of ACAM2000 (Group 2). Peak neutralizing antibody GMTs were significantly higher following 2 MVA-BN doses (153.5) compared with ACAM2000 (79.3), with a ratio of 1.935 (95% CI: 1.562, 2.397). At Day 14, neutralizing antibody GMTs were equal following a single dose of either MVA BN or ACAM2000 (16.2, ratio of 0.997, 95% CI: 0.738, 1.348), with similar seroconversion rates (90.8% vs. 91.8%, respectively). The median MLA induced by ACAM2000 was significantly reduced when subjects received prior MVA-BN in Group 1 (0 mm^2) compared with Group 2 (76.0 mm^2), suggesting protection against orthopoxvirus. MVA BN was well tolerated, demonstrating a better safety profile than ACAM2000.

Conclusion. Two doses of MVA-BN induce significantly higher peak neutralizing antibody responses compared with ACAM2000. A single dose induces an early neutralizing antibody response equal to ACAM2000 at Day 14, demonstrating the suitability of MVA BN in both pre- and post-outbreak scenarios. This study was partly funded by BARDA under contract HHSO100200700034C.

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LB12. A Randomized Controlled Trial of Antibody Response to 2018–2019 Cell-based vs. Egg-based Quadrivalent Inactivated Influenza Vaccine in Children

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Background. While vaccine effectiveness varies across seasons and age groups, influenza vaccination is still the most effective means of preventing influenza infection. Current vaccine effectiveness improvement efforts are focused on manufacturing methods whereby the use of eggs as a growth medium is being minimized to prevent egg adaptation mutations that render the vaccine less effective. This study compared children's immune response to two FDA-approved influenza vaccines, cell-based vs. egg-based, in an unblinded randomized controlled trial.

Methods. Racially diverse, healthy children ages 4–20 years were randomly assigned 1:1 in blocks of 4 to receiveeither quadrivalent inactivated cell-based or egg-based influenza vaccine. Blood was drawn at Day 0 before vaccination and at Day 28 post vaccination (range = 19–35 days) and analyzed for hemagglutination inhibition (HAI) titers using standard protocols against egg-grown vaccine antigens. Primary outcome measures were seropositivity, defined as HAI titer ≥1:110 and ≥1:40; seroconversion, defined as the HAI titer ratio of Day 28/Day 0 ≥4 and HAI titer at Day 28 ≥40; and fold-rise, defined as antilog of average log_2HAI titer ratio of Day 28/Day 0. Secondary outcomes were compared for those vaccinated and not vaccinated the previous year.

Results. Baseline demographics including age, sex, race, ethnicity, parental educational status, health insurance coverage, and exposure to household smoking did not differ between vaccine groups. There were no differences in any HAI antibody response between the two vaccine groups (table). Participants unvaccinated in the prior season (2017–2018, $N = 62$) were more likely than those vaccinated ($N = 86$) to seroconvert to any strain in 2018–2019 (≥1 strain seroconverted: 68% unvaccinated vs. 35% vaccinated in 2017–2018, $P < 0.001$). Day 28 titer fold-rise difference was 2.0 for A/H1N1, 0.65 for A/H3N2, 1.1 for B/Colorado and 0.9 for B/Phuket.

Conclusion. There were no differences for any HAI antibody titer outcome between children receiving the two vaccines. Overall, the cohort had HAI titers at levels sufficient to be considered seropositive at baseline. Those unvaccinated in the preceding season had higher seroconversion rates than those vaccinated in both seasons.

Pre- and post-vaccination HAI antibody titer outcomes overall and by vaccine type

HAI response	Cell-based vaccine N=75	Egg-based Vaccine N=73	*P* value[†]
A/H1N1			
Day 0 log_2 HAI GMT (95% CI)	117 (90 – 153)	103 (78 – 135)	0.49
Day 28 log_2 HAI GMT (95% CI)	292 (239 – 360)	242 (189 – 309)	0.23
Day 0 seropositive ≥110, n (%)	45 (60.0)	39 (53.4)	0.42
Day 28 seropositive ≥110, n (%)	66 (88.0)	58 (79.5)	0.16
Day 0 seropositive ≥40, n (%)	65 (86.7)	63 (86.3)	0.95
Day 28 seropositive ≥40, n (%)	74 (98.7)	71 (97.3)	0.62
Seroconversion, n (%)	20 (26.7)	14 (19.2)	0.28
Fold-rise in log_2 HAI titer (95% CI)	2.6 (2.0 – 3.4)	2.4 (1.9 – 3.1)	0.72
A/H3N2			
Day 0 log_2 HAI GMT (95% CI)	187 (150 – 232)	143 (111 – 182)	0.10
Day 28 log_2 HAI GMT (95% CI)	261 (208 – 326)	269 (218 – 331)	0.86
Day 0 seropositive ≥110, n (%)	51 (68.0)	45 (61.6)	0.42
Day 28 seropositive ≥110, n (%)	62 (82.7)	60 (82.2)	0.94
Day 0 seropositive ≥40, n (%)	74 (98.7)	70 (95.9)	0.36
Day 28 seropositive ≥40, n (%)	74 (98.7)	73 (100.0)	1.00
Seroconversion, n (%)	9 (12.0)	11 (15.1)	0.59
Fold-rise in log_2 HAI titer (95% CI)	1.6 (1.4 – 1.9)	1.9 (1.6 – 2.4)	0.16
B/Colorado			
Day 0 log_2 HAI GMT (95% CI)	112 (84 – 147)	105 (79 – 137)	0.53

Disclosures. Patricia Nowalk, PhD, Merck & Co. (Grant/Research Support); others, no reported disclosures .

LB13. Trivalent Hepatitis B (HepB) Vaccine Yields Superior Seroprotection Rates in Adults: Results from the Phase 3 Double-Blind, Randomized Study Comparing Immunogenicity and Safety of a 3-Dose Regimen of Sci-B-Vac™ and Engerix B® (PROTECT)

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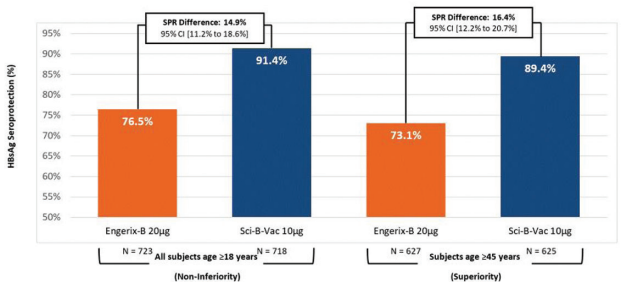
Background. Many adults fail to achieve seroprotection after receiving 3 doses of monovalent HepB vaccines such as Engerix-B® and the response decreases with age and with common co-morbidities. Sci-B-Vac™ is a trivalent HepB vaccine produced in mammalian cells, adjuvanted with aluminum hydroxide, which in addition to small S antigen, contains preS1 and preS2 antigens expressing highly immunogenic T- and B-cell epitopes that may enhance seroprotection rates (SPR) in adults.

Methods. In a multicentre study, the immunogenicity of 10 µg dose of Sci-B-Vac™ was compared with a 20-µg dose of Engerix-B® given at days 0, 28, and 168 (NCT03393754). Randomization was stratified by study center and age (18–44, 45–64, ≥65 years). Immunogenicity, including SPR (% subjects with anti-HBs levels ≥10 mIU/mL), and safety outcomes were followed to Day 336. The co-primary objectives were (1) non-inferiority in adults ≥18 years and (2) superiority in adults ≥45 years of SPR, 4 weeks after the third dose.

Results. Of 1,607 randomized subjects, 42.3% were from United States, 41.6% EU, and 16.1% Canada. Males (38.5%) and females (61.5%) were enrolled to 18–44 (18.6%), 45–64 (44.6%), and ≥ 65 year (36.8%) age groups. Both co-primary endpoints were met. In the non-inferiority analysis, SPR in Sci-B-Vac™ recipients aged ≥18 years was 91.4% vs. 76.5% for Engerix-B®; SPR difference: 14.9%; 95% confidence interval (CI) [11.2%, 18.6%]. Superiority analysis showed that SPR in Sci-B-Vac™ recipients aged ≥45 years was 89.4% vs. 73.1% for Engerix-B®—SPR difference: 16.4%; 95% CI [12.2%, 20.7%] (figure). Significantly higher SPR for Sci-B-Vac™ vs. Engerix-B® was noted in subgroups (gender, BMI, diabetes, smoking and particularly age—SPR difference for 45–64 (14.7% [9.8–19.8%]) and ≥ 65 (18.9% [11.6–26.1%]) years. No major safety signals were observed; solicited and unsolicited adverse events were consistent with the known vaccine safety profiles.

Conclusion. Sci-B-Vac™ met immunogenicity endpoints for non-inferiority in adults aged ≥ 8 years and was superior in adults aged ≥45 years, compared with the monovalent vaccine, Engerix-B®. Sci-B-Vac™ SPR was higher compared with Engerix-B® in key subgroups. No safety signals were observed and safety and tolerability were consistent with the known profile of Sci-B-Vac™.

Figure: Achievement of non-inferiority in subjects aged ≥ 18 years and clinical superiority in subjects aged ≥ 45 years



Disclosures. Timo Vesikari, MD, VBI (Grant/Research Support, I have received funding from VBI to carry out the reported clinical trial in Finland), Joanne M. Langley, MD, VBI Vaccines (Grant/Research Support), Johanna Spaans, BSc, MSc, VBI Vaccines (Employee), Nathalie Machluf, PhD, SciVac Ltd. (Employee), Dave Anderson, PhD, VBI Vaccines, Inc. (Employee, Shareholder), Vlad Popovic, MD, VBI Vaccines (Employee), Francisco Diaz-Mitoma, MD, VBI Vaccines, Inc. (Consultant, Shareholder, Independent Contractor). **Other Authors:** No reported disclosures.

LB14. Cerebrospinal Fluid Profiling of the Human Host Response Reveals Species-Specific Enterovirus Biosignatures in Acute Flaccid Myelitis Cases

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Background. Since 2014 there have been global biennial outbreaks of acute flaccid myelitis (AFM), a rare but severe "polio-like" illness of as yet-unknown etiology primarily affecting children. Enteroviruses (EVs),, especially EV-D68 and EV-A71, have been implicated in association with AFM cases, but proving causality has been difficult as EVs are rarely isolated from cerebrospinal fluid. In addition, early identification of EV-associated AFM is challenging given that the diagnosis is reliant on potentially subjective clinical and radiological criteria with no specific biomarkers described to date.

Methods. We leveraged existing and newly generated data from a clinical CSF metagenomic assay for pathogen identification at University of California, San Francisco (UCSF) to interrogate the host response at the transcriptome level by RNA sequencing (RNA-Seq). These transcriptome RNA-Seq data were used to create statistical classification models to discriminate among viral infections that have been linked to AFM, including EV-D68, EV-A71, West Nile virus, and Powassan virus. The dynamic range of CSF cellularity (0 to $>10^6$ cells/mL), resulting in varying trancriptome coverage, as well as technical variation across samples required the development and validation of novel normalization techniques. In total, we analyzed ~50 CSF samples split into independent training and test sets.

Results. We were able to demonstrate a distinct signature of AFM that was able to predict the virus associated with AFM in blinded test samples with >80% accuracy. The key transcriptional features that best discriminated EV-A71 from EV-D68-associated AFM involved protein targeting, viral transcription, viral gene expression, and translation initiation pathways.

Conclusion. Here we demonstrate a novel approach to diagnosis of AFM that relies on host transcriptional biomarkers from cerebrospinal fluid. In the future, this method might allow earlier diagnosis of AFM to drive appropriate therapies and vaccines and predict patient outcomes, as well as guide research studies on the pathophysiology of EV-associated AFM.

Disclosures. **All authors:** No reported disclosures.

LB15. Measles Outbreak in New York State (NYS) Outside of New York City, 2018–2019

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Background. The United States is experiencing one of the largest and longest measles outbreaks since elimination was declared in 2000 and is at risk of losing this status. Most cases occurring in NYS were reported in undervaccinated communities.

Methods. We included all confirmed NYS measles cases (excluding NYC) from outbreak counties from October 1, 2018 to July 25, 2019. We used the CSTE measles case definition requiring an acute febrile rash illness and either laboratory confirmation or direct epidemiologic linkage to a lab-confirmed case. For each case, demographic and clinical characteristics were obtained. A medical record review was completed for those reported to have an encounter at a hospital, emergency department, or urgent care center.

Results. There were 371 cases of measles reported, including 11 internationally imported cases. Most occurred in Rockland county (n = 283); followed by Orange (n = 55), Westchester (n = 18), Sullivan (n = 14) and Greene (n = 1) (Figures 1 and 2). The median age was 5.5 years; 79% of all cases occurred among children younger than 18 years of age (Figure 3). Most cases (79%) had not received any doses of measles vaccine. Of the 371 cases, 263 (71%) were children who had received 0 doses of measles, mumps, rubella vaccine (MMR), 218 (83%) of whom were over 1 year of age (Table 1). There have been no deaths or documented cases of encephalitis. Twenty-eight (8%) patients were diagnosed with pneumonia and 25 (7%) patients were hospitalized. Among 17 hospitalized children, 5 (29%) were admitted to the intensive care unit (ICU) (ages 1 day to 7 years). There were two preterm births at 34 and 25 weeks gestation to women with measles while pregnant. During October 1, 2018–July 31, 2019, providers in outbreak counties vaccinated 72,465 individuals with MMR, a 46% increase from the same period the year prior.

Conclusion. Unvaccinated children were identified as the largest group affected and experienced severe complications; nearly 30% of hospitalized children were admitted to an ICU. These data support the critical need for continued education and outreach on the risks of measles and the value of vaccination to prevent continued circulation in undervaccinated communities and potential further cases of severe disease.

Figure 1. Map of Measles Cases in the New York State outside of New York City, 2018-2019

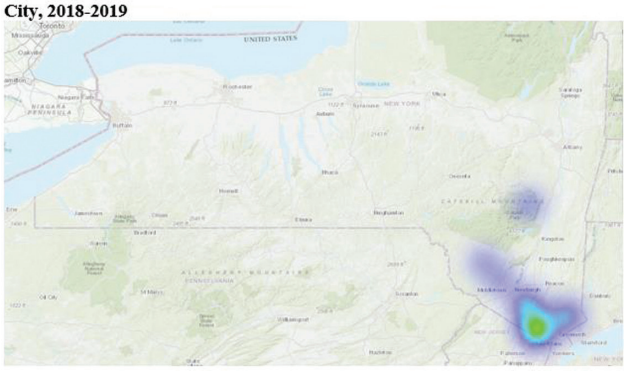

Figure 2: New York State (excluding New York City) Measles Cases by Week and County (by rash onset date), 2018-2019

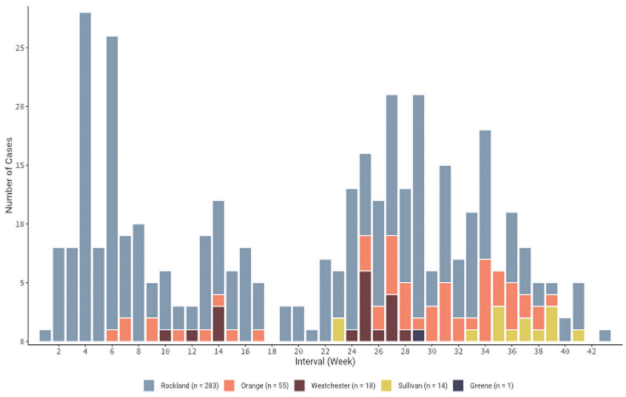

Figure 3: Age Distribution of Confirmed Measles Cases in New York State (excluding New York City), 2018-2019

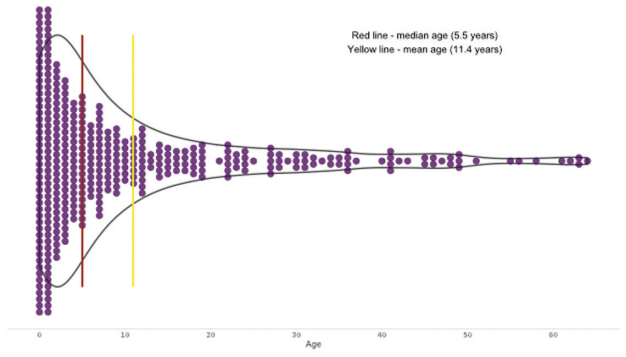

Table 1: Measles Vaccination Status by Age Group in New York State (excluding New York City), 2018-2019

Age Group	# MMR Doses				Total
	0	1	2	Unknown	
< 6 Months	17	0	0	0	**17 (4.6%)**
6 - 11 Months	28	3	0	0	**31 (8.4%)**
1-4 Years	108	13	2	1	**124 (33.4%)**
5-17 Years	110	1	3	6	**120 (32.3%)**
18+ Years	31	3	7	38	**79 (21.3%)**
Total	**294 (79.2%)**	**20 (5.4%)**	**12 (3.2%)**	**45 (12.1%)**	**371**