A POSITION PAPER FROM

NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

Monoclonal Antibodies

Inclusion in the Vaccines for Children Program

MARCH 2022

Diseases like respiratory syncytial virus pose a serious risk to all infants and young children, but preventive monoclonal antibodies can make a life-saving difference. Once approved, these passive immunizations should be available and accessible through the Vaccines for Children Program. Families will then have greater access to preventive care, ensuring that their infants and children are protected against RSV.

OVERVIEW

By warding off diseases like influenza and pertussis, immunizations play a critical role in infant and early childhood health. Immunizations protect infants from life-threatening diseases, which can lead to both hospitalization and long-term complications.

One such disease common among infants is respiratory syncytial virus, or RSV. RSV affects most children by the time they are two years old[1] and is the leading cause of hospitalization for all infants under age one.[2] Infants younger than one are 16 times more likely to be hospitalized for RSV than for the flu,[3] and RSV accounts for 500,000 emergency room visits in young children each year.[4] One in seven infants receive medical attention for a lower respiratory tract infection during the RSV season.[5]

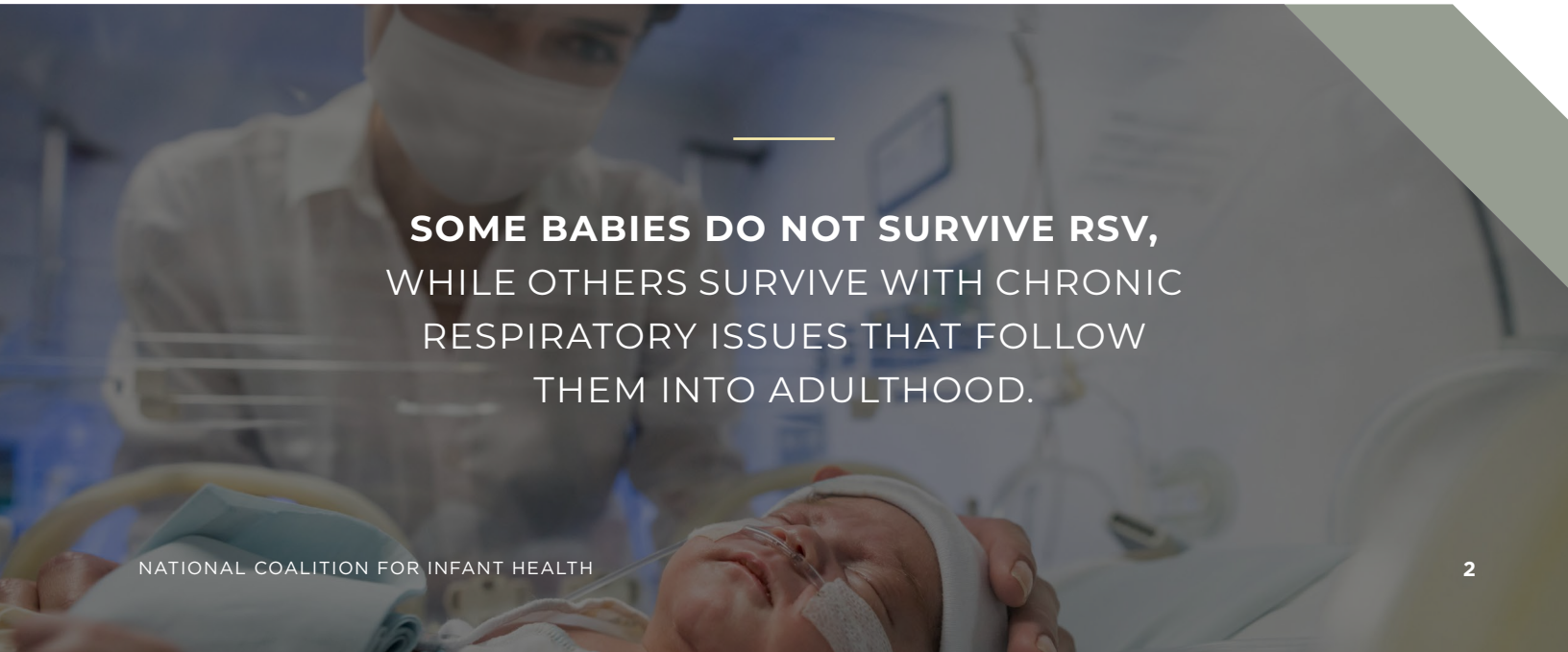
Some infants experience only mild cold-like symptoms, but for others, RSV can cause bronchiolitis, pneumonia and respiratory distress, which can lead to hospitalization and mechanical ventilation. Some babies do not survive, while others survive with chronic respiratory issues that follow them into adulthood.

While there is no vaccine for RSV, vaccine-like interventions are under development, and one is approved for a narrow population of infants born preterm or with certain underlying health conditions. These interventions are called monoclonal antibodies, which protect infants and young children from RSV.

Preventive monoclonal antibodies are considered vaccine-like because they offer protection against disease but in a different way. Instead of delivering a harmless strain of the virus to the immune system like vaccines do, these treatments provide the body's immune system with readily available, protective antibodies.

But while vaccines for diseases like influenza and pertussis may be widely accessible, preventive monoclonal antibodies can be more difficult to access. Even though vaccine-like interventions can offer live-saving preventive treatment, they may not be covered by insurance companies.

Questions of coverage are especially important when it comes to the Vaccines for Children program.[6] The program provides free child vaccinations for families who may not be able to afford them. Because infants covered under Medicaid are disproportionately impacted and experience higher rates of hospitalization,[7] the question of whether an intervention is on the program's list of pediatric vaccines makes a world of difference.



SOME BABIES DO NOT SURVIVE RSV, WHILE OTHERS SURVIVE WITH CHRONIC RESPIRATORY ISSUES THAT FOLLOW THEM INTO ADULTHOOD.

POSITION

RSV is a threat to all infants. From severe symptoms to hospitalization, this disease can take a serious toll on infants and their families. Ensuring all infants have equitable and timely access to interventions for this disease is key.

> **The National Coalition for Infant Health supports the Advisory Committee on Immunization Practices' (ACIP) schedule including these preventive monoclonal antibodies on the Vaccines for Children program's list of pediatric vaccines based on the following principles:**

PROTECTION FROM RSV SHOULD BE STANDARD FOR ALL INFANTS.

RSV is a common and highly contagious disease that almost all infants experience. Without a vaccine or vaccine-like intervention, it can be difficult to prevent RSV or decrease the disease burden in infants. These preventive monoclonal antibodies provide an effective solution for preventing RSV altogether, saving infants from potentially life-threatening illness and other life-long complications that may develop.

VACCINES AND VACCINE-LIKE INTERVENTIONS BENEFIT ALL INFANTS AND CHILDREN.

Monoclonal antibodies are like vaccines because they protect the body's immune system from diseases. The list of pediatric vaccines is not restricted to only vaccines and because of their similarities, vaccine-like interventions meet the Vaccines for Children program's requirements.

INFANTS DESERVE ACCESS TO PREVENTIVE INTERVENTIONS, REGARDLESS OF THEIR FAMILY'S FINANCES OR INSURANCE COVERAGE.

The Vaccines for Children program, which covers half of America's children, provides vaccines recommended by the ACIP to families at no cost. And vaccines included in the Vaccines for Children program are also covered by private insurance companies, as required by the Affordable Care Act.

ROBUST COVERAGE ENCOURAGES CONTINUED MEDICAL INNOVATION TO PROTECT INFANTS.

By including these vaccine-like interventions on the Vaccines for Children pediatric vaccine list, the ACIP will demonstrate its commitment to "prevention and control of communicable diseases" and support for innovative, life-saving interventions and equitable access for all infants.

RECOMMENDATION

To make a marked reduction in the burden of RSV, **all infants and children need timely and equitable access to preventive monoclonal antibodies.** This can be achieved by including these interventions on the recommended list of pediatric vaccines in the Vaccines for Children program.

REFERENCES

1. Centers for Disease Control and Prevention. (2020, December 18). RSV in Infants and Young Children. Centers for Disease Control and Prevention.
2. Leader S. (v1.0) J pediatr. 2003.
3. Zhou H, et al. 54:1427–36. Clin Infect Dis. 2012.
4. Hall, CB. et al. Respiratory Syncytial Virus-Associated Hospitalizations Among Children Less Than 24 Months of Age. Pediatrics, 132(2). doi: 10.1542/peds.2013-0303.
5. Rainisch G, Adhikari B, Meltzer MI, Langley G. Estimating the impact of multiple immunization products on medically-attended respiratory syncytial virus (RSV) infections in infants. Vaccine. 2020;38(2):251-257
6. Centers for Disease Control and Prevention. (2016, February 18). Vaccines for Children Program. Centers for Disease Control and Prevention.
7. Sangare L et al. J Pediatr 2006; 149:373-377

NCfIH National Coalition for Infant Health

Protecting Access for Premature Infants through Age Two

The National Coalition for Infant Health educates and advocates on behalf of premature infants from birth to age two. NCfIH envisions safe, healthy infants whose families can access the information, care and treatment their babies need.

InfantHealth.org

Facebook.com/CoalitionForInfantHealth

@InfantCoalition