humoral responses to RZV (1 month post-RZV dose 2) and PCV13 (1 month post-PCV13) in Co-Ad group compared to Control group. Solicited adverse events (AEs) until D7 post-vaccination and unsolicited AEs until D30 post-vaccination were recorded. Serious AEs (SAEs) and potential immune-mediated diseases (pIMDs) were collected through 12 months post-RZV dose 2. Immunogenicity was performed in the per-protocol set (PPS) and safety analyses in the exposed set.

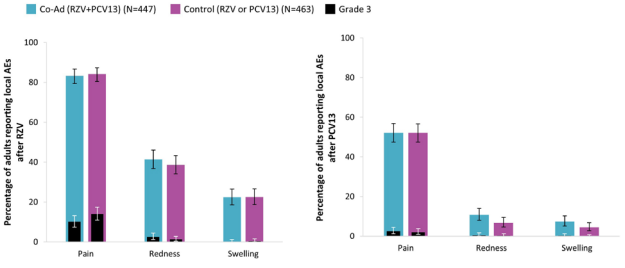
Results. Of 912 vaccinated adults, 863 were included in PPS (Co-Ad: 427; Control: 436). VRR for anti-glycoprotein E antibody concentrations was 99.1% in Co-Ad group. The predefined non-inferiority criteria for the humoral immune responses to RZV and PCV13 were met (Table 1). The overall frequency of solicited local AEs after RZV and PCV13 was comparable between Co-Ad and Control groups. Pain was the most common solicited local AE (Figure 1). The frequency of solicited general AEs was similar for the 1st RZV dose when co-administered with PCV13 or alone (57.4% vs 54.6%). Myalgia and fatigue were the most common solicited general AEs (Figure 2). The frequency (Co-Ad: 21.2%; Control: 23.1%) and nature of unsolicited AEs were balanced between groups. None of the reported SAEs, fatal SAEs, or pIMDs were vaccine-related.

Table 1. Co-primary confirmatory objectives: vaccine response rate (VRR), and non-inferiority of the immune responses to RZV (1 month post-dose 2) and to PCV13 (1 month post-vaccination) in the Co-Ad group vs the Control group (per-protocol set)

Statistical criteria	Antigen - Outcome (LL — UL)
VRR to RZV	
Lower limit (LL) of the 1-sided 95% confidence interval (CI) of the VRR for anti-glycoprotein E (anti-gE) antibody enzyme-linked immunosorbent assay (ELISA) concentrations in the Co-Ad group was ≥ 60%	Anti-gE: 97.6 (60, 80, 100) VRR
Non-inferiority of the Co-Ad group *vs* the Control group	
Upper limit (UL) of the 1-sided 95% CI of anti-gE antibody ELISA geometric mean concentration (GMC) ratio < 1.5	Anti-gE: 1.16 (0, 0.5, 1, 1.5) GMC ratio (Control/Co-Ad)*
UL of the 1-sided 95% CI of the multiplex opsonophagocytosis assay (MOPA) geometric mean titer (GMT) ratio < 2, for each of the 13 pneumococcal vaccine serotypes	Anti-1: 1.33; Anti-3: 1.22; Anti-4: 1.52; Anti-5: 1.32; Anti-6A: 1.56; Anti-6B: 1.73; Anti-7F: 1.44; Anti-9V: 1.39; Anti-14: 1.42; Anti-18C: 1.34; Anti-19A: 1.22; Anti-19F: 1.32; Anti-23F: 1.50 (0, 0.5, 1, 1.5, 2) GMT ratio (Control/Co-Ad)*

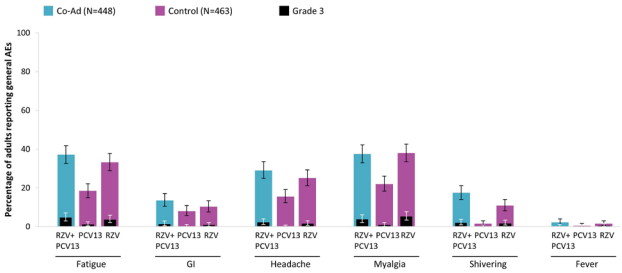
Note: Co-primary confirmatory objectives were assessed sequentially. *Adjusted for age and baseline concentration/titer; **VRR**, the percentage of adults who had a ≥ 4-fold increase in the anti-gE antibody concentrations post-RZV dose 2 as compared to the anti-gE antibody concentrations pre-vaccination, for adults who were seropositive at baseline, or a ≥ 4-fold increase in the anti-gE antibody concentrations post-RZV dose 2 as compared to the anti-gE antibodies cut-off value for seropositivity, for adults who were seronegative at baseline. The dotted lines represent the non-inferiority criteria.

Figure 1. The incidence of solicited local adverse events (AEs) occurring within 7 days post-vaccination (overall/adult, exposed set)



N, maximum number of adults with at least one documented dose; **Grade 3**, significant pain at rest that prevented normal everyday activities, diameter > 100 mm (redness and swelling). Error bars depict 95% confidence intervals.

Figure 2. The incidence of solicited general adverse events (AEs) post-dose 1 occurring within 7 days post-vaccination (exposed set)



N, maximum number of participants with documented dose; **GI**, gastrointestinal symptoms: nausea, vomiting, diarrhea and/or abdominal pain; **Fever**, temperature ≥ 38.0°C; **Grade 3**, headache, myalgia, fatigue, shivering, and GI symptoms that prevented normal activities, fever > 39.0°C. Error bars depict 95% confidence intervals.

Conclusion. Co-administration of the 1st RZV dose with PCV13 showed non-inferior immune responses to sequential administration. The reactogenicity and safety of RZV in the Co-Ad group were within the range of the established safety profile of RZV. Co-administration of RZV with PCV13 may improve vaccination rates in ≥ 50 YOA population.

Funding. GlaxoSmithKline Biologicals SA

Disclosures. **Ji-Young Min, PhD, GSK group of companies** (Employee) **Agnes Mwakingwe-Omar, MD, PhD, GSK group of companies** (Employee) **Megan Riley, PhD, GSK group of companies** (Employee, Shareholder) **Lifeter Yenwo Molo, BsC(hons) MSc(hons), GSK group of companies** (Employee) **Jyoti Soni, MA, GSK group of companies** (Employee) **Ginette Girard, MD, Diex Recherche Inc. Sherbrooke** (Scientific Research Study Investigator) **Jasur Danier, MD, GSK group of companies** (Employee, Shareholder)

10. Quadrivalent M2SR (M2-deficient Single Replication) Live Influenza Vaccine Provides Better Protection Than Inactivated Vaccine Against Drifted Influenza B Virus Challenge in Ferrets

Lindsay Hill-Batorski, PhD[1]; Yasuko Hatta, DVM, PhD[1]; Michael Moser, PhD[1]; David Marshall, BS[1]; Pamuk Bilsel, PhD[1]; [1]FluGen, Madison, Wisconsin

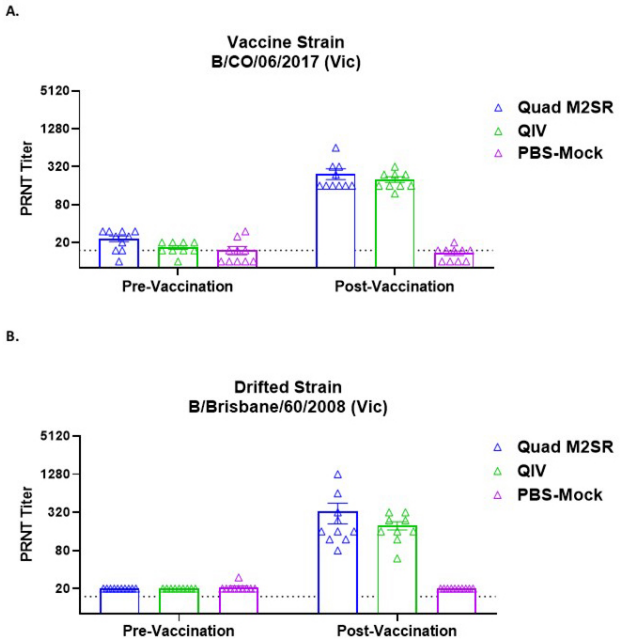
Session: P-02. Adult Vaccines

Background. Quadrivalent inactivated influenza vaccines (QIV) induce neutralizing antibodies (Abs) against the viral hemagglutinin (HA). Despite annual update of HA vaccine antigens to match circulating strains, current vaccines provide ~60% vaccine effectiveness (VE). QIV VE can be as low as 10% when circulating strains do not match vaccine HA. The live M2SR (M2-deficient single replication) influenza vaccine candidate has previously shown broad humoral, mucosal and cellular immune responses and protection against multiple influenza A subtypes. Here we show similar properties with the Quadrivalent M2SR (Quad M2SR) against drifted influenza B challenge in comparison to QIV.

Methods. Ferrets pre-infected with influenza H1N1 and B/Yamagata viruses, were immunized intranasally (IN) with PBS (Mock) or Quad M2SR, or intramuscularly with Fluzone QIV. Serum collected post-vaccination was evaluated for Ab responses. Forty-two days after vaccination, ferrets were challenged IN with 10^6 pfu of B/Brisbane/60/2008 (Victoria lineage) influenza virus. Nasal washes were taken for 7 days post-challenge and evaluated for challenge virus by $TCID_{50}$ assay. Nasal turbinates, trachea and lungs were also evaluated for virus.

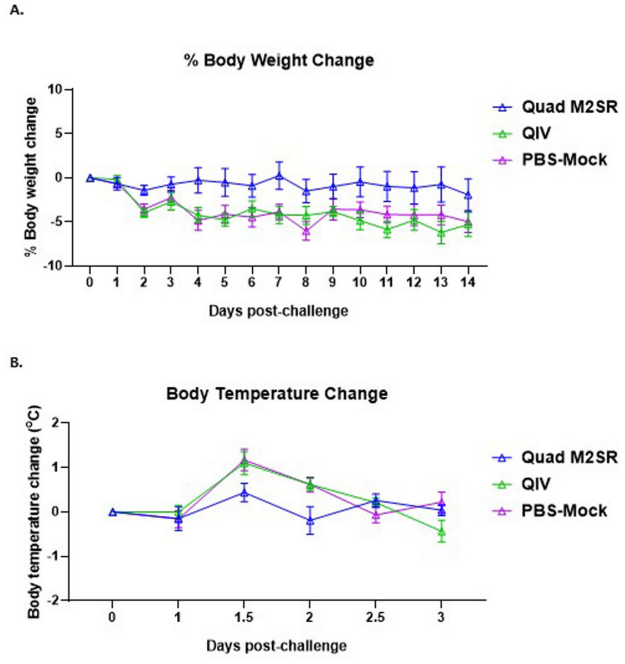
Results. Quad M2SR and QIV elicited high serum Abs against the vaccine strain B/Colorado/06/2017 (Fig. 1A) and against the drifted influenza B challenge strain B/Brisbane/60/2008 (Fig. 1B) in ferrets with preexisting immunity. Like Mock, ferrets who received QIV displayed both weight loss (6.2%, Fig. 2A) and a rise in temperature (1.1°C, Fig. 2B) after challenge. In contrast, the Quad M2SR group did not exhibit any significant weight or temperature changes after challenge. Quad M2SR controlled the drifted challenge virus better than QIV as evidenced by significantly lower or absent post-challenge virus titer in nasal washes (Fig. 3A) and nasal turbinates (Fig. 3B).

Figure 1. Serum Neutralization Titers Post-Vaccination



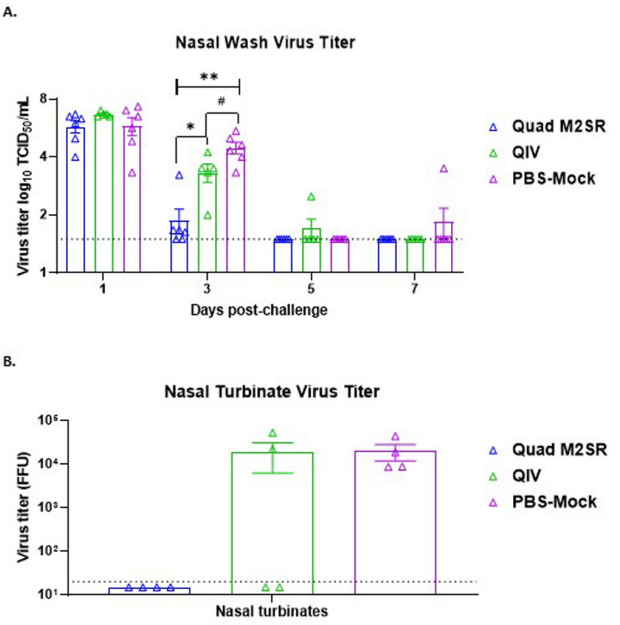
Plaque reduction neutralization test (PRNT) antibody titers for Quad M2SR and QIV against matched Influenza B vaccine strain B/Colorado/06/2017 (Fig. 1A) and drifted strain B/Brisbane/60/2008 (Fig. 1B) on pre-study (Day -3), pre-vaccination (Day 28), and 3 weeks post vaccination (Day 51). The detection limit of the assay (horizontal dashed line) was 15 PRNT50.

Figure 2. Post-challenge body weight and temperature changes



Percent body weight changes (Fig. 2A) and average body temperatures changes (Fig. 2B) following challenge with drifted Influenza B strain B/Brisbane/60/2008 for ferrets vaccinated with Quad M2SR or QIV.

Figure 3. Post-challenge virus titers in respiratory tract.



Viral titers in nasal washes (Fig. 3A) and nasal turbinates (Fig. 3B) collected post-challenge with Influenza B strain B/Brisbane/60/2008 in ferrets vaccinated with Quad M2SR or QIV. No virus was detected in the trachea or lungs. The detection limit of the assay (horizontal dashed line) was 1.5 log10 TCID50/mL and 20 FFU respectively. Virus titer between groups was significant on day 3 of the nasal washes: one-way analysis of variance (ANOVA) with Multiple t tests to compare between groups, #p<0.05,><0.01,><>

Conclusion. Despite eliciting similar Ab titers, the Quad M2SR demonstrated superior protection compared to QIV in a drifted influenza B challenge model in ferrets. These results suggest that the intranasal M2SR platform may confer additional advantages over currently available vaccines. Quad M2SR is in late-stage development for testing in a first-in-human clinical study.

Disclosures. **Lindsay Hill-Batorski, PhD**, **FluGen** (Employee) **Yasuko Hatta, DVM, PhD**, **FluGen** (Employee) **Michael Moser, PhD**, **FluGen** (Employee) **David Marshall, BS**, **FluGen** (Employee) **Pamuk Bilsel, PhD**, **FluGen** (Employee)

11. People Living with HIV During the COVID-19 Pandemic: Who Did (or Did Not) Receive Annual Influenza Vaccination?

Deborah A. Kahal, MD,MPH, FACP[1]; Brian Wharton, MSN, RN, CPEN, CPST[2]; Christopher James, PharmD, AAHIVP[2]; Richard Caplan, PhD[2]; Bincsik K. Arlene, RN, MS, CCRC, ACRN[2]; [1]Christiana Care Health System, Media, Pennsylvania; [2]ChristianaCare, Wilmington, Delaware

Session: P-02. Adult Vaccines

Background. Nationally, younger adults and racial minorities have lower levels of influenza vaccination (influenza vaccination = vaccine) than non-Hispanic White adults. During the 2015-16 season, most vaccine decliners in our program were male, black, and 45-66 years of age. As part of a quality improvement (QI) initiative to increase 2020-21 vaccine coverage amongst PLWH, we sought to compare patient characteristics between vaccine recipients and non-recipients.

Methods. Our program cares for 60% of Delawareans with HIV. The largest site in Wilmington was the QI site. IRB exemption was received, and pre-defined sociodemographic and HIV-specific variables were extracted from the EMR and CareWare from 1 Oct 2020 through 31 March 2021. Patient reports of external vaccine required confirmation. All PLWH ≥ 18 years of age, including those newly establishing care, met eligibility criteria. Comparisons between vaccinated and unvaccinated PLWH were performed using Wilcoxon rank sum tests for continuous variables and chi-squared tests for categorical variables. A multivariable logistic regression model, including age, sex, race, insurance, poverty level, HIV status, and virologic suppression, was used to predict vaccine.