



Zoster Vaccines Session: Summary of the Herpes Zoster Work Group's Interpretation of Recombinant Zoster Vaccine Safety Data

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LCDR Tara Anderson, DVM, MPH, PhD
CDC Lead, Herpes Zoster Work Group

Post-licensure Safety Monitoring of Recombinant Zoster Vaccine (RZV)

- **Vaccine Adverse Event Reporting System (VAERS)**
 - Serious adverse events rarely reported for RZV
 - RZV post-licensure safety monitoring findings in VAERS generally consistent with safety profile observed in pre-licensure clinical trials
- **Vaccine Safety Datalink (VSD) rapid cycle analysis (Jan 2018 – Dec 2019)**
 - Elevated risk for Guillain-Barré syndrome (GBS) based on ICD-9/10 codes attenuated over time, from a RR of 5.25 (at time of preliminary signal) to a RR of 1.24 (at end of 2-year surveillance period)
 - Chart-confirmed GBS case analysis:
 - RR = 1.55 (95% CI: 0.17, 18.60) [assuming 2 cases in Zostavax recipients]
 - RR = 1.03 (95% CI: 0.14, 7.73) [assuming 3 cases in Zostavax recipients]

FDA Assessments of the Risk of GBS following RZV in Medicare Data, in Collaboration with CDC and CMS

- **Cohort analysis comparing post-vaccination GBS rate between RZV and historical Zostavax (ZVL) controls among persons 65 years or older**
 - RZV vaccination window: Oct 2017 – Dec 2018
 - ZVL vaccination window: Oct 2012 – Sep 2017
 - Elevated adjusted RR = 2.34 (95% CI: 1.01, 5.41)
- **Claims based self-controlled case series analyses**
 - Primary analysis: RR = 4.30 (95% CI: 1.76, 10.53)
 - Medical record review analysis: RR = 4.96 (95% CI: 1.43, 17.27)
 - Extended analysis: RR = 2.84 (95% CI: 1.53, 5.27)

Risk of GBS following Herpes Zoster

- Possible temporal association between herpes zoster (HZ) and GBS noted in small number of case reports
- One previous epidemiologic study (Kang, Sheu, and Lin, 2010) reported an increased risk of GBS following recent HZ
- CDC self-controlled case series analysis using two different administrative data sources
 - Increased risk of GBS 1–42 days following HZ compared to primary control window of 100–365 days following HZ
 - 18–64 years (IBM MarketScan[®]): RR = 6.3 (95% CI: 1.8, 21.9)
 - 65 years and older (CMS Medicare): RR = 4.1 (95% CI: 1.9, 8.7)

RZV Risk-Benefit Analysis

- **Evaluated tradeoffs between benefits of averted cases of HZ and complications and risks of rare adverse events**
- **Estimated outcomes per 1,000,000 vaccinated individuals**
 - Averted cases of HZ, postherpetic neuralgia (PHN), other complications (e.g., GBS)
 - Rare adverse events (e.g., GBS)
- **Limited data for risk of GBS following HZ and vaccination**
- **Projected cases of GBS sensitive to parameter uncertainty**
- **Estimates of averted cases of HZ, complications, and deaths rely on published data and less sensitive to changes in parameter inputs**

Summary of Herpes Zoster Work Group Discussions

- **Clinical trials, observational studies, and the risk-benefit analysis confirm the considerable benefits of RZV vaccination in preventing HZ, severe disease, and complications**
- **GBS is rare, and data on the risk of GBS following HZ and vaccination are limited**
- **Based on available data, there was consensus among the work group that:**
 - No change to the current zoster vaccination recommendation is warranted at this time
 - Continued safety monitoring of RZV in VAERS and VSD is warranted

Thank You

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

