Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases

Respiratory Syncytial Virus Vaccine Administration Errors in Pregnant Persons and Young Children <2 Years Reported to VAERS During the 2023-2024 Respiratory Season

Anne Scheffey MPH, MS, BSN, RN
Immunization Safety Office
Centers for Disease Control and Prevention (CDC)

National Adult and Influenza Immunization Summit (NAIIS)
May 9, 2024

Background

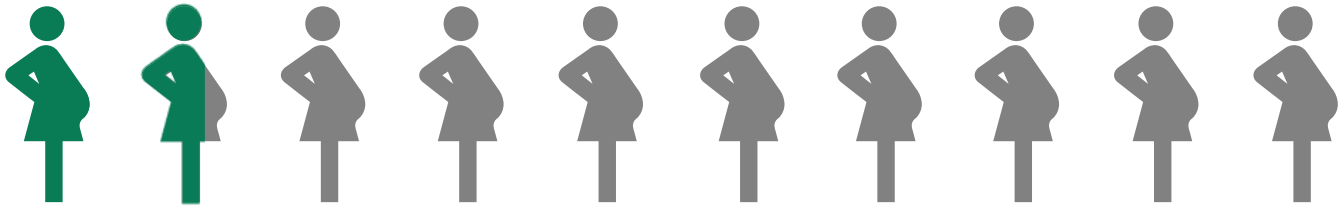
RSV Prevention Products: FDA Approvals*

Product (all injectable)	Approved for use†	Not approved for use
GSK RSV vaccine (Arexvy)	• Adults aged ≥60 years for the prevention of lower respiratory tract disease (LRTD) caused by RSV (May 3, 2023)	• Persons aged <60 years • During pregnancy • Children aged <2 years
Pfizer RSV vaccine (Abrysvo)	• Adults aged ≥60 years for the prevention of LRTD caused by RSV (May 31, 2023) • Pregnant persons at 32 through 36 weeks' gestation for the prevention of LRTD and severe LRTD caused by RSV in infants through aged 6 months (August 21, 2023)	• Persons aged <60 years who are not pregnant • Children aged <2 years
Nirsevimab (Beyfortus) (monoclonal antibody)	• Infants born or entering first RSV season to prevent LRTD caused by RSV • Children aged <24 months vulnerable to severe RSV during second RSV severe to prevent LRTD caused by RSV	• Children aged ≥2 years • Adults all ages

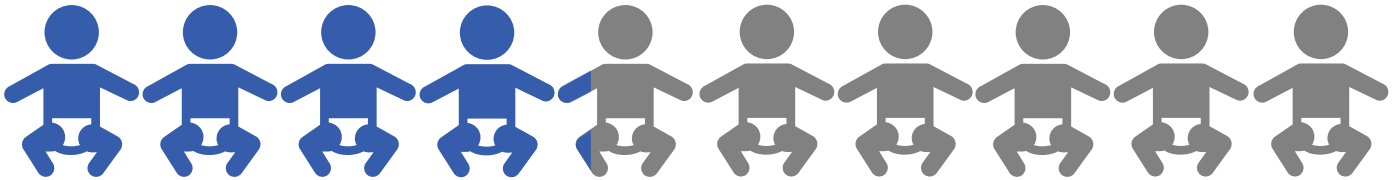
*Product package inserts: AREXVY | FDA; ABRYSVO | FDA; label (fda.gov) (nirsevimab)
†This table refers to FDA approvals for product use. CDC recommendations for the use of RSV prevention products are available here: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/rsv.html

RSV Immunization Coverage Estimates

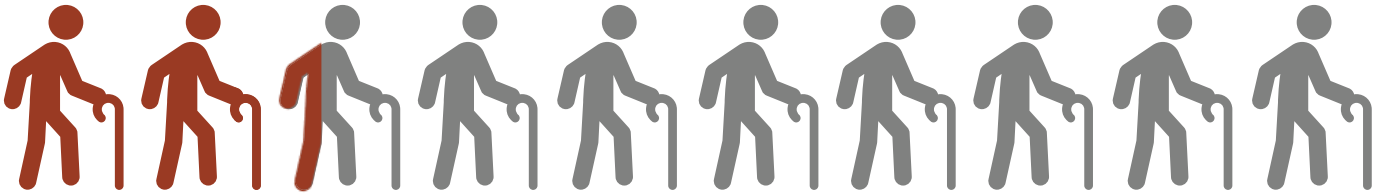
17.8% of pregnant persons have received the **RSV vaccine** as of January 2024



41.3% of infants <8 months received **nirsevimab** as of March 2024



23.8% of adults aged ≥60 years have received the **RSV vaccine** as of April 2024



https://www.cdc.gov/vaccines/imz-managers/coverage/rsvvaxview/index.html

Estimates for RSV vaccination coverage in pregnant persons are as of January 31, 2024; estimates of nirsevimab coverage in infants are as of March 2024; estimates of RSV vaccination coverage in adults aged ≥60 years are as of April 13, 2024

VAERS is the nation's early warning system for vaccine safety

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

- VAERS accepts all reports from all reporters without making judgments on causality or judging clinical seriousness of the event; VAERS accepts reports of vaccination errors irrespective if an adverse event was reported
- As a hypothesis generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

Vaccination Errors and VAERS: Background

- **Vaccination errors are known to occur and may be reported to VAERS**
- **A review described vaccination errors reported to VAERS from 2000 through 2013[1]**
  - Vaccination error reports to VAERS increased markedly during 2000-2013
  - Over 20,000 error reports were identified, 25% of reports also described an adverse health event (AHE)
    - 8% of error reports with an AHE were classified as serious*
- **Vaccination errors have also been reported to VAERS for vaccines introduced since 2013 for children and adults[2,3]**

* VAERS reports are classified as serious (based on FDA Code of Federal Regulations Title 21) if any of the following are reported: hospitalization, prolongation of hospitalization, life-threatening illness, permanent disability, congenital anomaly or birth defect, or death. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr

[1] Hibbs BF, et al. Vaccination errors reported to the Vaccine Adverse Event Reporting System, (VAERS) United States, 2000–2013. Vaccine. 2015;33(28):3171-3178. doi: 10.1016/j.vaccine.2015.05.006

[2] Shimabukuro TT, et al. Notes from the Field: Vaccine Administration Errors Involving Recombinant Zoster Vaccine - United States, 2017-2018. MMWR Morb Mortal Wkly Rep. 2018 May 25;67(20):585-586. doi: 10.15585/mmwr.mm6720a4. PMID: 29795075; PMCID: PMC6433334.

[3] Hause AM, et al. COVID-19 mRNA Vaccine Safety Among Children Aged 6 Months-5 Years - United States, June 18, 2022-August 21, 2022. MMWR Morb Mortal Wkly Rep. 2022 Sep 2;71(35):1115-1120. doi: 10.15585/mmwr.mm7135a3. PMID: 36048728; PMCID: PMC9472776.

Vaccination errors reported to the Vaccine Adverse Event Reporting System, (VAERS) United States, 2000–2013

Beth F. Hibbs*, Pedro L. Moro, Paige Lewis, Elaine R. Miller, Tom T. Shimabukuro

- **Most common error groups included "Inappropriate Schedule" (27%), "Storage and Dispensing" (23%) and "Wrong Vaccine Administered" (15%)**
  - Many "Wrong Vaccine" errors involved either similar antigen types indicated for different age groups or products with similar sounding names or acronyms
    - Example: Varicella and herpes zoster (shingles) vaccines; Pneumococcal conjugate and pneumococcal polysaccharide vaccines; and DTaP and Tdap
- **Authors proposed possible contributing factors to increased reports include:**
  - Increased size and complexity of the immunization schedule
  - Increased awareness of errors
  - Stimulated reporting to VAERS

Hibbs BF, Moro PL, Lewis P, Miller EM, Shimabukuro TT. Vaccination errors reported to the Vaccine Adverse Event Reporting System, (VAERS) United States, 2000–2013. Vaccine. 2015;33(28):3171-3178. doi: 10.1016/j.vaccine.2015.05.006

RSV Vaccine Administration Errors Happened During the 2023-2024 Season

COCA Now

CDC Clinician Outreach and Communication Activity

January 22, 2024

Information on Respiratory Syncytial Virus (RSV) Vaccine Administration Errors in Young Children and Pregnant People

Vaccine administration errors are known to occur and are routinely monitored through the Vaccine Adverse Event Reporting System[1] (VAERS). Since approval of RSV vaccines and the monoclonal antibody nirsevimab, **the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have received reports of the Pfizer (Abrysvo) or GSK (Arexvy) RSV vaccines being administered in error to young children. CDC and FDA have also received reports of the GSK RSV vaccine (Arexvy) being administered in error to pregnant people.** As of January 17, 2024, the number of reports received by VAERS suggests that these types of errors are uncommon in young children less than 2 years of age (25 reports) and pregnant people (128 reports) relative to an estimated 1 million infants protected from RSV either through infant receipt of nirsevimab or through vaccination of pregnant people.[2]

OBSTETRICS & GYNECOLOGY

Administration of the GSK Respiratory Syncytial Virus Vaccine to Pregnant Persons in Error

Moro, Pedro L.; Gallego, Ruth; Scheffey, Anne; Fleming-Dutra, Katherine E.; Hall, Elisha; Zhang, Bicheng; Marquez, Paige; Jones, Jefferson M.; Nair, Narayan; Broder, Karen R. Less

143(5):704-706, May 2024.

PEDIATRICS®

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]

Administration of the GSK Respiratory Syncytial Virus Vaccine to Pregnant Persons in Error

Reported to VAERS from August 21, 2023 through January 21, 2024

Search for GSK RSV Vaccine Pregnancy Reports and Clinical Review

- **Search of reports:**
  - Specific Medical Dictionary for Regulatory Activities (MedDRA)* codes: exposure during pregnancy, drug exposure during pregnancy, maternal exposure during pregnancy
  - Affirmative answer on Question 8 in VAERS form (pregnancy status)

  - Text string search of fields (symptoms, pre-existing illness, medical history) for 'preg'
- **Clinicians review reports to confirm they are pregnancy reports and categorize the main adverse events of interest and identify reports of GSK RSV vaccine administered in error**
- **Medical records requested for ALL pregnancy reports**

*Medical Dictionary for Regulatory Activities (MedDRA) home page. https://www.meddra.org/

Characteristics of GSK (Arexvy) Respiratory Syncytial Virus Vaccine Reports in Pregnant Persons—VAERS (Vaccine Adverse Event Reporting System), United States, August 21, 2023–January 21, 2024

Characteristic	Value
Total reports	113
Maternal age (y)*	33 (31–36)
Gestational age (wk)†	35 (34–36)
Type of reporter	
Manufacturer	67 (59.3)
Health care professional	31 (27.4)
Other	8 (7.1)
Patient	7 (6.2)
Facility where vaccine administered	
Pharmacy or drug store	70 (61.9)
Doctor's office, urgent care, or hospital	24 (21.2)
Public health or military medical centers	7 (6.2)
Unknown	12 (10.6)

Data are n, median (interquartile range), or n (%).
* Maternal age was not included in 23 reports.
† Among 75 reports with gestational age data at vaccination, two reported GSK RSV vaccination at less than 32 weeks of gestation. Three reports indicated that the GSK RSV vaccine was administered at 37 weeks of gestation, five reports indicated that GSK RSV vaccine was administered at 32–36 weeks, and 38 reports did not indicate gestational age at the time of GSK RSV vaccination.

Moro PL, Gallego R, Scheffey A, et al. Administration of the GSK Respiratory Syncytial Virus Vaccine to Pregnant Persons in Error. Obstetrics and Gynecology (New York 1953 Online)/Obstetrics and Gynecology. 2024;143(5):704-706. doi:10.1097/aog.0000000000005551

Characteristics of GSK (Arexvy) Respiratory Syncytial Virus Vaccine Reports in Pregnant Persons—VAERS (Vaccine Adverse Event Reporting System), United States, August 21, 2023–January 21, 2024

Characteristic	Value
AEs	
No AE reported	103 (91.2)
No AE noted by reporter	22 (19.5)
Serious AE report	1 (0.9)
SGA term birth with medical complications‡	1 (0.9)
Nonserious adverse event reports	9 (8.0)
Fever with or without chills	3 (2.7)
Contractions or loss of mucus plug	1 (0.9)
Cramping	1 (0.9)
Increased blood pressure	1 (0.9)
Injection site pain, headache, or myalgias	2 (1.8)
Injection site pain or erythema	1 (0.9)

AE, adverse event; SGA, small for gestational age; RSV, respiratory syncytial virus.
Data are n, median (interquartile range), or n (%).
‡ A serious report described AEs of SGA birth weight in a male newborn born at term (37 weeks of gestation) who was hospitalized with a diagnosis of hypoxic-ischemic encephalopathy. The mother received the GSK RSV vaccine at 35 weeks of gestation; labor was induced at 37 weeks because of medical complications.

Moro PL, Gallego R, Scheffey A, et al. Administration of the GSK Respiratory Syncytial Virus Vaccine to Pregnant Persons in Error. Obstetrics and Gynecology (New York 1953 Online)/Obstetrics and Gynecology. 2024;143(5):704-706. doi:10.1097/aog.0000000000005551

Characteristics of GSK (Arexvy) Respiratory Syncytial Virus Vaccine Reports in Pregnant Persons—VAERS (Vaccine Adverse Event Reporting System), United States, August 21, 2023–January 21, 2024

Characteristic	Value
Reason for administration error[§]	
Insufficient knowledge about the difference between the 2 products	10 (8.8)
Pfizer RSV vaccine not available at the facility	5 (4.4)
Physician's order indicated GSK RSV vaccine	3 (2.7)
Product name mix-up	2 (1.8)
Physician's order did not specify vaccine brand	1 (0.9)
Not reported	92 (81.4)

Data are n, median (interquartile range), or n (%).

[§] Most reports specified that the Pfizer RSV vaccine was the intended vaccine to be administered. No report indicated that administration of a vaccine other than the Pfizer RSV vaccine was intended for the pregnant person.

Moro PL, Gallego R, Scheffey A, et al. Administration of the GSK Respiratory Syncytial Virus Vaccine to Pregnant Persons in Error. Obstetrics and Gynecology (New York 1953 Online)/Obstetrics and Gynecology. 2024;143(5):704-706. doi:10.1097/aog.0000000000005551

Administration of Pfizer and GSK Respiratory Syncytial Virus Vaccines to Children Aged <2 Years in Error

Reported to VAERS from August 21, 2023 through March 18, 2024

Search for Reports of Pfizer and GSK RSV Vaccine Administration to Children Aged <2 Years in Error and Clinical Review

- VAERS database was searched for reports of children aged ≤24 months who received an RSV vaccine
- For reports where age was not provided, a text string search of fields (symptoms, laboratory data) was conducted for the words “infant,” “child,” “newborn,” “neonate,” “pediatric,” “month,” and “peds”
- Clinicians review reports to confirm they are reports of children aged <2 years and categorize the main adverse events of interest and identify reports of Pfizer and GSK RSV vaccine administered in error

Characteristics of Pfizer and GSK Respiratory Syncytial Virus Vaccine Reports in Infants and Children Aged <2 Years – VAERS, August 21, 2023 to March 18, 2024

Characteristic	No. (%)
Total reports*	34
Age group, months†	
<8	31 (91)
<2	7
2–<8	24
≥8	2 (6)
Manufacturer (trade name)	
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)

Characteristic	No. (%)
Facility where vaccine administered§	
Doctor's office, urgent care, or hospital	24 (71)
Family medicine practice	21 (62)
Pediatrician's office	3 (9)
Public health or military clinic¶	8 (24)
Unknown	2 (6)

*One additional report not included suggested that a potential error occurred that could not be verified

†One report describing an infant patient did not indicate patient's exact age

§All reports that indicated vaccination location occurred in an outpatient setting

¶Includes Indian Health Services facilities

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

Characteristics of Pfizer and GSK Respiratory Syncytial Virus Vaccine Reports in Infants and Children Aged <2 Years – VAERS, August 21, 2023 to March 18, 2024

Characteristic	No. (%)
Adverse event reported	
No adverse event reported	27 (79)
Serious adverse event report Cardiorespiratory arrest and other diagnoses in infant with congenital heart disease, (GSK RSV vaccine)*	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)

*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, 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 report.

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

Characteristics of Pfizer and GSK Respiratory Syncytial Virus Vaccine Reports in Infants and Children Aged <2 Years – VAERS, August 21, 2023 to March 18, 2024

Characteristic	No. (%)
Concomitant vaccine administration	
RSV vaccine only reported (no co-administration reported)	18 (53)
One or more additional vaccines received*	16 (47)
Intended injectable product	
Nirsevimab (Beyfortus)	17 (50)
Childhood vaccine†	1 (3)
Unknown	16 (47)
Reason for administration error	
Reason not reported	30 (88)
New staff member	2 (6)
Nirsevimab out of stock	1 (3)
Wrong product pulled	1 (3)

*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.

† 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.

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

Follow-up activities

- **CDC is conducting follow-up with healthcare providers on these RSV vaccine administration error reports to VAERS to assess:**
  - Health outcomes in persons who received RSV vaccine in error
    - Pregnant persons and their infants
    - Young children
  - Possible reasons for the error

RSV Vaccine Administration Error Reports in Adults Aged ≥60 Years – VAERS, May 3, 2023-April 14, 2024

- **Among VAERS reports of persons aged ≥60 years receiving an RSV vaccine, 346 (10.8%) of reports indicated a vaccination error**
  - Common errors included administration at inappropriate site, extra dose administered, and incorrect route of administration
  - Of these error reports, 18.5% indicated an adverse health event had occurred
  - Some reports may represent patients that received an RSV vaccine at the time of an error related to another vaccine

Unpublished data from CDC Immunization Safety Office, April 2024

Summary

- RSV vaccine administration errors involving pregnant people and young children aged <2 years have been reported to VAERS
- CDC and FDA continue to monitor VAERS for administration errors, including those involving RSV vaccines
- Education and training resources are available from CDC on strategies to prevent immunization errors

Acknowledgements

- **CDC Immunization Safety Office**
  - VAERS Team
  - Clinical Immunization Safety Assessment (CISA) Project
- **CDC National Center for Immunization and Respiratory Diseases**
  - Coronavirus and Other Respiratory Viruses Division
  - Immunization Services Division
- **Food and Drug Administration**

Closing Slide / Disclaimer

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.