SUPPLEMENTARY TABLE 2. Prespecified outcomes^{*,†} for recombinant zoster vaccine (RZV) in reports submitted to the Vaccine Adverse Events Reporting System (VAERS) — United States, October 2017–June 2018

accille Auverse Events Report		Reporting	Inited States, October 2017–June 2018
Pre-specified outcome	No. (%)	rate [§]	Physician reviewer impression and description of selected reports
Herpes zoster (HZ)	196 (4.5)	6.1	110 reports of physician-diagnosed cases of HZ; 4 reports were not physician- diagnosed; 82 reports were misclassified
Post-herpetic neuralgia	49 (1.1)	1.5	45 reports of neuralgia or nerve pain, 15 of which were physician-diagnosed cases of post-herpetic neuralgia; 4 reports were misclassified
Autoimmune disorders	20 (0.46)	0.7	8 reports of Guillain-Barré syndrome; 3 reports of patients with pre-existing autoimmune disorders; 1 report each of uveitis, transverse myelitis, and Steven-Johnson syndrome; 6 reports were misclassified
Neuropathy	16 (0.37)	0.5	10 reports of neuropathy, 5 of which were physician-diagnosed; 6 reports were misclassified
Inflammatory eye disease	14 (0.32)	0.4	9 reports of HZ near the eye, with subsequent ocular involvement (e.g., keratitis); 2 reports of primary HZ iridocyclicitis; 1 report each of ocular HZ, HZ keratoconjunvtivitis, and pre-existing ophthalmic HZ
Acute myocardial infarction (AMI)	11 (0.25)	0.3	2 reports of AMI (83-year-old female and a 65-year-old female); 9 reports described either "rule out" AMI or history of ischemic cardiomyopathy
Seizures/convulsions	11 (0.25)	0.3	2 reports met Brighton Level (BL) 1; 9 reports did not meet BL criteria
Bell's palsy	10 (0.23)	0.3	2 reports met BL3; 8 reports did not meet BL criteria
Death	8 (0.18)	0.3	[described in the Results section]
Guillain-Barré syndrome	8 (0.18)	0.3	5 reports met BL2, 1 report met BL3, 2 reports did not meet BL criteria; these are the same 8 Guillain-Barré syndrome reports as in the autoimmune disorders
Anaphylaxis	7 (0.16)	0.2	1 report met BL1, with symptom onset the day after vaccination; 2 reports met BL2, with symptom onset "45 minutes" and "within hours;" 4 reports were misclassified
Lymphadenitis	7 (0.16)	0.2	Reports primarily captured as a finding on physical exam, but not as the primary complaint or adverse event itself
Stroke/cerebrovascular event (CVA)	7 (0.16)	0.2	4 reports of CVA (51-year-old female with dyslipidemia and CVA the day after vaccination, 70-year-old female with hypercholesterolemia and CVA 2 days after vaccination, and incomplete information on remaining 2 reports); 3 reports were not CVA, but CVA was mentioned in the differential diagnosis
Co-administration of RZV with adjuvanted influenza vaccine and/or adjuvanted hepatitis B vaccine	3 (<0.1)	0.09	All 3 reports described injection site swelling and pain; in 1 report, vaccines were given in the same arm
Gout	3 (<0.1)	0.09	2 reports of gout in the adverse event description; 1 report of a patient with pre-existing gout
Autoimmune vasculitis	2 (<0.1)	0.06	Both reports were misclassified
Idiopathic thrombocytopenic purpura	2 (<0.1)	0.06	1 report of idiopathic thrombocytopenic purpura that responded to intravenous immunoglobulin and steroids; 1 report was misclassified
Meningitis	2 (<0.1)	0.06	1 report of presumed viral encephalitis and aseptic meningitis; 1 report of a patient with mental status changes – meningitis considered, but no explanation for symptoms found
Supraventricular tachyarrhythmias	1 (<0.1)	0.03	Report of a patient who experienced a supraventricular tachyarrhythmia during hospitalization for septic shock
Amyotrophic lateral sclerosis	0	0	No reports identified
Optic ischemic neuropathy	0	0	No reports identified
Osteonecrosis	0	0	No reports identified

* Reports of pre-specified outcomes were identified using the search strategy described in the electronic Appendix; a single report could include multiple pre-specified outcomes because the patient experienced multiple adverse events or because a single MedDRA Preferred Term used to code the adverse event maps to multiple different pre-specified outcomes

⁺ Brighton Collaboration standardized case definitions were available for seizures/convulsions, Bell's palsy, Guillain-Barré syndrome, and anaphylaxis; Brighton Level (BL) 1 represents the highest level of diagnostic certainty, followed by 2, 3 and 4

[§] Reports of pre-specified outcomes per 100,000 RZV doses distributed in the United States during the analytic period.