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Short communication

Efficacy of the adjuvanted recombinant zoster vaccine (RZV) by sex, geographic region, and geographic ancestry/ethnicity: A post-hoc analysis of the ZOE-50 and ZOE-70 randomized trials

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ABSTRACT

Background: Herpes zoster (HZ) risk appears to vary by sex and geographic ancestry/ethnicity.
Methods: In 2 randomized clinical trials, participants received 2 doses of adjuvanted recombinant zoster vaccine (RZV) or placebo intramuscularly, 2 months apart. In this post-hoc analysis, we investigate efficacy of RZV against HZ and postherpetic neuralgia (PHN) by sex, geographic region, and geographic ancestry/ethnicity in ≥50-year-olds (ZOE-50: NCT01165177) and ≥70-year-olds (pooled data from ZOE-50 and ZOE-70: NCT01165229).
Results: Vaccine efficacy against HZ or PHN was similar in women and men. Across geographic regions, efficacy against HZ ranged between 95.7 and 97.2% in ≥50-year-olds, and between 87.3% and 95.1% in ≥70-year-olds; efficacy against PHN ranged between 86.8 and 100% in ≥70-year-olds. Across ancestral/ethnic groups, efficacy ranged between 88.1 and 100% against HZ and between 65.9 and 100% against PHN in ≥70-year-olds.
Conclusions: While the ZOE-50/70 studies were not powered or pre-designed for these post-hoc analyses, RZV appears efficacious against HZ and PHN irrespective of sex, region, or geographic ancestry/ethnicity.

1. Introduction

After primary infection (chickenpox), varicella-zoster virus (VZV) establishes life-long latency in the sensory cranial or dorsal root ganglia, and may later reactivate, resulting in herpes zoster (HZ), also known as shingles. It affects approximately 1 in 3 individuals in their lifetime, and is associated with significant morbidity and impact on quality of life [1–3]. The most frequent complication of HZ is postherpetic neuralgia (PHN), occurring in up to 30% of patients [4].

Globally, the incidence of HZ increases with both age and immune-compromising conditions [5,6]. A recent systematic review of publications primarily from US, Canada, and Europe highlights that female sex and belonging to the white racial group may also increase risk for HZ [6]. The occurrence of specific VZV clades varies in different regions of the world due to distinctive environmental factors, evolutionary conditions, host-virus interactions, and/or importation of viral strains [7]. However, non-biological factors such as differences in healthcare seeking behavior and diagnostic/surveillance practices for HZ across countries may explain observed differences in the incidence of HZ by sex and geographic ancestry/ethnicity to some extent.

Two large-scale, randomized, observer-blind, placebo-controlled trials evaluated the efficacy and safety of the adjuvanted

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recombinant zoster vaccine (RZV) against HZ in adults aged ≥50 years (ZOE-50, NCT01165177) and ≥70 years (ZOE-70, NCT01165229) across 18 countries in North America, Latin America, Europe, and Australia/Asia [8,9]. Protocol summaries are available at http://www.gsk-clinicalstudyregister.com (study IDs 110390 and 113077). Over a period of >3 years, RZV demonstrated a 97.2% and 91.3% efficacy against HZ in adults ≥50 and ≥70 years of age (YOA), respectively, and, owing to the high efficacy against HZ, was also 91.2% and 88.8% efficacious in preventing PHN [8,9]. RZV has received licensure in several countries for the prevention of HZ and (in some of these) PHN, and a recommended use in adults ≥50 YOA [10–17].

Here, we present a post-hoc analysis of vaccine efficacy (VE) against HZ in the ZOE-50 population and in the pooled ZOE-50/70 population ≥70 YOA according to sex, geographic region, and/or geographic ancestry/ethnicity. In addition, we present efficacy against PHN in the pooled ZOE-50/70 population ≥70 YOA according to sex, geographic region, and geographic ancestry/ethnicity.

2. Methods

The ZOE-50/70 clinical trials were conducted in parallel at the same centers. Adults ≥70 YOA were randomly assigned to either trial. The design of the ZOE-50/70 studies allowed pooling of efficacy data from participants ≥70 YOA (referred to as pooled ZOE-50/70 population ≥70 YOA hereafter). Pooled safety data, also for sub-populations, are presented elsewhere [18]. Anonymized individual participant data and study documents may be requested for further research at www.clinicalstudydatarequest.com (study IDs 110390 and 113077).

Adults ≥50 YOA (ZOE-50) or ≥70 YOA (ZOE-70) were randomized 1:1 to receive 2 doses of either RZV or of placebo 2 months apart. Inclusion and exclusion criteria, as well as the composition of RZV have been described elsewhere [8,9].

In these post-hoc analyses, VE against HZ and PHN was evaluated in ≥50 and/or in ≥70-year-olds included in the modified total vaccinated cohort (mTVC) of the ZOE-50 study and pooled mTVC from the ZOE-50/70 studies, respectively. These cohorts consisted of all vaccinated participants who received both doses and who did not develop a confirmed HZ episode in the period between dose 1 and 30 days post-dose 2. Due to the low number of breakthrough events reported, efficacy against HZ according to geographic ancestry/ethnicity, as well as PHN in the subgroup calculations, was not estimated in ≥50-year-olds of the ZOE-50 study. Since PHN increases with age [4], this allowed for an estimation of VE against PHN as a primary objective for the pooled ZOE-50/70 population ≥70 YOA, for which subgroup analyses are presented herein.

Suspected HZ cases were confirmed by PCR, or if not possible by PCR, by unanimous agreement among the five members of an HZ ascertainment committee based on available clinical information, as described elsewhere [8,9]. PHN was defined as severe pain that persisted or developed more than 90 days after rash onset [9].

The 18 participating countries were grouped by geographic regions: North America (Canada and the U.S.), Latin America (Brazil and Mexico), Europe (Czech Republic, Estonia, Finland, France, Germany, Italy, Spain, Sweden, and the United Kingdom), and Australia/Asia (Australia, Hong Kong, Japan, Republic of Korea [South Korea], and Taiwan). In the analyses by geographic ancestry/ethnicity, the following categories were used: European ancestry (Caucasian/European Heritage or Arabic/North African Heritage), Asian ancestry (Central/South Asian Heritage or East Asian Heritage or Japanese Heritage or Southeast Asian Heritage), African ancestry (African Heritage/African American), and Hispanic ethnicity (Hispanic or Latino; a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of geographic ancestry). Geographic ancestries with a limited number of participants were grouped in Other ancestry (American Indian or Alaskan Native; Native Hawaiian or Other Pacific Islander or a person with several different heritages). Geographic ancestry and ethnicity were self-reported.

All statistical analyses were executed using SAS.

3. Results

3.1. Study population results

In the ZOE-50 study, vaccine efficacy was evaluated in 7340 RZV and in 7413 placebo recipients ≥50 YOA, having a mean age of 62.3

Table 1
Demographic characteristics (modified Total Vaccinated Cohort).

	ZOE-50 population ≥50 YOA		Pooled ZOE-50/70 population ≥70 YOA	
	RZV (N = 7340)	Placebo (N = 7413)	RZV (N = 8250)	Placebo (N = 8346)
Age (years)				
Mean age at first dose ± SD	62.3 ± 9.0	62.2 ± 9.0	75.5 ± 4.7	75.5 ± 4.7
Sex, n (%)				
Female	4480 (61.0)	4542 (61.3)	4514 (54.7)	4593 (55.0)
Male	2860 (39.0)	2871 (38.7)	3736 (45.3)	3753 (45.0)
Geographic region, n (%)				
Europe	3785 (51.6)	3828 (51.6)	4501 (54.6)	4543 (54.4)
Asia/Australia	1555 (21.2)	1574 (21.2)	1526 (18.5)	1559 (18.7)
North America	1291 (17.6)	1287 (17.4)	1626 (19.7)	1631 (19.5)
Latin America	709 (9.7)	724 (9.8)	597 (7.2)	613 (7.3)
Geographic ancestry/ethnicity, n (%)				
European ancestry	5319 (72.5)	5354 (72.2)	6423 (77.9)	6475 (77.6)
Asian ancestry	1390 (18.9)	1405 (19.0)	1410 (17.1)	1434 (17.2)
Japanese Heritage	*299 (4.1)*	*304 (4.1)*	*348 (4.2)*	*359 (4.3)*
African ancestry	126 (1.7)	122 (1.6)	85 (1.0)	81 (1.0)
Other ancestry	505 (6.9)	532 (7.2)	332 (4.0)	356 (4.3)
Hispanic ethnicity*	778 (10.6)	807 (10.9)	648 (7.9)	655 (7.8)

RZV = participants receiving the adjuvanted recombinant zoster vaccine; Placebo = participants receiving placebo; YOA, years of age; ZOE-50/70 = RZV efficacy studies in adults ≥50 YOA (NCT01165177) and ≥70 YOA (NCT01165229), respectively; N = number of participants in the (pooled) modified Total Vaccinated Cohort; n (%) = number (percentage) of participants in each category; SD = standard deviation.
European ancestry = Caucasian/European Heritage or Arabic/North African Heritage; Asian ancestry = Central/South Asian Heritage or East Asian Heritage or Japanese Heritage or Southeast Asian Heritage, African ancestry = African Heritage/African American, Other ancestry = American Indian or Alaskan Native; Native Hawaiian or Other Pacific Islander or a person with several different heritages; Hispanic = Hispanic or Latino; a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of geographic ancestry. Majority were from Mexico and Brazil. *Combined number of respondents from each geographic ancestral category who also self-reported as Hispanic or Latino.

and 62.2 years, respectively (Table 1). In the pooled ZOE-50/70 population ≥70 YOA, efficacy was evaluated in 8250 RZV and 8346 placebo recipients; the mean age was 75.5 years in each study group. More than half of participants were female. Most participants were of European ancestry, followed by Asian and African ancestry, and ≤10.9% were of Hispanic ethnicity. The majority of participants were enrolled in Europe (≥51.6%) followed by Asia/Australia and North America. Most participants of African ancestry were enrolled in North America, and the majority of participants of Hispanic ethnicity were enrolled in Brazil and Mexico. Demographic characteristics were balanced between RZV and placebo recipients (Table 1).

3.2. Efficacy against HZ and PHN according to sex

Point estimates for efficacy against HZ were >90% in both female and male participants in the ZOE-50/70 populations (Fig. 1, Supplementary table 1). In the pooled ZOE-50/70 popula-

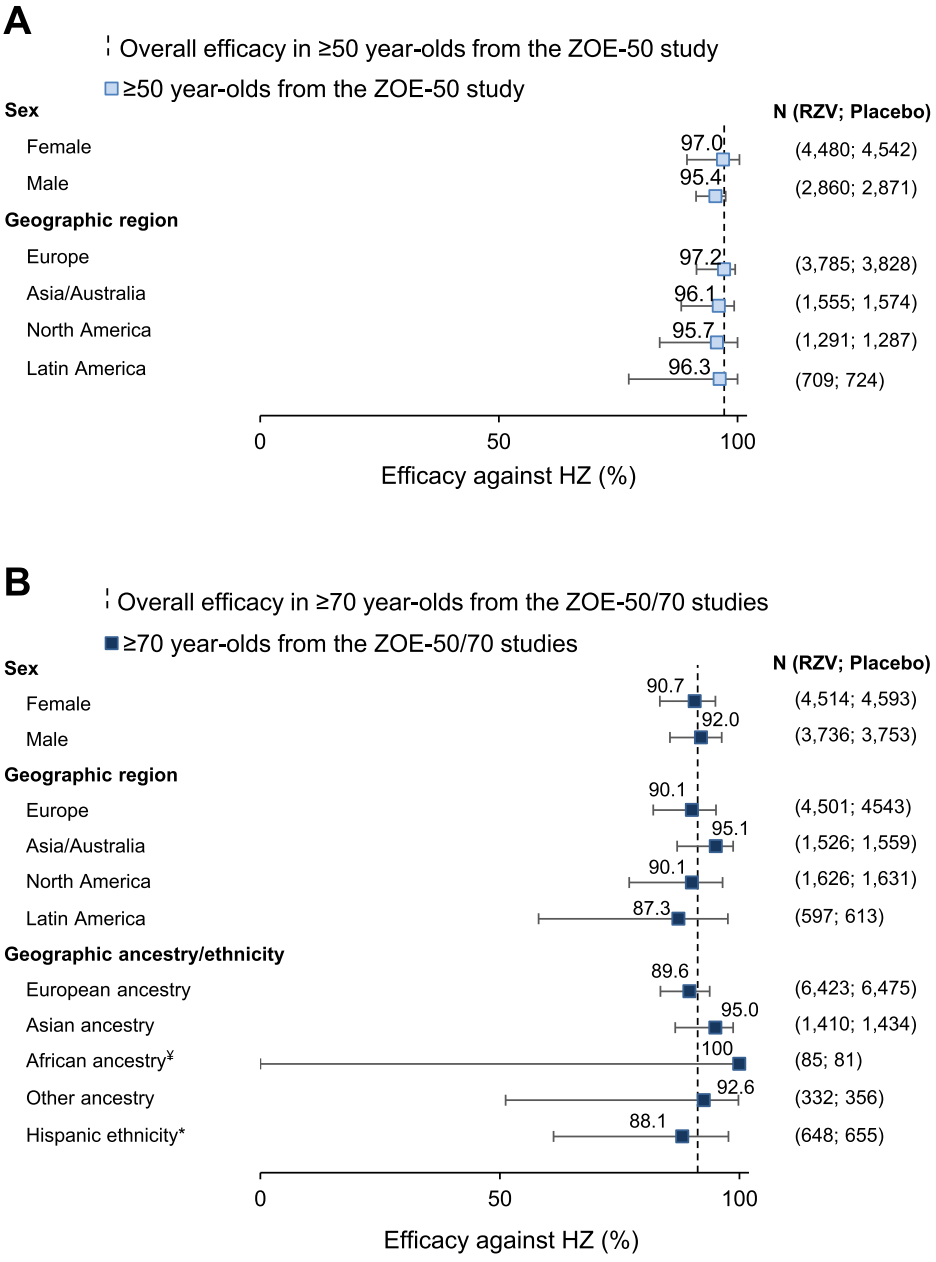

Fig. 1. Vaccine efficacy against first or only episode of HZ by sex, geographic region, and geographic ancestry/ethnicity in adults ≥50 YOA (A) and ≥70 YOA (B) (modified Total Vaccinated Cohort). HZ = herpes zoster; RZV = participants receiving the adjuvanted recombinant zoster vaccine; Placebo = participants receiving placebo; ZOE-50 and ZOE-70 = RZV efficacy studies in adults ≥50 YOA (NCT01165177) and ≥70 YOA (NCT01165229), respectively; N = number of participants in the (pooled) modified Total Vaccinated Cohort; YOA = years of age. European ancestry = Caucasian/European Heritage or Arabic/North African Heritage; Asian ancestry = Central/South Asian Heritage or East Asian Heritage or Japanese Heritage or Southeast Asian Heritage, African ancestry = African Heritage/African American, Other ancestry = American Indian or Alaskan Native; Native Hawaiian or Other Pacific Islander or a person with several different heritages; Hispanic = Hispanic or Latino; a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of geographic ancestry. Majority were from Mexico and Brazil. *Combined number of respondents from each geographic ancestral category who also self-reported as Hispanic or Latino. Errors bars depict 95% confidence intervals (CIs). ¥The lower limit of the 95% CI is <0. Note: vaccine efficacy was adjusted by age strata (all categories) and region (except for the analysis by region).

tion ≥70 YOA, efficacy against PHN was 91.5% (95% confidence interval [CI]: 65.7–99.1) and 83.3% (95%CI: 24.8–98.2) in female and male participants, respectively (Fig. 2, Supplementary table 2).

3.3. Efficacy against HZ and PHN according to geographic region

In the ZOE-50 population ≥50 YOA, efficacy against HZ ranged from 95.7% (95%CI: 83.7–100.0) for North America to 97.2% (95% CI: 91.4–99.5) for Europe. In the pooled ZOE-50/70 population ≥70 YOA, efficacy estimates for HZ ranged from 87.3% (95%CI: 58.1–97.6) for Latin America to 95.1% (95%CI: 87.0–98.7) for Asia/Australia (Fig. 1, Supplementary table 1).

In the pooled ZOE-50/70 population ≥70 YOA, efficacy against PHN was 90.8% (95%CI: 36.4–99.8) in Asia/Australia, 86.8% (95% CI: 42.2–98.6) in Europe, and 100% (95%CI: 31.2–100) in North America. The number of PHN cases for Latin America was insufficient to allow estimation of VE (Fig. 2).

3.4. Efficacy against HZ and PHN according to geographic ancestry/ethnicity

In the pooled ZOE-50/70 population ≥70 YOA, efficacy against HZ ranged from 89.6% (95%CI: 83.5–93.8) to 100% (95%CI: <0–100.0) in participants of European and African geographic ancestry, respectively. However, among participants with an African ancestry, only 1 placebo recipient had a confirmed HZ episode. Hence, the 95%CI for the point estimate in this subset was broad, with a negative lower limit. In participants of Hispanic ethnicity, efficacy was 88.1% (95%CI: 61.2–97.7) (Fig. 1, Supplementary table 1).

In the pooled ZOE-50/70 population ≥70 YOA, efficacy against PHN was 87.5% (95%CI: 58.7–97.6) and 89.8% (95%CI: 28.5–99.8) in participants of European and Asian ancestry, respectively (Fig. 2, Supplementary table 2). No PHN cases had occurred in participants of African ancestry and only a few PHN cases had occurred in participants of other ancestries or of Hispanic ethnicity. Hence, efficacy against PHN could not be estimated for the African ancestry subgroup, while for the remaining ancestries and Hispanic ethnicity, the 95% CIs for the point estimates were broad, with a negative lower limit.

4. Discussion

Most HZ cases occur in older adults and in persons with other immune-compromising conditions. Other factors such as female sex or belonging to the white racial group have been associated with an increased risk of HZ [6]. In the ZOE-50/70 trials, RZV demonstrated >90% efficacy against HZ in all age groups among adults ≥50 YOA, as well as high efficacy against PHN [8,9]. In other trials, RZV has also been shown to be efficacious in preventing HZ in immunocompromised populations ≥18 YOA such as hematopoietic stem cell transplant recipients and in patients with hematologic malignancies [19,20]. Our post-hoc analyses confirmed that RZV is efficacious against HZ and PHN irrespective of sex, geographic region, and geographic ancestry/ethnicity. These subgroup efficacy results are similar to the overall ZOE-50/70 results [8,9].

While several studies have shown an increased risk of HZ in women compared to men [6], our analysis showed a similar efficacy of RZV against HZ for both sexes. This recent meta-analysis also showed that the risk of HZ in white persons is approximately

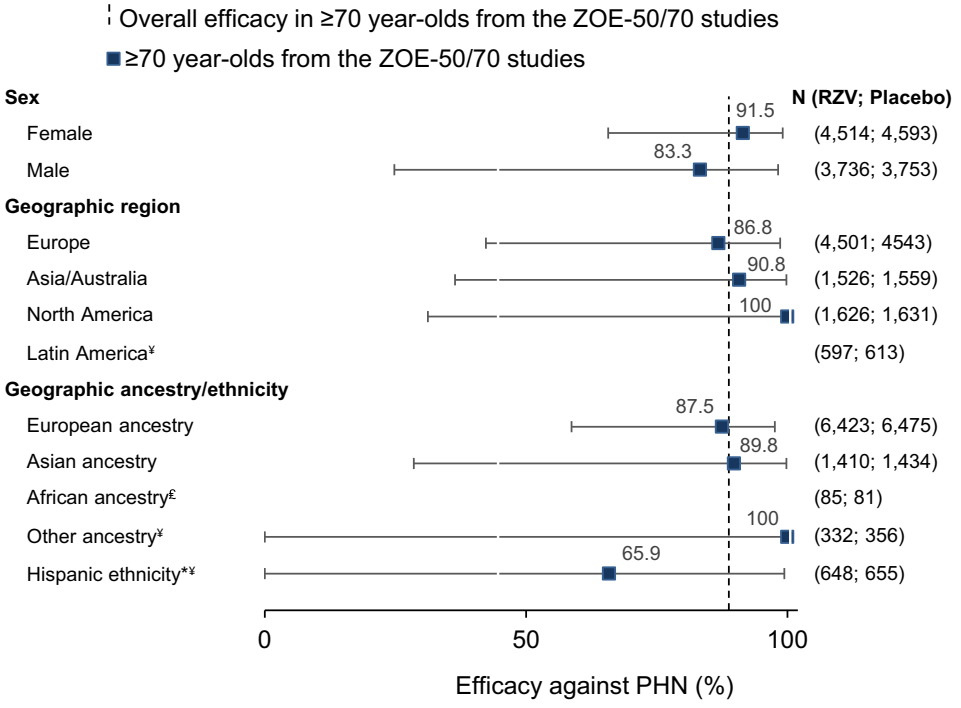

Fig. 2. Vaccine efficacy against first or only episode of PHN by sex, geographic region and geographic ancestry/ethnicity in adults ≥70 YOA (modified Total Vaccinated Cohort). PHN = postherpetic neuralgia; RZV = participants receiving the adjuvanted recombinant zoster vaccine; Placebo = participants receiving placebo; ZOE-50 and ZOE-70 = RZV efficacy studies in adults ≥50 YOA (NCT01165177) and ≥70 YOA (NCT01165229), respectively; N = number of participants in the (pooled) modified Total Vaccinated Cohort; YOA = years of age. European ancestry = Caucasian/European Heritage or Arabic/North African Heritage; Asian ancestry = Central/South Asian Heritage or East Asian Heritage or Japanese Heritage or Southeast Asian Heritage, African ancestry = African Heritage/African American, Other ancestry = American Indian or Alaskan Native; Native Hawaiian or Other Pacific Islander or a person with several different heritages; Hispanic = Hispanic or Latino; a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of geographic ancestry. Majority were from Mexico and Brazil. *Combined number of respondents from each geographic ancestral category who also self-reported as Hispanic or Latino. Errors bars depict 95% confidence intervals (CIs). £No PHN cases in either study group. ¥The lower limit of the 95% CI is <0. Note: vaccine efficacy was adjusted by age strata (all categories).

two-fold higher when compared to that in black persons [6]. In addition, a retrospective study of Medicare claims in the US also showed that among adults ≥65 YOA, HZ incidence is higher in white persons compared to that of black or Hispanic persons [21]. Our analysis shows a high efficacy against HZ irrespective of geographic ancestry/ethnicity. However, due to the limited sample size in some subgroups, robustness of efficacy data per geographic ancestry/ethnicity is limited.

The distribution of circulating VZV clades has been reported to differ by region: for example, in Europe, clade 1 (50%) and clade 3 (37%) are predominant; in Oceania, clade 1 (52%) and clade 3 (22%), in America, clade 1 (70%), and in Asia, clade 2 (74%) [7]. Our data shows >95% RZV efficacy against HZ in adults ≥50 YOA across all four geographic regions included in our analysis. Efficacy in ≥70-year-olds was also in similar ranges across these geographic regions, indicating that protection is similar against different clades. A pooled analysis of prospective cohort studies from North America, Latin America, and Asia shows a similar PHN risk in adults ≥50 YOA across these geographic regions [4]. The subgroups analyses of VE in the prevention of PHN was limited by the number of cases but appeared in line with the overall ZOE-50/70 population ≥70 YOA, in which RZV was 88.8% efficacious against PHN [9].

In line with the consistency of these subgroup analyses with overall efficacy findings, subgroup analyses on the pooled TVC of the ZOE-50/70 studies show no discrepancy between the safety profile of RZV in racial, ethnic, and gender subgroups and that in the overall ZOE-50/70 population [18].

This post-hoc analysis has limitations and its results should be interpreted with caution. The ZOE-50/70 studies were not powered to assess efficacy against HZ nor against PHN in specific subpopulations. By design, participants in the ZOE-50 and ZOE-70 studies were stratified by age and region and minimized by country and study site to ensure balance between the number of subjects in each group. The ZOE-50/70 studies were powered to assess efficacy against HZ in each of these studies, and against PHN in the pooled study population. In most subsets, enough HZ or PHN cases had occurred to allow the assessment of VE against HZ and PHN, respectively. Due to the low number of subjects and outcomes in some subsets (i.e., participants of African ancestry and Hispanic ethnicity), efficacy could not be estimated or the confidence intervals for these estimates were broad.

5. Conclusions

This post-hoc analysis confirmed that RZV is efficacious in preventing HZ and possibly PHN irrespective of sex, geographic region, and geographic ancestry/ethnicity. RZV efficacy against HZ or PHN in these subgroups appears similar to that in the overall ZOE-50/70 study population [8,9].

A plain language summary contextualizing the results and potential clinical research relevance and impact is displayed in the Focus on the Patient Section (Fig. 3).

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Colindres Romulo, Kim Joon Hyung, Oostvogels Lidia, Schuind Anne, Talarico Carla, Wascotte Valentine, Willer David and Zahaf Toufik were employees of the GSK group of companies (GSK) at the time this study was designed, initiated, and/or conducted. Colindres Romulo is currently employed as an independent biotechnology and vaccines consultant. Oostvogels Lidia is an employee of CureVac AG as of March 1, 2018, and is an inventor on a patent application related to the vaccine used in this study. Colindres Romulo, Kim Joon Hyung, Oostvogels Lidia, Schuind Anne, Talarico Carla, Wascotte Valentine, Willer David and Zahaf Toufik hold shares/stock options in GSK. Cunningham Anthony L. reports

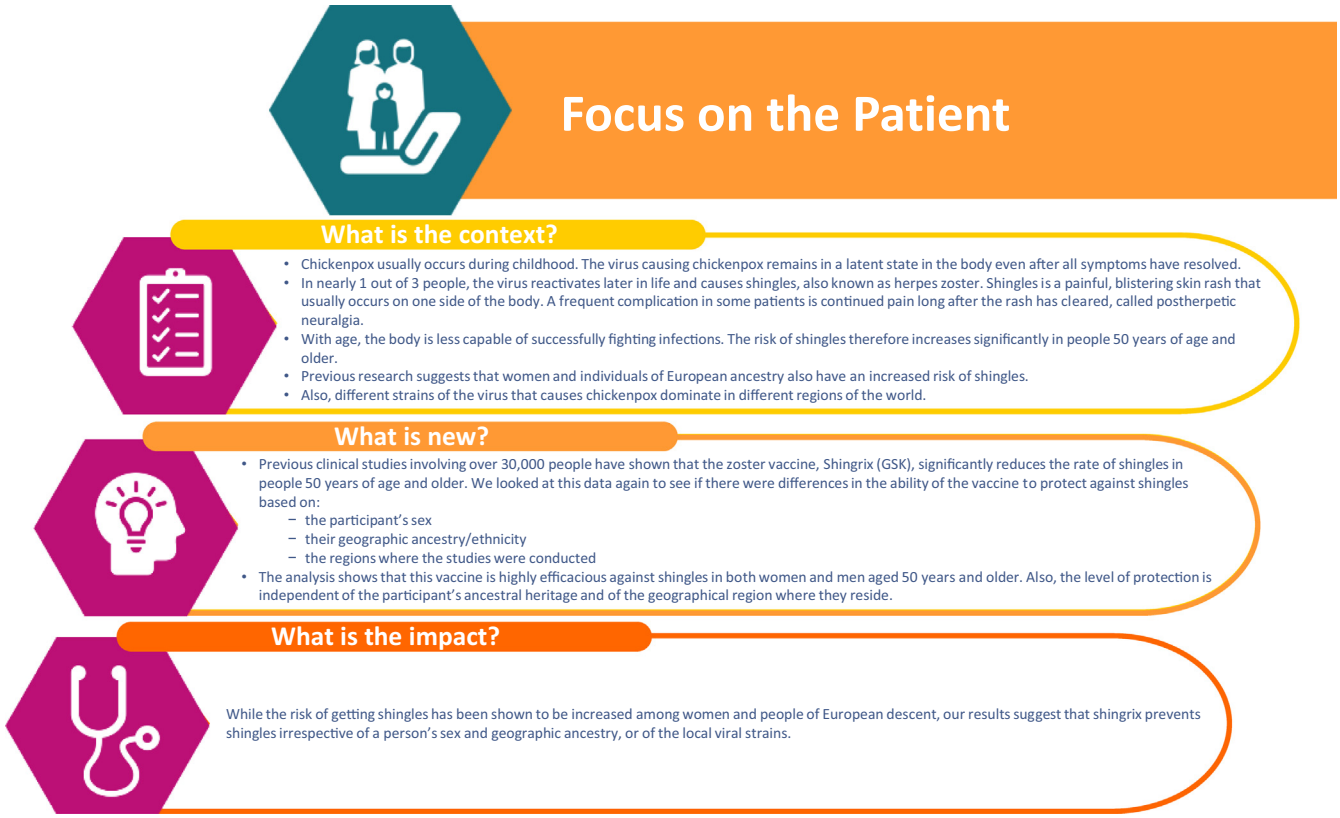

Fig. 3. Focus on the patient.

honoraria paid to his institution by GSK, Merck, and BioCSL/Sequirus for consultancies outside the submitted work. Gervais Pierre received personal fees as principal of the legal entity Q&T research which is mandated by GSK to conduct clinical studies. Gorfinkel Iris has received grants and lecture fees from GSK outside the submitted work and served on the Advisory Board for Shingrix in Canada. In addition, Gorfinkel Iris reports research grants from several other pharmaceutical companies outside the submitted work.

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Authors' contributions

Colindres Romulo: visualization, supervision, writing (review and editing), **Cunningham Anthony L.:** investigation, validation, writing (review and editing); **Gervais Pierre:** investigation, writing (review and editing); **Gorfinkel Iris:** investigation, writing (review and editing); **Kim Joon Hyung**: supervision, writing (review and editing), **Oostvogels Lidia**: conceptualization, methodology, supervision, writing (review and editing), **Schuind Anne**: conceptualization, supervision, writing (review and editing); **Talarico Carla:** validation, visualization, writing (review and editing); **Wascotte Valentine:** methodology, supervision, writing (review and editing). **Willer David O.**: visualization, writing (original draft), writing (review and editing), **Zahaf Toufik**: methodology, formal analysis, validation, writing (review and editing).

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.vaccine.2019.09.028.

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