

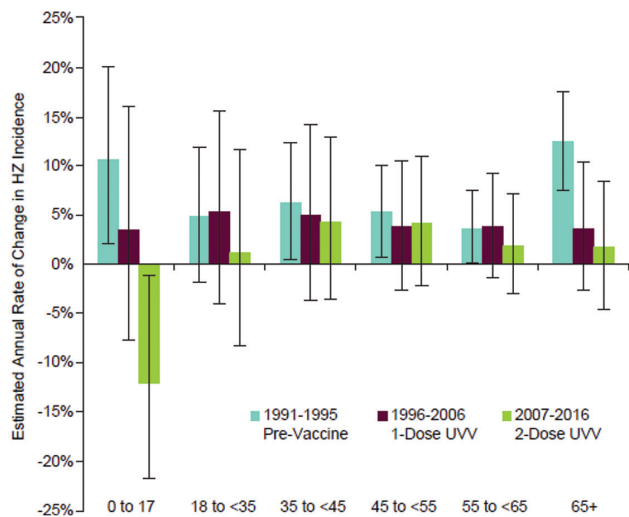
and the evidence to evaluate it is limited. Dynamic transmission model outcomes of impact and cost-effectiveness of universal varicella vaccination (UVV) are sensitive to EB characterization and assumptions, occasionally leading to conclusions that UVV programs may not be cost-effective and could lead to temporary increases in HZ incidence. The goal of this study was to use data from 20 years of UVV in the United States from 1996 to 2016 to evaluate whether the hypothesized increases in HZ incidence have been realized.

**Methods.** This is a retrospective study of de-identified administrative claims data from the US MarketScan® databases between 1991 and 2016. The incidence of HZ was analyzed by calendar year and age category using interrupted time series (ITS) analysis implemented through a negative binomial generalized linear regression model over three time periods: pre-UVV (1991–1995); 1 dose UVV (1996–2006); and 2 dose UVV (2007–2016). The ITS approach (Bernal et al., IJE, 2017) is an effective way to evaluate the impact of public health interventions implemented at specific time points.

**Results.** HZ incidence in the pre-UVV period increased at annual rates between 3.67% and 12.38%, with the highest increases in the 0–17 and 65+ age groups. The rate of HZ increase was lower in the 1 dose UVV period compared with the pre-UVV period for all age groups except for minor increases in the 18–35 (0.52%) and 55–65 (0.14%) groups. During the 2 dose UVV period, the rate of increase in HZ was lower in all groups than in the pre-UVV period, with the largest reductions in the 0–17 (–22.58%), 65+ (–10.68%), and 18–<35 (–3.57%) age groups.

**Conclusion.** This evaluation of the impact of UVV on rates of change in HZ does not support the hypothesis of an increase in HZ incidence due to UVV. While overall HZ incidence rates have been increasing year on year, the rate of that increase has been declining in both UVV periods. Our findings have implications on the assumptions used in economic evaluations of UVV programs.

**Figure 1: Rate of change in herpes zoster incidence by age groups before and during the implementation of one- and two-dose universal varicella vaccination (UVV) in the United States 1991–2016**



**Disclosures.** L. Wolfson, Merck & Co., Inc.: Employee and Shareholder, Salary. V. Daniels, Merck & Co., Inc.: Employee and Shareholder, Salary. Y. T. Chen, Merck & Co., Inc.: Employee and Shareholder, Salary. W. Ou, Merck & Co., Inc.: Employee and Shareholder, Salary.

**2479. Varicella Zoster Immune Globulin Is Effective up to 10 Days Following Varicella Exposure in Pregnant Women, Immunocompromised Patients, and Infants: Results From a Large, Open-Label Expanded-Access Program**  
Myron Levin, MD, FIDSA<sup>1</sup>; Jennifer Duchon, MDCM, MPH<sup>2</sup> and Geeta K. Swamy, MD<sup>3</sup>; <sup>1</sup>University of Colorado Denver Anschutz Medical Campus, Aurora, Colorado, <sup>2</sup>Tufts Floating Hospital for Children, Boston, Massachusetts, <sup>3</sup>Duke University, Durham, North Carolina

**Session:** 253. Vaccines for Herpes Zoster Virus  
*Saturday, October 6, 2018: 12:30 PM*

**Background.** There are more than 300,000 cases of varicella annually; nonimmune individuals exposed to varicella-zoster (VZ) virus have a high likelihood of developing varicella. VZ immune globulin (VARIZIG<sup>®</sup>) is used for postexposure prophylaxis to prevent or attenuate VZ infection in high-risk individuals. We assessed varicella incidence and severity in high-risk subjects after administration of VZ immune globulin.

**Methods.** This open-label expanded-access program provided VZ immune globulin to physician-identified, high-risk subjects exposed to varicella. Subjects included immunocompromised children/adults, infants (including preterm infants, newborns whose mothers had VZ infection <5 days before or <2 days after delivery, and infants <1 year of age), and pregnant women. VZ immune globulin (125 IU/10 kg [up to 625 IU]) was administered intramuscularly, ideally ≤96 hours, but up to 10 days,

postexposure. Incidence of varicella rash and severity (>100 pox, pneumonia, encephalitis) were assessed up to 42 days after administration.

**Results.** The efficacy population (n = 505) included 263 immunocompromised subjects (32 adults, 231 pediatric), 137 pregnant women, and 105 infants. More than 97% of exposures fit the CDC definition. Varicella incidence was low in immunocompromised subjects (4.5%, n = 12/269), pregnant women (7.3%, n = 10/137), and infants (11.4%, n = 12/105) and was similar when comparing administration ≤ 96 hours vs. up to 10 days postexposure (6.2% vs. 9.4%, respectively). Of 34 subjects with varicella, 54% were exposed in the household; 5 were considered severe. Common adverse events were pyrexia (4%), neutropenia (3%), and headache (3%). There were no product-related deaths and only 1 serious adverse event (serum sickness) considered probably related to VZ immune globulin.

**Conclusion.** Postexposure administration of VZ immune globulin resulted in low rates of varicella in high-risk subjects, regardless of administration timing within 10 days postexposure. VZ immune globulin—which is FDA-approved, recommended by the CDC, and widely available—was well tolerated and safe in high-risk subjects.

**Disclosures.** M. Levin, Merck: Consultant and Scientific Advisor, Consulting fee and Research support. GlaxoSmithKline: Consultant and Scientific Advisor, Consulting fee and Research support. Saol Therapeutics: Consultant and Scientific Advisor, Consulting fee. J. Duchon, Saol Therapeutics: Consultant and Scientific Advisor, Consulting fee. G. K. Swamy, Saol Therapeutics: Consultant and Scientific Advisor, Consulting fee.

**2480. Real-World Effectiveness of the Live Zoster Vaccine in Preventing Herpes Zoster: A Systematic Review**

Patricia Saddier, MD, PhD<sup>1</sup>; Morgan A. Marks, PhD<sup>1</sup>; Shawna Calhoun, MPH<sup>1</sup>; Kelly Johnson, PhD, MPH<sup>1</sup> and Yola Moride, PhD, FISPE<sup>2</sup>; <sup>1</sup>Merck & Co., Inc., Center for Observational and Real-World Evidence, Kenilworth, New Jersey, <sup>2</sup>YOLARX Consultants, Montreal, QC, Canada

**Session:** 253. Vaccines for Herpes Zoster Virus  
*Saturday, October 6, 2018: 12:30 PM*

**Background.** Several studies of the real-world effectiveness of Zostavax<sup>™</sup>, a live zoster vaccine (ZVL), have been published since its licensure in 2006. The objective of this review was to summarize available evidence on vaccine effectiveness (VE) of ZVL against herpes zoster (HZ) and post-herpetic neuralgia (PHN) in the general population.

**Methods.** An extensive literature search was performed in Embase and Medline for the period January 2007 to January 2018 to identify peer-reviewed, original, English study manuscripts reporting the results of observational studies of ZVL VE. In all studies, HZ cases were identified from HZ diagnosis codes, with only two studies also requiring HZ-specific antiviral use. For PHN, different case definitions were used across studies, usually without validation from medical chart review.

**Results.** Seven original effectiveness studies were identified (5 from the United States and 1 each from the UK and Canada) that assessed HZ effectiveness in the general population. Five of these studies also assessed PHN effectiveness. Vaccine effectiveness to prevent HZ was similar across studies in the early years following vaccination, but tended to diverge in the later years (overall VE against HZ ranged from 33% to 62%, clustering around ~50% across studies providing this information). Overall VE against PHN ranged from 55% to 88%, clustering around ~65%.

**Conclusion.** Real-world observational studies assessing the effectiveness of ZVL in preventing HZ and PHN in the general population reported generally similar results. Differences in VE estimates across studies were likely driven by differences in study design and methods, including sample size and age of study population, HZ and PHN case definition, duration of follow-up, and methods of covariate selection, definition and adjustment. We are currently conducting a meta-analysis to identify and quantify the potential heterogeneity across studies and calculate summary VE estimates.

**Disclosures.** P. Saddier, Merck and Co. Inc.: Employee and Shareholder, Salary. M. A. Marks, Merck and Co. Inc.: Employee and Shareholder, Salary. S. Calhoun, Merck and Co. Inc.: Employee, Salary. K. Johnson, Merck & Co., Inc.: Employee, Salary. Y. Moride, Merck: Research Contractor, Consulting fee.

**2481. Impact of Sex and Race/Ethnicity on the Effectiveness of Live Zoster Vaccine**  
Morgan A. Marks, PhD<sup>1</sup>; Joan Bartlett, MPH, MPP<sup>2</sup>; Bruce Fireman, MA<sup>2</sup>; John Hansen, MPH<sup>2</sup>; Ned Lewis, MPH<sup>3</sup>; Laurie Aukes, RN<sup>2</sup>; Patricia Saddier, MD, PhD<sup>1</sup> and Nicola P. Klein, MD, PhD<sup>3</sup>; <sup>1</sup>Pharmacoepidemiology Department, Merck & Co., Inc., Kenilworth, New Jersey, <sup>2</sup>Kaiser Permanente Vaccine Study Center, Oakland, California, <sup>3</sup>Division of Research, Kaiser Permanente Vaccine Study Center, Oakland, California

**Session:** 253. Vaccines for Herpes Zoster Virus  
*Saturday, October 6, 2018: 12:30 PM*

**Background.** Zostavax<sup>™</sup>, a live zoster vaccine licensed as 1 dose, is indicated in the United States for the prevention of herpes zoster (HZ) in people 50 years or older. Real-world vaccine effectiveness (VE) and duration of protection are being evaluated in an ongoing study. Compared with randomized clinical trials, this large observational study includes a more diverse population and offers a unique opportunity to assess VE across sex and race/ethnic groups.

**Methods.** Kaiser Permanente Northern California members enter the ongoing cohort study when age-eligible for zoster vaccine, starting in 2007. Incident HZ is defined as a new HZ diagnosis accompanied by an antiviral prescription or a positive varicella-zoster virus test, with no HZ diagnosis in the preceding 12 months. VE by sex