and race/ethnicity was estimated using Cox regression models controlling for age and adjusting for healthcare use, comorbidities and immunocompromise status.

Results. During 2007–2014, 1,355,720 individuals entered the study, including 724,283 (53.4%) females. Among the unvaccinated, the incidence rate of HZ was 7.5 and 10.2 cases per 1,000 person-years (PY) among males and females, respectively. VE was 51.6% [95% CI: 49.2, 53.9] in males and 47.7% [45.8, 49.6] in females. The study included 818,361 (60.4%) Whites, 208,248 (15.4%) Asian/Pacific Islanders, 171,949 (12.7%) Hispanics, 98,914 (7.3%) African Americans, and 58,248 (4.3%) with Other/Unknown race/ethnic group. HZ incidence among the unvaccinated was highest among Hispanics (10.1 per 1,000 PY) and lowest among African Americans (6.7 per 1,000 PY). VE was somewhat higher among Hispanics (57.0% [52.7, 61.0]) compared with Whites (48.1% [46.3, 49.9], Asian/Pacific Islanders (49.7% [46.0, 53.3]), and African Americans (50.5% [42.3, 57.6]).

Conclusion. Overall, VE against HZ was generally similar across sex and race/ethnic groups, except for a somewhat higher VE among Hispanics. This small difference in VE may be due to differences in time since vaccination, since VE tends to wane over time (e.g., average follow-up was 2.2 years for vaccinated Hispanics vs. 2.8 for Whites, resulting in Hispanics having relatively more follow-up closer to vaccination when VE is higher). Longer study follow-up may help to interpret these findings.

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2482. Impact of a Recombinant Zoster Vaccine on Quality of Life: Data from a Randomized, Placebo-Controlled, Phase 3 Trial in Adult Hematopoietic Stem Cell Transplant Recipients

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Background. Herpes zoster (HZ) and its complications can have a substantial impact on patients' quality of life (QoL), particularly in immunocompromised patients. The vaccine efficacy (VE) of an adjuvanted recombinant zoster vaccine (RZV) was studied in a randomized, placebo-controlled, phase 3 study in adult hematopoietic stem cell transplant (HSCT) recipients (NCT01610414). The VE in preventing HZ cases was 68.2% (95% CI: 55.6%–77.5%). Herein we report the impact of the vaccine on patients' quality of life (QoL) associated with HZ episodes.

Methods. HSCT recipients were randomized 1:1 to receive 2 doses of RZV or placebo, given 1–2 months apart and followed for the occurrence of HZ. QoL parameters were measured by the Short-Form health survey (SF-36) and Euro-Quality of Life-5 Dimension (EQ-5D) at baseline, 1 month and 1 year post-dose 2, as well as during suspected HZ episodes in conjunction with the Zoster Brief Pain Inventory (ZBPI). For confirmed HZ cases, QoL scores were compared between the vaccine and placebo groups. The RZV impact in reducing the ZBPI Burden of Illness and Burden of Interference scores was estimated in patients in the modified total vaccinated cohort (mTVC). The 2 scores were calculated from the area under the curve (Days 0 to 182) of the ZBPI Worst Pain and ZBPI Activities of Daily Living scores, respectively, assuming a score of 0 for patients who did not have a confirmed HZ episode.

Results. Both the ZBPI maximum Worst Pain and Average Pain scores were significantly lower in the vaccine than placebo group (Table 1), suggesting less burden in breakthrough HZ cases following RZV. Consequently, the HZ Burden of Illness and Burden of Interference VE estimates were higher than the HZ VE estimate. RZV showed statistically significantly better QoL scores than placebo one week following rash-onset among patients with confirmed HZ, i.e., SF-36 bodily pain, social functioning, role emotional, mental health and mental component scores, and the EQ-5D Utility Score.

Table 1. Analysis of ZBPI questionnaire (mTVC)

	RZV	Placebo
HSCT Recipients	870	851
HZ Confirmed Cases	49	135
HZ ZBPI Evaluable Cases	44	125
Maximum Worst Pain: Mean	5.8	7.1
Wilcoxon Test	P=0.0111	
Maximum Average Pain: Mean	4.7	5.7
Wilcoxon Test	P=0.0183	
HZ Burden of Illness VE	82.5% (95% CI: 73.6%–91.4%)	
HZ Burden of Interference VE	82.8% (95% CI: 73.3%–92.3%)	

RZV, adjuvanted recombinant zoster vaccine; **HZ**, herpes zoster; **ZBPI**, Zoster Brief Pain Inventory; **VE**, vaccine efficacy; **mTVC**, modified total vaccinated cohort: Included HSCT patients who received the second dose of vaccine and did not have a confirmed diagnosis of herpes zoster within 1 month after the second dose. **HZ ZBPI Evaluable Cases:** HZ confirmed cases with an evaluable ZBPI questionnaire within 14 days post-HZ rash onset.

Conclusion. In addition to reducing the risk of HZ and HZ complications, RZV significantly reduces the impact of HZ on patient's QoL in those who develop breakthrough disease.

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2483. Twelve-Month Immunogenicity and Safety of an Adjuvanted Recombinant Zoster Vaccine in Immunosuppressed Adults Post Renal Transplant: a Phase III Randomized Clinical Trial

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Background. The efficacy of the non-live adjuvanted recombinant zoster vaccine (RZV, containing a truncated form of varicella-zoster glycoprotein E [gE] and Adjuvant System $AS01_B$) is >90% in adults ≥50 years of age (YOA) (ZOE-50/70) and >68% in hematopoietic stem cell transplant recipients ≥18 YOA (ZOE-HSCT).[1] This study (NCT02058589) evaluated immunogenicity and safety of RZV in renal transplant recipients ≥18 YOA receiving immunosuppressive therapy. Previously unreported reactogenicity and 12-month post-last dose safety and immune persistence data are presented.

Methods. In this phase III, 1:1 randomized, observer-blind, multicenter trial, patients received 2 doses of RZV or placebo. gE-specific immune responses were assessed at 1 (M2) and 12 (M13) months post-dose 2: humoral immunity by vaccine response rate (VRR) and geometric mean antibody concentration (GMC), and cell-mediated immunity (CMI) by VRR and $CD4^+$ T-cell frequency. Solicited general and unsolicited adverse events (AEs) were collected 7 days pre-dose 1 as a within-participant control. Solicited and unsolicited AEs were also recorded for 7 and 30 days after each dose, respectively. Serious AEs (SAE) and potential immune-mediated diseases (pIMDs) were recorded up to study end (M13).