Internet access (OR: 0.14; 95% CI: 0.062–0.305) as well as among adults who did not also get a seasonal influenza vaccine (OR: 0.05; 95% CI: 0.048–0.052). Time to vaccination was longer in rural areas (B=8.3, p< 0.0001) and communities with less Internet access (B=75.6, p< 0.001).

Conclusion: Results suggest that some social determinants may be influencing pneumococcal vaccine-seeking behavior among those deemed high-risk. A more formal framework must be assessed to determine the full impact of these factors across vaccines recommended in adults.

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36. Safety and Reactogenicity of the Adjuvanted Recombinant Zoster Vaccine after Allogeneic Hematopoietic Stem Cell Transplantation

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Session: P-2. Adult Vaccines

Background: Herpes zoster (HZ) is common after allogeneic hematopoietic stem cell transplantation (HCT) and associated with high morbidity. While antiviral prophylaxis reduces incidence, increased risk remains after discontinuation and vaccination strategies are needed. A non-live adjuvanted recombinant zoster vaccine (RZV) has been developed but not yet studied in this population.

Methods: In this single center prospective observational cohort study, allogeneic HCT recipients ³18 years old and 9–24 months from HCT were eligible to receive 2 doses of RZV separated by ³8 weeks as part of revised institutional vaccination guidelines. The primary endpoint was safety and reactogenicity in the total vaccinated cohort (TVC). The secondary endpoints were incidence and severity of chronic graft versus host disease (cGVHD) in the TVC compared to historical controls and incidence rates of HZ in the TVC and modified total vaccinated cohort (mTVC).

Results: Of the 158 participants (mean age 55 years, 91 [58%] male) in the TVC, 150 (95%) received second vaccine. 92.1% had solicited reactions with 87.3% injection site reactions (18.7% grade 3) and 82.8% general reactions (26.5% grade 3). In the subgroup receiving first vaccine at 9–12 months after HCT, cumulative incidence of cGVHD was similar to historical controls at predefined time points between 9–15 months (unadjusted incidence rate ratio [IRR] 1.1 [95% CI 0.84–1.44], adjusted IRR 1.05 [95% CI 0.8–1.38]); there was also no difference in severity of cGVHD, or incidence of death or disease relapse. There were 4 (2.5%) HZ cases during the study period with IR 28.34/1000 person-years over median follow up 281 days (IQR 190, 354) in the mTVC. All cases occurred after antiviral prophylaxis discontinuation and one case resulted in death.

Conclusion: Two doses of RZV after allogeneic HCT was safe and acceptable despite high rates of reactogenicity. There was no evidence of an increase in cGVHD, relapse, or death compared to historical controls and overall low rates of breakthrough HZ similar to those reported after autologous HCT. Immunogenicity studies and placebo-controlled trials are needed to determine vaccine response and efficacy so that timing of RZV and its potential impact on discontinuation of antiviral prophylaxis can be determined.

Disclosures: **Nicolas C. Issa, MD**, **AiCuris** (Scientific Research Study Investigator)**Astellas** (Scientific Research Study Investigator)**GSK** (Scientific Research Study Investigator)**Merck** (Scientific Research Study Investigator)

37. Safety Profile of the Adjuvanted Recombinant Zoster Vaccine (RZV) in Immunocompromised Populations: an Overview of 6 Trials

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Session: P-2. Adult Vaccines

Background: Immunocompromised (IC) populations are at increased risk of herpes zoster (HZ) and its related complications. RZV demonstrated > 68% efficacy against HZ in autologous hematopoietic stem cell transplant (HSCT) recipients ≥ 18 years of age (YOA). Here we present the safety data across 6 clinical trials in IC populations: autologous HSCT recipients, HIV-infected adults, renal transplant recipients, patients with solid tumor and patients with hematological malignancies.

Methods: All 6 studies (**Table 1**) enrolled IC adults ≥ 18 YOA in RZV and Placebo groups. Safety was evaluated in the total vaccinated cohort (TVC). Solicited adverse events (AEs) were collected for 7 days and unsolicited AEs for 30 days after each dose. Serious AEs (SAEs), and potential immune-mediated diseases (pIMDs) were collected from dose 1 until 1 year post-last dose or study end (for causally related [assessed by investigator] and fatal SAEs). Data are presented by age group: 18–49 YOA and ≥ 50 YOA. Reactogenicity data are pooled across the 6 studies and other safety data are presented by study.

Table 1. Clinical trials with immunocompromised populations included in our analysis

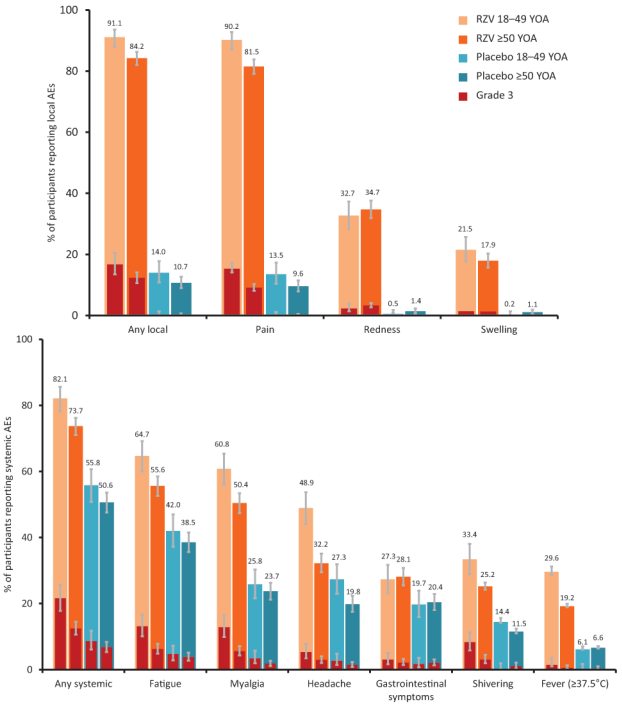
Populations (reference used for the study)	Total Vaccinated Cohort				Study type and registration numbers	Vaccination schedule and doses administered/groups
	RZV		Placebo			
	18–49 YOA	≥50 YOA	18–49 YOA	≥50 YOA		
Autologous Hematopoietic Stem Cell Transplant recipients (HSCT*)	N=10 N'=4	N=20 N'=25	N=4	N=26	Phase I/IIa, randomized, observer-blind, placebo controlled NCT00920218	3 doses (at months 0, 1 and 3): 3 RZV doses or 3 gE/AS01$_B$ doses or 1 placebo + 2 RZV doses or 3 placebo doses
HIV-infected adults (HIV)	N=46	N=28	N=34	N=15	Phase I/IIa, randomized, observer-blind, placebo controlled NCT01185203	3 doses (at months 0, 2 and 6): 3 RZV doses or 3 placebo doses
Autologous Hematopoietic Stem Cell Transplant recipients (HSCT)	N=230	N=692	N=229	N=695	Phase III, randomized, observer-blind, placebo-controlled efficacy study NCT01610414	2 doses (at months 0 and 1–2): 2 RZV doses or 2 placebo doses
Hematologic malignancy patients (HM)	N=74	N=209	N=73	N=206	Phase III, randomized, observer-blind, placebo-controlled study NCT01767467	2 doses (at months 0 and 1–2): 2 RZV doses or 2 placebo doses
Solid tumor patients on chemotherapy (ST)	N=31	N=86	N=30	N=85	Phase II/III, randomized, observer-blind, placebo-controlled study NCT01798056	2 doses (month 0 and 1–2): 2 RZV doses or 2 placebo doses
Renal transplant recipients (RT)	N=88	N=84	N=49	N=83	Phase III, randomized, observer-blind, placebo-controlled study. NCT02058589	2 doses (at months 0 and 1-2): 2 RZV doses or 2 placebo doses

N, number of patients/subgroup receiving at least 1 dose of RZV or placebo (total vaccinated cohort [TVC]) in each study; **N'**, number of patients receiving 1 placebo dose followed by 2 RZV doses whom were additionally included into the RZV group in the pooled TVC; **YOA,** years of age; **RZV**, adjuvanted recombinant zoster vaccine; **HIV**, human immunodeficiency virus; **gE/AS01$_B$**, glycoprotein E/ Adjuvant System containing MPL, QS-21 and liposome (25 µg MPL and 25 µg QS-21). All studies are registered on clinicaltrials.gov.

Results: 1587 (RZV) and 1529 (Placebo) adults were included in the pooled TVC. Solicited AEs were more frequently reported in the RZV than Placebo group. Pain, fatigue, headache, myalgia, shivering and fever were reported more frequently in the RZV 18–49 YOA than in the RZV ≥ 50 YOA (**Figure 1**). Solicited AEs were mostly mild/moderate and lasted ≤3 days and grade 3 solicited AEs lasted ≤ 2 days (median duration). Across studies, the percentage of adults reporting ≥ 1 unsolicited AE was similar between RZV (18–49 YOA: 37.4–80.6%; ≥ 50 YOA: 36.9–87.2%) and Placebo (18–49 YOA: 31.4–90.0%; ≥ 50 YOA: 30.1–89.4%) (**Figure 2**). Overall, the percentage of adults with ≥ 1 SAE (**Figure 3**), causally related SAEs, fatal SAEs and pIMDs was similar between RZV and Placebo and between age groups. Overall, no safety concern was identified.

Figure 1. Percentage of participants with solicited local and systemic AEs, reported across 6 pooled studies (7 days post-vaccination, overall/participant, pooled total vaccinated cohort)

Figure 1. Percentage of participants with solicited local and systemic AEs, reported across 6 pooled studies (7 days post-vaccination, overall/participant, pooled total vaccinated cohort)



AE, adverse event; **RZV,** adjuvanted recombinant zoster vaccine; **YOA,** years of age. **Grade 3** was defined as follows: pain that prevented normal activity; >100 mm diameter for redness and swelling; symptoms that prevented normal activity for headache, myalgia, fatigue and gastrointestinal symptoms; fever >39.0°C (axillary/oral temperature). For the systemic AEs fatigue, headache (all, related), myalgia, shivering, and fever (all, related) were reported with higher incidences in the RZV 18–49 YOA group than in the RZV ≥50 YOA group.