Key Message 3:

- Infants with pulmonary abnormalities or neuromuscular disease which impairs their ability to clear lung secretions MAY be considered eligible for respiratory syncytial virus (RSV) prophylaxis with palivizumab in their first year of life. Such prophylaxis is not likely to be of benefit in the second year of life.
- Immunocompromised infants and children MAY be considered eligible for RSV prophylaxis using palivizumab if they are <24 months of age at season onset.

Pulmonary abnormalities, neuromuscular disease

- Risk of RSV related hospitalizations is not well defined for this population.
- These conditions include nonproductive cough, recurrent gastroesophageal tract reflux, malformation of the lungs, tracheoesophageal fistula, and upper-airway conditions - especially those requiring a tracheostomy.

Immunosuppression

- A severe clinical course of RSV has been demonstrated in children receiving chemotherapy or immunosuppressed for other reasons.
- RSV in these patients may progress to further complications including death.
- More specific risk factors include age ≤2 years, lymphopenia, early presentation of lower respiratory tract symptoms, and corticosteroid therapy.
- Underlying diagnosis, degree of immunosuppression, RSV load, and concentration of anti-RSV antibodies have NOT been shown to correlate with poor outcomes.

Summary of changes in RSV prophylaxis recommendations from the AAP.3,4

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infants with anatomic pulmonary abnormalities or neuromuscular disease</strong></td>
<td><strong>Infants with anatomic pulmonary abnormalities or neuromuscular disease</strong></td>
</tr>
<tr>
<td>GA &lt;35 weeks and chronologic age &lt;12 months at season onset2</td>
<td>Chronologic age &lt;12 months at season onset</td>
</tr>
<tr>
<td>Impaired clearance of secretions from upper respiratory tract</td>
<td>Otherwise consistent</td>
</tr>
<tr>
<td><strong>Immunocompromised infants and children</strong></td>
<td><strong>Immunocompromised infants and children</strong></td>
</tr>
<tr>
<td>Chronic age &lt;24 months at season onset</td>
<td>Consistent</td>
</tr>
<tr>
<td>Profoundly immunocompromised</td>
<td></td>
</tr>
</tbody>
</table>

*New York State Department of Health designates RSV season as October 16 – March 31


http://nypep.nysdoh.suny.edu • E-mail: PEP@nysdoh.suny.edu • Last reviewed Nov. 2014
Limited data exist for the following populations. The following studies indicate that immunocompromised infants may benefit from prophylaxis if they are in their first 24 months of life, as they are likely to experience adverse outcomes associated with RSV progression. This is especially true for those exposed to smoke, radiation, or who present with an absolute lymphocyte count (ALC) ≤100 cells/mm. Infants with neuromuscular impairment or pulmonary abnormalities are more likely to require intensive care and mechanical ventilation associated with RSV, and may therefore be considered for prophylaxis in their first year of life.

<table>
<thead>
<tr>
<th>Trial</th>
<th>Design</th>
<th>Population</th>
<th>Endpoints</th>
<th>Results</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wilkesmann 2007⁴</td>
<td>P, MC cohort</td>
<td>n=1,541 with clinically relevant NMI identified based on physician recommendations, compared to those without NMI over 6 consecutive RSV seasons (1999-2005), in Germany</td>
<td>Clinically relevant aspects of the management of NMI inpatients with RSV infection</td>
<td>Total of 1,568 RSV infections NMI vs. Without NMI</td>
<td>Children with clinically relevant NMI hospitalized with RSV infection are more likely to be admitted to the PICU and require mechanical ventilation.</td>
</tr>
<tr>
<td>El Saleeby 2007⁵</td>
<td>Retrospective cohort</td>
<td>n=58 patients aged &lt;21 yr with neoplasias, hematologic disorders, immunodeficiency syndromes, or HSCTs with RSV, between 1997 and 2005, in hospital in Tennessee</td>
<td>Risk factors for severe RSV infection and death (multivariate and univariate regression, respectively)</td>
<td>Risk factors for LRTI: Diagnosis</td>
<td>Profound lymphopenia and young age are independently associated with RSV LRTI. LRTI may progress to death, particularly in HSCT patients age 2 years or less being treated for AML</td>
</tr>
</tbody>
</table>

References:

http://nypep.nysdoh.suny.edu • E-mail: PEP@nysdoh.suny.edu • Last Reviewed Nov. 2014
<table>
<thead>
<tr>
<th>Trial</th>
<th>Design</th>
<th>Population</th>
<th>Endpoints</th>
<th>Results</th>
<th>Conclusions</th>
</tr>
</thead>
</table>
| Asner 2013 | Retrospective   | n=117 RSV-positive immunocompromised pediatric inpatients age <18 years between 2006 and 2011 in Toronto | Risk factors for acquisition and outcomes from RSV infections in this population | • 45.9% patients presented with N-RSV  
• >1/3 presented with a LRTI  
• 28% ICU admission rate  
• 5% mortality rate, all CA-RSV patients  
LRTI:  
• N-RSV: 13 (31%)  
• CA-RSV: 39 (52%)  
  OR 2.5, 95% CI 1.1 to 5.6  
Prolonged hospital stay:  
• OR 0.7; 95% CI 0.5 to 0.8  
Median duration of stay:  
• N-RSV: 24 days  
• CA-RSV: 11.5 days  
  OR 0.96, 95% CI 0.93 to 0.98 | N-RSV patients were more likely to require a prolonged hospital stay while those with CA-RSV were more likely to progress to LRTI. Differences among those with CA-RSV compared with N-RSV warrant further study. |
| Kim 2014   | Retrospective   | n=181 HSCT recipients with RSV upper respiratory tract infection             | The significance of various factors in the progression to LRTI:  
• Lymphocyte engraftment dynamics  
• Lung function  
• Smoking history  
• Corticosteroid  
• Antiviral treatment  
• Viral subtypes  
• RSV-specific neutralizing antibodies | Progression to LRTI:  
Smoking history:  
• Smoke exposure vs none: OR 2.5, 95% CI 1.1 to 5.6  
Irradiation:  
• High-dose total body irradiation vs none: OR 2.5, 95% CI 1.1 to 5.6  
• None/low irradiation: OR 2.1, 95% CI 0.8 to 5.2  
Lymphopenia at URTI onset vs. ALC>500:  
• ALC ≤100/mm³: OR 6.0, 95% CI 1.9 to 18.9  
• ALC >100: OR 2.1, 95% CI 0.7 to 5.8 | Host and transplant related factors appear to determine the risk of progression to LRTI more than viral factors, specifically lymphopenia, smoke exposure, and radiation exposure. |

ALC=absolute lymphocyte count; CA=community-acquired; HSCT=hematopoietic stem cell transplant; LRTI=lower respiratory tract infection; N=nosocomial; NMI=neuromuscular impairment; PICU=pediatric intensive care unit; SCIDS=severe combined immunodeficiency syndrome; URTI=upper respiratory tract infection