough hygiene cover mouth, cough into elbow, dispose of tissues immediately
- Avoid exposure to combustible tobacco
- If possible, avoid daycare during RSV season

What about grandma and grandpa?

Adults who get infected with RSV may be asymptomatic or have mild symptoms. Symptoms include rhinorrhea, pharyngitis, cough, headache, fatigue, and fever. Disease usually lasts less than five days.

Some adults, however, may have more severe symptoms consistent with a lower respiratory tract infection, such as pneumonia. High-risk elderly patients include:

- Age 65 years and older
- Adults with chronic lung or heart disease
- Adults with weakened immune systems

RSV in elderly patients may exacerbate:

- Asthma
- Chronic obstructive pulmonary disease (COPD)
- Congestive heart failure

Although these symptoms sound rather generalized, there are tests that can help with the diagnosis with RSV:

- Reverse transcriptase-polymerase chain reaction (rRT-PCR), which is more sensitive than culture and antigen testing. This is the best option for older patients.
- Antigen testing is 80-90% accurate in children due to sensitivity, but not is sensitive in adults

There is a lot of information online about this drug, but I am most fortunate to be able to consult with a pediatric hospital pharmacist. After a previous Micro CE, Dr. Rebecca Wytiaz Kendsersky, PharmD, reached out to me and offered to help me discuss palivizumab which as a community pharmacist, I have had no experience with. Becca did a residency in pediatric pharmacy and currently works at Children's Hospital of Philadelphia (CHOP). Here are her comments:

Ah yes, palivizumab definitely has a special pocket in the pediatrics world :) Happy to share more info!

- Date Range: Typical RSV/palivizumab season is November to March, however the past two years have thrown us for a loop so we've started seeing RSV cases as early as August. Because palivizumab is a bit expensive, we limit dispensing in the hospital to only during "Synagis (palivizumab) season". This year, we deemed the season to begin in September and will likely go through (at least) March, depending on the RSV trends in the area and nation.
 - Of note, patients are eligible to receive up to 5 doses of monthly palivizumab per year as it is thought to provide coverage through the entire season. I'm curious if this recommendation will change as the season is showing to start earlier and earlier.
 - If patients contract RSV during "Synagis season", then they are no longer eligible to receive palivizumab for the remainder of the season, since the chance that they'll be reinfected with RSV in the same season is highly unlikely

- Cost: CHOP carries the 100 mg/mL vials, which is a ripe \$3,947.86! While not the most expensive drug in the world, this is certainly not a small cost. Although, the cost of treatment is definitely cheaper than a hospital admission!
- Administration: CHOP (and the other hospitals I've worked at) administer palivizumab via intramuscular route for qualifying patients within 72 hours of discharge. It is not administered while admitted due to a cost-savings and risk/benefit analysis. CHOP limits administration to Mondays, Wednesdays, and Fridays, so we can batch the doses prepared and also reduce costs in that way. After patients receive their doses on their way out the door from an inpatient admission, they'll follow up with their outpatient physicians to receive subsequent IM doses during the season.
 - One last point is that palivizumab is not a vaccine (a common misnomer by many of our resident physicians) but rather a prophylactic IM injection via monoclonal antibodies. I like to avoid the "vaccine" classification just in case qualifying patients have anti-vaccine parents who may automatically reject this therapy without knowing more about it.

--Have a great day on the bench!!

Activity Test

Overview of RSV

Activity tests must be completed online at <u>www.freeCE.com</u>.

A passing grade of 70 or higher and completion of an online activity evaluation are required to earn credit.

- 1. Which patient population is at highest risk for developing RSV
 - A. Children
 - B. Elderly
 - C. Young adults
 - D. Pregnant women

2. What is a qualifying indication to receive palivizumab for preventing RSV?

- A. Aged 75 and older
- B. Previous smoking history
- C. Children born prematurely
- D. Patients who have been previously infected with RSV