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Background. Annual national estimates of influenza vaccine effectiveness (VE) typically measure protection against outpatient medically attended influenza illness. We assessed influenza VE in preventing laboratory-confirmed influenza hospitalization in children across two influenza A(H3N2)-predominant seasons.

Methods. Children < 18 years hospitalized with acute respiratory illness were enrolled at 7 pediatric hospitals in the New Vaccine Surveillance Network. We included subjects ≥6 months with ≤10 days of symptoms enrolled during the 2016–2017 and 2017–2018 seasons (date of first through last influenza-positive case for each site). Combined mid-turbinate and throat swabs were tested using molecular assays. We estimated age-stratified VE from a test-negative design using logistic regression to compare the odds of vaccination among cases positive for influenza with controls testing negative, adjusting for age, enrollment month, site, underlying comorbidities, and race/ethnicity. Full/partial vaccination was defined using ACIP criteria. We verified vaccine receipt from state immunization registries and/or provider records.

Results. Among 3441 children with complete preliminary data, in 2016–2017, 156/1,710 (9%) tested positive for influenza: 91 (58%) with influenza A(H3N2), 5 (3%) with A(H1N1), and 60 (38%) with B viruses. In 2017–2018, 193/1,731 (11%) tested positive: 87 (45%) with influenza A(H3N2), 47 (24%) with A(H1N1), and 58 (30%) with B. VE for all vaccinated children (full and partial) against any influenza was 48% (95% confidence interval, 26%–63%) in 2016–2017 and 45% (24%–60%) in 2017–2018. Combining seasons, VE for fully and partially vaccinated children against any influenza type was 46% (32%–58%); by virus, VE was 30% (4%–49%) for influenza A(H3N2), 71% (46%–85%) for A(H1N1), and 57% (36%–70%) for B viruses. There was no statistically significant difference in VE by age or full/partial vaccination status for any virus (table).

Conclusion. Vaccination in the 2016–2017 and 2017–2018 seasons nearly halved the risk of children being hospitalized with influenza. These findings support the use of vaccination to prevent severe illness in children. Our study highlights the need for a better understanding of the lower VE against influenza A(H3N2) viruses.

Table. Preliminary vaccine effectiveness estimates, by vaccination status and by age group, for 2016–17 and 2017–18 combined seasons.

	A(H3N2)	A(H1N1)	B	All Viruses
By vaccination status				
Any (fully and partial)	30% (4%-49%)	71% (46%-85%)	57% (36%-70%)	46% (32%-58%)
Fully vaccinated	25% (-5%-46%)	73% (45%-87%)	56% (33%-71%)	45% (28%-57%)
Partially vaccinated	41% (-4%-67%)	62% (2%-85%)	53% (7%-76%)	48% (21%-66%)
Any vaccination (full and partial), by age group				
6 mos – 8 yrs	38% (11%-57%)	76% (52%-88%)	63% (42%-76%)	54% (40%-65%)
9 – 17 yrs	23% (-38%-58%)	54% (-35%-84%)	50% (-4%-76%)	37% (-1%-61%)

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900. Effect of Influenza Vaccine Priming on Current Season Vaccine Effectiveness among Children and Adolescents, US Flu VE Network 2014–2015 Through 2017–2018

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Background. Studies have demonstrated that optimal protection against child-hood influenza requires two “priming” doses of influenza vaccine in the first season of vaccination. Two doses of influenza vaccine are recommended for US children aged 6 months–8 years who received ≤1 dose in prior seasons. We examined risk of influenza among children fully or partially vaccinated during study seasons and vaccine effectiveness (VE) by the number of priming doses.

Methods. Analyses included children aged 6 months–17 years enrolled during outpatient visits for acute illness for ≤7 days with cough in the US Influenza Vaccine Effectiveness Network during 2014–2015 through 2017–2018. Participants' respiratory specimens were tested for influenza by rRT-PCR. Vaccination histories back to birth year were obtained from electronic immunization records. VE was calculated by comparing vaccination odds among influenza-positive cases to test-negative controls, as 100 × (1 – odds ratio) adjusted for season, site, age, high-risk status, and calendar time.

Results. Of 7,583 children, 6,362 (84%) had received ≥1 dose in their lifetime. Among vaccinated children, 90% were primed prior to the enrollment season, and 80% were primed prior to age 2 years. Most (55%) received two priming doses in their first season. Among children recommended to receive two priming doses in the enrollment season, receipt of two doses vs. one was associated with a lower risk of influenza illness (aOR: 0.60; 95% CL: 0.36, 1.00). VE of ≥1 dose in the enrollment season against any influenza among unprimed children was 53% (95% CL: 36, 66). VE of ≥1 dose in the enrollment season was similar among children primed with one dose in their first season (46%; 95% CL: 34, 55) and among those primed with two doses (46%; 95% CL: 35, 55). Overall results were similar when stratified by age and for A/H3N2 viruses, which predominated during study years.

Conclusion. Among the US children recommended to receive two priming doses of vaccine in the enrollment season, receipt of two doses provided optimal protection. VE in seasons after the priming did not differ by the number of priming doses. Results were driven by predominance of A/H3N2 viruses and may not be similar for A/H1N1pdm09 or B viruses. Current US influenza vaccine recommendations for children are effective and appropriate.

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901. MEDI8897 Prevents Serious RSV Disease in Healthy Preterm Infants

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Background. RSV is the principal cause of lower respiratory tract infection (LRTI) among infants, and a significant unmet need exists for RSV prevention in healthy infants. We have developed a highly potent, extended half-life monoclonal antibody (mAb), to protect infants for an entire RSV season using a single IM dose. Here we report the efficacy, safety, pharmacokinetics, and anti-drug antibody (ADA) responses for MEDI8897 in palivizumab-ineligible preterm infants born between 29 and 35 weeks gestation.

Methods. A total of 1,453 Infants were randomized 2:1 to receive a single 50 mg IM injection of MEDI8897 (n = 969) or placebo (n = 484) and followed for 360 days. Enrollment occurred just prior to the 2016 and 2017 RSV seasons in 23 northern and southern hemisphere countries. Blood was collected periodically. Infants with a medically attended (MA) LRTI (outpatient or inpatient) had nasal swabs obtained for central RSV testing by RT-PCR. Predefined clinical criteria were used for the case definition.

Results. A total of 1,417 (97.5%) subjects completed the 150-day efficacy follow-up period and 1,367 (94.1%) completed the study. In the MEDI8897 group, a 70.1% (95% CI: 52.3%, 81.2%; P < 0.0001) reduction in the incidence of medically attended RSV LRTI and a 78.4% (95% CI: 51.9%, 90.3%; P = 0.0002) reduction in the incidence of RSV LRTI hospitalization was achieved. These efficacy results were consistent when analyzed by hemisphere, RSV subtype, and subject demographics. Similar proportions of adverse events (86.8% placebo; 86.2% MEDI8897) and serious adverse events (16.9% placebo; 11.2% MEDI8897) were reported in study subjects. There were no significant hypersensitivity reactions with similar proportions reported for both groups (0.6% placebo; 0.5% MEDI8897). The incidence of ADA detected any time post baseline was low (3.8% placebo; 5.6% MEDI8897) with no impact on PK or safety. The occurrence of non-RSV LRTIs was similar for both groups indicating no replacement by other pathogens.

Conclusion. In this large randomized study of RSV prophylaxis in healthy pre-term infants, MEDI8897 immunoprophylaxis provided a significant reduction in RSV MA-LRTI and hospitalization. These results have promising implications for the future of RSV prophylaxis for all infants.

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902. A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy of a Single Immunization of Ad26.RSV.pF against RSV Infection in a Viral Challenge Model in Healthy Adults

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