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 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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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: 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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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.

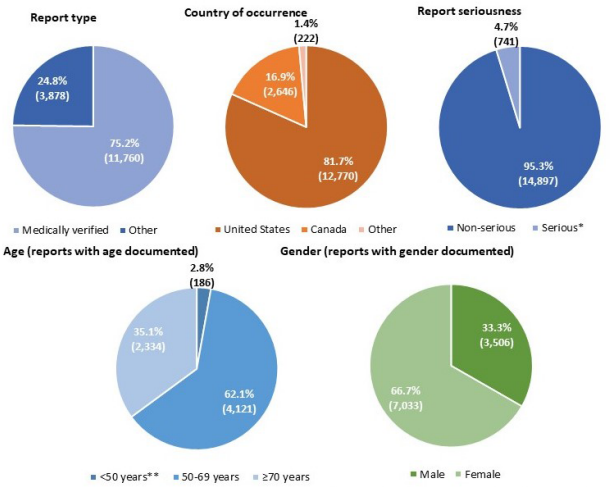
Methods: Descriptive analyses were conducted on all spontaneous reports involving RZV from October 13, 2017 to February 10, 2019. Observed-to-expected analyses were performed for the outcomes of interest: all-cause mortality and the 2 most commonly reported potential immune-mediated diseases, Guillain–Barré 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.

Funding: GlaxoSmithKline Biologicals SA.

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



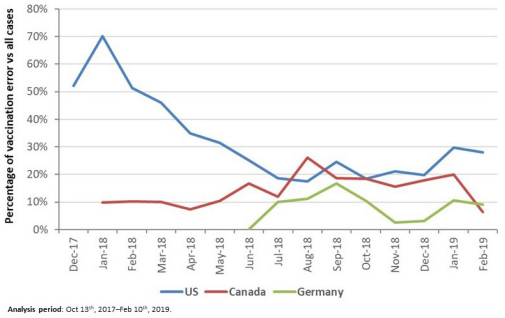
Analysis period: Oct 13th, 2017–Feb 10th, 2019. **Note**: Percentage (number of reports) are shown *Includes hospitalization, prolongation of existing hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, medically significant, and death. **RZV is not approved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

Table 1. Most commonly reported* sign/symptoms events involving RZV vaccination

Sign/Symptoms**	Reporting rate***
Injection-site pain	18.2
Pyrexia	17.8
Pain in extremity	15.7
Pain	14.2
Chills	13.3
Injection-site erythema	13.1
Fatigue	11.6
Headache	11.5
Influenza like illness	9.3
Herpes zoster	9.0
Myalgia	8.6
Injection-site swelling	8.4
Erythema	7.0
Malaise	6.9
Nausea	6.0
Rash	5.8
Injection-site warmth	4.3
Pruritus	3.4
Arthralgia	3.3
Peripheral swelling	3.2
Asthenia	2.6
Dizziness	2.6
Swelling	2.6
Injection-site pruritus	2.5
Feeling abnormal	2.4
Injection-site rash	2.2

Analysis period: Oct 13th, 2017–Feb 10th, 2019. *Only adverse events with a reporting rate >2.0 per 100,000 distributed doses are shown. Vaccination errors were not included in the list. **Based on Medical Dictionary for Regulatory Activities (MedDRA, version 21.1) preferred term; a single report may contain more than 1 MedDRA preferred term. ***Reports per 100,000 RZV doses distributed worldwide during the analytic period.

Figure 2. Evolution of the percentage of vaccination error reports versus all reports with RZV, by country



Analysis period: Oct 13th, 2017–Feb 10th, 2019.

Table 2. Number (%) of reports* of vaccination errors involving RZV

Vaccination error group** (description)	Number (%) of reports* (N=3,579)
Product preparation/reconstitution errors	1,062 (29.7)
Inappropriate/incomplete course of administration	956 (26.7)
Incorrect route of administration	585 (16.4)
Product storage error	463 (12.9)
Other errors	513 (14.3)

Analysis period: Oct 13th, 2017–Feb 10th, 2019. *A report may describe more than 1 error. **A group contains multiple MedDRA preferred terms.

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

2777. Live-Attenuated Vaccine Against RSV Generates Robust Cellular and Humoral Immune Responses

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Background: In people over 65, there are on average 177,000 hospitalizations and 14,000 deaths because of respiratory syncytial virus (RSV) each year. Elderly patients infected with RSV can suffer serious infections leading to pneumonia and congestive heart failure. RSV vaccines have failed in the elderly in part because they have been unable to mount a robust cellular immune response.

Methods: RSV-MinL4.0 is a live-attenuated intranasal vaccine candidate that was generated by codon pair deoptimization of the L gene followed by the addition of four stabilizing mutations found via stress passaging. Four African Green Monkeys (AGMs) per group were vaccinated with RSV-MinL4.0 or wild-type (WT) RSV at 2×10^6 PFU, boosted on day 28 and challenged with wild-type (WT) RSV on day 104. Oropharyngeal swabs and tracheal lavage were collected daily and every other day, respectively, to evaluate virus shedding (qPCR) and blood was drawn on days 1, 14, 21, 28, and 49 for antibody titers ($PRNT_{50}$), and PBMC activation (IFNγ ELISPOT with whole inactivated virus).

Results: MinL4.0 was 2 to 3 $\log_{10}$ attenuated when compared with WT RSV in AGMs. Despite the presence of antibodies on day 28, there was a "take" of the boost indicating the potential for this vaccine to be immunogenic in the elderly with pre-existing circulating antibodies (Figure 1A). MinL4.0 led to robust activation of PBMCs comparable to WT RSV (> 2,000 spots per 10^6 total cells, Figure 1B). Shedding of the vaccine and challenge viruses was minimal (data not shown).

Conclusion: MinL4.0 led to robust activation of cellular and humoral immune responses, which are critical for induction of protective immunity in the elderly. Animals were protected from WT challenge. Preliminary data in AGMs with pre-existing antibodies to RSV indicate that circulating antibodies do not prevent vaccine "take," critical for a vaccine targeting sero-positive elderly individuals.

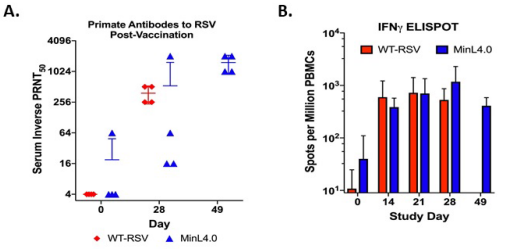

Figure 1: RSV-MinL4.0 generates robust activation of humoral (A) and cellular (B) immunity against RSV

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

2778. Impact of Reactogenicity on Quality of Life and Physical Functioning in Adults ≥50 Years Receiving Both Doses of the Adjuvanted Recombinant Zoster Vaccine

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Saturday, October 5, 2019: 12:15 PM

Background: The adjuvanted recombinant zoster vaccine (RZV) is efficacious in preventing herpes zoster in adults ≥ 50 years. The current study investigates whether the vaccinees' quality of life (QoL) and physical functioning (PF) are impacted by local and systemic reactions due to RZV. In a previous report of this phase III, open-label, multicenter study (NCT02979639), overall PF and QoL were not significantly affected by a first RZV dose. [1] Here we report the results from the same study after a second RZV dose and safety results from dose 1 up to study end.

Methods: Adults aged ≥ 50 years were to receive 2 doses of RZV 2 months apart. Changes in mean Short Form health survey (SF-36) PF score between pre- and post-each RZV dose for 7 days, QoL, reactogenicity and safety were assessed.

Results: 401 adults received dose 1 and 391 received dose 2 of RZV. Post-second RZV dose, the reported solicited local symptoms were pain (75.1%), erythema (22.4%) and swelling (13.9%), and the most frequent solicited systemic symptoms were fatigue (46.3%), headache (37.5%) and myalgia (32.9%). Grade 3 solicited symptoms were reported by 7.2% (local) and 11.1% (general) of participants, and 5 (1.2%) participants reported reactogenicity triggering medical attention post-second RZV dose. From first dose up to study end, 14 (3.5%) participants reported 21 serious adverse events, none related to RZV. In days 1–2, post-second RZV dose, a transient, clinically-important decrease in SF-36 PF score (table) was seen in those reporting grade 3 solicited symptoms, which impacted activities such as walking and climbing stairs. Overall, during the 7 days post-second RZV dose, a mean change of –0.4 points was observed from the mean baseline score, indicating the PF was not clinically meaningfully impacted. No overall quality-adjusted-life-year loss was recorded.