

occurring in the first months of life. We assessed the efficacy of maternal immunization with an RSV F protein vaccine against RSV LRTI over the first 180 days of life.

**Methods:** We enrolled 4,636 women with low-risk third trimester singleton pregnancies in 11 countries to receive RSV F vaccine or placebo in a randomized, observer-blind trial. Women were followed for 6 months post-delivery, and infants for ~1 year. Surveillance for RSV LRTI in infants, identified by RT-PCR detection of RSV, physical examination, and pulse oximetry, was carried out for 180 days from delivery.

**Results:** The RSV F vaccine induced modest reactogenicity and no excess fever. Live births resulted from 98.7% of pregnancies, with no difference between treatment groups in prematurity (< 37 weeks) or mean interval from treatment to delivery. There were no apparent negative impacts on pregnancy, delivery, or infant well-being. Vaccine immunogenicity resembled that in non-pregnant women. Transplacental transfer of vaccine-induced antibodies was markedly more efficient when the interval from immunization to delivery was  $\geq 30$  days. 85 to 95% of primary and secondary endpoint RSV LRTI events in the placebo group occurred in the first 90 days of life (see Figure 1). Overall, through 180 days of infant life, RSV was associated with 11.3% of all acute respiratory illnesses and 16.7% of all LRTI, but 49.1% of LRTI with  $SpO_2 < 95\%$  or tachypnea, and 60.3% of all LRTI with  $SpO_2 < 92\%$  in the placebo group. Vaccine efficacy was greatest in the first 75 days of life but clearly persisted to the primary, per-protocol analysis at 90 days, and was supported by the ITT analysis, per Table 1. Efficacy against all-cause LRTI with severe hypoxemia (46.0%) or hospitalization (27.8%) was observed in the per-protocol population, as well as an apparent impact on the clinical diagnosis of pneumonia through both 180 and 364 days.

**Conclusion:** RSV F vaccine in the third trimester was safe and had clinically-meaningful impacts on RSV and all-cause LRTI over the first 6 months of life.

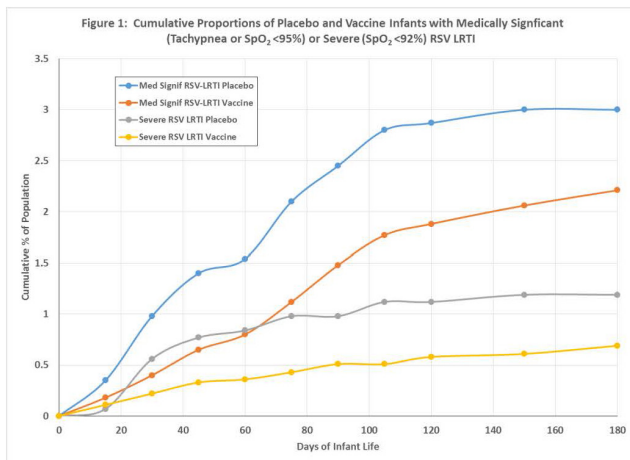


Table 1:

Endpoint	Per-protocol population		Intent-to-Treat population	
	Point estimate	95% CI	97.52% CI	95% CI
Medically significant RSV LRTI ( $SpO_2 < 95\%$ or tachypnea)	39.4%	5.3, 61.2%	-1.0, 63.7%	32.2, -4.2, 55.9%
RSV LRTI with severe hypoxemia ( $SpO_2 < 92\%$ )	48.2%	-8.3, 75.3%	ND	44.4%, -14.9, 73.1%
RSV LRTI with hospitalization	44.4%	19.6, 61.5%	ND	48.1%, 26.1, 63.5%

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**2638. Respiratory Syncytial Virus Hospitalizations (RSVH) and All-Cause Bronchiolitis Hospitalizations (BH) Among 29–34 Weeks Gestational Age (wGA) Preterm Infants Before and After the 2014 American Academy of Pediatrics (AAP) Immunoprophylaxis Policy Change Using the Children's Hospital Association's Pediatric Health Information System (PHIS)**

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**Background:** In 2014, the AAP stopped recommending RSV immunoprophylaxis for otherwise healthy 29–34 wGA preterm infants. This study examined the risk of RSVH and BH among 29–34 wGA infants before the AAP policy change (November 1, 2010–March 31, 2014) and after (November 1, 2014–March 31, 2017) using PHIS hospital-level encounter data from 51 US children's hospitals.

**Methods:** The study population included the first November to March RSVH (ICD9 = 79.6, 480.1, 466.1.1, ICD10 = B97.4, J12.1, J21.0) or BH (RSVH or unspecified bronchiolitis [ICD9 = 466.19, ICD10 = J21.1, J21.8, J21.9]) among infants 6 months of age or younger admitted to a PHIS hospital between November 1, 2010 and March 31, 2017. The proportion of RSVH and BH by wGA categories (22–28 wGA, 29–34 wGA,

35–36 wGA, and term infants [37+ wGA]) were compared in the time period before and after 2014. Frequencies and proportions were calculated overall for all infants and by demographic and clinical factors for 29–34 wGA infants for RSVH and BH, separately. Statistically significant differences before and after the AAP policy were compared using  $\chi^2$  test or Wilcoxon rank-sum test, as appropriate.

**Results:** 96,281 infants with BH, including 67,570 with RSVH, were studied. Among infants with known gestational age, the proportions of hospitalizations for RSVH and BH increased after the AAP policy change for all wGA categories, except for term infants (table). Infants 29–34 wGA represented 8.7% of all RSVH before the policy change and 14.2% of all RSVH after the policy change ( $P < 0.0001$ ). No significant differences were found by gender or co-morbidity for infants 29–34 wGA. Among infants 29–34 wGA, the intensive care unit admission rate increased significantly for RSVH (from 54.5% to 64.2%,  $P < 0.0001$ ) and BH (from 46.7% to 54.5%,  $P < 0.0001$ ) after the policy change. The median RSVH length of stay (from 6 to 7 days,  $P = 0.047$ ) and median adjusted estimated cost (from \$14,077 to \$16,058,  $P = 0.038$ ) increased significantly after the policy change.

**Conclusion:** RSV and all-cause bronchiolitis hospitalizations and their severity increased among preterm infants 29–34 wGA in the 3-year period following the 2014 AAP policy change on RSV immunoprophylaxis.

Table. Proportion of RSVH and BH by wGA

	RSV hospitalizations				P-value	All-cause bronchiolitis hospitalizations				
	11/1/2010-3/31/2014		11/1/2014-3/31/2017			11/1/2010-3/31/2014		11/1/2014-3/31/2017		p-value
	N	%	N	%		N	%	N	%	
22-28 wGA	233	1.9	243	2.3	0.052	505	3.0	591	3.6	0.001
29-34 wGA	1061	8.7	1524	14.2	<0.0001	1661	9.8	2270	13.9	<0.0001
35-36 wGA	1692	13.8	1503	14.0	0.624	2283	13.4	2201	13.5	0.785
37+ wGA	9253	75.6	7428	69.4	<0.0001	12563	73.8	11215	68.9	<0.0001
All	12239	100.0	10698	100.0		17012	100.0	16277	100.0	

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**2639. Respiratory Virus Detections in Asthma-Related Pediatric Hospitalizations: New Vaccine Surveillance Network, United States**

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**Background:** Respiratory viruses are associated with most asthma exacerbations (AEx) in children; however, the role of different viruses in AEx is unclear. We describe respiratory virus detections among pediatric inpatients with AEx (AEx-inpatients).

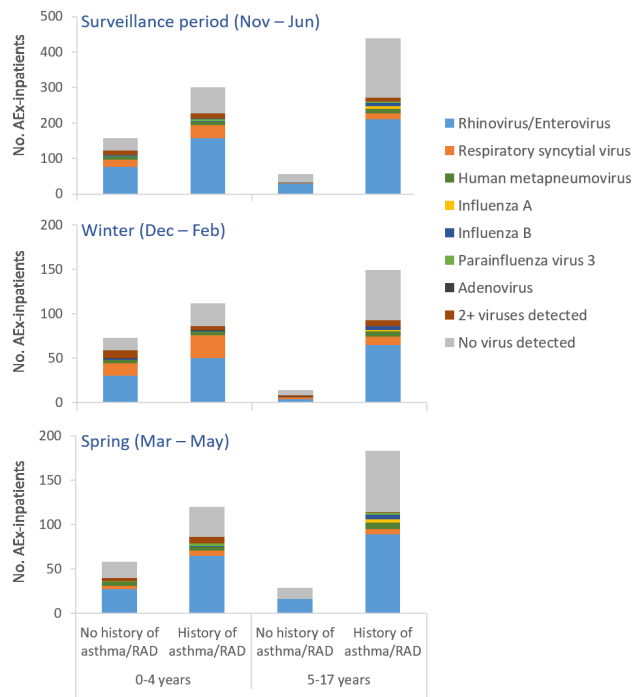
**Methods:** Through active, prospective surveillance at 7 US medical centers, we enrolled inpatients (<18 years) with acute respiratory illness (ARI) during November 1, 2015–June 30, 2016. We defined an AEx-inpatient as an inpatient with a principal admission or discharge diagnosis of asthma (ICD-10-CM, J45.xx). Mid-turbinate nasal and/or throat swabs were tested by molecular assays for influenza A or B, respiratory syncytial virus (RSV), parainfluenza virus 1–3, rhinovirus or enterovirus (RV/EV), human metapneumovirus and adenovirus. We assessed virus detections among AEx-inpatients throughout the surveillance period or by season (winter:

December–February; spring: March–May), and by patient age and history of asthma/reactive airway disease (asthma/RAD).

**Results:** We tested 3,897 inpatients with ARI; of whom, 954 were AEx-inpatients. Most AEx-inpatients (741/954 [78%]) reported an asthma/RAD history. Viruses were more frequently detected among AEx-inpatients <5 years (350/458 [76%]) than 5–17 years (305/496 [61%],  $P < 0.001$ ). Most (615/655 [94%]) detections were of single viruses. The most frequent single virus detections were RV/EV (474/954 [50%]) and RSV (76/954 [8%]) but the frequency of each virus varied by season and age group (figure). Single RV/EVs were the most common virus detections in both seasons and all groups. Single RSV detections were prominent among <5 year olds in winter (40/185 [22%]). Among those with single RV/EV or RSV detections, 285/474 (60%) and 49/76 (64%) required supplemental oxygen, respectively ( $P = 0.676$ ); median length of stay was 1 day (range: 0–45; IQR: 1–2) and 2 days (range: 0–6; IQR: 1–2.5), respectively ( $P < 0.001$ ).

**Conclusion:** AEx-inpatients <5 years were more likely to have respiratory virus detections than those 5–17 years. Single RV/EVs formed the majority of virus detections throughout the surveillance period, regardless of age. RSV played a notable role in winter among patients <5 years. These findings could inform prevention or treatment strategies for virus-associated AEx.

#### Virus detections among inpatients with asthma exacerbations (AEx-inpatients)



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#### 2640. Aerosol vs. Oral Ribavirin for the Treatment of Community-Acquired Respiratory Virus Infections in Lung Transplant Recipients

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**Background:** Community-acquired respiratory virus (CARV) infections are associated with an increased risk of chronic lung allograft dysfunction (CLAD) and graft loss in lung transplant recipients (LTR). Administration of ribavirin by aerosol was the standard of care at Stanford Health Care in the management of CARV infections. Given the sparse evidence of benefit with aerosol ribavirin (AR) and its increasing cost and teratogenic risk for exposed healthcare personnel, AR was restricted to the treatment of respiratory syncytial virus (RSV) in 2016 and was ultimately removed from formulary in 2017. Oral (PO) ribavirin was used at the discretion of the transplant team. The objective of this study was to evaluate the clinical outcomes of AR compared with PO ribavirin in lung transplant recipients.

**Methods:** We performed a retrospective cohort analysis of adult lung transplant recipients diagnosed with CARV (metapneumovirus, parainfluenza virus, and RSV)

infections treated with either AR or PO ribavirin. The analysis included the first treatment course of ribavirin by either route and patients were excluded if they received ribavirin in the prior 12 months. The primary outcome was the development/progression of CLAD, acute organ rejection, and overall mortality.

**Results:** Of 85 patients, 41 received AR and 44 received PO ribavirin. There was no significant difference in the following clinical outcomes with AR and oral ribavirin, respectively: development or progression of CLAD (30 days: 9.7% vs. 4.5%,  $P = 0.4227$ ; 90 days: 14.6% vs. 6.8%,  $P = 0.303$ ; 6 months: 17% vs. 9%,  $P = 0.3413$ ; 12 months: 24% vs. 15.9%,  $P = 0.4188$ ), acute organ rejection (90 days: 7.3% vs. 4.5%,  $P = 0.6689$ ; 6 months: 12.1% vs. 9%,  $P = 0.7329$ ; 12 months: 19.5% vs. 13.6%,  $P = 0.5635$ ), and overall mortality (30 days: 0% vs. 4.5%,  $P = 0.4947$ ; 90 days: 7.3% vs. 4.5%,  $P = 0.6689$ ; 6 months: 7.3% vs. 9%,  $P = 1.0$ ; 12 months: 7.3% vs. 13.6%,  $P = 0.4858$ ). There was no observable difference in reported adverse effects between AR and PO ribavirin.

**Conclusion:** Lung transplant recipients with CARV infections had similar outcomes when treated with AR or PO ribavirin. Oral ribavirin is a less costly treatment than AR, but the efficacy of ribavirin by any route remains questionable.

**TABLE 1. Baseline Characteristics**

Patient Variable	Aerosol Ribavirin (n=41)	Oral Ribavirin (n=44)
Age, years (mean)	48.9	53.0
Male gender (%)	23 (56%)	25 (57%)
Ethnicity		
White	32	27
Hispanic	3	9
Asian	1	3
Other	5	5
Underlying Diagnosis		
Cystic Fibrosis	15	10
Pulmonary hypertension	1	3
Interstitial lung disease	17	18
Chronic obstructive pulmonary disease (COPD)	6	9
Lymphangioleiomyomatosis (LAM)	0	2
Other	2	2
Rejection History		
History of CLAD prior to CARV event	10	20
History of acute organ rejection prior to CARV event	20	23
Active acute rejection at CARV event	2	4
Respiratory Virus Treated		
Metapneumovirus (MPV)	12	15
Parainfluenza Virus (PIV)	16	20
Respiratory Syncytial Virus (RSV)	13	9

**TABLE 2. Outcomes of Lung Transplant Recipients Treated with Aerosol or Oral Ribavirin for CARV Infections**

Outcome	Aerosol Ribavirin (n=41)	Oral Ribavirin (n=44)	p-value
Development/Progression of Chronic Lung Allograft Dysfunction (CLAD)			
30-days	4 (9.7%)	2 (4.5%)	0.4227
90-days	6 (14.6%)	3 (6.8%)	0.303
6-months	7 (17.0%)	4 (9%)	0.3413
12-months	10 (24%)	7 (15.9%)	0.4188
Acute Rejection			
90-days	3 (7.3%)	2 (4.5%)	0.6689
6-months	5 (12.1%)	4 (9%)	0.7329
12-months	8 (19.5%)	6 (13.6%)	0.5635
Mortality			
30-days	0 (0%)	2 (4.5%)	0.4947
90-days	3 (7.3%)	2 (4.5%)	0.6689
6-months	3 (7.3%)	4 (9%)	1
12-months	3 (7.3%)	6 (13.6%)	0.4858
Other outcomes			
Upper respiratory tract infection (URTI)	26 (63.4%)	22 (50%)	0.2748
Progression to Lower respiratory tract infection (LRTI)	2 (7.7%)	1 (4.5%)	0.6073
ICU admission	0	2 (4%)	0.4947
Mechanical ventilation	0	1 (2.2%)	1
Concurrent infection	6 (14.6%)	12 (27.2%)	0.1897

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#### 2641. The Characteristics of Influenza-Like Illness (ILI) Management in Japan

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**Background:** Influenza-like illness (ILI) is a common disease that imposes a severe disease burden at the population level. ILI management is important in view of population health, and Japan's management is distinct from that in other countries, especially regarding diagnosis and treatment of seasonal influenza. This study's main objective was to quantitatively assess ILI management in Japanese healthcare settings.

**Methods:** In February 2019, we conducted an online survey of 600 participants in 200 households concerning ILI and its management in Japan. Respondents reported ILI episodes they and/or their family members experienced during January 2019. The 12-Item Short-Form Health Survey, Version 2 (SF-12v2) was included in the questionnaire to estimate quality of life (QOL) lost through ILI, and quality-adjusted life years (QALYs) lost in that way. We analyzed participants' healthcare-seeking behavior to clarify the characteristics of Japanese ambulatory care for ILI.

**Results:** Of the participants, 261 of 600 (43.5%) reported at least one episode of ILI during January 2019. Of these, 194 (75.5%) visited healthcare facilities and 167 (86.1%) visited facilities within 2 days of symptom onset. A rapid influenza diagnostic test (RIDT) was given to 169 of 191 (88.5%) and 101 patients received a diagnosis of influenza, rather than ILI. Antivirals were used to treat 92.2% of the influenza cases.