

# Burden of HZ Disease and Efficacy and Effectiveness of HZ Vaccine in Older Adults

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# Outline

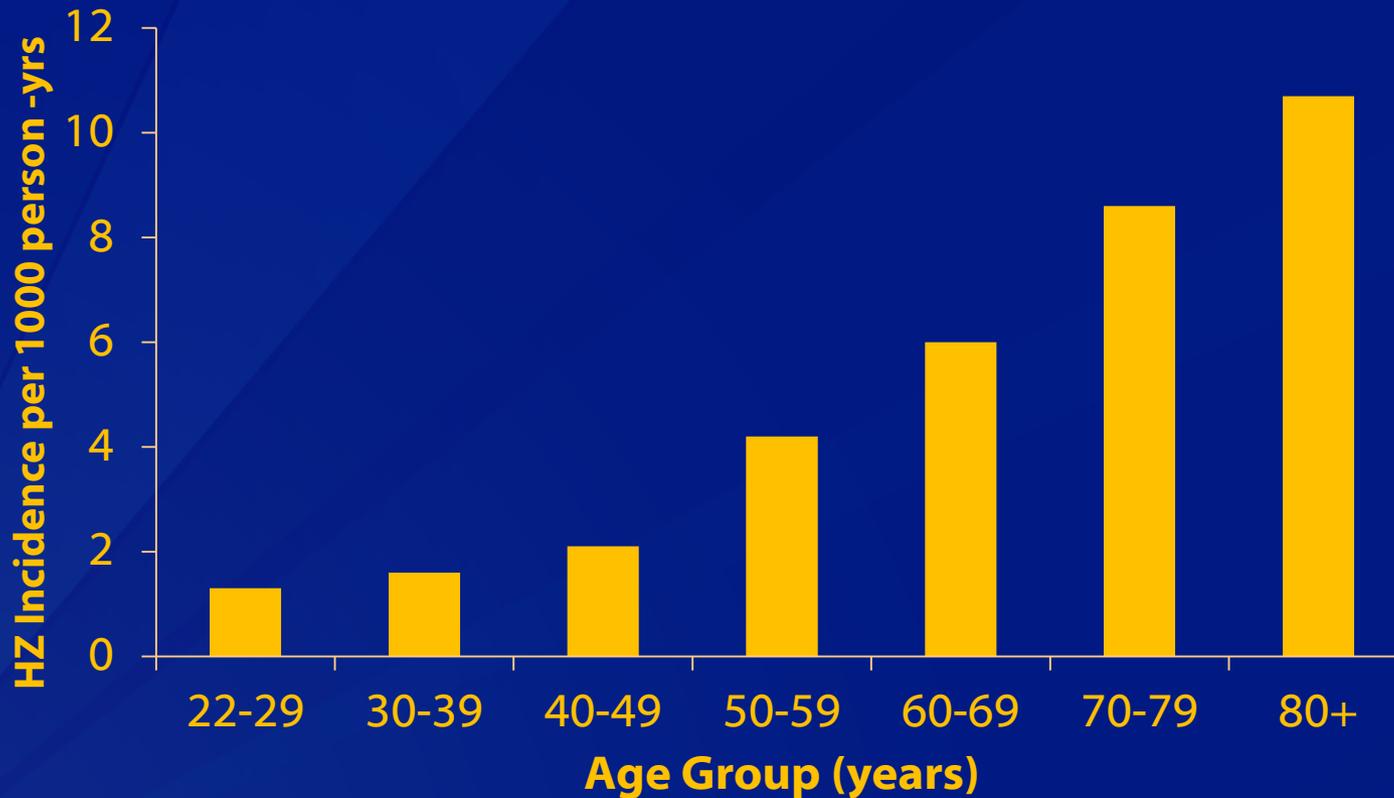
- ❑ **Burden of HZ disease in adults**
- ❑ **Short term vaccine efficacy and effectiveness**

# **BURDEN OF HZ DISEASE IN ADULTS**

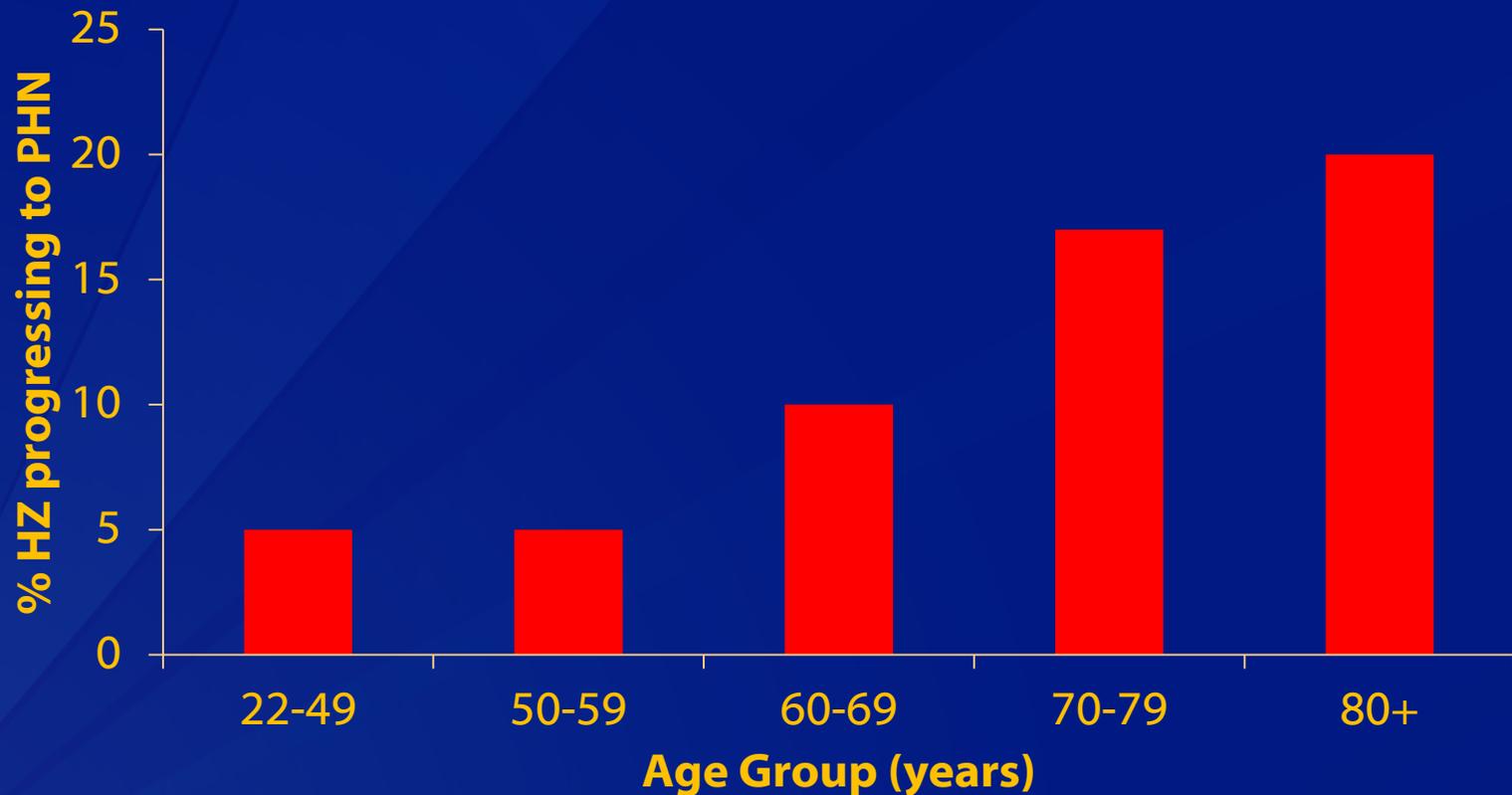
# Clinical Manifestations of HZ

- ❑ **Acute, self-limited pain – can be disabling**
- ❑ **Post-herpetic neuralgia (PHN)**
  - Pain persisting months to years after resolution of rash
  - Mild to excruciating chronic pain
  - Disrupts sleep, mood, work, activities of daily living
  - Can lead to social withdrawal and depression
- ❑ **Secondary bacterial infections**
- ❑ **Ocular complications, including permanent visual impairment**
- ❑ **Neurologic complications**
  - Palsies
  - Meningitis
  - Ischemic stroke syndrome

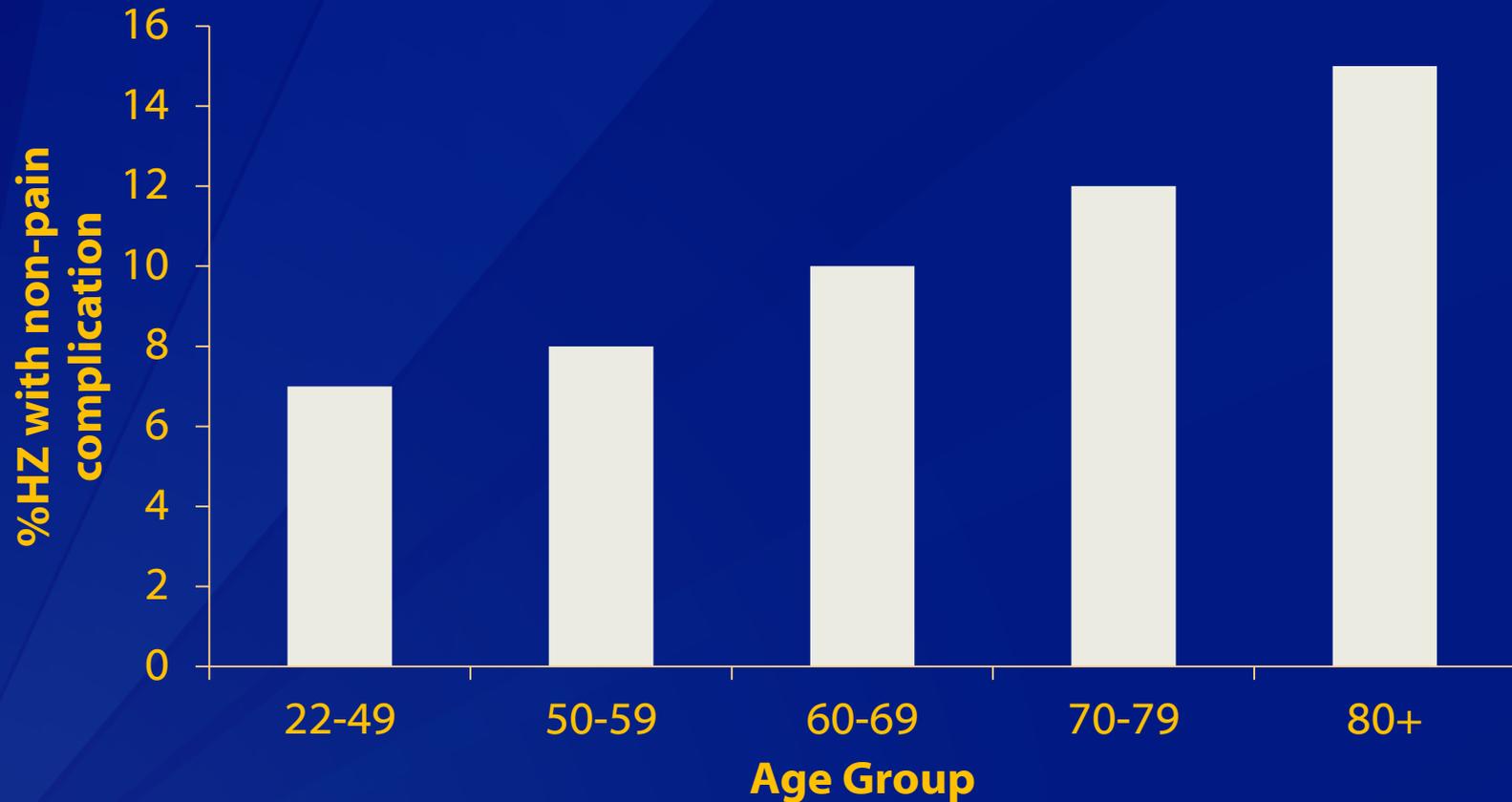
## HZ Incidence by Age: Olmsted County, MN, 1996-2001



## Proportion of HZ Progressing to PHN\*, by Age: Olmsted County, MN, 1996-2001

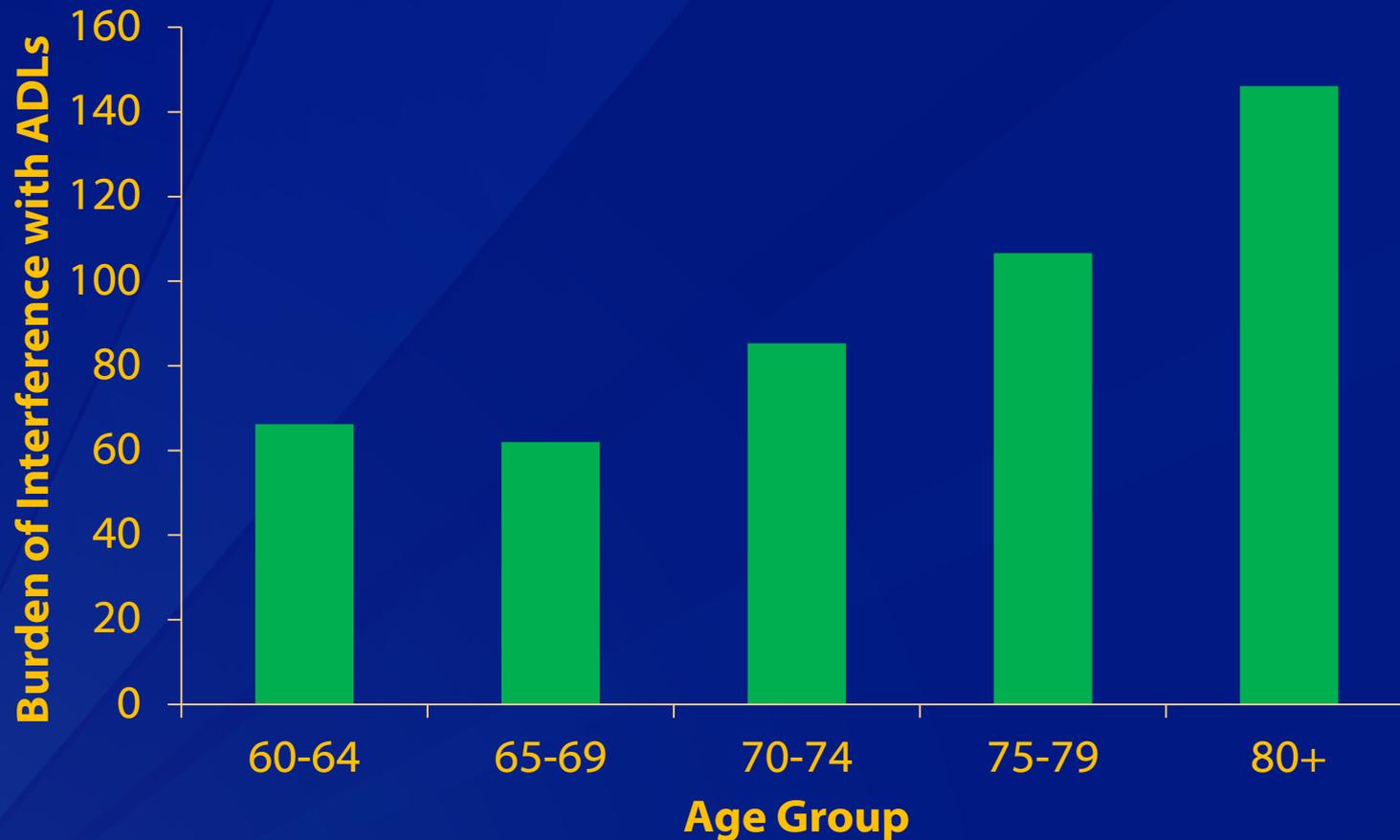


## Proportion of HZ with Non-Pain Complications\*, by Age: Olmsted County, MN, 1996-2001



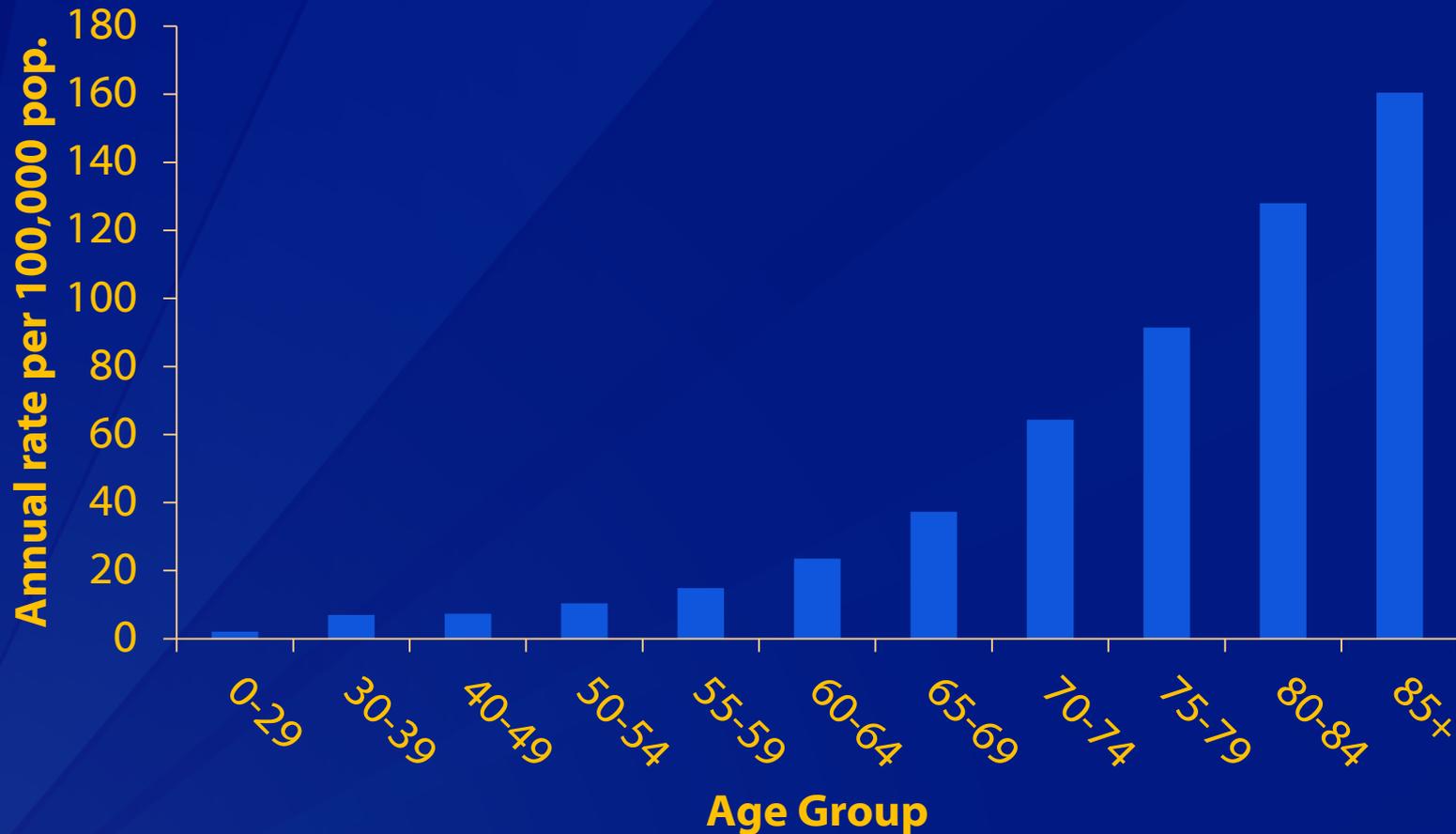
\*Ocular and neurological complications, secondary skin infection, disseminated HZ

# Interference with Activities of Daily Living (ADLs)\* In Persons With HZ, By Age



\*Mean interference with 7 ADLs over 6 months: General activity, mood, walking ability, work, relations with others, sleep, enjoyment of life.

## Rate of HZ-Related Hospitalization by Age: Connecticut, 1986-1995



74% of HZ-related hospitalizations in persons  $\geq 60$  years

# **SHORT TERM VACCINE EFFICACY AND EFFECTIVENESS**

## **Vaccine efficacy**

- ❑ **Reduction of disease in vaccinated persons relative to unvaccinated persons under optimum conditions**
- ❑ **Measured in a double-blinded, randomized, placebo-controlled clinical trial**

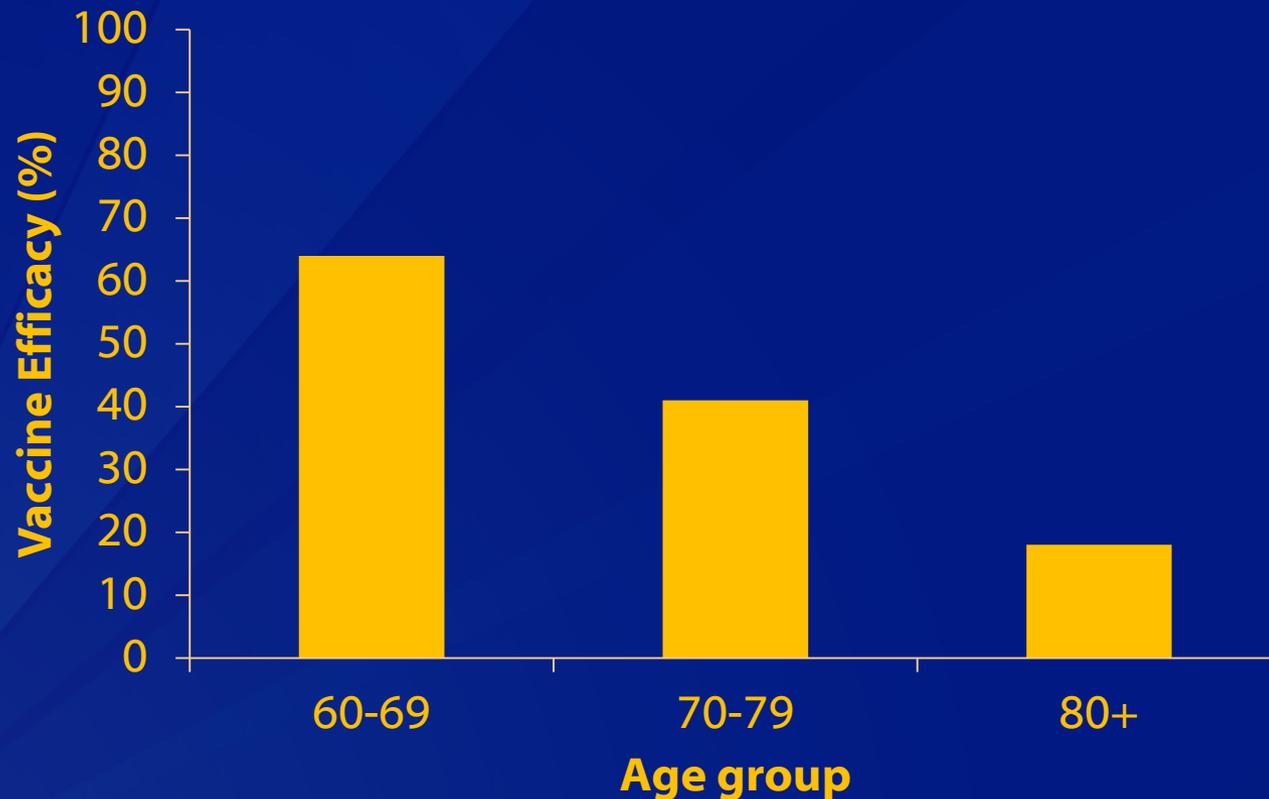
## **Vaccine effectiveness**

- ❑ **Reduction in disease in vaccinated persons relative to unvaccinated persons under “real world” conditions**
- ❑ **Measured in observational studies**

# Short Term Vaccine Efficacy in Adults $\geq 60$ Years of Age

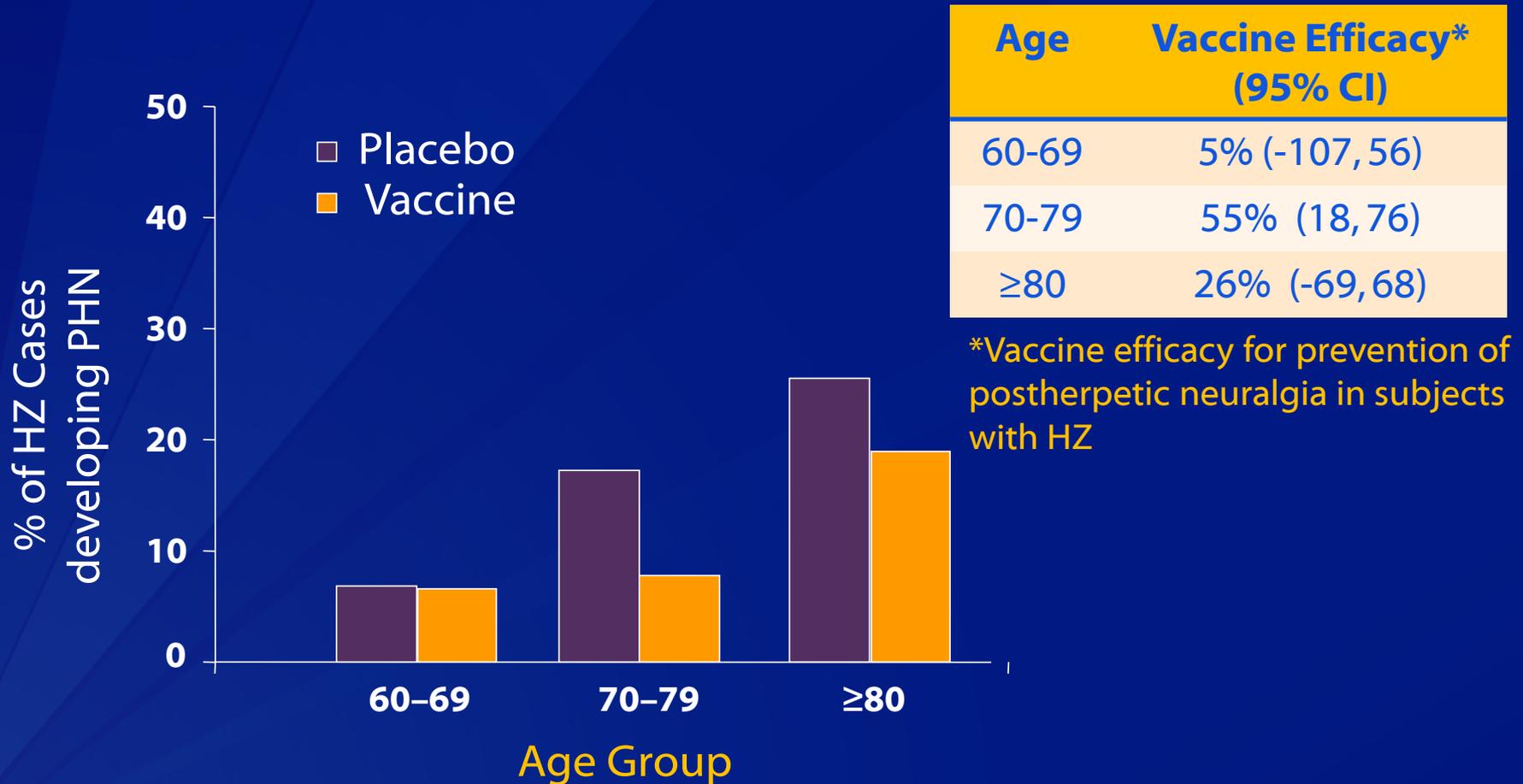
Shingles Prevention Study (SPS)	Short Term Persistence Substudy (STPS)
Randomized controlled trial (RCT)	Continuation of SPS
38.5K subjects	14K subjects
1-4 years after vaccination	4-7 years after vaccination
Vaccine efficacy for prevention of HZ = 51% (95% CI, 44 to 58)	Vaccine efficacy for prevention of HZ = 40% (95% CI 18, 56)
Vaccine efficacy for prevention of PHN = 67% (95% CI, 48 to 79)	Vaccine efficacy for prevention of PHN = 60% (95% CI, -10 to 87)

# Short term Vaccine Efficacy for Prevention of HZ in Shingles Prevention Study\*

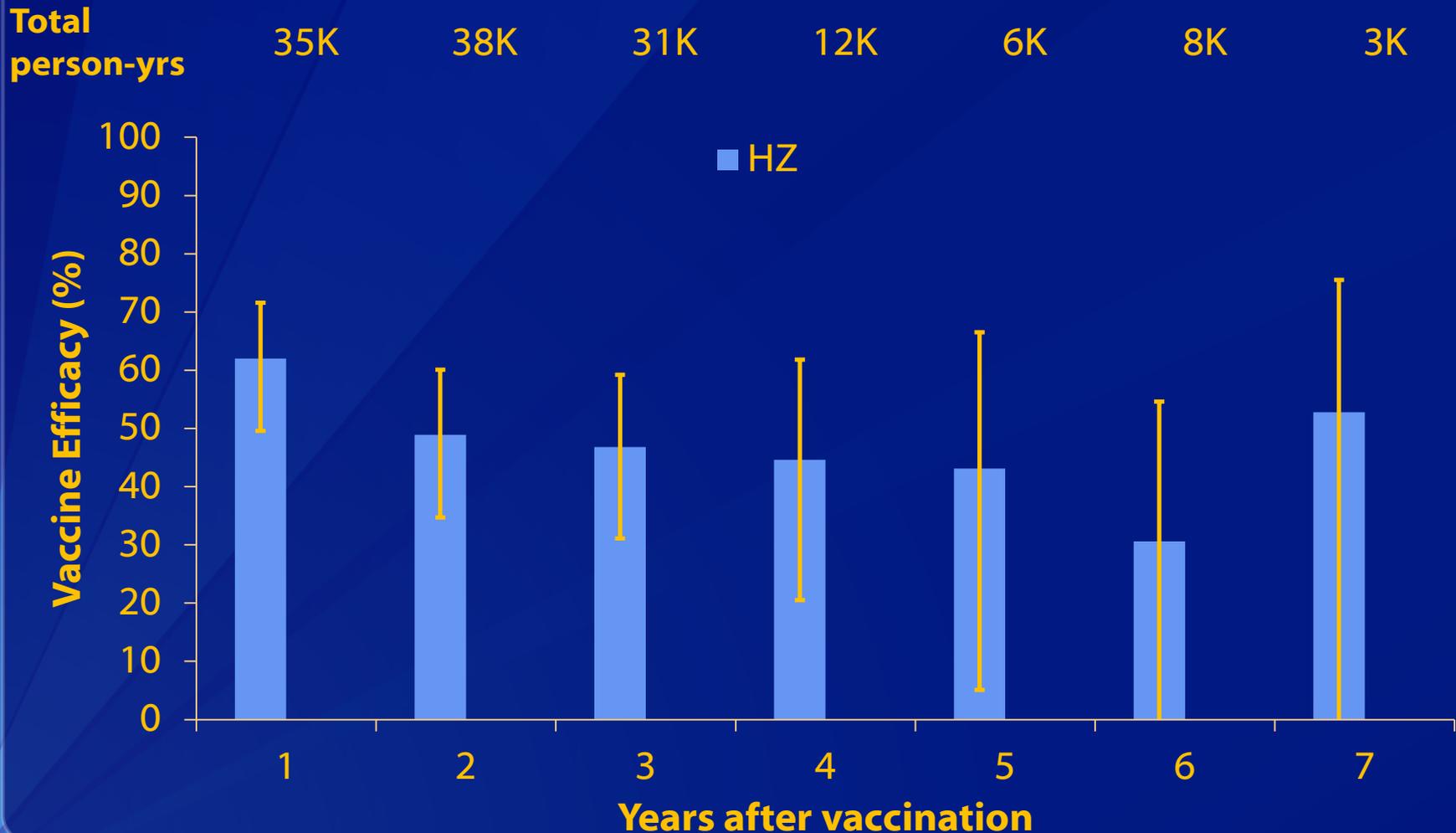


\*Mean follow up time 3.1 y

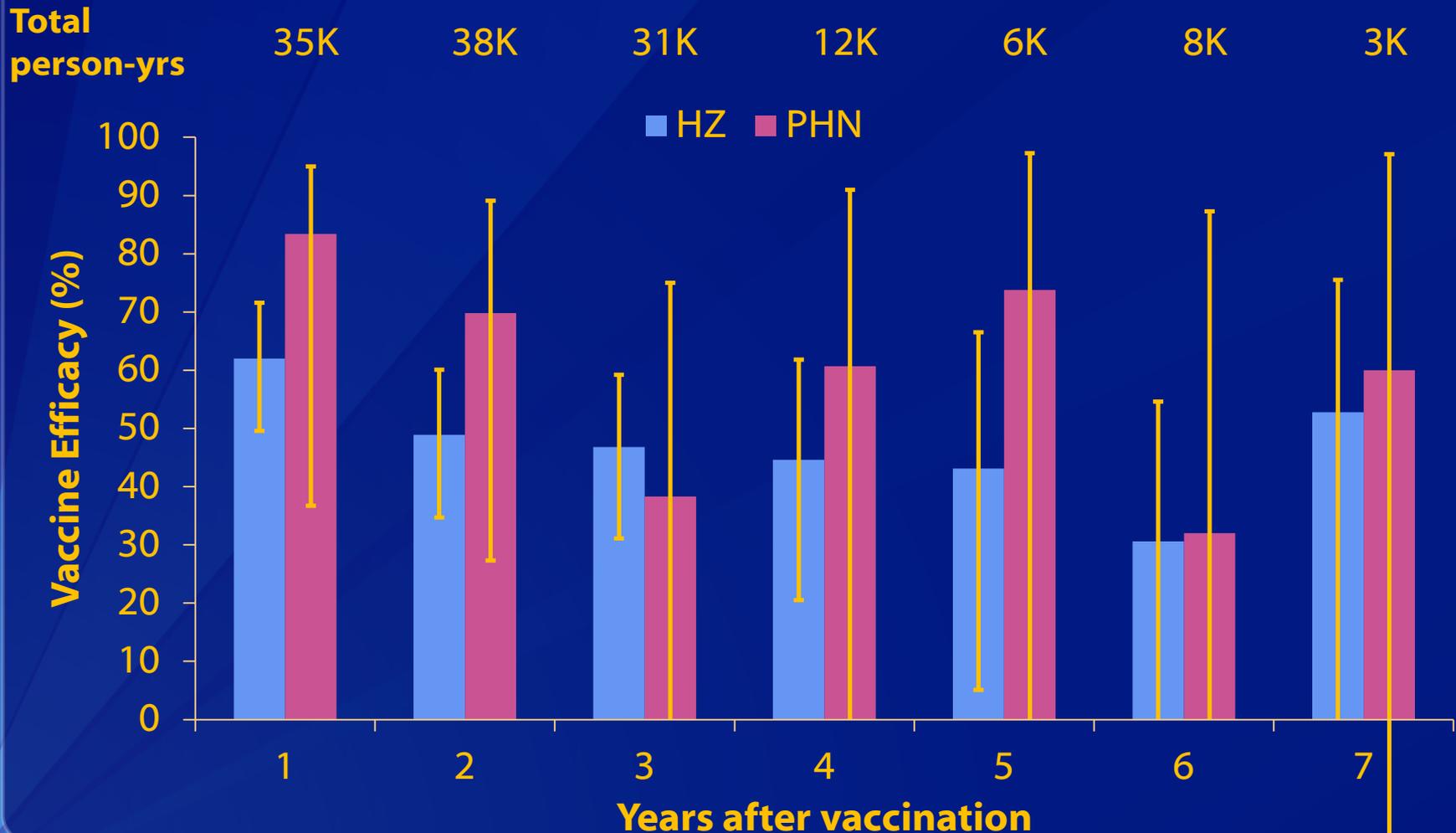
# Vaccine Efficacy Against PHN in Subjects who Develop HZ Post-Vaccination



# Short Term Vaccine Efficacy for Prevention of HZ in Adults $\geq 60$ Years of Age



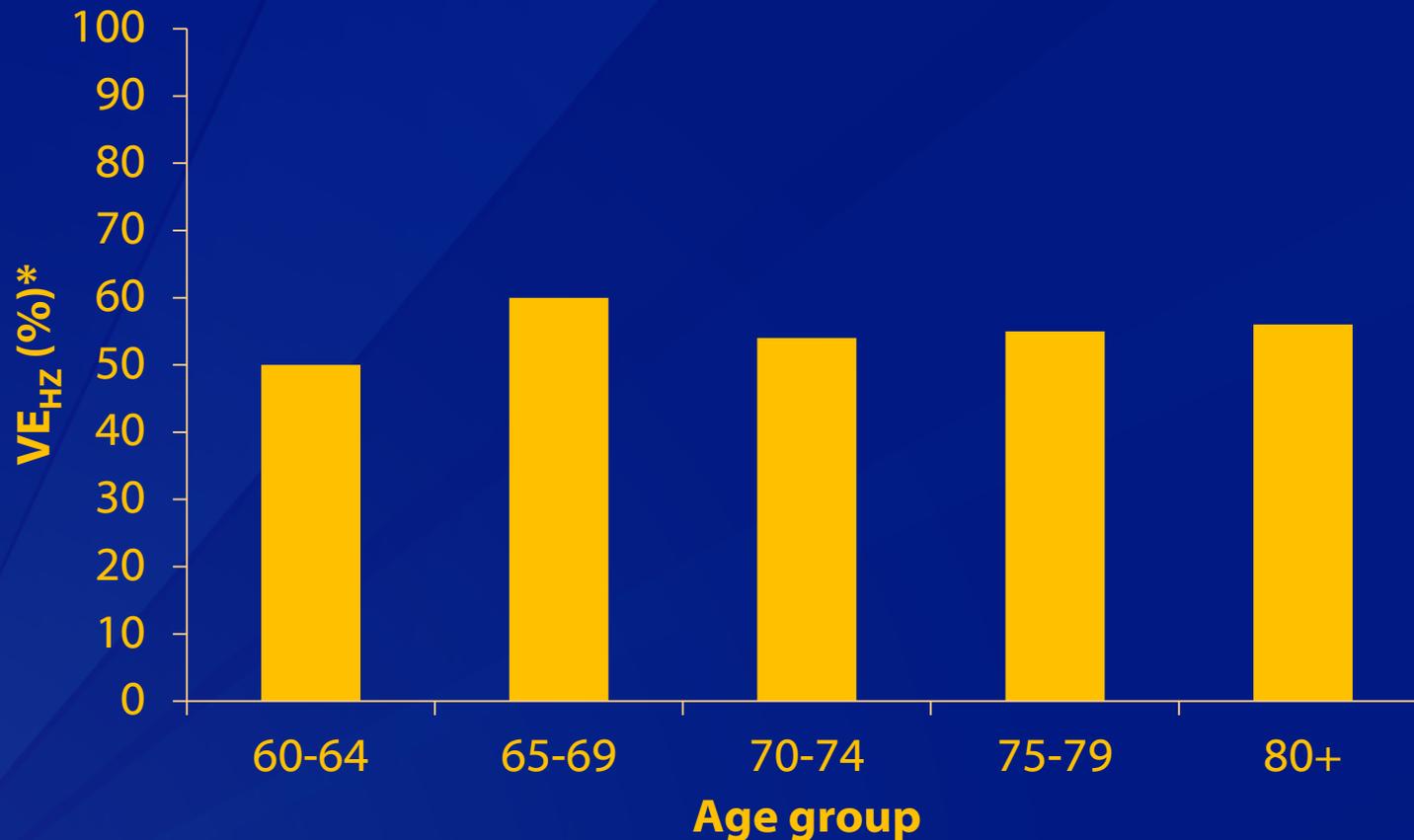
# Short Term Vaccine Efficacy for Prevention of HZ and PHN in Adults $\geq 60$ Years of Age



# Short Term Vaccine Effectiveness in Adults $\geq 60$ Years of Age

Health Maintenance Organization (HMO) (Tseng 2011)	Medicare (Langan 2013)
303K individuals	766K individuals
Mean follow up time: $\approx 1.6$ years	Mean follow up time: $\approx 2$ years
VE for prevention of HZ = 55% (95% CI, 52 to 58)	VE for prevention of HZ = 48% (95% CI, 39 to 56)
VE for prevention of HZ-related hospitalization = 65% (95% CI, 49 to 76)	VE for prevention of PHN = 59% (95% CI, 21 to 79)

# Short term Vaccine Effectiveness for Prevention of HZ in an HMO

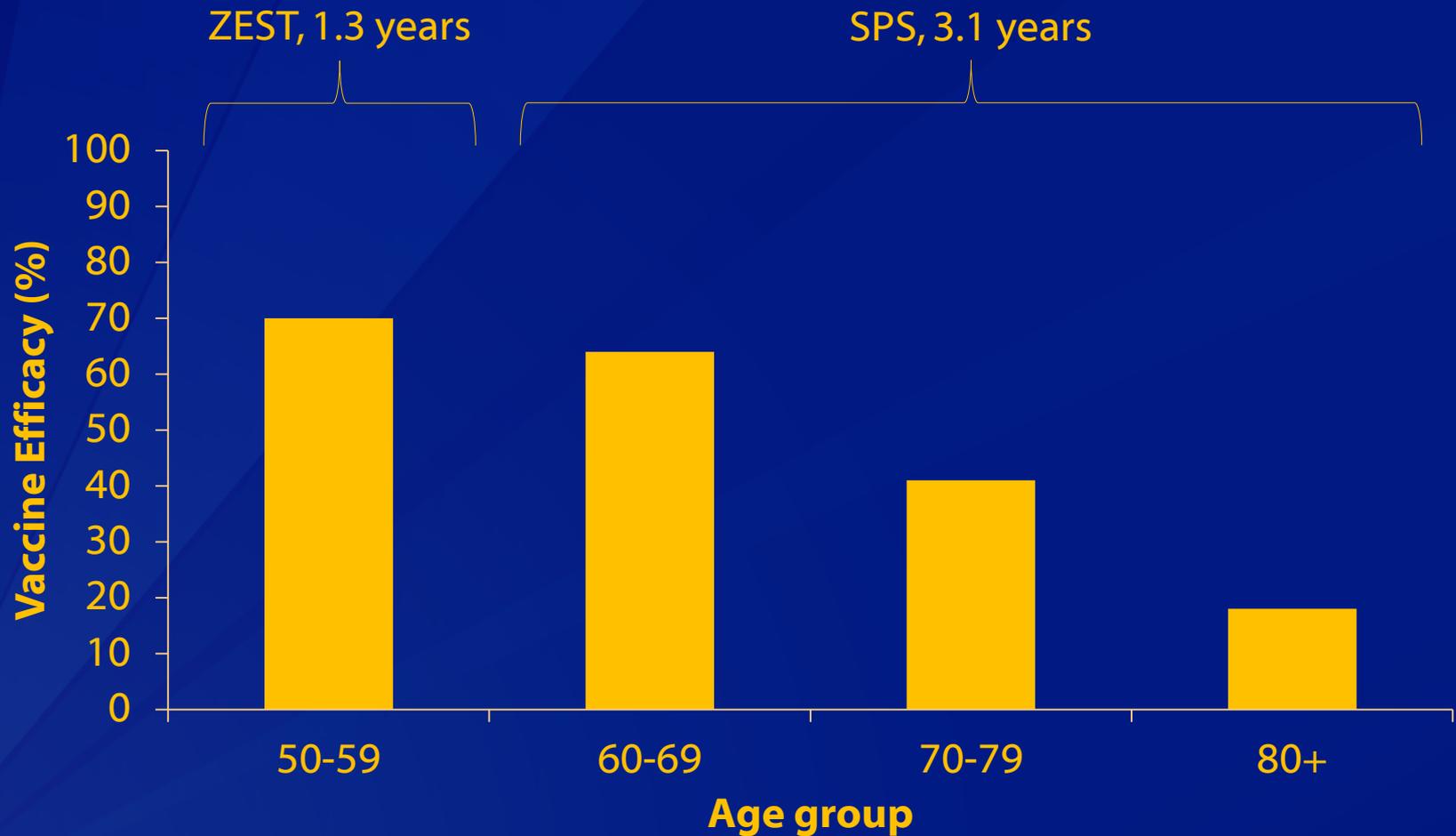


# Short Term Vaccine Efficacy in Adults 50-59 Years of Age

## □ ZEST Clinical trial

- RCT, 22.4K subjects
- Mean follow up time: 1.3 years
- Vaccine efficacy for prevention of HZ: 70%
- Vaccine efficacy for prevention of postherpetic neuralgia not studied

# Short term Vaccine Efficacy for Prevention of HZ in Clinical Trials



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