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
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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 shortage, 59.2% of these patients were referred to another clinic for Stamaril and 7.1% were unable to get the vaccine before 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 benefitted 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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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: This was 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 + 1×10^{11} vp Ad26.RSV.preF on Day 1 and placebo on Day 29 (Group 1), or Fluarix + placebo on Day 1 and 1×10^{11} vp 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/Brisbane 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. Both groups exhibited an increase from baseline in HI antibody response on Day 29. The 95% one-sided upper confidence limit of all GMT ratios were below the non-inferiority margin of 2. The frequency of solicited adverse events (AE) after Ad26.RSV.preF vaccination was similar with and without influenza 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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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 potential immune-mediated diseases, Guillain–Barré 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 the15,638 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.

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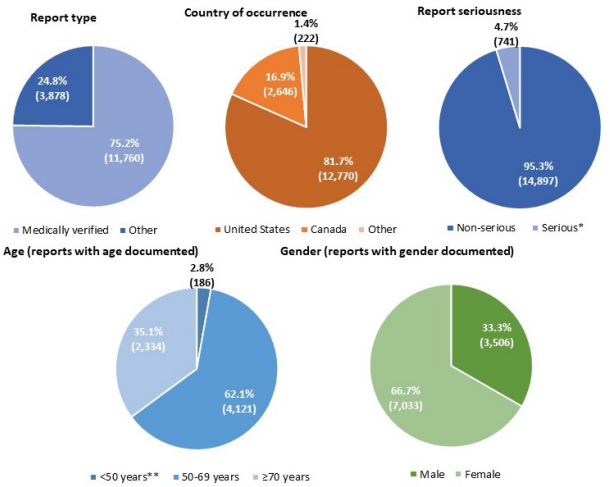
Figure 1. Characteristics of spontaneous RZV reports submitted to the company



Analysis period: Oct 13th, 2017–Feb 10th, 2019. **Note**: Percentage (number of reports) are shown *Includes hospitalization, prolongation of existing hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, medically significant, and death. **RZV is not approved for this age group.