Update on post-licensure safety monitoring of recombinant zoster vaccine (RZV, Shingrix)

February 2019 Advisory Committee on Immunization Practices (ACIP) meeting

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Disclaimer

- The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of CDC and FDA
- The use of product trade names is for identification purposes only

Recombinant Zoster Vaccine (RZV)

- Adjuvanted ($AS01_B$) glycoprotein vaccine
- Licensed by FDA in October 2017
- Preferentially recommended by ACIP for adults ≥50 years in October 2017
  - Previously-licensed live-attenuated zoster vaccine (ZVL, Zostavax) is recommended for adults ≥60 years
- 85% of vaccinated study participants in pre-licensure clinical trials reported local or systemic reactions
  - 17% experienced grade 3 reactions*
- Rates of serious adverse events similar between RZV and placebo groups

*Erythema or induration >3.5 inches or systemic symptoms that interfere with normal activity

Vaccine safety monitoring and research terms

Term	Explanation
Adverse event	An adverse medical or health event following vaccination (a temporally associated event), which may or may not be related to vaccination (i.e., coincidental).
Adverse reaction	An adverse health event following vaccination where substantial evidence exists to suggest the event is causally related to vaccination.
MedDRA	A clinically-validated international medical terminology used by regulatory authorities to describe health outcomes and events.
ICD-10 and 9	A system used by physicians and other healthcare providers to classify and code diagnoses, symptoms and procedures associated with healthcare.
Automated analysis	Analysis on administrative or claims data or non-chart/health record confirmed data.
Chart confirmed/medical record confirmed case	A case where review of medical charts and records by physicians or medical personnel confirms the diagnosis as valid and with accurate onset relative to timing of vaccination.
Incident case	A new case occurring for the first time ever or during a specified time period.
Historical/prevalent case	A case that has been diagnosed in the past prior to vaccination or prior the study period that has become part of the patient's past medical history and therefore is not new.
Biologically plausible risk interval	The time interval following vaccination where it is biologically plausible, based on the best available science, that an observed adverse event could be related to vaccination.
Statistical signal	A finding from an analysis where a calculated value (i.e., the test statistic) exceeds a specified statistical threshold; a statistical signal does not necessarily represent a vaccine safety problem and requires further assessment before conclusions can be drawn.

Overview

- Post-licensure safety monitoring of recombinant zoster vaccine (RZV, Shingrix) during initial uptake period
  - Vaccine Adverse Event Reporting System (VAERS) monitoring
  - Vaccine Safety Datalink (VSD) Rapid Cycle Analysis (RCA)
  - Next steps

Vaccine Adverse Event Reporting System (VAERS) monitoring for recombinant zoster vaccine (RZV)

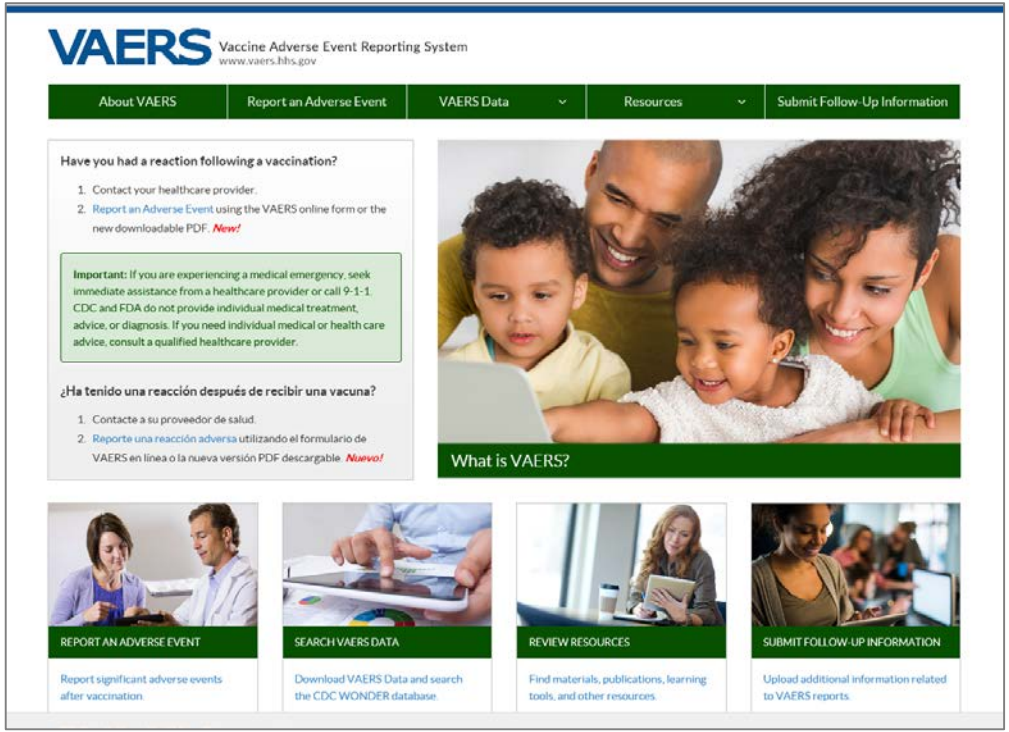
Vaccine safety monitoring

VAERS

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

https://vaers.hhs.gov



Vaccine Adverse Event Reporting System (VAERS)*

Strengths

- National data
- Accepts reports from anyone
- Rapidly detects safety signals
- Can detect rare adverse events
- Data available to public

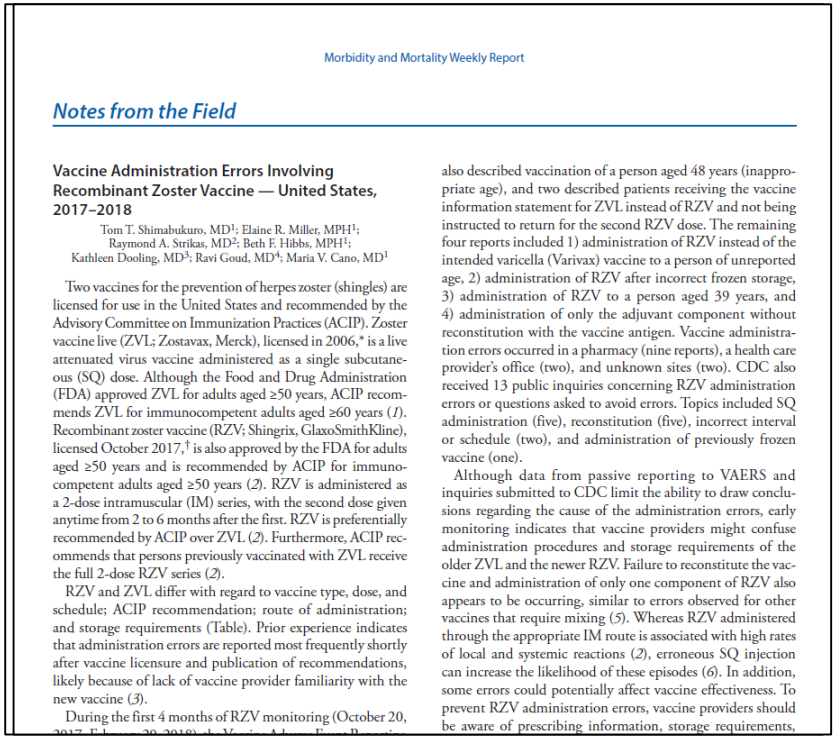
Limitations

- Reporting bias
- Inconsistent data quality and completeness
- Lack of unvaccinated comparison group
- Generally cannot assess causality

As a hypothesis generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

*Co-managed by CDC and FDA (https://vaers.hhs.gov)

Post-licensure safety monitoring publications for RZV



Morbidity and Mortality Weekly Report

Notes from the Field

Vaccine Administration Errors Involving Recombinant Zoster Vaccine — United States, 2017–2018

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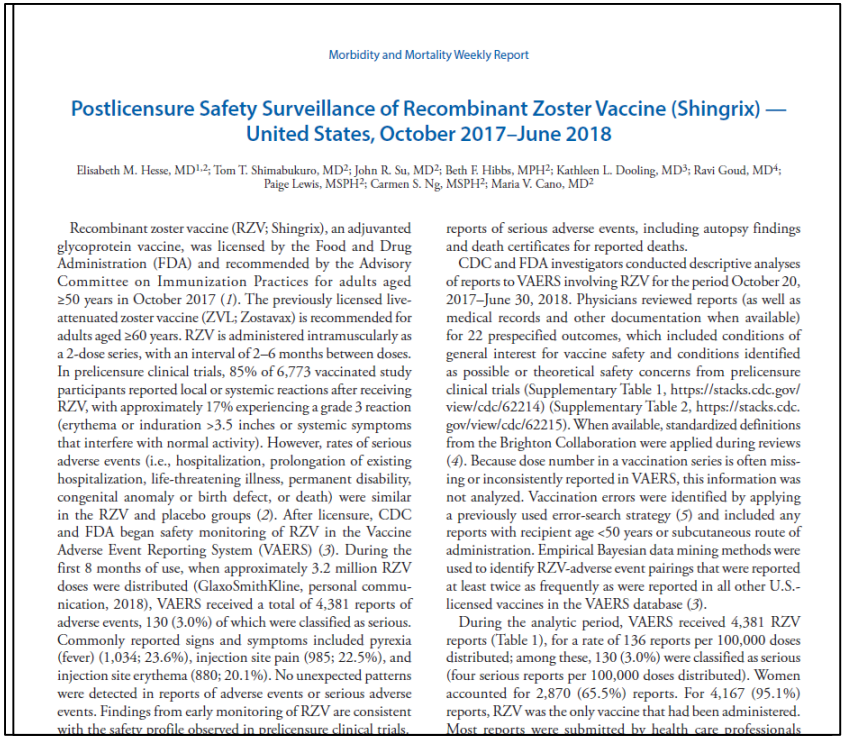
Two vaccines for the prevention of herpes zoster (shingles) are licensed for use in the United States and recommended by the Advisory Committee on Immunization Practices (ACIP). Zoster vaccine live (ZVL; Zostavax, Merck), licensed in 2006,* is a live attenuated virus vaccine administered as a single subcutaneous (SQ) dose. Although the Food and Drug Administration (FDA) approved ZVL for adults aged ≥50 years, ACIP recommends ZVL for immunocompetent adults aged ≥60 years (*1*). Recombinant zoster vaccine (RZV; Shingrix, GlaxoSmithKline), licensed October 2017,† is also approved by the FDA for adults aged ≥50 years and is recommended by ACIP for immunocompetent adults aged ≥50 years (*2*). RZV is administered as a 2-dose intramuscular (IM) series, with the second dose given anytime from 2 to 6 months after the first. RZV is preferentially recommended by ACIP over ZVL (*2*). Furthermore, ACIP recommends that persons previously vaccinated with ZVL receive the full 2-dose RZV series (*2*).

RZV and ZVL differ with regard to vaccine type, dose, and schedule; ACIP recommendation; route of administration; and storage requirements (Table). Prior experience indicates that administration errors are reported most frequently shortly after vaccine licensure and publication of recommendations, likely because of lack of vaccine provider familiarity with the new vaccine (*3*).

During the first 4 months of RZV monitoring (October 20, 2017–February 28, 2018), the Vaccine Adverse Event Reporting System also described vaccination of a person aged 48 years (inappropriate age), and two described patients receiving the vaccine information statement for ZVL instead of RZV and not being instructed to return for the second RZV dose. The remaining four reports included 1) administration of RZV instead of the intended varicella (Varivax) vaccine to a person of unreported age, 2) administration of RZV after incorrect frozen storage, 3) administration of RZV to a person aged 39 years, and 4) administration of only the adjuvant component without reconstitution with the vaccine antigen. Vaccine administration errors occurred in a pharmacy (nine reports), a health care provider's office (two), and unknown sites (two). CDC also received 13 public inquiries concerning RZV administration errors or questions asked to avoid errors. Topics included SQ administration (five), reconstitution (five), incorrect interval or schedule (two), and administration of previously frozen vaccine (one).

Although data from passive reporting to VAERS and inquiries submitted to CDC limit the ability to draw conclusions regarding the cause of the administration errors, early monitoring indicates that vaccine providers might confuse administration procedures and storage requirements of the older ZVL and the newer RZV. Failure to reconstitute the vaccine and administration of only one component of RZV also appears to be occurring, similar to errors observed for other vaccines that require mixing (*5*). Whereas RZV administered through the appropriate IM route is associated with high rates of local and systemic reactions (*2*), erroneous SQ injection can increase the likelihood of these episodes (*6*). In addition, some errors could potentially affect vaccine effectiveness. To prevent RZV administration errors, vaccine providers should be aware of prescribing information, storage requirements,

https://www.cdc.gov/mmwr/volumes/67/wr/mm6720a4.htm?s_cid=mm6720a4_w



Morbidity and Mortality Weekly Report

Postlicensure Safety Surveillance of Recombinant Zoster Vaccine (Shingrix) — United States, October 2017–June 2018

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Recombinant zoster vaccine (RZV; Shingrix), an adjuvanted glycoprotein vaccine, was licensed by the Food and Drug Administration (FDA) and recommended by the Advisory Committee on Immunization Practices for adults aged ≥50 years in October 2017 (*1*). The previously licensed live-attenuated zoster vaccine (ZVL; Zostavax) is recommended for adults aged ≥60 years. RZV is administered intramuscularly as a 2-dose series, with an interval of 2–6 months between doses. In prelicensure clinical trials, 85% of 6,773 vaccinated study participants reported local or systemic reactions after receiving RZV, with approximately 17% experiencing a grade 3 reaction (erythema or induration >3.5 inches or systemic symptoms that interfere with normal activity). However, rates of serious adverse events (i.e., hospitalization, prolongation of existing hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death) were similar in the RZV and placebo groups (*2*). After licensure, CDC and FDA began safety monitoring of RZV in the Vaccine Adverse Event Reporting System (VAERS) (*3*). During the first 8 months of use, when approximately 3.2 million RZV doses were distributed (GlaxoSmithKline, personal communication, 2018), VAERS received a total of 4,381 reports of adverse events, 130 (3.0%) of which were classified as serious. Commonly reported signs and symptoms included pyrexia (fever) (1,034; 23.6%), injection site pain (985; 22.5%), and injection site erythema (880; 20.1%). No unexpected patterns were detected in reports of adverse events or serious adverse events. Findings from early monitoring of RZV are consistent with the safety profile observed in prelicensure clinical trials. reports of serious adverse events, including autopsy findings and death certificates for reported deaths.

CDC and FDA investigators conducted descriptive analyses of reports to VAERS involving RZV for the period October 20, 2017–June 30, 2018. Physicians reviewed reports (as well as medical records and other documentation when available) for 22 prespecified outcomes, which included conditions of general interest for vaccine safety and conditions identified as possible or theoretical safety concerns from prelicensure clinical trials (Supplementary Table 1, https://stacks.cdc.gov/view/cdc/62214) (Supplementary Table 2, https://stacks.cdc.gov/view/cdc/62215). When available, standardized definitions from the Brighton Collaboration were applied during reviews (*4*). Because dose number in a vaccination series is often missing or inconsistently reported in VAERS, this information was not analyzed. Vaccination errors were identified by applying a previously used error-search strategy (*5*) and included any reports with recipient age <50 years or subcutaneous route of administration. Empirical Bayesian data mining methods were used to identify RZV-adverse event pairings that were reported at least twice as frequently as were reported in all other U.S.-licensed vaccines in the VAERS database (*3*).

During the analytic period, VAERS received 4,381 RZV reports (Table 1), for a rate of 136 reports per 100,000 doses distributed; among these, 130 (3.0%) were classified as serious (four serious reports per 100,000 doses distributed). Women accounted for 2,870 (65.5%) reports. For 4,167 (95.1%) reports, RZV was the only vaccine that had been administered. Most reports were submitted by health care professionals

https://www.ncbi.nlm.nih.gov/pubmed/30703077

Methods: VAERS monitoring

- Descriptive analysis of RZV reports received Oct 20, 2017-Dec 31, 2018
  - Signs, symptoms, and diagnoses coded using Medical Dictionary for Regulatory Activities (MedDRA) terms
- Reporting rates (based on 8.59 million RZV doses distributed for the U.S. market, courtesy GSK)
- Empirical Bayesian data mining to detect disproportional reporting for vaccine-adverse event pairings
- Clinical review of reports (includes medical records when available):
  - 22 pre-specified outcomes

Pre-specified outcomes (based on pre-licensure trials and ZVL reports)

- Acute myocardial infarction
- Amyotrophic lateral sclerosis
- Anaphylaxis
- Autoimmune disorders
- Autoimmune vasculitis
- Bell's Palsy
- Co-administration with another adjuvanted vaccine
- Death
- Gout
- Guillain-Barré syndrome
- Herpes zoster
- Idiopathic thrombocytopenia
- Inflammatory eye disease
- Lymphadenitis
- Meningitis
- Neuropathy
- Optic ischemic neuropathy
- Osteonecrosis
- Post-herpetic neuralgia
- Seizures / convulsions
- Stroke / CVA
- Supraventricular tachyarrhythmias

Reports to VAERS following RZV

- Reporting rates (based on 8.59 million doses distributed)
  - All reports: 167 per 100,000 doses distributed
  - Serious reports*: 4 per 100,000 doses distributed

Report characteristics	N (%)
Total reports	14,381
Female	9694 (67.4)
Non-serious	14,029 (97.6)
Type of reporter	
Manufacturer	5196 (36.1)
Healthcare professional	5179 (36.0)
Patient	3201 (22.3)
Other	805 (5.6)
Age groups (years)	
<50†	72 (0.5)
50-59	2919 (20.3)
60-69	4947 (34.3)
70-79	3166 (22.0)
80+	873 (6.1)
Not reported or unknown	2404 (16.7)
RZV given alone	13,465 (93.6)

*Based on the Code of Federal Regulations if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization or permanent disability (FDA routinely reviews all serious reports)

†RZV not approved for use in <50 y/o

Most common signs and symptoms in reports to VAERS following RZV and review of pre-specified outcomes

Signs and symptoms (MedDRA Preferred Terms)*	14,381 total reports n (%)
Pyrexia (fever)	3619 (25.2)
Chills	3005 (20.9)
Injection site pain	2973 (20.7)
Pain	2864 (19.9)
Headache	2681(18.6)
Injection site erythema	2432 (16.9)
Pain in extremity	2301 (16.0)
Fatigue	2300 (16.0)
Myalgia	1705 (11.9)
Injection site swelling	1666 (11.6)

*Not mutually exclusive; a report may contain more than one MedDRA Preferred Term

- Systemic signs and symptoms and injection site reactions were the most commonly reported AEs
- No unexpected patterns detected by physician reviewers of reports of the 22 pre-specified outcomes

Data mining

- Empirical Bayesian (EB) data mining identifies AEs that are reported more frequently than expected, adjusting for age, sex, and the year in which reports are received
  - Identifies AEs that are reported at least twice as frequently as would be expected by chance following a given vaccine (i.e., lower bound of the 90% confidence interval surrounding the EB geometric mean [EB05] >2)
- One empirical Bayesian data mining finding to date for RZV for the MedDRA PT:
  - “Product administered to patient of inappropriate age” when looking at individuals aged 19-44.9 years old

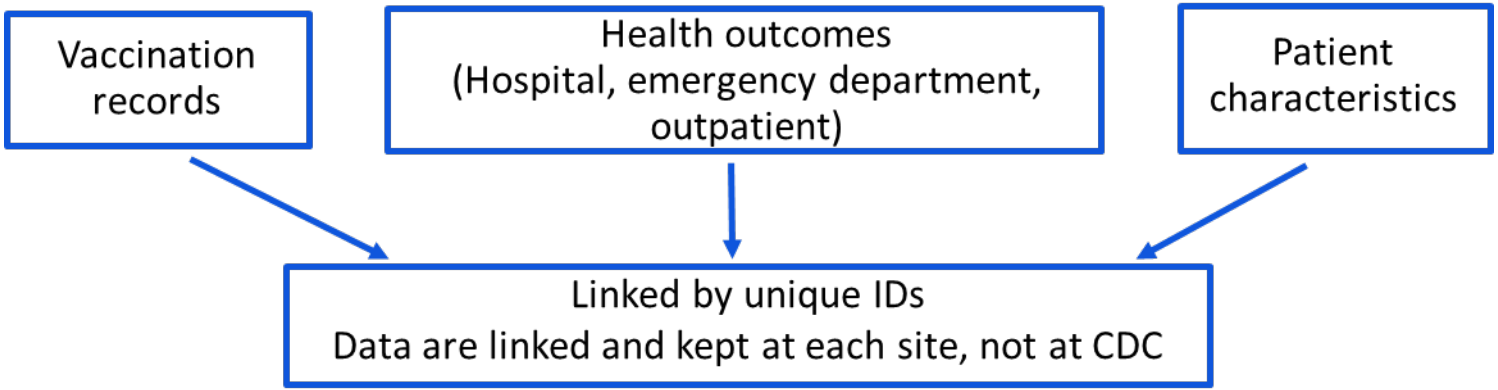
Summary of VAERS review of RZV reports

- RZV post-licensure safety monitoring findings in VAERS are generally consistent with the safety profile observed in pre-licensure clinical trials
- Self-limited systemic signs and symptoms and injection site reactions were the most commonly reported adverse events
- Serious adverse events were rarely reported (2.4% of reports – similar to other vaccines given in same age group)
- No empirical Bayesian data mining findings for any RZV-AE pairings except for “Product administered to patient of inappropriate age”

Vaccine Safety Datalink (VSD) Rapid Cycle Analysis (RCA) for recombinant zoster vaccine (RZV)

Vaccine Safety Datalink (VSD)

- Established in 1990
- Collaboration between CDC and several integrated healthcare plans
- Medical care and demographic data on over 12.1 million persons per year (~3.7% of U.S. population)
- Links vaccination data to health outcome data
- Used for surveillance and research

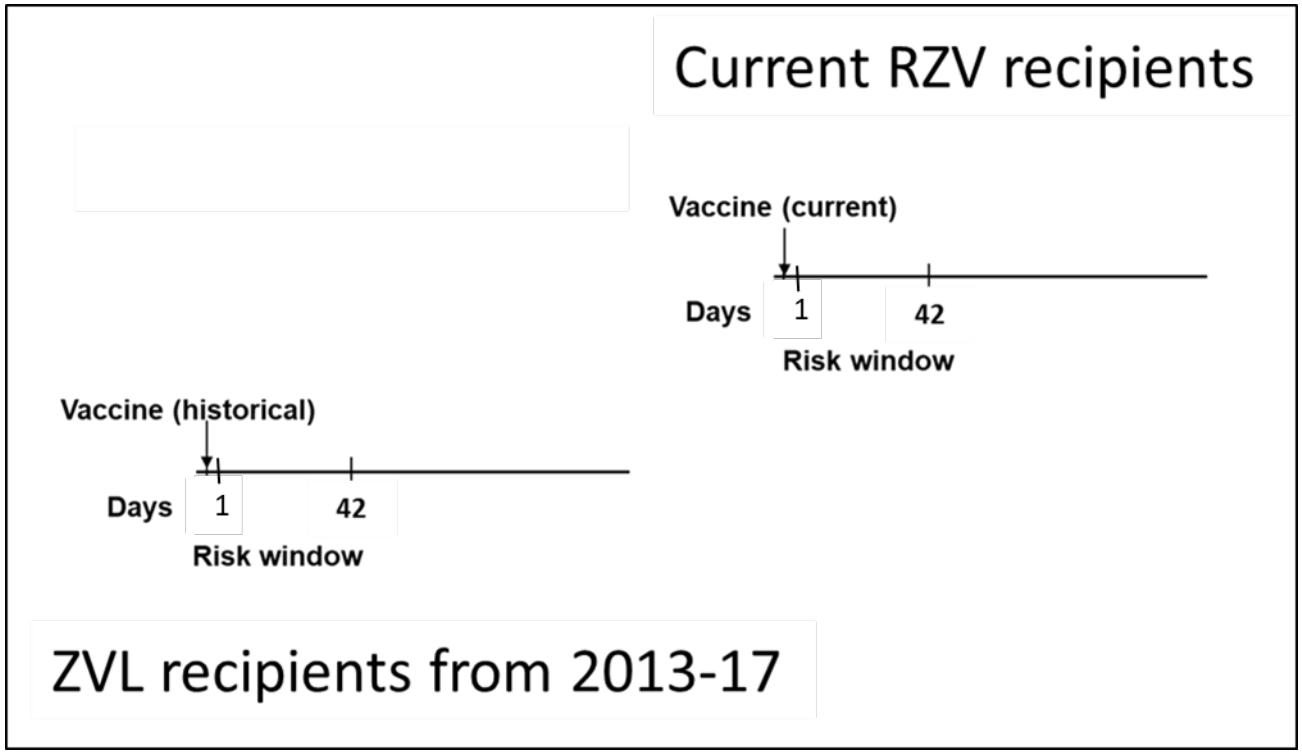


Rapid Cycle Analysis (RCA) in VSD

- A powerful and sophisticated tool for near real-time vaccine-safety monitoring
- A surveillance activity (signal detection and signal refinement), which is not the same as an epidemiologic study (signal evaluation, causality assessment)
- Requires careful thought and customization in the design, set-up, interpretation
- Employs an automated analysis that uses ICD-coded diagnoses from claims data
- Designed to detect statistical signals (values above specified statistical thresholds)
- Not all statistical signals represent a true increase in risk for an adverse event
- When a statistical signal occurs, CDC conducts a series of evaluations using traditional epidemiologic methods
- Chart-confirmation of diagnoses to confirm or exclude cases as true incident cases is a key part of statistical signal assessment

Primary analysis for RZV RCA is a historical comparator design

- Monthly near real-time sequential monitoring of pre-specified outcomes
- 18 planned monthly analyses (1st at 6 months), with an 18 week data lag
- Uses ICD-10/9 coded diagnoses
- 3rd analysis has been completed
- **Test statistic:** Adjusted likelihood ratio test (H_0: RR=1 versus H_A: RR>1)



10 pre-specified RZV RCA outcomes*

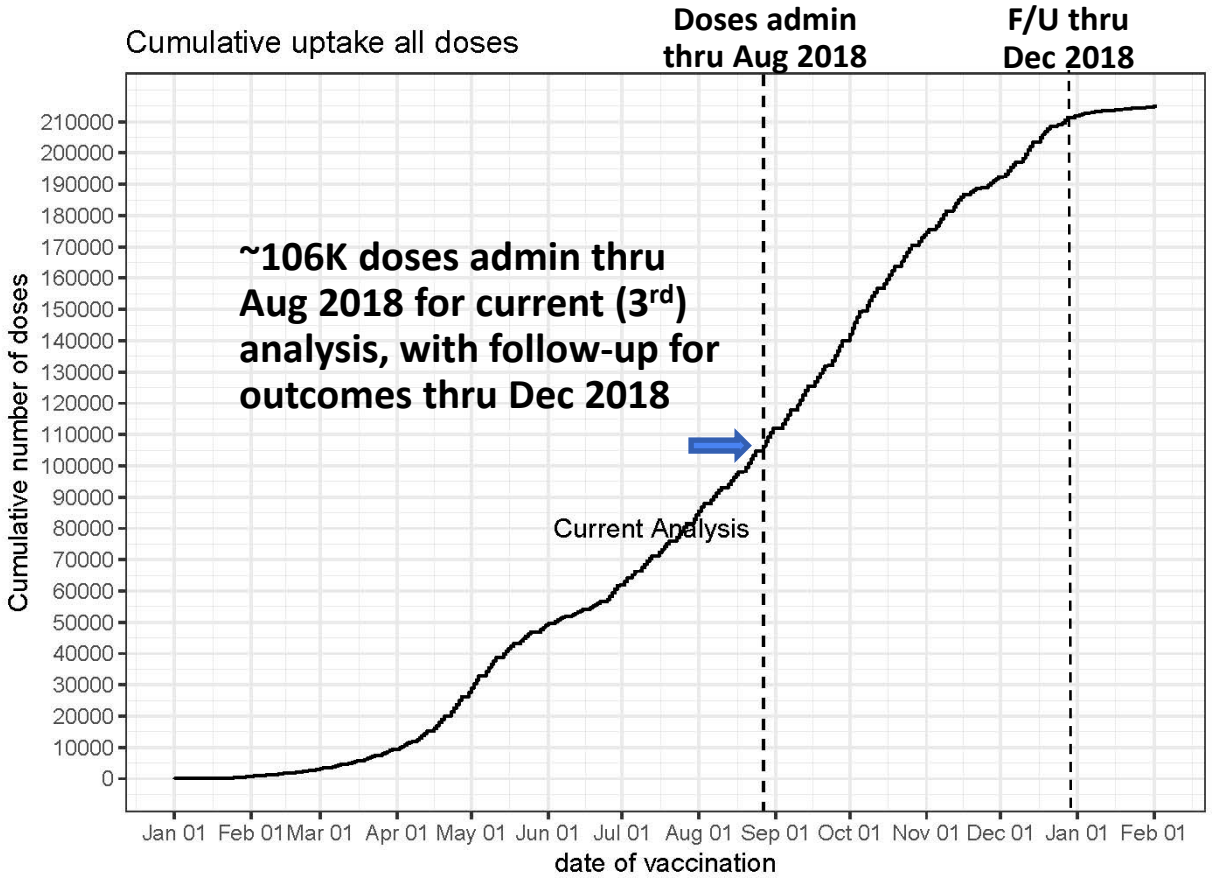
High priority pre-specified outcomes	Risk interval (days)
Acute myocardial infarction	1-42
Anaphylaxis	0-1
Bell's palsy	1-42
Convulsion	1-42
Giant cell arteritis	1-42
Guillain-Barré syndrome	1-42
Optic ischemic neuropathy	1-42
Polymyalgia rheumatica	1-42
Stroke	1-42
Supraventricular tachycardia	1-42

*Other outcomes for descriptive analysis only include: gout, keratitis, local reactions, non-specific adverse effects, pneumonia, systemic reactions, uveitis and retinitis, and zoster ocular disease

Secondary analyses for RZV RCA in the VSD uses 2 concurrent comparators

1. Had an ICD-10 coded well-visit during the RZV uptake period
2. Received some other vaccine (e.g., for pneumonia, Td, Tdap, IIV) during the RZV uptake period

Results: RZV uptake at all VSD sites for 3rd analysis



RZV RCA results: statistical signal for GBS detected

High priority outcomes	Obs events	Exp events	Obs rate (per 100K)	RR	Prelim statistical signal
Stroke	61	63	57.5	0.97	No
Acute MI	56	62	52.8	0.90	No
Polymyalgia rheumatic	16	27	15.1	0.60	No
Supraventricular tachycardia	19	20	17.9	0.94	No
Convulsion assoc. terms	20	20	18.8	0.99	No
Bell's palsy	23	15	21.7	1.52	No
Anaphylaxis	4	3	3.8	1.39	No
Giant cell arteritis	3	8	2.8	0.36	No
Optic ischemic neuropathy	5	8	4.7	0.59	No
Guillain-Barré syndrome (GBS)	4	0.8*	3.8	5.06	Yes**

*Based on 5 historical GBS events

**GBS had 1st preliminary statistical signal at 2nd analysis (3 events vs 0.6 expected; RR=5.25)

Signal assessment: short chart review of automated cases

Description of the four ICD-10 coded cases of GBS	Adjudication
65 y/o with a history of GBS diagnosed years prior, no recurrence or exacerbation after RZV	Historical case, not a true incident (i.e., 'new') case
72 y/o with a history of GBS diagnosed years prior, no recurrence or exacerbation after RZV	Historical case, not a true incident (i.e., 'new') case
68 y/o female who received concurrent PCV13 and had ZVL 7 years prior, had GBS symptom onset 13 days post-vaccination and was hospitalized 15 days post-vaccination	Short chart review confirmed case, Brighton Criteria level 2*
59 y/o female who received concurrent hepatitis B vaccination had chart documented GBS onset no later than 1 day post-vaccination, but sx may have started prior to vaccination. Patient had some signs and sx in the month prior and in the days leading up to vaccination suggestive of an infection (i.e., vague sx and respiratory and GI sx prior to GBS admission)	Short chart review confirmed case, Brighton Criteria level 1*, actual GBS symptom onset uncertain

*Sejvar et al. Guillain-Barré syndrome and Fisher syndrome: case definitions and guidelines for collection, analysis, and presentation of immunization safety data. Vaccine. 2011;29(3):599-612.

Signal assessment:

2 cases ruled out, 1 confirmed, 1 confirmed with uncertain onset

Description of the four ICD-10 coded cases of GBS	Adjudication
65 y/o with a history of GBS diagnosed years prior, no recurrence or exacerbation after RZV	Historical case, not a true incident (i.e., 'new') case
72 y/o with a history of GBS diagnosed years prior, no recurrence or exacerbation after RZV	Historical case, not a true incident (i.e., 'new') case
68 y/o female who received concurrent PCV13 and had ZVL 7 years prior, had GBS symptom onset 13 days post-vaccination and was hospitalized 15 days post-vaccination	Short chart review confirmed case, Brighton Criteria level 2
59 y/o female who received concurrent hepatitis B vaccination had chart documented GBS onset no later than 1 day post-vaccination, but sx may have started prior to vaccination. Patient had some signs and sx in the month prior and in the days leading up to vaccination suggestive of an infection (i.e., vague sx and respiratory and GI sx prior to GBS admission)	Short chart review confirmed case, Brighton Criteria level 1, actual GBS symptom onset uncertain

Summary of VSD RCA for RZV (3rd analysis of 18 planned)

- 106,121 doses of RZV administered in VSD, Jan-Aug 2018
- No evidence of increased risk for any of the pre-specified outcomes except GBS (in automated, ICD-10/9 analyses)
- Detected a statistical signal* for GBS in primary (ZVL historical comparator) analysis and consistently elevated RR across other comparators
  - RR=5.06 for ZVL comparators*
  - RR=2.95 for well-visit comparators†
  - RR=3.25 for 'received some other vaccine' comparators†

*Likelihood ratio exceeded critical value; †adjusted likelihood ratio test not conducted on secondary analyses

Summary of VSD RCA for RZV (cont.)

- Full clinician narratives have been requested for review for the 2 ‘valid’ GBS cases (i.e., symptoms and onset, physical findings, relevant testing, physician assessments, etc.)
- Plan to also chart review the GBS cases following ZVL in the historical comparator group

VAERS reports of GBS following RZV (Oct 2017-Dec 2018)

- 35 reports had a MedDRA Preferred Term for GBS assigned; upon review:
  - 19 case reports met Brighton criteria for GBS: level 1 (1), level 2 (15), level 3 (3)
  - 6 case reports did not meet Brighton criteria or had insufficient information, but were explicitly described as physician-diagnosed GBS
  - 10 case reports did not meet Brighton criteria and were not physician diagnosed
- Of the 25 cases that met Brighton criteria level 1-3, or were physician diagnosed:
  - 24 had symptom onset w/in a 0-42 day risk window following RZV (1 w/concurrent IIV)
    - Translates to reporting rate of 2.8 GBS cases per million RZV doses distributed
- Proportional Reporting Ratio (PRR) analysis did not detect any disproportional reporting for RZV-GBS when either ZVL, IIV or PPSV23 vaccines were used as comparators

Next steps

- FDA is exploring options for an analysis of GBS following RZV in the CMS database
- CDC will continue to monitor this preliminary VSD RCA statistical signal for GBS following RZV by tracking additional counts of GBS, conducting rapid chart review, and estimating the RR for chart-confirmed GBS over time as more doses of RZV accumulate
- CDC will continue enhanced monitoring for RZV in VAERS, to include clinical review of all GBS reports following RZV

RZV safety monitoring timeline (not to scale)

Oct 2017

- RZV lic & rec
- VAERS monitoring begins

Jun 2018

- Analytic period for initial surveillance review in VAERS*

Oct 2018

- 1st VSD RCA analysis for RZV
- No statistical signals

Nov 2018

- 2nd VSD RCA analysis detects statistical signal for GBS
- Signal assessment begins
- 3 GBS cases† (2 historical, 1 confirmed)

Dec 2018

- 3rd VSD RCA analysis, LLR continues to exceed critical value
- Signal assessment continues
- 4 GBS cases† (2 hist., 1 confirm., 1 confirm. w/uncertain onset)

Jan 2019

- Statistical finding for GBS persists after initial assessment
- CDC immunization program and FDA notified

Feb 2019

- ACIP Zoster WG briefed Feb 11
- ACIP Zoster WG updated Feb 25
- Full ACIP briefed on RZV safety Feb 28

*https://www.ncbi.nlm.nih.gov/pubmed/30703077

†Based on ICD-10 codes

Closing thoughts

- Still in the initial uptake period for RZV and early in the post-licensure monitoring process
- Overall, safety profile of RZV is consistent with pre-licensure clinical trial data
- VAERS data indicate systemic signs and symptoms and local reactions are commonly reported, with no findings of disproportional reporting for GBS or any other pre-specified outcomes
- Limited number of doses administered in VSD (~106K doses thru Aug 2018) at the 3rd of 18 planned sequential analyses
- Statistical signal detected in VSD RCA was based on a small number of GBS cases using automated data – 3 ICD-10 coded GBS cases (currently 4)
  - Upon review, 1 confirmed case in risk interval, 1 confirmed case with questionable onset timing and possible infectious trigger, 2 historical cases

Closing thoughts (cont.)

- Our post-licensure safety monitoring systems and surveillance methods are designed to be rapid and sensitive and to allow for quick assessment of statistical signals (which do not necessarily represent a true safety problem)
- Our policy is to be transparent and to communicate vaccine safety information in a timely manner
- Preliminary data are insufficient to conclude that a safety problem exists for GBS, but further evaluation and continued vigilance are warranted
- The RZV-GBS statistical signal detection and assessment demonstrates the robust and responsive U.S. vaccine safety monitoring system in action, working as intended
- CDC will update the Zoster Workgroup as information comes available and will be available to update ACIP as requested

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Thank you

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