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.

Disclosures. Jane Maclennan, BSc MRPharmS, Bavarian Nordic (Employee), Bavarian Nordic (Employee, Shareholder), Heinz Weidenthaler, MD, Bavarian Nordic (Employee, Shareholder), Phillip Pittman, MD, Bavarian Nordic (Scientific Research Study Investigator), Darja Schmidt, PhD, Bavarian Nordic (Employee, Shareholder), Paul Chaplin, PhD, Bavarian Nordic (Board Member, Employee, Shareholder), Bavarian Nordic (Employee, Shareholder).

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

Krissy Moehling, PhD[1]; Chyongchiou Lin, PhD[1]; Judith Martin, MD[1]; John F. Alcorn, PhD[1]; Michael Susick, MPH[1]; Patricia Nowalk, PhD[1]; Min Levine, PhD[2]; Brendan Flannery, PhD[2]; Brendan Flannery, PhD[2]; Richard K. Zimmerman, MA, MD, MPH, MS[1]; [1]University of Pittsburgh, Pittsburgh, Pennsylvania,; [2]Centers for Diease Control and Prevention, Atlanta, Georgia

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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)

Timo Vesikari, MD[1]; Joanne M. Langley, MD[2]; Joanne M. Langley, MD[2]; Bruce Smith, PhD[2]; Pierre van Damme, MD, PhD[3]; Isabel Leroux-Roels, MD, PhD[4]; Geert Leroux-Roels, MD[5]; Johanna Spaans, BSc, MSc[6]; Nathalie Machluf, PhD[7]; Bebi Yassin-Rajkumar, n/a[8]; Dave Anderson, PhD[9]; Vlad Popovic, MD[9]; Francisco Diaz-Mitoma, MD[9]; [1]Vaccine Research Center, Tampere, Pirkanmaa, Finland,; [2]Dalhousie University, Halifax, Nova Scotia, Canada,; [3]University of Antwerp, Campus Drie Eiken, Wilrijk, Antwerpen, Belgium,; [4]Ghent University and Ghent University Hospital, Ghent, Oost-Vlaanderen, Belgium,; [5]Ghent University Hospital, Ghent, Oost-Vlaanderen, Belgium,; [6]VBI Vaccines Inc., Ottawa, Ontario, Canada,; [7]SciVac Ltd., Rehovot, HaMerkaz, Israel,; [8]Sponsor, Ottawa, Ontario, Canada,; [9]VBI Vaccines, Cambridge, Massachusetts

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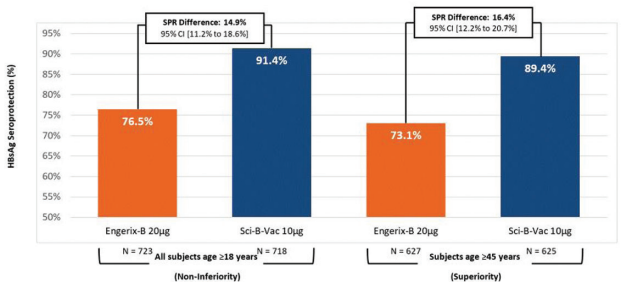
Background. Many adults fail to achieve seroprotection after receiving 3 doses of monovalent HepB vaccines such as Engerix-B® and the response decreases with age and with common co-morbidities. Sci-B-Vac™ is a trivalent HepB vaccine produced in mammalian cells, adjuvanted with aluminum hydroxide, which 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

Benjamin J. Briggs, MD, PhD[1]; Yale Santos, BS[1]; Akshaya Ramesh, PhD[1]; Manfred Grabherr, PhD[2]; Asmeeta Achari, MS, BS[1]; Guixia Yu, BS[1]; Steve Miller, MD, PhD[3]; Steve Miller, MD, PhD[3]; Scot Federman, BA[1]; Shaun Arevalo, BS[1]; Hannah Sample, BS[1]; Kelsey Zorn, MHS, BA[1]; Kathleen Harriman, PhD, MPH, RN,[4]; Sharon Messenger, PhD[4]; Samuel Dominguez, MD, PhD[5]; Samuel Dominguez, MD, PhD[5]; Carol Glaser, MD, DVM[6]; Debra Wadford, PhD[3]; Kevin Messacar, MD[7]; Kevin Messacar, MD[7]; Michael Wilson, MD[1]; Charles Chiu, MD, PhD[1]; Charles Chiu, MD, PhD[1]; [1]University of California, San Francisco, San Francisco,