Background

- Respiratory Syncytial Virus (RSV)-associated illness (RSV-AI) is a major public health concern for children worldwide. 1
- RSV is the most common cause of bronchiolitis, which is the leading cause of hospitalization of infants and young children in the United States. 2
- Therapies for prevention and treatment of RSV-AI are currently limited, and new products are needed. 3
- Drug and vaccine development can benefit from the study of RSV epidemiology.
- FDA's Sentinel System is a robust active surveillance system that uses electronic healthcare data comprised primarily of administrative claims. Data partners, most of which are commercial insurers, provide information from members across the U.S.
- Sentinel has focused on post-marketing safety of medical products, mostly in adults. 4
- This project demonstrates the utility of Sentinel for pediatric epidemiology research and anti-infective drug development, which are more novel applications.

Objectives

- To collect epidemiologic information about RSV-AI in the United States, which may be used to inform future development of novel drugs for the treatment and prevention of RSV-AI.
- To demonstrate that the Sentinel database can be used to generate robust epidemiological data for common, acute pediatric medical conditions, using RSV-AI as a case example.

Methods

- Two analyses were conducted in the Sentinel database using data from 16 data partners.
- In the first analysis, we examined trends in the timing of RSV cases, palivizumab dispensing, and diagnostic testing among children 1 to 24 months (mo) of age. Data from 1/1/2008 to 9/30/2015 were included.
- The second analysis examined clinical features of RSV-AI cases in children <5 years of age, such as baseline characteristics, RSV risk factors (prematurity, chronic lung disease [CLD], chronic heart disease [CHD]), and care setting. Data from 1/1/2008 to 6/30/2016 were included.
- For both queries, RSV-AI cases were defined as patients with incident RSV ICD-9/ICD-10 diagnosis codes.

Results

Figure 1: Seasonality trends of RSV Cases in Any Care Setting, January 1, 2008 to September 30, 2015

Analysis 1:

- 89,537 cases of RSV-AI were identified in the outpatient setting.
- Timing of RSV-AI cases followed an expected seasonal pattern consistent with published data 5 (Figure 1).
- RSV diagnostic testing was also seasonal but continued year round, even when RSV-AI cases were infrequent.
- As expected, palivizumab dispensation occurred prior to peak RSV season. A notable decrease in palivizumab use was noted in the 2014-2015 RSV season, which coincides with the revised 2014 guidelines from the American Academy of Pediatrics. 1

Analysis 2:

- 317,928 RSV-AI cases were identified in the inpatient and outpatient setting.
- The majority of RSV-AI cases were managed in the ambulatory setting: 81% for infants 1-6 mo old, 84% for children 7-60 mo old.
- Patients with traditional risk factors for RSV-AI comprise a small proportion of total RSV cases in both the inpatient and outpatient setting (Table 1).

Limitations

- Results are only descriptive in nature.
- Observational data, including claims data in Sentinel, are subject to inherent limitations such as differences in coding practices.
- Since these data come primarily from commercially insured children, the findings may not be generalizable to the US population at large.

Conclusions

- While acknowledging the significance of CLD, CHD, and prematurity as risk factors for RSV-AI, we also highlight that the majority of RSV-AI coded cases occurred in children without traditional risk factors.
- To lessen the overall public health burden of RSV-AI, future development of new prophylactics and therapeutics may need to be inclusive of both healthy and high-risk groups.
- Our results demonstrate the ability of Sentinel to provide useful epidemiologic data regarding a common pediatric illness.

Acknowledgements & Disclaimers

- The authors have no conflicts of interest to disclose.
- The opinions expressed in this poster are those of the authors and not necessarily of the U.S. FDA.
- Many thanks are due to the Data Partners who provided data used in the

Table 1. Baseline Characteristics of Patients with Incident RSV-AI in Any Care Setting, January 1, 2008 - June 30, 2016

<table>
<thead>
<tr>
<th>Any Care Setting</th>
<th>Inpatient Care Setting</th>
<th>Outpatient Care Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 1-6 mo</td>
<td>Age 6-70 mo</td>
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</tr>
<tr>
<td>N=138,669</td>
<td>N=79,344</td>
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</tr>
<tr>
<td>Male Sex</td>
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<tr>
<td>79,344 (57%)</td>
<td>44,000 (54%)</td>
<td>65,812 (57%)</td>
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</tbody>
</table>

References