Discordance between DTP3 coverage and seroprotection might be due to underestimating vaccination coverage by recall. Lack of long-term protection against tetanus or diphtheria is consistent with declining antibody concentrations by school-age after the primary DTP series, indicating the need for a booster dose. Seroprotection against measles and rubella viruses was lower than levels needed to prevent transmission, particularly in the West region; re-introduction of either virus could lead to an epidemic. Haiti should reach ≥95% DTP3 and two-dose MR coverage and add tetanus and diphtheria vaccine booster doses per global recommendations. Figure 1. Vaccination Coverage and Seroprotection Among 5-7 Years Old — Haiti, 2017.

Conclusion: Discordance between DTP3 coverage and seroprotection might be due to underestimating vaccination coverage by recall. Lack of long-term protection against tetanus or diphtheria is consistent with declining antibody concentrations by school-age after the primary DTP series, indicating the need for a booster dose. Seroprotection against measles and rubella viruses was lower than levels needed to prevent transmission, particularly in the West region; re-introduction of either virus could lead to an epidemic. Haiti should reach ≥95% DTP3 and two-dose MR coverage and add tetanus and diphtheria vaccine booster doses per global recommendations. Figure 1. Vaccination Coverage and Seroprotection Among 5-7 Years Old — Haiti, 2017.

Disclosures. All authors: No reported disclosures.

2772. HCMV gB Ectodomain Subunit and gB mRNA Vaccines Reduce AD-3 Immunodominance and Elicit More Durable Antibody Responses Than gB/MF59 Immunization

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Session: 279. Vaccines: Viral Non Influenza

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Background: A vaccine to prevent maternal acquisition of human cytomegalovirus (HCMV) during pregnancy is one potential strategy to reduce the incidence of congenital disease. The MF59-adjuvanted glycoprotein B (gB/MF59) protein subunit vaccine is the most efficacious tested to-date, though achieved only 50% efficacy in a congenital disease. The MF59-adjuvanted glycoprotein B (gB/MF59) protein subunit vaccine is the most efficacious tested to-date, though achieved only 50% efficacy in a congenital disease. The MF59-adjuvanted glycoprotein B (gB/MF59) protein subunit vaccine is the most efficacious tested to-date, though achieved only 50% efficacy in a congenital disease.

Methods: Groups of juvenile New Zealand White rabbits (n = 6) were administered 3 sequential doses of gB protein with an MF59-like squelane adjuvant IM, gB ectodomain protein (lacking AD-3) + squelane adjuvant IM, or lipid nanoparticle (LNP)-packaged nucleoside-modified mRNA encoding gB ID.

Results: The AD-3 immunodominant IgG response seen in human vaccinees was closely mimicked in rabbits, with 78% of binding antibodies directed against this region in the gB protein group compared with 1% and 46% in the ectodomain and mRNA-LNP-immunized rabbits respectively (Figure 2). All vaccines were highly immunogenic with similar kinetics and comparable peak gB-binding/functional antibody responses. However, both ectodomain and mRNA-LNP-immunized rabbits exhibited enhanced durability of IgG binding to gB protein (P = 0.04 and 0.02, respectively), and the mRNA-LNP group had more durable binding of cell membrane-associated gB (P < 0.001) (Figure 3). Additionally, ectodomain and mRNA-LNP-vaccinated rabbits had increased durability of antibodies targeting neutralizing epitopes AD-4 and AD-5 (P < 0.01). Finally, low-magnitude gB-specific T-cell activity was observed in the gB protein and mRNA-LNP groups, though not in ectodomain-vaccinated rabbits.

Conclusion: Altogether these data suggest that gB ectodomain subunit and gB mRNA-LNP vaccine formulations reduced targeting of non-neutralizing epitope AD-3 and elicited more durable IgG responses than gB protein vaccination. These next-generation HCMV vaccine candidates aiming to improve upon the partial efficacy of gB/ MF59 vaccination should be further evaluated in preclinical models.

Disclosures. All authors: No reported disclosures.

2773. Safety and Immunogenicity Study of Eastern Equine Encephalitis Vaccine

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Session: 279. Vaccines: Viral Non Influenza

Saturday, October 5, 2019: 12:15 PM

Background: Eastern equine encephalitis virus (EEEV) is an alphavirus with a high mortality rate and serious neurological sequelae in infected persons making this virus an important human pathogen.

Methods: Following written informed consent, eligible subjects received two priming doses of EEEV vaccine, inactivated, TSL-GSD 104, 0.5 mL subcutaneously on days 0 and 28 days followed by a mandatory booster, 0.1 mL intradermal, at 6 months. Serum samples were collected pre-vaccination, days 21–35 following dose 2, as well as before and 21–35 days after dose 3. Sera with a Plaque Reduction Neutralization Test, titer (PRNT<sub>50</sub>) ≥ 1:40 were considered responders with adequate titers for the purpose of biocontainment suite entry.

Results: Sixty-seven (67) subjects were enrolled in this study to receive the primary vaccination series. All 67 subjects received at least 1 primary vaccination; 66 completed the 2 primary doses; 58 completed the 2 primary doses and the 6-month dose. Of these, 38 (56.7%) reported one or more adverse events. Fatigue was reported in 13 (19.4%), headache in 9 (13.4%), upper respiratory tract infection in 6 (9.0%), nausea in 5 (7.5%), pyrexia in 5 (7.5%), oropharyngeal pain in 4 (6.0%), myalgia in 4 (6.0%), injection site pain in 7 (10.4%), injection site hematoma in 4 (6.0%) and injection site erythema in 3 (4.5%) subjects. Adverse events were mostly mild or moderate and transient. PRNT<sub>50</sub> titer ≥ 1:40 was observed in 39/65 (60%) subjects who received both primary doses of EEEV vaccine compared with 48/57 (84%) subjects who completed the 2-dose primary series and the 6-month dose and also had blood drawn for titer. Females had a higher response rate (61.5%) at the pre 6-month boost titer than did males (34.3%) (p = 0.0231). Similarly, the pre 6-month boost geometric mean titer (GMT) for females
was 35.5 vs. 21.9 for males (p = 0.0231). The post-6 month boost GMT for females was 146.7 and 181.5 for males (p = 0.13).

**Conclusion:** Inactivated Eastern Equine Encephalitis Virus vaccine, TSI-GSD 104, Lot 2-1-89 appears to be safe and immunogenic. This Phase 2 vaccine study supports a priming dose schedule of Days 0 and 28 and 6-month. The 6-month dose is anamnestic improving the overall response rate and level of antibody for this primary dosing schedule.

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

2774. Impact of Yellow Fever Vaccine and Recombinant Zoster Vaccine Shortages on Patients Presenting to a Travel Clinic

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**Session:** 279. Vaccines: Viral Non Influenza

**Saturday, October 5, 2019: 12:15 PM**

**Background:** In 2017, the United States experienced a national shortage of the yellow fever vaccine (YF-Vax). In response to this, the US Food and Drug Administration (FDA) approved the use of Stamaril in a limited number of clinics across the country. This was soon followed by a shortage of the recently approved recombinant zoster vaccine (RZV) in 2018. This project describes the impact of both vaccine shortages on patients presenting to the Travel Health Clinic at Froedtert and the Medical College of Wisconsin.

**Methods:** A retrospective review of Travel Health Clinic medical records between January and December of 2018 was performed. Information regarding patient demographics, travel destination, vaccination rates, reasons for not vaccinating, and referral information was obtained.

**Results:** Of the 306 patients seen in 2018, 98 were traveling to countries with active yellow fever transmission. Due to the YF-Vax shortages, 59.2% of these patients were referred to another clinic for Stamaril and 7.1% were unable to get the vaccine before the departure. The remaining patients qualified for a medical exemption, had an itinerary that was lower risk for yellow fever, or their subsequent vaccine history was unknown. Additional cost for Stamaril at referral locations ranged from $169.50-$315.00 per person with a travel distance of 15-272 miles to the referred clinic. Regarding RZV, 134 clinic patients were qualified to receive the vaccine. 57.5% did not receive RZV due to vaccine shortage, 15.7% were referred to another clinic for RZV, while 15.7% were able to receive the vaccine during their appointment. Of these patients, 31.3% were covered under Medicare, thus necessitating referral to a pharmacy for vaccine coverage.

**Conclusion:** We encountered high rates of unvaccinated travelers who would have qualified for and benefited from YF-Vax and RZV in 2018. Even among those who could receive the recommended vaccines, there was substantial additional cost and inconvenience. This illustrates the considerable negative impact of the YF-Vax and RZV vaccine shortages. Further efforts are necessary to make these vaccines more accessible to the community.

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

2775. Safety and Immunogenicity of a Seasonal Influenza Vaccine and Ad26.RSV.pref Vaccine With and Without Co-Administration: A Randomized, Double-Blind, Placebo-Controlled Phase 2a Study in Adults Aged ≥ 60 Years

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**Session:** 279. Vaccines: Viral Non Influenza

**Saturday, October 5, 2019: 12:15 PM**

**Background:** Influenza and RSV can cause respiratory tract infections leading to severe illness, hospitalization and mortality in at-risk populations, particularly the elderly. The seasonality of influenza and RSV present the potential to co-administer vaccines. This study aimed to demonstrate the non-inferiority of co-administration of the experimental RSV vaccine Ad26.RSV.pref with an influenza vaccine (Fluarix) vs. Fluarix alone in terms of immunogenicity against influenza.

**Methods:** A single-center, randomized, double-blind, placebo-controlled Phase 2a study (NCT03339713) in healthy adults ≥ 60 years old. Volunteers were randomized 1:1 to receive Fluarix + placebo on Day 1 and Ad26.RSV.pref on Day 28, or Fluarix + placebo on Day 29 (Group 1), or Fluarix + placebo on Day 1 and Ad26.RSV.pref on Day 29 (Group 2). Blood samples were taken prior to each vaccination and at Day 57.

The primary endpoints were geometric mean titers (GMTs) of hemagglutination inhibition (HI) antibody titers against Fluarix strains (A/Michigan, A/Hong Kong, B/Brussels and B/Phuket) and the safety and tolerability of Ad26.RSV.pref administered with or without Fluarix. A key secondary endpoint was neutralizing antibody titers to RSV A2.

**Results:** Volunteers (N = 180) were included in Group 1 (n = 90) or Group 2 (n = 90). Most volunteers were white (89%) and female (63%), with a median age of 65 years. The primary endpoint of HI GMTs was numerically higher in the Fluarix group compared to Ad26.RSV.pref regardless of co-administration. Solicited AEs were mainly of Grade 1 and 2 and of transient duration. Most unsolicited AEs were considered unrelated to the study vaccination and were Grade 1 or 2. There were no serious AEs related to the study vaccine and there were no discontinuations due to AEs. RSV neutralizing antibody titers 29 days post-Ad26.RSV.pref immunization were similar in both groups (1404, Group 1; 1690, Group 2).

**Conclusion:** Co-administration of Ad26.RSV.pref with Fluarix was non-inferior to Fluarix alone in terms of immunogenicity against influenza and had an acceptable tolerability profile.

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

2776. Post-marketing Safety Surveillance for the Adjuvanted Recombinant Zoster Vaccine: Review of Spontaneous Reports Since Introduction

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**Session:** 279. Vaccines: Viral Non Influenza

**Saturday, October 5, 2019: 12:15 PM**

**Background:** The adjuvanted recombinant zoster vaccine (RZV, GSK), indicated for the prevention of herpes zoster (HZ) in adults ≥ 50 years of age, received its first marketing authorization in October 2017. We reviewed the post-marketing spontaneous adverse event (AE) reports submitted to GSK’s worldwide safety database since RZV introduction.

**Methods:** Descriptive analyses were conducted on all spontaneous reports involving RZV from October 13, 2017 to February 10, 2019. Observed-to-expected analyses were performed for the outcomes of interest: all-cause mortality and the 2 most commonly reported postmarketing immune-mediated diseases, Guillain–Barre syndrome (GBS) and Bell’s palsy. Data mining was done to detect quantitative signals by identifying RZV-AE pairings with disproportionate reporting or evidence of an unexpected time-to-onset distribution.

**Results:** Most of the 15,638 spontaneous reports received were medically verified (75.2%), originated from the United States (81.7%) and were non-serious (95.3%). Reports were mainly from individuals 50–69 years old (62.1%) and females (66.7%), when documented (Figure 1). Of all reports, 12,059 (77.1%) described signs/symptoms and 3,579 (22.9%) described vaccination errors, majority of which were without associated signs/symptoms (2,961; 82.7%). Overall, the most commonly reported signs/symptoms were consistent with vaccine reactogenicity (such as injection-site reactions, pyrexia, pain, chills, headache, fatigue), which were previously reported after RZV (Table 1). The observed reporting rates of outcomes of interest likely represent temporary associated events that are occurring as background incidence in the general population. No unexpected reporting patterns were detected overall. The proportion of RZV vaccination errors over time, by country, is shown in Figure 2. Overall, most reports described errors in vaccine preparation and reconstitution (29.7%) (Table 2).

**Conclusion:** Overall, the safety profile of RZV, following the first year of post-marketing use, is reassuring and consistent with that observed in clinical trials. Ongoing surveillance will continue to monitor RZV safety, as it is an early stage in the implementation, when real-life data are limited.

**Funding:** GlaxoSmithKline Biologics SA.

**Figure 1.** Characteristics of spontaneous RZV reports submitted to the company.