Respiratory Illness Season and Prevention

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1

Respiratory Illness Season

- During the fall and winter months, there tends to be a increase in respiratory infections.
  - Influenza
  - Respiratory Syncytial Virus (RSV)
  - COVID-19?
- Respiratory infections are easily transmissible.
- Immunizations can prevent severe illness.

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2

Respiratory Symptoms Comparison

Influenza, RSV, and COVID-19 have many common symptoms – testing generally necessary for diagnosis.

3

Severe Respiratory Illness Prevention

- Severe respiratory illness prevention:
  - **Immunizations** are the best way to prevent severe illness!
  - Wash hands often or use an alcohol-based hand sanitizer.
  - Avoid touching your face.
  - Avoid close contact with people who have cold-like symptoms.
  - Cover your coughs and sneezes.
  - Clean and disinfect surfaces.
  - Stay home when you are sick.

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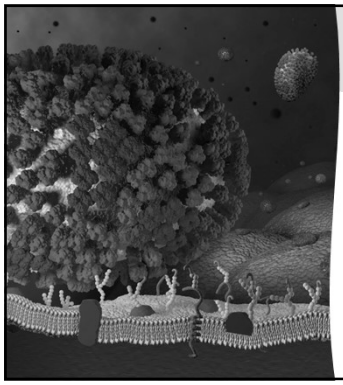
4



Influenza

- Influenza is a contagious respiratory illness caused by influenza viruses.
- It typically infects the nose, throat, and lungs.
- 2 main types:
  - Influenza A
  - Influenza B
- It may cause mild to severe illness.

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5

Influenza

- Influenza is generally spread via respiratory droplets when infected people cough, sneeze, or talk.
- It can be spread before symptoms develop, from one day before and up to 7 days after becoming sick.
  - Some people are infectious for longer periods.
- Symptoms typically develop 1-4 days after infection.
- Influenza can cause complications including bacterial pneumonia, ear infections, sinus infections, and worsening of chronic medical conditions such as congestive heart failure, asthma, and diabetes.

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Influenza

- Each year, 3-11% of the U.S. population contract influenza.
- This is an estimate, as not everyone will get tested.

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Influenza

- The severity and number of people impacted varies from year to year.
- During the 2022-2023 season, CDC estimates that there were 27-54 million flu illness, 300,000-650,000 flu hospitalizations, and 19,000-58,000 flu deaths.
- People 65 years and older, young children, pregnant women, and people with certain health conditions are at a higher risk of serious flu complications.

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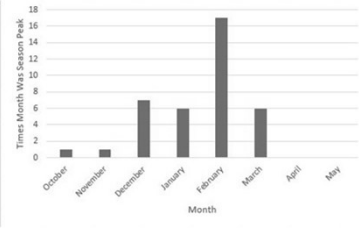
8

Influenza Seasonality

- While influenza viruses spread year-round, most of the time flu activity peaks between December and February, but activity can last as late as May.
- In North Dakota, influenza activity typically peaks between late February-early March.



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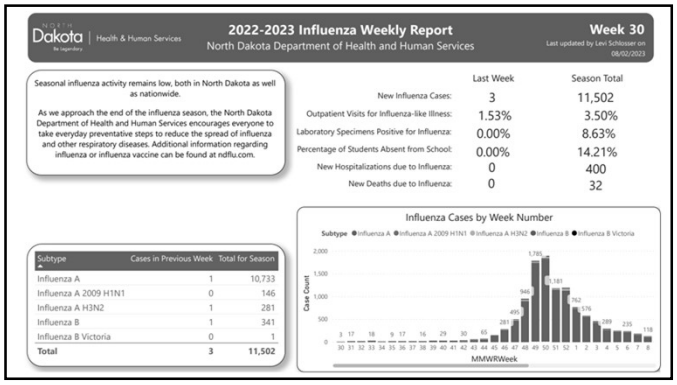

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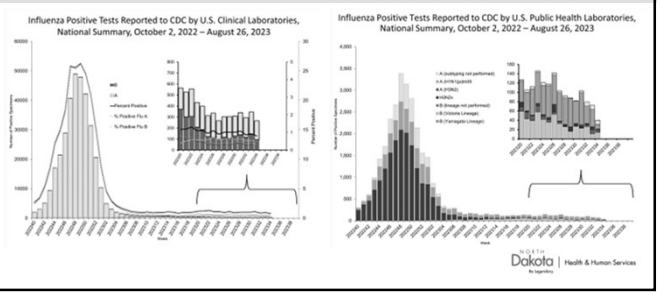
Outpatient Influenza-like Illness (ILI)



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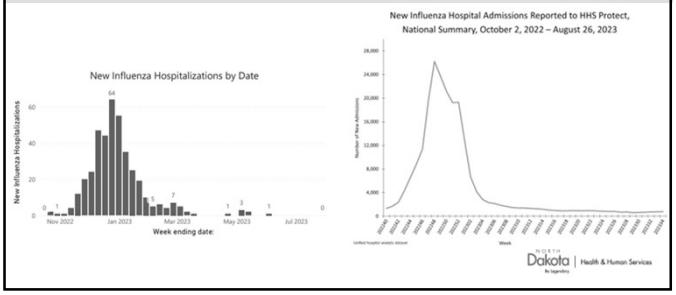
Influenza Hospitalizations



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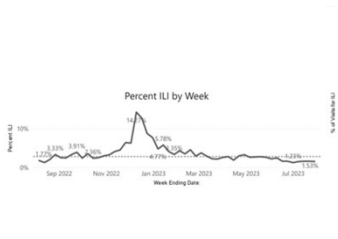
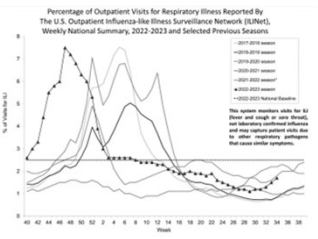
National Influenza Data





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13

Influenza Vaccine

- Influenza viruses are constantly changing.
- Each year, the prior season's circulating influenza viruses are evaluated to identify the most common strains.
- If dominant strains have changed, a new vaccine will be developed.
- Each flu vaccine protects against 4 flu strains.
- In seasons when the vaccine strain composition is considered to be a "good" match, flu vaccines can reduce the need to see a doctor by 40% to 60%.
- 2022-23 flu season vaccine effectiveness:
  - Vaccinated children were 68% less likely to be hospitalized and 42% less likely to visit an emergency department with flu illness or related complications.
  - Vaccinated adults were 43% less likely to be hospitalized with flu illness or related complications.

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14

Influenza Vaccine 2023-2024

What is different this season?

- The 2023-2024 seasonal influenza vaccine composition
  - U.S. flu vaccines will contain an updated influenza A(H1N1)pdm09 component: A/Victoria/4897/2022 (H1N1)pdm09-like virus for egg-based vaccines and A/Wisconsin/67/2022 (H1N1)pdm09-like virus for cell-based or recombinant vaccines.
- Updated ACIP recommendations regarding influenza vaccination of persons with egg allergy
  - All persons ≥6 months with egg allergy should receive influenza vaccine.
  - Any vaccine (egg-based or non-egg-based) this is otherwise appropriate for the recipient's age and health status can be used.
  - Additional precautions or safety measures are no longer recommended for anyone who has had an allergic reaction to egg in the past as all vaccines should be administered in settings in which personnel and equipment needed for rapid recognition and treatment of acute hypersensitivity reactions are available.

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15

Influenza Vaccine

When to get vaccinated:

- Before the end of October if possible before flu begins circulating as it takes two weeks for the flu vaccine to become fully effective.
- Vaccination during July and August can be considered for pregnant people in the third trimester of pregnancy during those months – this can help protect their infants for the first few months after birth when they are too young to be vaccinated.
- As long as seasonal flu vaccines remain available, it is not too late to be vaccinated.

- Coadministration with other recommended immunizations is encouraged.
  - Inactivated influenza vaccine (IIV)
  - Live, attenuated influenza vaccine (LAIV)

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16

Influenza Vaccine

- Flu vaccine benefits:
  - Reduced flu infection or severity of infection and symptoms
  - Decreased clinic visits
  - Avoid missed work or school days
  - Decrease number of flu-related hospitalizations and deaths

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17

Influenza Vaccine

Who should get a flu vaccine?

- Recommended for everyone 6 months and older in the United States.
- Do to the changing viruses and vaccines, as well as waning protection, a flu vaccine is needed each year.
- Special attention should be paid to those who are at an increased risk for serious health outcomes from influenza. That includes children under 5, adults over 65, those with compromised immune systems or chronic health conditions, pregnant women, and American Indians or Alaskan Natives.
- Those in contact with those at high risk for complications should also be vaccinated, including health care workers, long term care employees and family members.
- Children between the ages of 6 months and 8 years need two doses of influenza vaccine one month apart if it is their first time being vaccinated for influenza.
- People 65 and older should receive an enhanced (high-dose, recombinant or adjuvanted) influenza vaccine, to make sure they produce a better immune response to the vaccine.

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18

Influenza Vaccine

2023-2024 Influenza Vaccine Products:

- Egg-based standard-dose inactivated influenza vaccines – approved for ages ≥6 months
- Cell-based standard-dose inactivated influenza vaccine – approved for ages ≥6 months
  - Produced by growing virus in cultured cells of mammalian origin instead of eggs (egg-free).
- High-dose inactivated influenza vaccine* – approved for ages ≥65 years
  - Contains 4 times the antigen for each virus compared with standard-dose inactivated vaccines.
- Recombinant influenza vaccine* – approved for ages ≥18 years
  - Contains 3 times the antigen for each virus compared with standard-dose inactivated vaccines.
  - Produced without influenza viruses or eggs (egg-free).
- Adjuvanted inactivated influenza vaccine* – approved for ages ≥65 years
  - Contains and adjuvant (an ingredient intended to help promote a better immune response).
- Live attenuated Influenza Vaccine (nasal spray) – approved for ages 2-49 years
  - Contains live influenza viruses grown in eggs and weakened so they don't cause illness.

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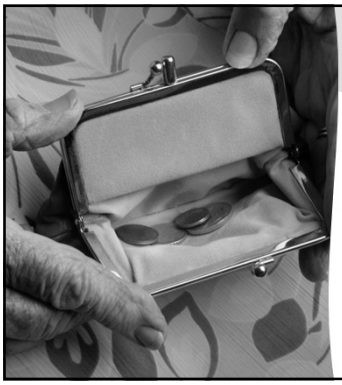
* Preferentially recommended for ages ≥65 years

19



Influenza Vaccine

- 2023-2024 Influenza Vaccine Coverage:
  - Cost should not be a barrier.
  - Children
    - Covered by insurance
    - Provided by Vaccines for Children Program (VFC) for children ages ≤18 years who are American Indian or Alaska Native, Medicaid-eligible, uninsured, or underinsured (child has health insurance, but policy doesn't cover any or certain recommended vaccines).
  - Adults
    - Covered by insurance
    - Provided by Vaccines for Adults Program (VFA) for uninsured adults ages ≥19 years.

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20

Respiratory Syncytial Virus (RSV)

- RSV is a common respiratory virus that generally causes mild, cold-like symptoms including runny nose, coughing, sneezing, fever, wheezing, and decreased appetite.
  - Infants may only be more irritable, less active, or appear to have difficulty breathing.
- RSV season generally in fall and winter months, October-March .
- Most people recover in 1-2 weeks.
- Recurrent infections occur throughout lifetime.

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21

Respiratory Syncytial Virus (RSV)

- RSV is spread by respiratory droplets from an infected person either through the air, direct contact, or surface contact.
- Infected individuals my be contagious up to 1-2 days before signs of illness are apparent.
- RSV can survive for many hours on hard surfaces.
- Older adults and infants are at greater risk of more severe illness.

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22

RSV Disease Burden in Adults 65+

- RSV is a major cause of hospitalization and mortality for adults 65+.
- Estimated 60,000-160,000 hospitalizations annually in the US.
- Estimated 6,000-10,000 deaths annually in the US.

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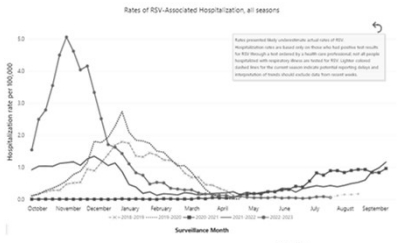
JCC-mAb_One Page Analysis 06.15.23.pdf https://synagishcp.com/synagis-palivizumab-efficacy.html#:~:text=and%20without%20RSV-,The%20efficacy%20of%20DYNAGIS%20in%20preterm%20infants%20and%20children%20with,disease%20by%20more%20than%20half.

23

RSV Disease Burden Nationwide

- 2022 saw much earlier and higher RSV activity than previous seasons.



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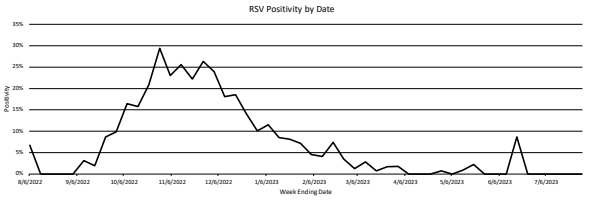
24

RSV Disease Burden in ND



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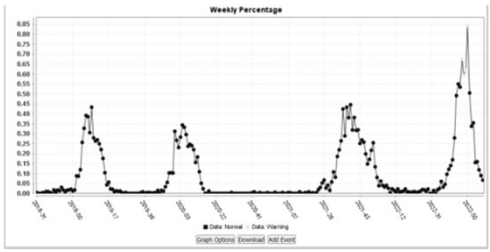
25

RSV Disease Burden in ND



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26

RSV in Older Adults

- Older adults at highest risk:
  - Adults with chronic heart or lung disease
  - Adults with weakened immune systems
  - Adults with certain underlying medical conditions
  - Adults living in nursing homes or long-term care facilities
  - The average age of American Indian adults hospitalized is 56 years versus 73 years for non-Hispanic Whites.

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27

RSV in Older Adults

- Severe RSV infection in older adults is possible due to weakening of immune system with advancing age.
  - Lung infection or pneumonia
  - Worsening of conditions such as asthma, chronic obstructive pulmonary disease (COPD), or congestive heart failure
  - Hospitalization
  - Death

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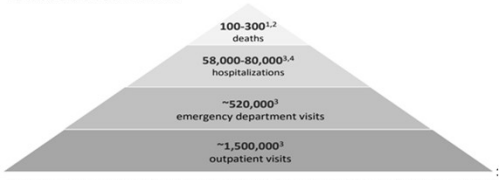
28

RSV Disease Burden in Children

Each year in U.S. children aged less than 5 years, RSV is associated with…



[1]Thompson et al, JAMA, 2003; [2]Hansen et al, JAMA Network Open, 2022; [3]Hall et al, NEJM, 2009; [4]McLaughlin et al, J Infect Dis, 2022
(*estimate 80,000 hospitalizations in infants <1y)

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29

RSV Disease Burden in Children

- RSV is the leading cause of hospitalization in infants.
- United States season typically goes from November through March.
- RSV infects 97% of children by age 2.
- Repeated infections are possible.
- 79% of hospitalized children <2yo had no underlying medical conditions.
- Hospitalization rates are 3 times higher for preterm (<30wks) infants.

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30

RSV in Infants and Young Children

- Children at highest risk:
  - Premature infants
  - The very young - infants up to 12 months, particularly those 6 months and younger
  - Children younger than 2 years with chronic lung disease or congenital heart disease
  - Children with weakened immune systems
  - Children who have neuromuscular disorders
  - American Indian children under 2 years old are 4-10 times more likely to be hospitalized related to RSV.

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31

RSV in Infants and Young Children

- Severe RSV infection in infants and young children is also possible.
  - Bronchiolitis
  - Pneumonia
- 2-3 out of every 100 infants diagnosed with RSV may need to be hospitalized.
  - Oxygen
  - IV fluids
  - Mechanical ventilation

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32

RSV Prevention 60 years and up

2 RSV vaccines, Arexvy™ and Abrysvo™, are approved for older adults.

- For use in adults 60 years and older
- For prevention of lower respiratory tract disease caused by RSV
- Using shared clinical decision-making between patient and medical provider

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33

Shared Clinical Decision Making

What does "shared clinical decision making" mean?

- A patient-individualized decision made between the patient and their trusted medical provider.
- Incorporate best available evidence of benefit patient may expect, as well as any possible side effects they may experience.
- Consider the patient's individual characteristics, values, and preferences.
- Involve the medical provider's clinical discretion.
- Assess the characteristics of the vaccine being considered.

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34

RSV Prevention – 60 Years and Up

- Arexvy™ and Abrysvo™ are covered by insurance, including Medicare Part D.
- May be co-administered with other vaccines.
- Clinical trials demonstrated greater than 80% efficacy against lower respiratory tract illness through one RSV season.
- Two cases of neurological issues in Pfizer's and three cases in GSK's were identified (including Guillain-Barré Syndrome-GBS) during the clinical trials of these vaccines, but underdetermined if caused by RSV vaccine.
  - Studies are being conducted to determine cause.
  - RSV vaccines will continue to be monitored for safety.
- Subsequent or booster doses not recommended at this time, but this may change as additional study data becomes available.

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35

RSV Prevention – Infants

RSV Immunization – nirsevimab (Beyfortus™)

- For all infants born during RSV season within one week of birth.
- For all infants born outside RSV season aged <8 months – shortly before the start of RSV season.
- For all children aged 8 through 19 months who are at increased risk of severe RSV disease – shortly before the start of their second RSV season.

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36

RSV Prevention – Infants

Children at increased risk of severe RSV should receive a second season RSV dose include:

- Children with chronic lung disease of prematurity who required medical support any time during the 6-month window prior to the start of the second RSV season
- Children with severe immunocompromise
- Children with cycstic fibrosis who have manifestations of severe lung disease
- **American Indian** and Alaska Native children

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37

RSV Prevention – Infants

- Nirsevimab provides short-term protection to infants through their first RSV season when they are at highest risk of severe RSV infection.
- Nirsevimab is shown to be over 80% effective at preventing RSV lower respiratory tract infection hospitalizations.
- Study side effects were generally mild, including pain, redness, and swelling at the injection site.
- Nirsevimab should be administered at the same time as other recommended immunizations.

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38

Nirsevimab Storage & Handling

- Storage at refrigerator temperatures (2°C - 8°C)
- May be kept at room temperature (20°C - 25°C) for a maximum of 8 hours if protected from light.
- Pre-filled syringes

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39

Nirsevimab Trial Results in Social Media

- Numerous posts about 12 deaths during the nirsevimab clinical trials.
- 12 out of 3,710 infants (3.2 per 1,000) who received nirsevimab and 4 out of 1,797 infants (2.2 per 1,000) in the control group died of various causes over at least 360 days of follow-up.
  - These deaths were closely reviewed, including the causes, timing, and children's medical conditions. This review of deaths during clinical trials is standard practice.
- Of the 12 deaths in the nirsevimab group:
  - 8 had causes clearly unrelated to nirsevimab, including motor vehicle accident, cancer, COVID-19, congenital heart disease, and gastroenteritis.
  - 2 deaths were considered to be related to underlying conditions.
  - 1 was due to a possible undiagnosed underlying condition.
  - 1 was considered consistent with sudden infant death syndrome.
- Consensus from FDA and CDC scientists, as well as pediatric infectious disease specialists, is that RSV causes hundreds of deaths in children each year, while there is no evidence of nirsevimab causing any deaths.

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40

RSV Prevention – Infants

- All infants born during RSV season are recommended to receive nirsevimab within 7 days of birth, ideally prior to birthing hospital discharge.
  - Dosing is 50mg/0.5mL if <5kg and 100mg/1mL if ≥5kg.
- All infants born outside of RSV season are recommended to receive nirsevimab when entering their first RSV season.
  - Dosing is 50mg/0.5mL if <5kg and 100mg/1mL if ≥5kg.
- Children at higher risk of severe RSV are recommended to receive a dose when entering their second RSV season
  - Dosing is 200mg – two 100mg/1mL injections

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41

RSV Prevention – Infants

- What about pavilizumab (Synagis™)?
  - If nirsevimab is administered, pavilizumab should not be administered later that season.
  - If nirsevimab is not available, the American Academy of Pediatrics (AAP) recommends children receive pavilizumab if they meet drug eligibility criteria.
  - Eligible children who receive fewer than 5 doses of pavilizumab in the 2023-2024 season may receive on dose of nirsevimab, but then should receive no additional pavilizumab doses.
  - Children who received pavilizumab during their first RSV season who are at high risk of severe RSV entering their second season should receive nirsevimab if available.

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42

RSV Prevention – Infants

- All infants will have access to nirsevimab, regardless of insurance status.
  - Cost $495/dose first season, $990/dose second season
  - Covered by private insurance.
  - Included in the North Dakota Vaccines for Children (VFC) Program, which provides recommended immunization products to uninsured, underinsured, Medicaid-eligible, and American Indian or Alaska Native children.
  - Providers will need to maintain both private stock and VFC stock.

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43

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The U.S. Food and Drug Administration approved Beyfortus (nirsevimab-alip) for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in neonates and infants born during or entering their first RSV season, and in children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

The Advisory Committee on Immunization Practices (ACIP) recommends one dose of Nirsevimab for infants ages <8 months born during or entering their first RSV season* (50 mg for infants <5kg and 100 mg for infants ≥5 kg). Additionally, one dose of Nirsevimab is recommended for children ages 8 through 19 months who are at increased risk^ for severe RSV disease and entering their second RSV season (200 mg).

Below is a planning checklist that is subject to change depending on forthcoming federal guidance. The North Dakota Department of Health and Human Services (ND HHS) Immunization Unit will update this list and further educate healthcare providers about Nirsevimab when additional information becomes available.

Nirsevimab Planning Checklist

North Dakota Immunization Information System (NDIIS)/Documentation	
	Update and/or complete NDIIS provider agreement, if needed.
	Request NDIIS user access for individuals at your facility who may administer Nirsevimab monoclonal antibody or need to look up immunization/administration records.
	Verify that your electronic medical record (EMR) is set up to document Nirsevimab doses, and how it will electronically send doses to NDIIS. If not, establish a process for reporting doses to the NDIIS. CVX codes: IIS | Code Sets | CVX | Vaccines | CDC
Product Storage and Handling	
	Plan for purchasing Nirsevimab for privately insured children. According to the manufacturer, Nirsevimab will cost about $495 per dose on the private market.
	Ensure storage units are working well, have adequate storage space for prefilled syringes (on top of influenza, COVID-19 and other vaccines) and temperatures are being monitored 24 hours a day using a digital data logger. Nirsevimab is stored in the refrigerator at 2–8°C.
	Ensure staff review CDC's vaccine storage and handling toolkit.
Facility Protocol and Education	
	Ensure that your facility is enrolled in the VFC Program. Nirsevimab will be included in the VFC Program. Your facility should establish a process to document VFC eligibility in the EMR/patient record for each Nirsevimab dose administered.
	Establish a process to make birthing hospital and clinic staff aware of Nirsevimab availability and recommendations. Please note that IM dosage varies by weight, 50 mg if <5 kg, 100 mg if ≥5 kg, 200 mg (2x100 mg) for high risk entering 2nd RSV season.
	Plan how to communicate Nirsevimab availability, priority groups and safety/efficacy to patients.
	Ensure education on documentation needs (EMR, electronic birth certificate, NDIIS) are provided to staff.
	Update billing processes for private insurance and VFC-eligible children, as needed.
	Establish a process to obtain parental consent for Nirsevimab. A patient information sheet is forthcoming from CDC.
	Update current facility vaccination/medication administration protocols, if needed.
	Determine when Nirsevimab will be administered post-delivery and pre-discharge at the hospital.
	Develop a process for outpatient clinic administration to infants born outside of RSV season (well-child visits, walk-in clinics, influenza clinics, etc.). Nirsevimab can be co-administered with vaccines.
	Establish a mechanism to inform parents of infants born outside of traditional RSV season of the need to return for Nirsevimab administration ahead of their first RSV season.
	Develop a process for administration of Nirsevimab to infants at higher risk of RSV complications entering their second RSV season. Please note that ACIP recommendations for second RSV season administration include AI/AN and American Indians.
	Adverse events following administration of Nirsevimab should be reported. Educate staff that if administered alone, adverse events should be reported to MedWatch. If administered simultaneously with any vaccine, report to VAERS.

*Based on pre-pandemic patterns, Nirsevimab could be administered from October through the end of March. Providers can adjust administration schedules based on local epidemiology, which will be communicated by ND HHS.

^Infants at increased risk:
- Children with chronic lung disease of prematurity who required medical support any time during the six-month period before the start of the second RSV season
- Children with severe immunocompromise
- Children with cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight-for-length < 10th percentile
- American Indian and Alaska Native Children

Please contact the ND HHS Immunization Unit at vaccine@nd.gov with any immunization-related questions.

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44

Nirsevimab – Planning Checklist

North Dakota Immunization Information System (NDIIS)/Documentation	
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	Request NDIIS user access for individuals at your facility who may administer Nirsevimab monoclonal antibody or need to look up immunization/administration records.
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45

Nirsevimab – Planning Checklist

	Product Storage and Handling
	Plan for purchasing Nirsevimab for privately insured children. According to the manufacturer, Nirsevimab will cost about $495 per dose on the private market.
	Ensure storage units are working well, have adequate storage space for prefilled syringes (on top of influenza, COVID-19 and other vaccines) and temperatures are being monitored 24 hours a day using a digital data logger. Nirsevimab is stored in the refrigerator at 2-8˚C.
	Ensure staff review CDC's vaccine storage and handling toolkit.

46

Nirsevimab – Planning Checklist

	Facility Protocol and Education
	Ensure that your facility is enrolled in the VFC Program. Nirsevimab will be included in the VFC Program. Your facility should establish a process to document VFC eligibility in the EMR/patient record for each Nirsevimab dose administered.
	Establish a process to make birthing hospital and clinic staff aware of Nirsevimab availability and recommendations. Please note that IM dosage varies by weight, 50 mg if <5 kg, 100 mg if ≥5 kg, 200 mg (2x100 mg) for high risk entering 2nd RSV season.
	Plan how to communicate Nirsevimab availability, priority groups and safety/efficacy to patients.
	Ensure education on documentation needs (EMR, electronic birth certificate, NDIIS) are provided to staff.
	Update billing processes for private insurance and VFC-eligible children, as needed.
	Establish a process to obtain parental consent for Nirsevimab. A patient information sheet is forthcoming from CDC.

47

Nirsevimab – Planning Checklist

	Update current facility vaccination/medication administration protocols, if needed.
	Determine when Nirsevimab will be administered post-delivery and pre-discharge at the hospital.
	Develop a process for outpatient clinic administration to infants born outside of RSV season (well-child visits, walk-in clinics, influenza clinics, etc.). Nirsevimab can be co-administered with vaccines.
	Establish a mechanism to inform parents of infants born outside of traditional RSV season of the need to return for Nirsevimab administration ahead of their first RSV season.
	Develop a process for administration of Nirsevimab to infants at higher risk of RSV complications entering their second RSV season. Please note that ACIP recommendations for second RSV season administration include ALL American Indians.
	Adverse events following administration of Nirsevimab should be reported. Educate staff that if administered alone, adverse events should be reported to MedWatch. If administered simultaneously with any vaccine, report to VAERS.

48

RSV Prevention – Infants

- Pregnant individuals
  - On August 21, 2023, the FDA approved Pfizer's Abrysvo™ for use in pregnant individuals to prevent lower respiratory tract disease (LRTD) and severe LRTD in infants from birth through 6 months of age.
    - Approved for use as single intramuscular injection at 32 through 36 weeks gestational age of pregnancy.
  - Clinical study showed that Abrysvo™ reduced the risk of severe LRTD 81.8% within 90 days of birth and by 69.4% withing 180 days of birth.
  - A study numerical imbalance in preterm births in Abrysvo™ recipients (5.6%) occurred compared to those who received placebo (4.7%).
    - Available data is insufficient to establish or exclude a causal relationship.
  - The ACIP is scheduled to continue their ongoing review of Abrysvo™ for use in pregnant individuals and vote on possible recommendations on Sepbember 22, 2023.

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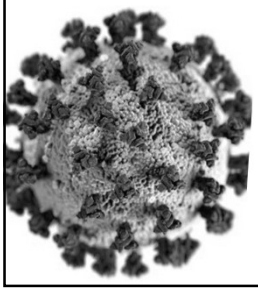
49

COVID-19



- COVID-19 is very contagious and spreads quickly when an infected person breathes out small droplets and particles and sometimes from contact with contaminated surfaces.
- COVID-19 can spread when people are asymptomatic
- It can cause mild or severe illness.
- It causes respiratory symptoms, but can also impact other parts of the body.
- People who are older, immunocompromised, have certain disabilities, or certain health conditions are at increased risk of more severe infection.

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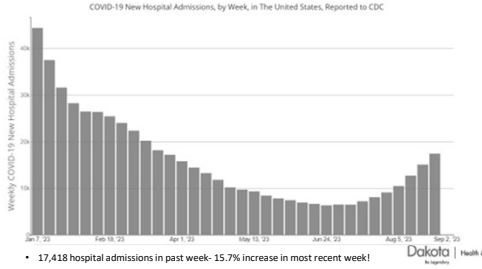
50

COVID-19 National Data



- 17,418 hospital admissions in past week- 15.7% increase in most recent week!

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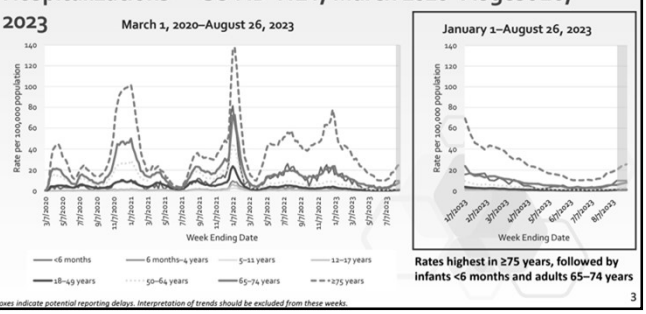
51

Weekly Population-Based Rates of COVID-19-Associated Hospitalizations — COVID-NET, March 2020–August 26, 2023



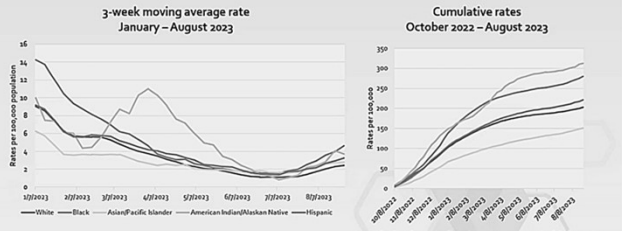
Rates highest in ≥75 years, followed by infants <6 months and adults 65–74 years

Gray boxes indicate potential reporting delays. Interpretation of trends should be excluded from these weeks.

3

52

Age-adjusted COVID-19-associated hospitalization rates by race and ethnicity* — COVID-NET, October 2022 – August 2023



Cumulative hospitalization rates remain highest in American Indian/Alaska Native and Black persons

* Black, White, American Indian/Alaska Native and Asian/Pacific Islander people were categorized as non-Hispanic; Hispanic people could be of any race.

Source: COVID-NET: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html. Data March 1, 2020 through August 26, 2023.

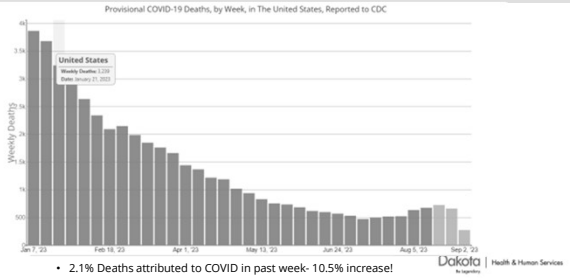
53

COVID-19-associated hospitalizations

- Hospitalization rates increased in all age groups since mid-July
- Hospitalization rates highest in older adults and infants <6 months
- Most children <5 years hospitalized with COVID-19 illness have no underlying medical conditions
  - A higher proportion of hospitalized children and adolescents 5-17 years have underlying medical conditions
  - Most hospitalized adults have multiple underlying medical conditions
- COVID-19 continues to cause severe illness; clinical outcomes generally comparable to influenza-associated hospitalizations
- Most children and adults hospitalized for COVID-19 since January 2023 had not received an updated bivalent booster

54

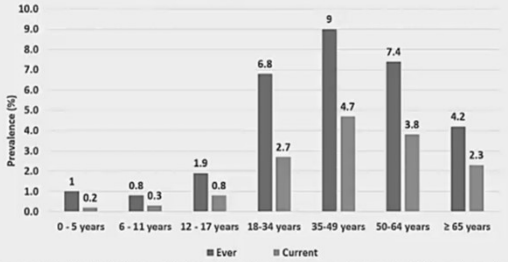
COVID-19 National Data



- 2.1% Deaths attributed to COVID in past week- 10.5% increase!

55

Prevalence of on-going symptoms lasting at least 3 months after COVID-19 by age, regardless of COVID status: U.S.



Nationally representative of non-institutional population in the U.S., statistical software was used to account for NHIS's complex sampling design.

UNPUBLISHED CDC DATA – Preliminary estimates from 2022 National Health Interview Survey

56

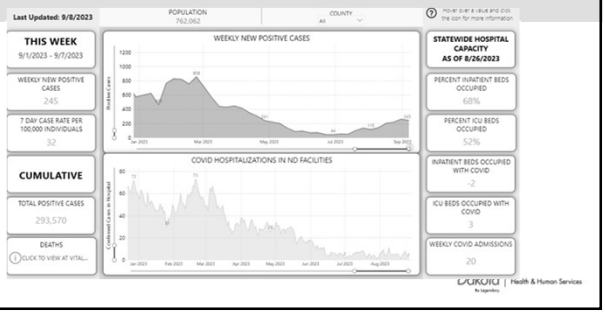
Groups associated with a higher likelihood of developing Long COVID

- Female sex
- Older age (sometimes)
  - Adolescents compared to younger children
  - Middle-aged adults compared to younger and older adults for symptoms
  - Older adults compared to younger adults for incident conditions
- Severity of COVID-19 illness
- Underlying health conditions prior to COVID-19
- Lower socio-economic status
- Did not get COVID-19 vaccine

Maglietta G et al. Prognostic Factors for Post-COVID-19 Syndrome: A Systematic Review and Meta-Analysis. JCM 2022
Socioeconomic inequalities of Long COVID-UK. Shabnam et al. 2023 (sagepub.com)
Hastie, et al. Outcomes among confirmed cases and matched comparison groups in the Long COVID in Scotland Study. Nature 2022
Epidemiology of Long Coronavirus Disease in US Adults. | Clinical Infectious Diseases | Oxford Academic (oup.com)
Frontiers. | Hospital admission and vaccination as predictive factors of long COVID-19 symptoms (frontiersin.org)

57

COVID-19 North Dakota Data



58

COVID-19 Treatment

- Most people with COVID-19 have mild illness and can recover at home. You can treat symptoms with over-the-counter medicines
- There are several FDA-authorized or approved antiviral medications used to treat mild to moderate COVID-19 in people who are more likely to get very sick.
- This includes:
  - Older adults (ages 50 years or more, with risk increasing with age)
  - People who are unvaccinated
  - People with certain medical conditions, such as chronic lung disease, heart disease, or a weakened immune system.

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59

COVID-19 Treatment

Treatment	Who	When	How
Nirmatrelvir w/Ritonavir (Paxlovid)	Adults; children ages 12 years and older	Start as soon as possible; must begin within 5 days of symptom start	Taken at home by mouth (orally)
Remdesivir (Veklury)	Adults and children	Start as soon as possible; must begin within 7 days of symptom start	Intravenous (IVS) infusions at a healthcare facility for 3 consecutive days
Molnupiravir (Lagevrio)	Adults	Start as soon as possible; must begin within 5 days of symptom start	Taken at home by mouth (orally)

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COVID-19 Vaccine

- Like influenza, the COVID-19 virus is constantly changing.
- At any time, there may be many different types, or variants, of COVID-19 circulating.
- Also like influenza, COVID-19 vaccines are reviewed and updated periodically to try to give the best protection from dominant variants.
- Unlike influenza, some people (including those who had minor or no symptoms) develop Post-COVID Conditions or "Long COVID".
- The COVID-19 vaccine is the best protection from severe COVID-19 infection and Long COVID.

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61

COVID-19 Variants

- New COVID-19 variants in the news:
  - EG.5 (Eris)
    - Currently the most prevalent variant in the United States
    - Highly transmissible
    - Closely related to the XBB variants
  - BA.2.86 (Pirola)
    - Has >35 amino acid changes compared to XBB.1.5
    - Has been identified in 9 states from both human (CO, DE, MI, OH, PA, VA, WA) and wastewater (NY and OH) specimens and in at least 7 other countries
    - Too early to know potential illness severity or transmissibility
- New COVID-19 vaccines are expected to provide protection against severe disease from either EG.5 or BA.2.86.

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62

COVID-19 Vaccine

- Who should get a COVID-19 vaccine?
  - Recommended for everyone 6 months and older in the United States.
  - Do to the changing viruses and vaccines, a vaccine or booster is needed periodically.
  - Exceptions are rare.
- COVID-19 vaccine benefits:
  - It can reduce COVID-19 infection or severity of infection and symptoms.
  - Decreased clinic visits
  - Avoid missed work or school days
  - Decrease number of COVID-19 related hospitalizations and deaths

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63

COVID-19 Vaccine

- On September 11, 2023, the FDA approved and authorized for use COVID-19 mRNA vaccines updated to include a monovalent component that corresponds to the Omicron variant XBB.1.5.
- On September 12, 2023, the ACIP voted13-1 to universally recommend the COVID-19 mRNA vaccines as approved or authorized by the FDA.
- The updated vaccines are expected to provide good protection against currently circulating variants.
- A similar side effect profile to previous mRNA vaccine side effects is expected.

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64

COVID-19 Vaccine

New recommendations:

- Individuals 5 years of age and older (regardless of previous vaccination) are eligible to receive a single dose of an updated mRNA COVID-19 vaccine at least 2 months after the last dose of any COVID-19 vaccine.
- Individuals 6 months through 4 years of age who have been vaccinated against COVID-19 are eligible to receive one or two doses of an updated mRNA COVID-19 vaccine (timing and number of doses to administer depends on the previous COVID-19 vaccine received).
- Unvaccinated individuals 6 months through 4 years of age are eligible to receive three doses of the updated authorized Pfizer-BioNTech COVID-19 Vaccine or two doses of the updated authorized Moderna COVID-19 Vaccine.

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65

COVID-19 Vaccine

New recommendations details:

- Authorization of Moderna COVID-19 Vaccine for emergency use in individuals 6 months through 11 years of age to include the 2023-2024 formula and lower the age eligibility for receipt of a single dose from 6 years to 5 years of age. Additional doses are also authorized for certain immunocompromised individuals ages 6 months through 11 years, as described in the fact sheets.
- Authorization of Pfizer-BioNTech COVID-19 Vaccine for emergency use in individuals 6 months through 11 years of age to include the 2023-2024 formula. Additional doses are also authorized for certain immunocompromised individuals ages 6 months through 11 years, as described in the fact sheets.
- Approval of Comirnaty (COVID-19 Vaccine, mRNA) to include the 2023-2024 formula, and a change to a single dose for individuals 12 years of age and older. Comirnaty was previously approved as a two-dose series for individuals 12 years of age and older.
- Approval of Spikevax (COVID-19 Vaccine, mRNA) to include the 2023-2024 formula, a change to a single dose for individuals 18 years of age and older, and approval of a single dose for individuals 12 through 17 years of age. Spikevax was previously approved as a two-dose series for individuals 18 years of age and older.

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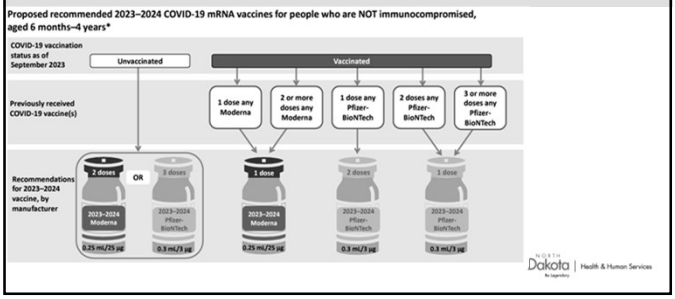
66

COVID-19 Vaccine



67

COVID-19 Vaccine

- All bivalent Moderna and Pfizer vaccine should be immediately removed from storage units as they are no longer authorized for use.
  - Dispose of vials in accordance with local, state, and federal regulations.
  - Report disposed inventory as vaccine wastage in the NDIIS.
  - Discard any diluent received with bivalent vaccine orders. Do not save to use with other products.
- Novavax formulation and recommendations have not yet changed, so existing Novavax may be administered if it is determined that the individual should not wait for a 2023-2024 Novavax vaccine.

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68

COVID-19 Vaccine

- The new 2023-2024 COVID-19 vaccines will be added to the NDIIS.
- The NDIIS forecaster will not have the rules for the new vaccines until after the vendor makes necessary changes.
  - Meanwhile, the forecaster PDF will show information for the de-authorized bivalent products.
  - The Immunization Unit will share when the forecaster is updated and you are again able to utilize this information.
- North Dakota has received a limited initial vaccine allocation, and providers may start receiving doses as soon as this week.

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69

COVID-19 Vaccine Safety

- After the bivalent COVID-19 Vaccine, only 2 myocarditis cases were verified our of ~650,000 doses.

Per million doses in 12 – 17-year-olds over 6 months[2]

19 – 95 hospitalizations prevented

5 –19 ICU admissions prevented

0 – 1 death prevented

0 myocarditis[3] cases in **55,649 males** with a bivalent dose

0 myocarditis[3] cases in **57,776 females** with a bivalent dose

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70

SIRVA

- SIRVA – Shoulder Injury Related to Vaccine Administration
  - Most local reactions following immunizations are mild and short-lived.
  - Rarely, more persistent and serious shoulder injuries may result, causing significant problems.
  - SIRVA is due to an injection-related injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.).
  - SIRVA can cause pain and limited range of motion, and may require medical intervention such as physical therapy or surgery.
  - SIRVA is NOT a reaction to the vaccine product, but is damage related to the administration.

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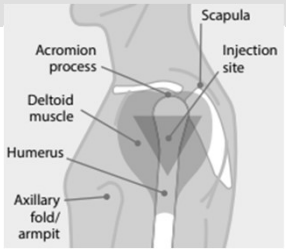
71

SIRVA

- SIRVA prevention:
  - Ensure ability to recognize the anatomical landmarks for identifying the deltoid muscle.
  - Use proper sterile technique.
  - Use correct intramuscular administration technique.
  - Use the correct size needle based on patient age and body mass.



Adult

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72

Post-Test

- Post-test
  - Nurses interested in continuing education credit, visit https://ndhealth.co1.qualtrics.com/jfe/form/SV_2fSR6jnXuCzBvv0
  - Successfully complete the five-question post-test to receive your certificate
  - Credit for this session will not expire until October 10, 2023.
- This presentation will be posted to our website: www.hhs.nd.gov/immunizations

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73

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74

Respiratory Illness Season and Prevention

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75