



Zoster Vaccine Session: Summary and planned risk-benefit analysis regarding use of RZV in immunocompetent adults

ACIP Meeting

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Post-licensure Safety Monitoring of RZV

■ VAERS

- Serious adverse events rarely reported
- RZV post-licensure safety monitoring findings in VAERS generally consistent with safety profile observed in pre-licensure clinical trials

■ VSD rapid cycle analysis (Jan 2018 – Dec 2019)

- Chart-confirmed GBS case analysis
 - RR = 1.55 (95% CI: 0.17, 18.60) [assuming 2 ZVL cases]
 - RR = 1.03 (95% CI: 0.14, 7.73) [assuming 3 ZVL cases]
- VSD has insufficient evidence to determine if there is an increased risk of GBS

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 ZVL controls among persons 65 years or older**
 - RZV vaccination window: Oct 2017 – Dec 2018
 - ZVL vaccination window: Oct 2012 – Sep 2017
 - Elevated adjusted rate ratio = 2.34 (95% CI 1.01, 5.41)
- **FDA has additional results available from the claims based self-controlled analysis and medical record review self-controlled analysis**
 - Results are currently under review at FDA, and will be shared at a future ACIP meeting

Risk of GBS following Herpes Zoster

- Possible temporal association between 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-led self-controlled case series analysis
 - Increased risk of GBS 1–42 days following HZ compared to primary control window
 - Across adult age groups, in two different administrative data sources

Summary of Herpes Zoster Work Group (HZWG) Discussions

- **HZWG currently reviewing evidence regarding use of RZV in immunocompromised adults**
- **HZWG reviewing and discussing findings regarding possible risk of GBS following both disease and vaccination, and agree that**
 - Continued safety monitoring of RZV in VAERS and VSD is warranted
 - A dynamic risk-benefit assessment that incorporates new data on risk of GBS associated with disease and vaccination will inform recommendations on use of RZV in immunocompetent and immunocompromised adults

Planned Risk-Benefit Analysis regarding Use of RZV in Immunocompetent Adults

- Evaluate benefits of averted HZ cases and complications vs. risks of adverse events
- Will collaborate with SMEs and HZWG on model parameters and scenarios
- Outcomes per 1,000,000 vaccinated individuals to be estimated
 - Episodes of HZ
 - Episodes of postherpetic neuralgia, other HZ complications (e.g., GBS)
 - Injection site reactions
 - Systemic reactions
 - Rare adverse events (e.g., GBS)

Next Steps

- **Discussion of today's presentations**
- **Future ACIP meeting presentations**
 - FDA assessment of the risk of GBS following RZV in Medicare data
 - Risk-benefit analysis results regarding use of RZV in immunocompetent adults
 - RZV use in immunocompromised adults

Questions for ACIP

- **Any other suggested follow up regarding RZV safety monitoring?**
- **Any feedback on planned risk-benefit analysis for use of RZV in immunocompetent adults, particularly any other outcomes of interest?**

Thank You!

For more information, contact CDC
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