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

ACIP Meeting
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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
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)

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.