





DUBAI | UAE | 22 to 24 APRIL

DUBAI WORLD TRADE CENTRE







Importance of Shingles Prevention In Older Adults



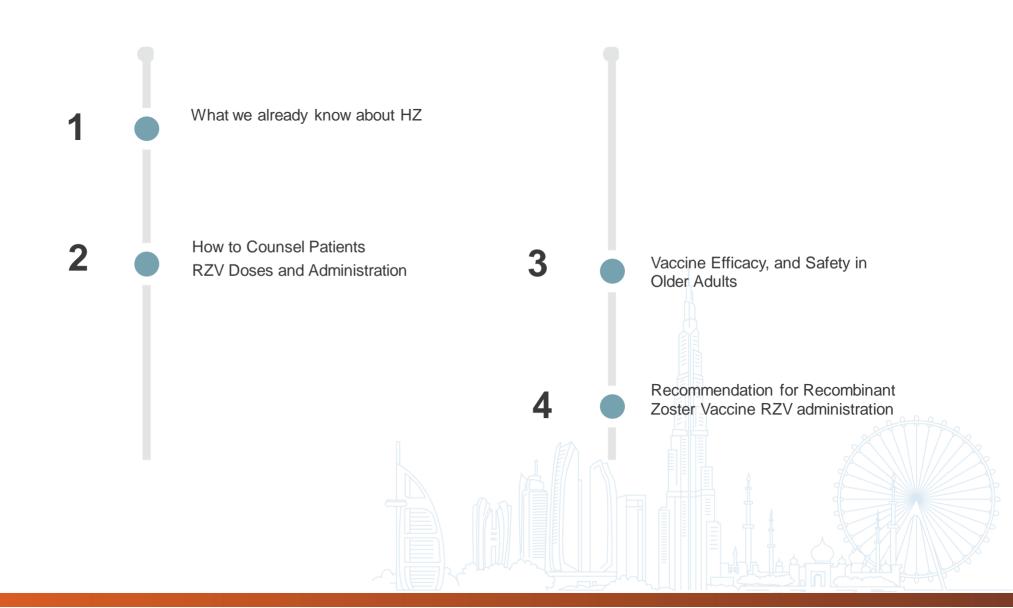


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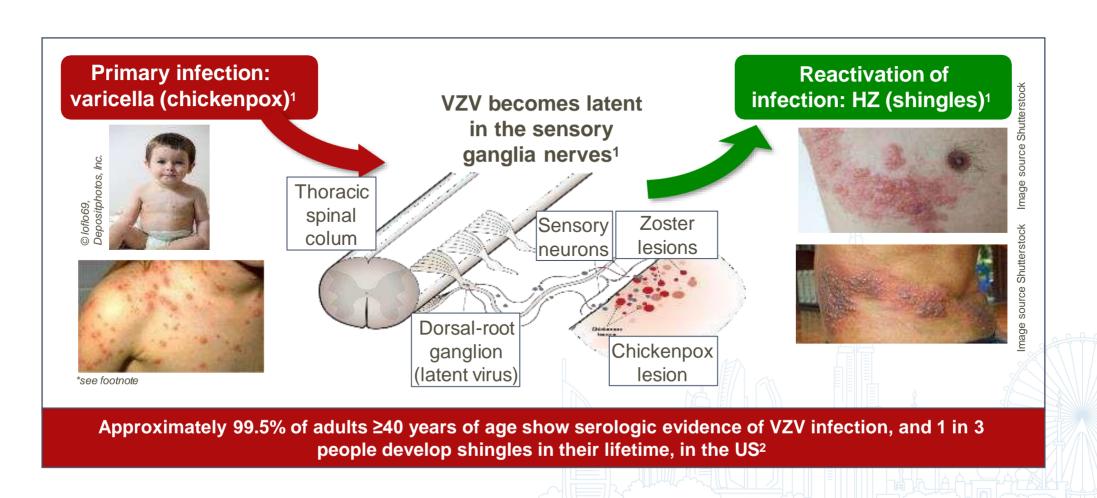




1.
Introduction to herpes zoster (HZ) and comorbidities

EFMS (1)

HZ is caused by the reactivation of the dormant varicella zoster virus¹





For many patients, herpes zoster can lead to serious complications

Neuropathic pain that persists for ≥90 days after the onset of HZ rash²

5% to over 30%* of patients with HZ³

Aseptic meningitis, encephalitis, cerebral infarction associated with granulomatous vasculitis, myelitis, Guillain-Barré syndrome, Ramsay Hunt syndrome and Bell's palsy

<1% of patients with HZ^{4†}

Post-herpetic neuralgia¹

Herpes zoster ophthalmicus³

Cerebrovascular and cardiovascular8

HZO occurs in **10–15%** of patients with HZ³

Eye-related complications occur in **30–78%** of patients with HZO³

Stroke, TIA, myocardial infarction, cardiovascular disease

1% of patients with HZ⁹

Approximately 10% of patients with HZ aged ≥50 years experience ≥1 non-PHN complication³

^{*}Data collected across 26 countries, the risk of PHN may have differed across countries due to the varying prevalence of disability and other underlying comorbidities in the elderly population; Aged ≥50 years. HZ, herpes zoster, HZO; herpes zoster ophthalmicus; PHN, post-herpetic neuralgia; TIA, transient ischaemic attack

^{1.} Cohen JI et al. N Engl J Med 2013;369:255–263; 2. Harpaz R et al. MMWR Recomm Rep 2008;57:1–30; 3. Kawai K et al. BMJ Open 2014;4:e004833; 4. Meyers J et al. Vaccine 2019;37:1235–1244; 5. Nakajima H et al. Neurological complications of varicella-zoster virus infection. In: Thomasini RL (ed). Human Herpesvirus Infection - Biological Features, Transmission, Symptoms, Diagnosis and Treatment. InTechOpen, 2019. doi: 10.5772/intechopen.83036; 6. Kang JH et al. Clin Infect Dis 2010;5:525–530; 7. Zandian A et al. BMC Infect Dis 2015;15:488

The natural course of herpes zoster consists of prodromal and acute phases which can be followed by chronic complications

Prodromal phase

4 days-2 weeks¹



Acute phase

2-4 weeks²



Subacute phase³

Up to 3 months



5 to >30% of patients⁴

Post-herpetic neuralgia³

Months/years



Headache, photophobia, malaise, abnormal skin sensations, pain, fever (less common)²

Unilateral, vesicular rash, associated acute pain²

PHN is defined as neuropathic pain that persists for ≥90 days after the onset of HZ rash^{2,5}

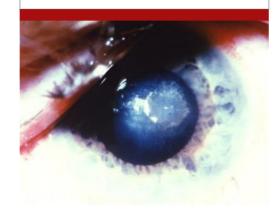
Approximately 10–15% of herpes zoster cases involve the ophthalmic division of the trigeminal nerve, causing herpes zoster ophthalmicus¹

Eyelid swelling, vesicular rash



Severe acute skin rash with haemorrhagic ulcerative lesions²

Eyelid swelling, vesicular rash



Epithelial keratitis, can lead to corneal scarring³

Herpes zoster ophthalmicus can result in a variety of potential eye complications^{2,3}

Corneal involvement occurs in 65% of HZO cases:³

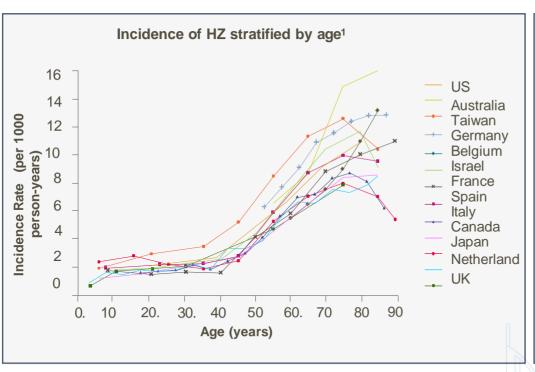
- Epithelial keratitis
- Neurotrophic keratopathy
- Stromal keratitis

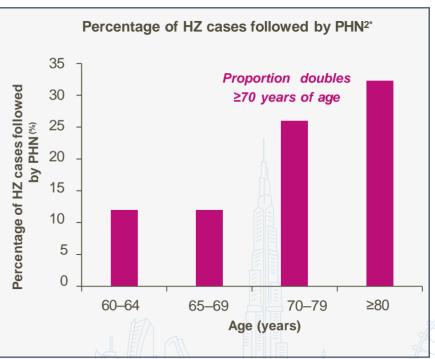
Other ocular complications include conjunctivitis, uveitis, episcleritis and ocular hypertension²



The incidence of HZ and PHN increases with age^{1,2}

The incidence of HZ, and consequently PHN, are expected to rise due to the ageing population^{3,4} and the development of immunocompromising conditions associated with ageing⁴

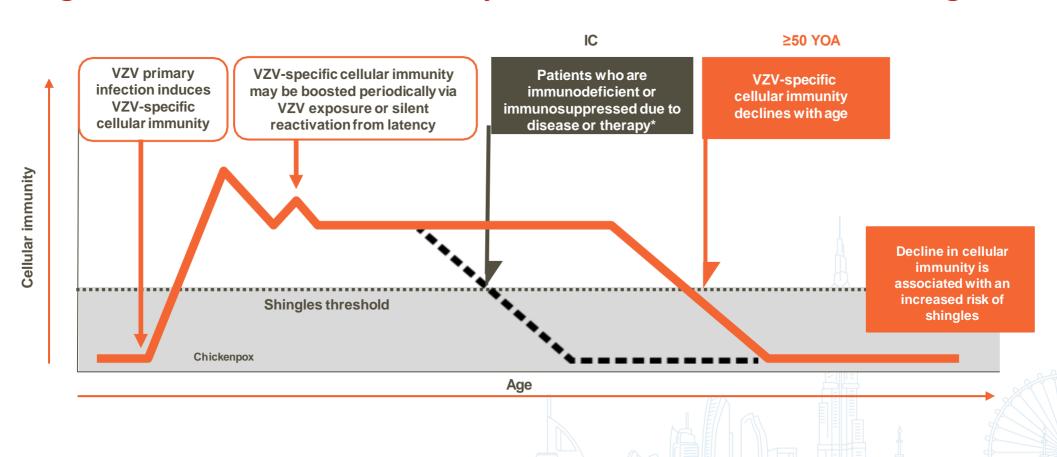




Reproduced from BMJ Open, Kosuke Kawai, Berhanu G Gebremeskel, Camilo J Acosta, Systematic review of incidence and complications of herpes zoster: towards a global perspective, 4, Page No. Copyright
© 2017. with permission from BMJ Publishing Group Ltd. *PHN, postherpetic neuralgia; PHN cases were defined as those patient records coded with postherpetic trigeminal neuralgia, postherpetic polyneuropathy, or other nervous system complications or neuralgia, 4–12 months after HZ diagnosis



Age-related decline in immunity and IC conditions increase shingles risk*1-3



Conceptual depiction of disease state. Adapted from Arvin. Aging, Immunity, and the Varicella-Zoster Virus. 2005 ²

1. Harpaz R, et al. MMWR RecommRep 2008;57:1–30; 2. Arvin. Aging, Immunity, and the Varicella–Zoster Virus. N Engl J Med 2005; 352:2266-2267; 3. Tseng HF, et al. J Infect Dis 2016;213:1872–5

^{*}Immunodeficiency caused by medical conditions or immunosuppressive medications may also increase the risk of shingles¹ IC, immunocompromised; VZV, varicella zoster virus; YOA, years of age

A compromised immune system increases the risk of herpes zoster^{1,2}

HZ risk increases with decline in immune system function^{2,3}

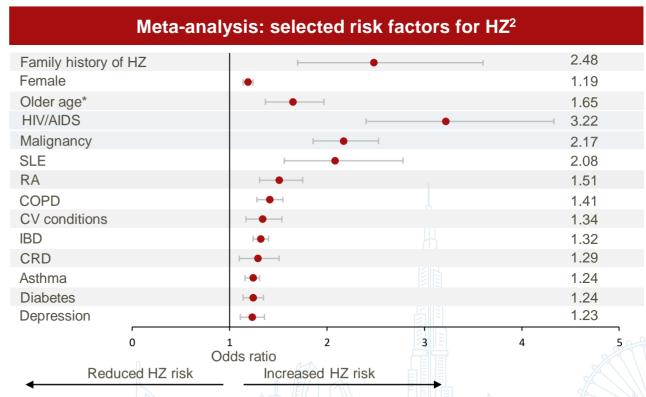
Compromised immune system

Patients with **immunodeficient conditions**² and those on **immunosuppressive drugs**⁴

HIV infection

HIV-related immunosuppression significantly increases the risk of HZ (RR, 3.22)²

 The incidence of HZ is substantially lower among HIV patients who are receiving ART⁵



The graph has been independently created by GSK from the original data published in Marra et al. 2020.

^{*}Studies reported HZ risk within the following age groups: ≥60 years (36 studies), ≥50 years (2 studies), ≥40 years (1 study)

AIDS, acquired immune deficiency syndrome; ART, antiretroviral therapy; COPD, chronic obstructive pulmonary disease; CRD, chonic renal disease; CV, cardiovascular; HIV, human immunodeficiency virus; HZ, herpes zoster; IBD, inflammatory bowel disorder; RA, rheumatoid arthritis; RR, relative risk; SLE, systemic lupus erythematosus

^{1.} John A, Canaday DH. Infect Dis Clin North Am 2017;31:811–826; 2. Marra F et al. Open Forum Infect Dis 2020;7:1–8; 3. Government of Canada Herpes zoster (shingles) vaccine: Canadian Immunization Guide 2022. <a href="https://www.canada.ca/en/public-health/services/public-he

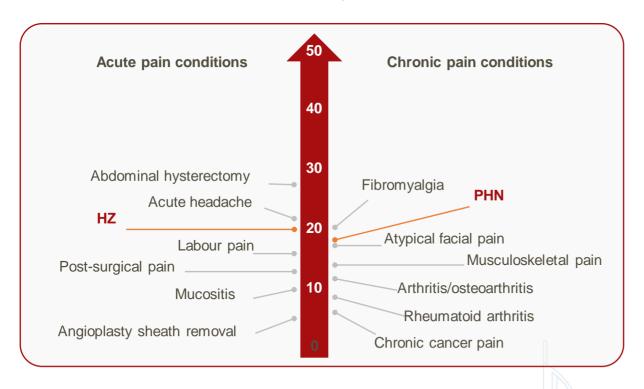


2. Patient Counselling



Herpes zoster-related pain can be extremely debilitating for the patient1-3

Level of pain reported for different conditions using the short-form McGill Pain Questionnaire⁴



"I got shingles on the right side of my abdomen...the pain was out of this world" 1

- Ann, patient with HZ

"I would rather have ten babies than the pain I've endured for the past ten years"²

- Etta, patient with PHN, IAC patient testimonial

"Five years later, I still take prescription medication for pain. My shingles rash quickly developed into open, oozing sores that...required me to be hospitalised...It was totally debilitating."³

 A 63-year-old harpist who was unable to continue playing due to HZ

HZ, herpes zoster; IAC, Immunization Action Coalition; PHN, post-herpetic neuralgia. Figure reproduced from Katz J et al. Surg Clin North Am 1999;79:231–252, with permission from Elsevier

1. Tuzi A, Watson CP. Herpes zoster: A patient's perspective. In: Watson CP et al. (eds). Herpes Zoster: Postherpetic Neuralgia and Other Complications. Cham, Switzerland: Adis, 2017; 2. Zamula E. Immunization Action Coalition 2001. Available at: https://www.immunize.org/report/89.asp (accessed February 2021);

^{3.} Centers for Disease Control and Prevention. Shingles (herpes zoster): Fact Sheet 20181; 4. Katz J et al. Surg Clin North Am 1999;79:231–252



Herpes zoster-related pain interferes with multiple aspects of life

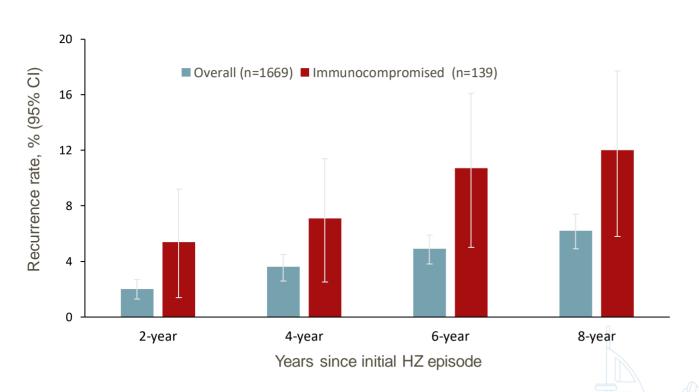
Activity	Interference of HZ pain (n=874)	Interference of PHN (n=131)
General activity	4.4	5.2
Mood	4.5	5.7
Walking ability	2.8	4.5
Normal work	4.1	5.4
Social relations	3.3	4.5
Sleep	4.7	6.3
Enjoyment of life	3.9	5.2
0 → Mean in	terference score → 10 0 -	→ Mean interference score → 10

21% of respondents reported high interference of HZ pain/PHN on their overall QoL

Recurrence of Herpes Zoster:

Recurrence study in the United States, 1996–2007

Recurrence rate after initial HZ episode



Among 1669 patients with initial HZ, the recurrence rate was **6.2%** over a mean of 7.3 years' follow-up

Recurrence was observed in a different dermatome to the initial episode in 45% of cases

HZ recurrence ranged from **96 days to 10 years** after the initial episode

HZ recurrence was more common in patients with pain duration ≥30 days;

HR: 2.8 (95% CI: 1.8-4.3), P<0.01



3.

Vaccine Efficacy and Safety





Current HZ treatment is suboptimal; Effective preventative strategies are required¹

Treatment of acute HZ²

- Antivirals started within 72 hours of rash onset
- However, treatment within this timeframe is often not achievable

Management of HZ pain²

- Simple analgesics
- Drugs for neuropathic pain
- Combination therapy3
- Current treatment options for PHN are suboptimal and commonly involve a high degree of polypharmacy

Prevention of HZ¹

- Since 2006, Zoster Vaccine Live (ZVL)^{4,5}
- Limited efficacy across older age groups
- ❖ Decline in efficacy over time
- Contraindicated in IC populations
- Since 2017, Recombinant Zoster Vaccine (RZV)^{6,7}



^{1.} Johnson RW, et al. BMC Med 2010;8:37; 2. Harpaz R, et al. MMWR Recomm Rep 2008;57:1–30; 3. Massengill JS, Kittredge JL. J Pain Res 2014;7:125–32; 4. Merck & Co. Zostavax Prescribing information: 1, FDA; [updated Sept 2019]. Available from: https://www.merck.com/product/usa/pi_circulars/z/zostavax/zostavax_pi2.pdf; 5. Tseng.HF, et al. J Infect Dis 2016;213:1872–5; 6. Shingrix Prescribing information: US FDA; [revised Oct 2019]. Available from: https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing Information/Shingrix/pdf/SHINGRIX.PDF; 7. Shingrix product Monograph, Canada [revised March 2019]. Available from: http://ca.gsk.com/media/1350788/shingrix_pm-2017-10-13.pdf;



RZV Efficacy



VEHZ for RZV in ZOE-50 and ZOE-70^{1,2}

Overall and by age group

		RZV*		Placebo*		
Age (years)	HZ cases (N)	Rate of HZ (per 1,000 person-years)	HZ cases (N)	Rate of HZ (per 1,000 person-years)	VE _{HZ} (95% CI) [†]	
		ZO	E-50 ^{1‡}			
Overall (≥50)	6 (7,344)	0.3	210 (7,415)	9.1	97.2 (93.7, 99.0)	
50–59	3 (3,492)	0.3	87 (3,525)	7.8	96.6 (89.6, 99.3)	
60–69	2 (2,141)	0.3	75 (2,166)	10.8	97.4 (90.1, 99.7)	
Pooled analysis of ZOE-50 and ZOE-70 ²						
Overall (≥70)	25 (8,250)	0.8	284 (8,346)	9.3	91.3 (86.8, 94.5)	
70–79	19 (6,468)	0.8	216 (6,554)	8.9	91.3 (86.0, 94.9)	
≥80	6 (1,782)	1.0	68 (1,792)	11.1	91.4 (80.2, 97.0)	

^{*}Modified vaccinated cohort (excludes subjects not receiving dose 2 or who developed HZ within 1 month after dose 2); †p<0.001 for all comparisons vs placebo; †Mean follow-up 3.2 years; CI, confidence interval; N, number of subjects; HZ, herpes zoster; RZV, recombinant zoster vaccine; VE_{HZ}, vaccine efficacy for HZ 1. Lal H, et al. N Engl J Med 2015;372:2087–96; 2. Cunningham AL, et al. N Engl J Med 2016;75:1019–32

HZ *COMPLICATIONS* among groups ≥50 and ≥70 years of age*

Prespecified, pooled analysis of ZOE-50 and ZOE-70*

	RZV*		Placebo*		
Age (years)	PHN cases [†] (N)	Rate of PHN (per 1,000 person-years)	PHN cases [†] (N)	Rate of PHN (per 1,000 person-years)	VE _{PHN} (95% CI) [‡]
≥50	4 (13,881)	0.1	46 (14,035)	0.9	<mark>91.2%</mark> (75.9, 97.7)
≥70	4 (8250)	0.1	36 (8346)	1.2	88.8% (68.7, 97.1)

In a post-hoc, pooled analysis (ZOE-50 and ZOE-70): RZV reduced non-PHN complications (such as HZ vasculitis, disseminated, ophthalmic and neurological disease) versus placebo²

VE in subjects

≥50 years

of age was 93.7% (95% CI 59.5, 99.9), p=0.0003

VE in subjects

≥70 years

of age was 91.6% (95% CI 43.3, 99.8), p=0.0035



VEHZ by current baseline condition (pooled ZOE-50/70 analysis, subjects ≥50 YOA)¹

mTVC; First or only episode of HZ during the entire study period by baseline condition using Poisson method

Medical condition	RZV		Placebo		VE % (95% CI)
	N	Rate HZ/1000 py	N	Rate HZ/1000 py	
lypertension	7,206	0.8	7,226	9.5	91.9 (87.3–95.1)
steoarthritis and/or vertebral disorders	4,951	0.9	5,032	9.6	<mark>91.1 (85.1–95.0)</mark>
yslipidemia	4,628	0.9	4,707	9.7	91.2 (85.1–95.2)
iabetes	2,350	0.8	2,372	9.2	91.2 (81.1–96.6)
steoporosis/Osteopenia	1,481	0.9	1,528	13.0	92.9 (82.7–97.8)
astroesophageal reflux disease	1,334	1.2	1,313	9.1	86.9 (69.0–95.4)
eep disorder	1,304	0.8	1,309	11.7	93.1 (81.4–98.2)
ostatic diseases	1,244	0.4	1,285	10.7	<mark>96.1 (85.1–99.5)</mark>
ypothyroidism	1,167	0.9	1,147	6.6	86.2 (60.4–96.5)
epression	1,017	0.5	987	8.1	93.4 (74.1–99.2)
oronary heart disease	1,003	0.3	1,055	8.9	97.0 (82.3–99.9)
ataract	782	1.3	800	14.0	90.4 (73.4–97.5)
sthma	646	1.2	689	10.9	88.8 (63.6–97.8)
espiratory disorders*	614	1.4	560	8.7	84.5 (46.4–97.1)
enal disorders	308	0.9	300	7.0	86.6 (-4.5-99.7)

^{*}Other than asthma

mTVC, modified total vaccinated cohort; N = number of subjects included in each group; n = number of subjects having at least one confirmed HZ episode, LL, UL = 95% Lower and Upper confidence limits; py, person years; VE (%) = Vaccine Efficacy (Poisson method); YOA, years of age

^{1.} Oostvogels et al, Hum Vaccin Immunother. 2019;15(12):2865-2872.

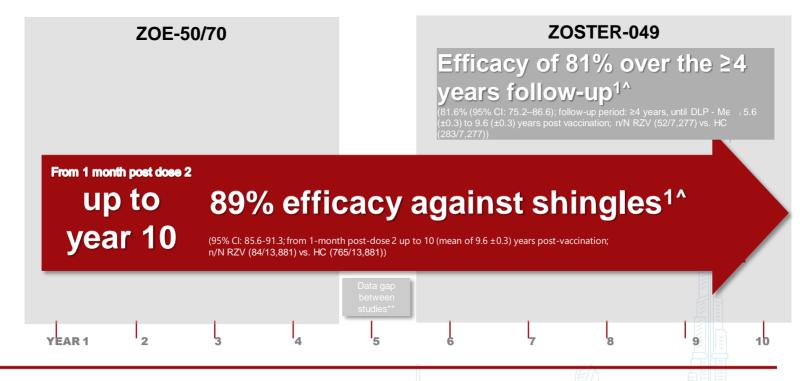


Long-term Follow-Up Study (ZOE-LTFU)

Zoster-049 - Extension study of ZOE-50 and ZOE-70 to assess RZV-induced immunogenicity persistence and long-term vaccine efficacy against HZ

SHINGLES PROTECTION THAT LASTS UP TO YEAR 101

ZOSTER-049 interim analysis:



The same results were first published in Strezova A, et al. Open Forum Infectious Diseases, 2022. The graph has been independently created by GSK from the original data:

**No data are available for year 5 because that period corresponds to the gap between ZOE-50/70 and the Zoster-049 follow-up study!

CI=confidence interval; DLP=data lock point, DLP set when the last participant had reached 4-years of follow-up; HC=historical controls; HZ=herpes zoster; mTVC, modified total vaccinated cohort; N, number of individuals included in each group; n, number of individuals having at least one confirmed herpes zoster episode; RZV, recombinant zoster vaccine.

[^] Of the 14,648 ZOE-50/70 participants who received at least 1 RZV dose, 7,413 (50.6%) were enrolled in ZOSTER-049. Of these, 7,277 had previously received both RZV doses and were included in the mTVC for the efficacy assessments. In the absence of an unvaccinated placebo group for the LTFU study, the efficacy analyses in ZOSTER-049 used historical control estimates from the ZOE-50/70 placebo groups recorded during the trials. At this DLP, data accrual was complete through year 9. Results for year 10 are also included although still incomplete, precision of estimates for this time point will increase at the final analysis.^{1,2}



RZV Safety



Any grade and grade 3 solicited local adverse reactions reported up to 7 days post-vaccination*1-4

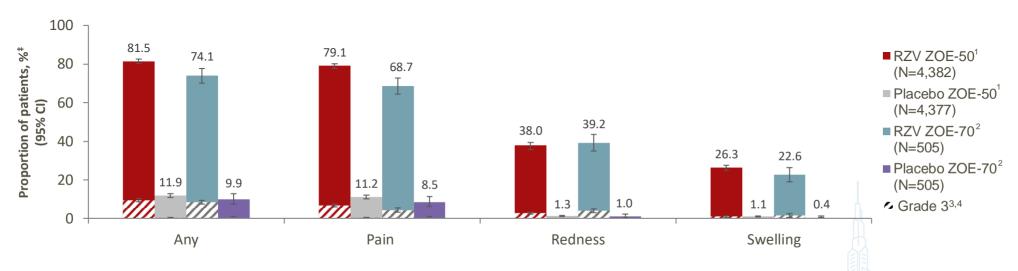


Figure drafted from raw data within article from Lal H, et al. N Engl J Med 2015;372:2087–96; Cunningham AL, et al. N Engl J Med 2016

Median duration of any grade solicited local reactions

ZOE-50: pain, redness and swelling = 3 days³

ZOE-70: pain = 2 days; redness and swelling = 3 days²

Median duration of grade 3[†] solicited local reactions

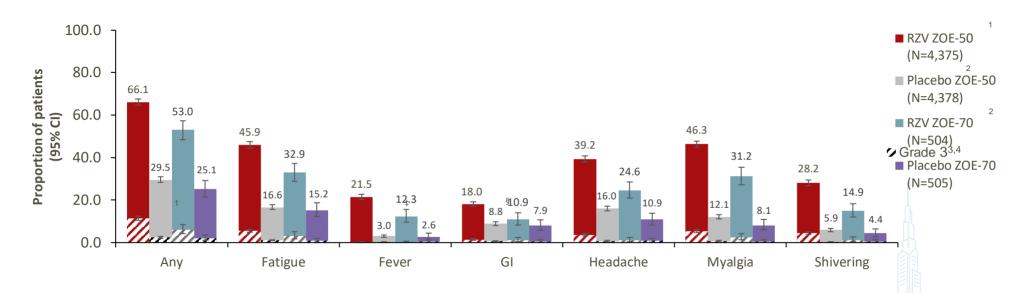
ZOE-50: pain = 1 day; redness and swelling = 2 days¹

ZOE-70: pain = 1.5 days; redness = 2 days; swelling = 1 day²

^{*}Subgroup of age stratified subjects recorded injection-site reactions and systemic reactions on diary cards for 7 days after each injection; †Grade 3, redness and swelling at the injection site were scored as grade 3 for those more than 100 mm. All other symptoms were scored as 3 for preventing normal activity; ‡Percentage of subjects reporting the symptom at least once when the intensity is maximum 1. Lal H, et al. N Engl J Med 2015;372:2087–96; 2. Cunningham AL, et al. N Engl J Med 2016;75:1019–32; 3. Study 110390: GSK Clinical Study Report 2016.

Available at: https://www.gsk-studyregister.com/en/trial-details/?id=113077

Any grade and grade 3 solicited systemic adverse reactions reported post-vaccination*1-4



Median duration of any grade solicited systemic reactions

ZOE-50: fatigue, GI, headache and myalgia = 2 days; fever and shivering = 1 day^3 ZOE-70: fatigue, fever GI, headache, amd myalgia = 2 days; shivering = 1 day^2

Median duration of grade 3[†] solicited systemic reactions

ZOE-50: all grade 3 adverse reactions = 1 day^1 ZOE-70: fatigue, GI, HA and shivering = 1 day; myalgia = 2 days^2

^{*}Subgroup of age stratified subjects recorded injection-site reactions and systemic reactions on diary cards for 7 days after each injection; †Grade 3: temperature >39°C (preferred route: oral); all other symptoms were scored as 3 for preventing normal activity. ‡Fever (≥37.5°C/≥99.5°F); §GI symptoms included nausea, vomiting, diarrhea, and/or abdominal pain; GI, gastrointestinal; N, number of subjects with at least 1 documented dose; %, percentage of subjects reporting the symptom at least once when the intensity is maximum

1. Lal H, et al. N Engl J Med 2015;372:2087–96; 2. Cunningham AL, et al. N Engl J Med 2016;75:1019–32; 3. Study 110390: GSK Clinical Study Report 2016. Available at: https://www.gsk-studyregister.com/study/3283; 4. Study 113077: GSK Clinical Study Report 2016. Available at: https://www.gsk-studyregister.com/en/trial-details/?id=113077



4.

Recommendations for HZ vaccine by DHA

Recommendations of herpes zoster vaccines by DHA

Zoster vaccination (Routine vaccination)

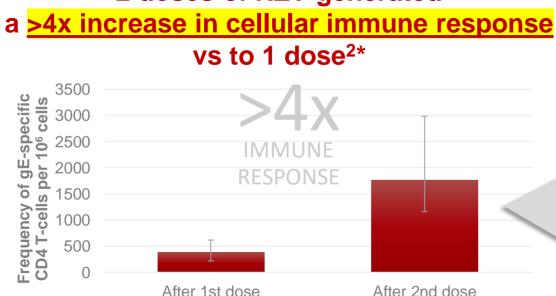
- Age 50 years or older:
 - a) 2-dose series RZV (Shingrix) 2–6 months apart (minimum interval:4 weeks; repeat dose if administered too soon), regardless of previous herpes zoster or history of zoster vaccine live (ZVL, Zostavax) vaccination (administer RZV at least 2 months after ZVL).

• Immunocompromising conditions:

- a) Adults with immunosuppression should generally avoid live vaccines. Inactivated vaccines (e.g., pneumococcal vaccines) are generally acceptable.
- b) High-level immunosuppression includes HIV infection with a CD4 cell count <200 cells/µL, receipt of daily corticosteroid therapy with ≥20 mg of prednisone or equivalent for ≥14 days, primary immunodeficiency disorder (e.g., severe combined immunodeficiency or complement component deficiency), and receipt of cancer chemotherapy.
- c) Other immunocompromising conditions and immunosuppressive medications to consider when vaccinating adults can be found in IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host. Additional information on vaccinating immunocompromised adults is in General Best Practice Guidelines for Immunization.
 - Diabetes Type 1 and Type 2
 - Cardiovascular Disease
 - · Liver Disease.
 - Renal Disease.
 - · Weakened Immune System.
 - Lung Disease including Asthma.
 - HIV Infection.
 - · Heart Disease Stroke or Other

Two Doses of RZV are required to induce strong immune response against VZV^1

2 doses of RZV generated



Vaccination schedule consists of initial dose followed by a second dose 2
months later¹

If flexibility is necessary, the second dose can be administered between 2 and 6
months after the first dose¹

For Adults 50 years of
age or older

Months 0 1 2 3 4 5 6

The same results were first published in Vaccine. Figure independently created by GSK from the original data published in Chlibek R, et al. 2014.²

An immunological correlate of protection has not been established; therefore, the level of immune response that provides protection against HZ is unknown. 1
*Data in subjects 60+. CD4=cluster of differentiation 4; gE=glycoprotein E; HZ=herpes zoster; VZV=varicella zoster virus.

^{1.} Shingrix local prescribing information; 2. Chlibek R, et al. Vaccine. 2014;32(15):1745-1753.



Data Supports Co-Administration* with the following vaccines:

- ✓ Influenza (unadjuvanted inactivated seasonal)^{1,2}
- ✓ Pneumococcal (PPV23)1,3
- ✓ Diphtheria-Tetanus-Pertussis (Tdap)¹,⁴

Coadministration generally well tolerated 1-4

No safety issue raised1-4

No immunologic interference observed 1-4†

PI=prescribing information; PPV23=23-valent pneumococcal polysaccharide vaccine; SMPC=summary of product characteristics; Tdap=tetanus, diphtheria and acellular pertussis vaccine.

1. Shingrix local prescribing information; 2. Schwarz TF, et al. J infect Dis. 2017;216(1):1352–1361; 3. Marechal C, et al. Vaccine. 2018;38(29):4278–4286.

 $\textbf{4.}\, \textbf{Strezova}\, \textbf{A}, \textbf{et al.}\, \textbf{Vaccine.}\, \textbf{2019;} \textbf{37(39):} \textbf{5877-85.}\, \textbf{5.}\, \textbf{Shingrix}\, \textbf{(prescribing information)}.\, \textbf{GlaxoSmithKline;} \textbf{2021}$

^{*}All 3 completed studies included in EU SMPC. Only inactivated influenza vaccine co-administration included in US PI. 1,5

[†]Non-inferiority criterion met for humoral response to SHINGRIX and for all Tdap antigens except pertactin. Clinical relevance unknown.⁴



Closing thoughts





How can HCPs communicate effectively with public about vaccines?

PATIENT COUNSELING



Use patient-friendly language³



Gain their trust²



Reinforce understanding of the benefits/risks of vaccines³

increase the awareness of the public on vaccines and vaccination-related topics

HCPs have a responsibility to

Maltezou HC, Poland GA, Healthcare (Basel) 2016:4

Harmsen IA, et al. BMC Public Health 2013;13;1183

WHO, 2016. Vaccine Safety communication. https://iris.who.int/bitstream/handle/10665/208263/9789290617464_eng.pdf?sequence=1. (accesses April 2024).

PRESCRIBING INFORMATION FOR UAE Herpes zoster vaccine (recombinant, adjuvanted)

Please scan the QR code for the Shingrix PI



EFMS (i)



For more information, please refer to the prescribing information or contact GlaxoSmithKline via gcc.medinfo@gsk.com

To report Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com
To report quality complaint/s associated with the use of GSK product/s, please contact us via Gulf.ProductQualityComplaints@gsk.com







