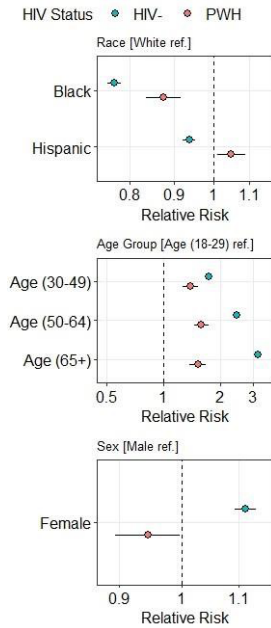


Adjusted relative risk of influenza vaccination by race, age, and sex

Figure. Adjusted relative risk of influenza vaccination by race, age, and sex



**Conclusion:** PWH were more likely to be vaccinated against influenza than HIV-. In both PWH and HIV-, Blacks and younger age groups were less likely to be vaccinated, although these associations were attenuated in PWH. The effect of sex varied by HIV status with increased vaccination rates for female HIV- but reduced rates for female PWH. Targeted efforts are needed to continue to close the gap in demographic disparities regarding influenza vaccination rates among PWH.

**Disclosures:** Michael Silverberg, PhD, MPH, Gilead Sciences, Inc. (Grant/Research Support)

### 33. Intranasal M2SR (M2-deficient Single Replication) Live H3N2 Influenza Investigational Vaccine Induces Serum HAI & Broad Immune Responses in High Proportion of Adults

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**Session:** P-2. Adult Vaccines

**Background:** A single intranasal (IN) dose of 10<sup>8</sup> TCID<sub>50</sub> M2SR protected a responder subset of adults against infection and disease in a prior human influenza challenge study (EudraCT number: 2017-004971-30). Higher dose levels of M2SR were assessed in this phase 1b study to enhance immune responses and further increase protection levels in adults.

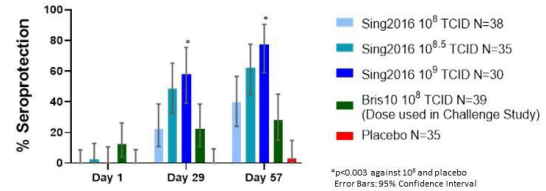
**Methods:** A double-blind, randomized, placebo-controlled dose escalation study (NCT03999554) was conducted at 4 US study sites with two different H3N2 M2SR vaccines that contained HA & NA from either A/Brisbane/10/2007 or A/Singapore/INFIMH-16-0019/2016. Serosusceptible 18-49 year old subjects (n = 206) received 2 IN doses of either saline or 1 of 3 different dose levels of vaccine (10<sup>8</sup> - 10<sup>9</sup> TCID<sub>50</sub>), administered 28 days apart.

**Results:** Study vaccination was well-tolerated at all dose levels. A single 10<sup>9</sup> dose of A/Singapore/2016 M2SR generated significantly increased serum HAI responses compared to the 10<sup>8</sup> dose of A/Brisbane/10/2007 M2SR that had provided protection against infection & illness in an earlier human influenza challenge study (Fig.

1). HAI titers ≥40 were achieved in 0%, 23% & 58% of subjects after the first dose of placebo, 10<sup>8</sup> or 10<sup>9</sup> M2SR, respectively (p < 0.003). Increases also were stimulated in serum microneutralization titers (MNT) to drifted strains of H3N2 (Fig 2) & in serum NAI (Fig 3) and mucosal sIgA (Fig 4) titers. Further increases in serum and mucosal immune response were noted after a 2<sup>nd</sup> IN vaccination.

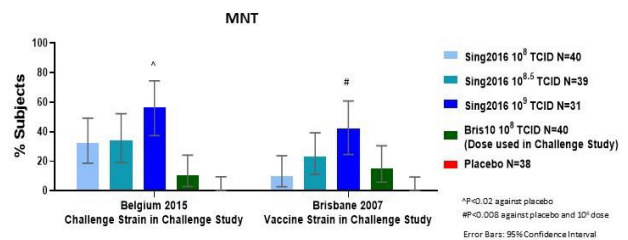
Proportion of subjects with seroprotective HAI titers after vaccination

Figure 1. Proportion of study subjects with HAI titers ≥ 40 at pre-vaccination (Day 1), and after first (Day 29) and second (Day 57) vaccinations for each study group shown in the Figure legend. Sing2016 = A/Singapore/INFIMH-16-0019/2016 H3N2 M2SR. Bris10 = A/Brisbane/10/2007 H3N2 M2SR.



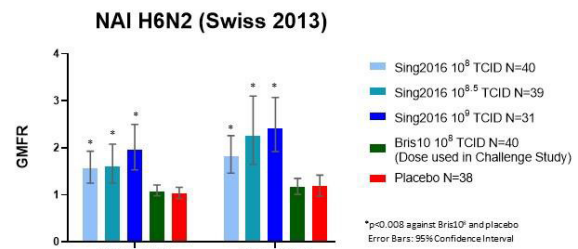
Proportion of subjects with increased microneutralization titers against drifted H3N2 viruses after vaccination

Figure 2. Proportion of study subjects with ≥4-fold increase in microneutralization titers (MNT) against drifted H3N2 viruses 28 days after first vaccination. Study group immunizations are shown in the figure legend (right) and MNT test strains are indicated below the X-axis



Geometric mean fold rise in serum neuraminidase inhibition antibody titers after vaccination

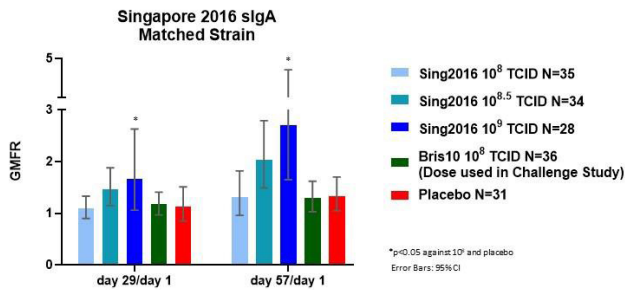
Figure 3. Geometric Mean Fold Rises (GMFR) in serum neuraminidase inhibition (NAI) titers following first (Day 29) and second (Day 57) immunizations for each study group shown in the legend. Sing2016 = A/Singapore/INFIMH-16-0019/2016 H3N2 M2SR. Bris10 = A/Brisbane/10/2007 H3N2 M2SR.



**Conclusion:** An earlier clinical trial with a 10<sup>8</sup> dose of M2SR provided protection against infection and illness upon challenge with a highly drifted strain of H3N2. Protection correlated with vaccine induced serum MNT responses. In the current study, a single, 10<sup>9</sup> dose of M2SR significantly increased serum MNT, HAI & NAI titers as well as mucosal immune responses among greater proportions of study subjects. Since HAI, alone, is a well-accepted surrogate marker for vaccine protection against influenza, these broader enhancements indicate the potential for M2SR to protect against both matched and drifted strains of influenza in a high proportion of adults and strongly support clinical assessment in younger and older age groups as well as development of multivalent M2SR.

Geometric mean fold rise in nasal mucosal secretory IgA antibody titers after vaccination

**Figure 4.** Geometric Mean Fold Rises (GMFR) in nasal mucosal sIgA titers (ELISA, normalized to total nasal sIgA) against A/Singapore/INF16H-0019/2016 H3N2 following first (Day 29) and second (Day 57) immunizations for each study group shown in the legend. Sing2016 = A/Singapore/INF16H-0019/2016 H3N2 M2SR. Bris10 = A/Brisbane/10/2007 H3N2 M2SR.



**Disclosures:** Joseph Eiden, MD, PhD, FluGen (Consultant) Ruth Ellis, MD, FluGen (Consultant) Roger Aitchison, ScM, FluGen (Consultant) Renee Herber, BS, FluGen (Employee) Pamuk Bilsel, PhD, FluGen (Employee)

### 34. Oops, I Didn't Follow My Post Vaccination Instructions

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**Session:** P-2. Adult Vaccines

**Background:** Smallpox vaccine is derived from vaccinia virus, a large, double-stranded DNA virus. With the worldwide eradication of smallpox, routine vaccination with vaccinia virus is no longer performed. However, at-risk laboratory and health care personnel continue to be vaccinated against smallpox, and large numbers of military personnel in the United States resumed smallpox vaccination after the anthrax bioterrorism in 2001. Two available smallpox vaccines are part of the strategic stockpile in the United States; one is a replication-deficient modified vaccinia Ankara vaccine (MVA), and the other is a replication-competent smallpox vaccine (ACAM2000). Among others, one of the potential complications of smallpox vaccine is an accidental autoinoculation or accidental inoculation of close contacts.

**Methods:** A 27-year-old female presented to the employee health clinic at Vidant Medical Center with a 7-day lesion on her right upper extremity. She denied any fever, chills, pets at home, insect bites or trauma to the area. She was using inhaled nebulizers for her asthma and lived in Greenville, NC, with her boyfriend. The lesion was non itchy, approximately 5 mm blister like rash that ulcerated with a grayish, white center and had a surrounding red border. On further questioning, she disclosed that her boyfriend was a marine, who was recently vaccinated against smallpox two weeks before she developed the skin lesion, but he did not cover the site as instructed. Her lesion was unroofed and a sample was collected and sent to NC State Laboratory of Public Health for identification. It was also reported to the NC State Department of Health for possible contact transmission of smallpox. In the meantime, the patient was instructed to cover the area while at work, keep the lesion open to air at home, and avoid skin-to-skin contact.

Initial Lesion



**Figure 1:** Initial Lesion on the Right Upper Extremity

Lesion after Unroofing



**Figure 2:** Lesion after Unroofing for Specimen Collection

**Results:** The sample returned positive for *Orthopoxvirus* DNA by PCR.

**Conclusion:** Recipients of smallpox vaccine have a potential for autoinoculation and inoculation of close contacts. Hence, the vaccine recipients should be well educated about proper care of the vaccination site for preventing possible contact transmission of the virus. These include covering the vaccination site, proper hand washing after bandage changes, and avoiding skin-to-skin contact.

**Disclosures:** All Authors: No reported disclosures

### 35. Pneumococcal Vaccination in High-Risk Adults: An Initial Analysis Incorporating Social Determinants of Health

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**Session:** P-2. Adult Vaccines

**Background:** Despite CDC's recommendation, vaccination rates for adults at high-risk of invasive pneumococcal disease are below HealthyPeople 2020 goals. Comparatively little is known about influencers on vaccine-seeking behavior in this population, particularly related to social determinants of health. To address this gap, this study assessed the potential influence of select social determinants on uptake and time to pneumococcal vaccination among a high-risk, insured US population.

**Methods:** Using the MarketScan commercial claims databases between 2013–2016, adult patients (aged 18–64 years) were followed from their first diagnosis for a condition deeming them high-risk for invasive pneumococcal disease through one year following the diagnosis and observed for pneumococcal vaccination in outpatient clinics and pharmacies. Publicly-available data on select social determinants of health were incorporated into analyses, guided by the WHO vaccine hesitancy matrix. Logistic regression determined predictors of vaccination and a generalized linear model compared days to being vaccinated while controlling for baseline demographic and clinical characteristics.

**Results:** A total of 173,712 patients were analyzed of which 25.3% were vaccinated against invasive pneumococcal disease within the first year of being deemed high risk, nearly all of which (98.5%) were received in outpatient clinics. The odds of vaccination were higher in urban areas (OR: 1.18; 95% CI: 1.144–1.223), areas of higher health literacy (OR: 1.02; 95% CI: 1.019–1.025), and more liberal-voting communities (OR: 1.5; 95% CI: 1.23–1.88). Conversely, the odds of vaccination were particularly low in areas of higher poverty (OR: 0.14; 95% CI: 0.068–0.304) and with more limited