Incorrect Administration of Adult RSV Vaccines to Young Children

Pedro L. Moro, MD, MPH,[a] Anne Scheffey, MPH, MS, BSN,[a] Ruth Gallego, RN, MPH,[a] Jefferson M. Jones, MD,[b] Elisha Hall, PhD, MS, RD,[c] Bicheng Zhang, MS,[a] Katherine E. Fleming-Dutra, MD,[b] Karen R. Broder, MD[a]

In May 2023, the US Food and Drug Administration (FDA) approved the first vaccines for the prevention of respiratory syncytial virus (RSV)-associated lower respiratory tract disease (LRTD) for use in adults aged ≥60 years: 1 manufactured by GSK (Arexvy)[1] and 1 by Pfizer (Abrysvo).[2] In July 2023, FDA approved nirsevimab (Beyfortus, Sanofi, and AstraZeneca), a long-acting monoclonal antibody for passive immunization to prevent RSV-associated LRTD among infants and children aged <24 months.[3] In August 2023, FDA approved the Pfizer RSV vaccine for pregnant persons, with administration indicated at 32 to 36 weeks' gestation to prevent RSV-associated LRTD and severe LRTD in infants aged <6 months.[2] GSK RSV vaccine is not approved for use during pregnancy.[1] In August 2023, the Advisory Committee on Immunization Practices and the Centers for Disease Control and Prevention (CDC) recommended nirsevimab for all infants aged <8 months who are born during or entering their first RSV season and for infants and children aged 8 through 19 months entering their second RSV season who are at increased risk for severe RSV disease.[4] Administration of either maternal Pfizer RSV vaccine during pregnancy at 32 through 36 weeks' gestation or nirsevimab to the infant is recommended to prevent RSV-associated LRTD in infants, but both are not needed for most infants.[5] Pfizer and GSK RSV vaccines are not approved for use in infants and young children.[1,2]

Health care facilities that provide preventive care for children and adults might store and administer Pfizer and GSK RSV vaccines, other routine vaccines, and nirsevimab; thus, the potential exists for Pfizer or GSK RSV vaccines to be administered in error to infants and young children.

METHODS

The Vaccine Adverse Event Reporting System (VAERS) is a national, spontaneous reporting (passive surveillance) system comanaged by CDC and FDA.[6] VAERS reports are classified as serious if any of the following are reported: hospitalization, prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death.[7] To assess vaccine administration errors of Pfizer or GSK RSV vaccine use in infants and young children aged <2 years, the VAERS database was searched for reports of children aged <24 months who received an RSV vaccine, and a text string search was conducted for the words "infant," "child," "newborn," "neonate," "pediatric," "month," and "peds" within the fields' symptom text or laboratory data for those reports where age was not provided. This activity was reviewed by CDC and was conducted consistent with applicable federal law and CDC policy.[8]

RESULTS

From August 21, 2023, to March 18, 2024, the VAERS database included 34 reports of administration errors indicating that either Pfizer or GSK RSV vaccine had been administered to children aged <2 years; 31 were in infants aged <8 months (Table 1). For 21 reports, a family medicine practice was the

[a]*Immunization Safety Office, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, and* [b]*Divisions of Coronavirus and Other Respiratory Viruses and* [c]*Immunization Services, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia*

Dr Moro originated the study, supervised its implementation, conducted the analysis, and led the writing of the manuscript summarizing the findings; Ms Scheffey, Ms Gallego, Mr Zhang, and Drs Jones, Hall, Fleming-Dutra, and Broder assisted in 1 or more aspects, including study design, review of Vaccine Adverse Event Reporting System reports and medical records, technical advice, administrative support, and writing of the report; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

DOI: https://doi.org/10.1542/peds.2024-066174

Accepted for publication Mar 25, 2024

Address correspondence to Pedro L. Moro, MD, MPH, Vaccine Adverse Event Reporting System Project and Response Team, Immunization Safety Office, Centers for Disease Control and Prevention, 1600 Clifton Rd, Atlanta, GA 30329. E-mail: psm9@cdc.gov

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FUNDING: No external funding.

CONFLICT OF INTEREST DISCLOSURES: The authors have indicated they have no potential conflicts of interest to disclose.

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.

To cite: Moro PL, Scheffey A, Gallego R, et al. Incorrect Administration of Adult RSV Vaccines to Young Children. *Pediatrics*. 2024;153(6):e2024066174

TABLE 1 Characteristics of Respiratory Syncytial Virus Vaccine Reports in Infants and Children Aged <2 Years, Vaccine Adverse Event Reporting System, United States, August 21 to March 18, 2024

Characteristic	No. (%)
Total reports[a]	34
Age group, mo[b]	
<8	31 (91)
<2	7
2–<8	24
≥8	2 (6)
Brands of RSV vaccine	
Pfizer (Abrysvo)	27 (79)
GSK (Arexvy)	7 (21)
Type of reporter	
Health care provider	30 (88)
Parent, guardian, or caregiver	2 (6)
Manufacturer	2 (6)
Facility where vaccine administered[c]	
Doctor's office, urgent care, or hospital	24 (71)
Family medicine practice	21 (62)
Pediatrician's office	3 (9)
Public health or military clinic[d]	8 (24)
Unknown	2 (6)
Adverse event reported	
No adverse event reported	27 (79)
Serious adverse event report	1 (3)
Cardiorespiratory arrest and other diagnoses in infant with congenital heart disease, (GSK RSV vaccine)[e]	1 (3)
Nonserious adverse event reports	6 (18)
Injection site swelling or redness	1 (3)
Crying, irritability, and decreased feeding	1 (3)
Crying, vomiting, irritability, pyrexia, and poor feeding	1 (3)
Increased sleeping, spitting up, cough	1 (3)
Discomfort, pyrexia	1 (3)
Diarrhea, pyrexia	1 (3)
Concomitant administration	
RSV vaccine only reported	18 (53)
One or more additional vaccines received[f]	16 (47)
Intended injectable product	
Nirsevimab (Beyfortus)	17 (50)
Childhood vaccine[g]	1 (3)
Unknown	16 (47)
Reason for administration error	
Reason not reported	30 (88)
New staff member[h]	2 (6)
Nirsevimab out of stock	1 (3)
Wrong product pulled	1 (3)

[a] One additional report not included in this analysis suggested that a potential error occurred that could not be verified.
[b] One report describing an infant patient did not indicate patient's exact age.
[c] All reports that indicated vaccination location occurred in an outpatient setting.
[d] Includes reports from Indian Health Services facilities.
[e] Infant aged 7 months with history of aortic stenosis had cardiorespiratory arrest within 24 hours after receiving GSK RSV vaccine and routine 6-month childhood vaccines (quadrivalent inactivated influenza vaccine; combination diphtheria, tetanus, acellular pertussis, hepatitis B and inactivated poliovirus vaccine; and 20-valent pneumococcal conjugate vaccine) in the outpatient setting; at time of the arrest, the patient also had fever and respiratory viral infection (respiratory panel positive for rhinovirus/enterovirus, negative for other pathogens including RSV). The patient was hospitalized and improving at the time of the VAERS report.
[f] Age-appropriate vaccines received at same visit included 13-valent pneumococcal conjugate vaccine; 15-valent pneumococcal conjugate vaccine; 20-valent pneumococcal conjugate vaccine; hepatitis A vaccine; hepatitis B vaccine; quadrivalent inactivated influenza vaccine; coronavirus disease 2019 vaccine; *Haemophilus influenzae* type b vaccine; pentavalent rotavirus vaccine; monovalent rotavirus vaccine; combination measles, mumps, rubella, and varicella vaccine; combination diphtheria, tetanus, acellular pertussis, hepatitis B, and inactivated poliovirus vaccine; combination diphtheria, tetanus, acellular pertussis, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine; and combination diphtheria, tetanus, acellular pertussis, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine.
[g] Patient received Pfizer RSV vaccine instead of pneumococcal conjugate vaccine. Error identified as a storage/labeling confusion with Pfizer RSV vaccine in bin labeled for pneumococcal conjugate vaccine.
[h] One report noted that a staff member was new and had not received training and that clinic was short-staffed.

vaccination location. Twenty-seven reports involved Pfizer and 7 involved GSK RSV vaccine. Twenty-seven reports included no adverse health events. Seven reports described at least 1 adverse health event, including a serious report of an infant with a history of congenital heart disease hospitalized for cardiorespiratory arrest within 24 hours after

receipt of GSK RSV vaccine in addition to routine childhood vaccines (Table 1). Six reports described injection site or systemic reactions (eg, irritability) after administration of Pfizer or GSK RSV vaccine.

DISCUSSION

This review found infrequent reports of Pfizer and GSK RSV vaccines administered to infants and young children aged <2 years in error. VAERS limitations include reporting biases (over- or underreporting) and inconsistency in quality and completeness of reports.[6] Health care providers should not administer Pfizer or GSK RSV vaccine to infants and young children.[1,2,5] Administration errors are preventable with proper education and training, ordering only products that are approved for the patient population a facility serves, electronic health record alerts or warnings, close attention to labeling, storage best practices, and other preventive measures.[9] To increase awareness and help prevent these vaccine administration errors, CDC is working to educate health care providers administering vaccinations and nirsevimab to young children aged <2 years.[10] Health care providers are encouraged to report vaccination errors to VAERS,[11] including those involving Pfizer or GSK RSV vaccines.[12] CDC and FDA will continue to monitor VAERS for these administration errors.[6]

ACKNOWLEDGMENTS

We thank Elaine Miller, Tom Shimabukuro, John Su, Hannah Brown, and Carol Ennulat, CDC; Immunization Safety Office, CDC; Meghna Alimchandani and Narayan Nair; Center for Biologics Evaluation and Research, FDA; and General Dynamics Information Technology.

ABBREVIATIONS

CDC: Centers for Disease Control and Prevention
FDA: US Food and Drug Administration
LRTD: lower respiratory tract disease
RSV: respiratory syncytial virus
VAERS: Vaccine Adverse Event Reporting System

REFERENCES

1. FDA; US Department of Health and Human Services. AREXVY package insert. Available at: https://www.fda.gov/vaccines-blood-biologics/arexvy. Accessed March 2, 2024
2. FDA; US Department of Health and Human Services. ABRYSVO package insert. Available at: https://www.fda.gov/vaccines-blood-biologics/abrysvo. Accessed March 2, 2024
3. FDA; US Department of Health and Human Services. Beyfortus (nirsevimab-alip) product label. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf. Accessed March 2, 2024
4. Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of nirsevimab for the prevention of respiratory syncytial virus disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices–United States, 2023. *MMWR Morb Mortal Wkly Rep*. 2023;72(34):920–925
5. Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer respiratory syncytial virus vaccine during pregnancy for the prevention of respiratory syncytial virus-associated lower respiratory tract disease in infants: recommendations of the Advisory Committee on Immunization Practices–United States, 2023. *MMWR Morb Mortal Wkly Rep*. 2023;72(41):1115–1122
6. Shimabukuro TT, Nguyen M, Martin D, DeStefano F. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*. 2015;33(36):4398–4405
7. FDA. CFR–Code of Federal Regulations Title 21. Available at: www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr. Accessed March 2, 2024
8. 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq
9. CDC. Epidemiology and prevention of vaccine-preventable diseases. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html. Accessed March 2, 2024
10. CDC. CDC clinician outreach and communication activity. Available at: emergency.cdc.gov/newsletters/coca/2024/012224.html. Accessed February 2, 2024
11. VAERS. Available at: https://vaers.hhs.gov. Accessed March 2, 2024
12. Moro PL, Gallego R, Scheffey A, et al. Administration of the GSK respiratory syncytial virus vaccine to pregnant persons in error. [Published online ahead of print February 23, 2024] *Obstet Gynecol*. 2024. 10.1097/AOG.0000000000005551