

From: dph.immunizations@ct.gov <noreply@everbridge.net>
Sent: Tuesday, January 23, 2024 2:59 PM
Subject: CDC Clinical Outreach and Communication Activity (COCA) Now message: Information on Respiratory Syncytial Virus (RSV) Vaccine Administration Errors in Young Children and Pregnant People



DEPARTMENT OF PUBLIC HEALTH

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January 23, 2024

Subject: CDC Clinical Outreach and Communication Activity (COCA) Now message: Information on Respiratory Syncytial Virus (RSV) Vaccine Administration Errors in Young Children and Pregnant People

The Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) have received reports of RSV vaccines being administered in error to young children and pregnant people – see the full COCA Now Message below and link [here](#) for additional information. Healthcare providers should take action to prevent vaccine administration errors and promptly report errors that occur to VAERS.

COCA Now, 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 System¹ ([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

In August and September 2023, CDC and the Advisory Committee on Immunization Practices recommended two RSV prevention products to prevent RSV-associated lower respiratory tract disease in infants. Nirsevimab (Beyfortus, Sanofi, and AstraZeneca) is only [recommended for infants and some young children at increased risk for severe RSV disease](#). RSV vaccines (Pfizer Abrysvo, GSK Arexvy) are NOT approved for use in infants or young children. Pfizer (Abrysvo) is the only [RSV vaccine recommended for](#)

[pregnant people](#). The GSK RSV vaccine (Arexvy) is NOT approved for use during pregnancy.

Most reports of administration errors in young children occurred in infants younger than 8 months. Administration errors for both young children and pregnant people occurred in outpatient settings, including doctor's offices; administration errors of the GSK RSV vaccine (Arexvy) in pregnant people also occurred in pharmacies. Most of these administration error reports described no adverse event. When an adverse event was concurrently reported to VAERS, most reports were classified as nonserious¹. CDC, FDA, and other federal agencies continue to monitor the safety of RSV vaccines and reports of vaccine administration errors and will share information with the public as it becomes available.

Recommendations for Healthcare Providers who Have Administered Incorrect RSV Vaccine Products to Their Patients

1. For [infants and young children](#) who are [recommended](#) to receive nirsevimab but received either the Pfizer (Abrysvo) or GSK (Arexvy) RSV vaccine in error, administer a dose of nirsevimab.
2. For [pregnant people](#) who have received the GSK RSV vaccine (Arexvy) in error, do not give a dose of the Pfizer RSV vaccine (Abrysvo). Instead, the infant (if younger than 8 months) should receive nirsevimab during RSV season (October through March in most of the continental United States).
3. Healthcare providers and facilities should ensure use of the correct RSV prevention product in the correct population and take actions to [prevent vaccine administration errors](#), including automating error prevention alerts in electronic health record systems, ensuring proper education and training on vaccine recommendations, paying close attention to labeling, and following proper storage and administration best practices.
4. Healthcare providers are strongly encouraged to report vaccine administration errors to [VAERS](#).
5. For questions about vaccine administration errors, healthcare providers can submit their questions to NIPINFO@cdc.gov.
6. Healthcare providers in the United States with a complex vaccine safety question may request consultation on a vaccine administration error event for a specific patient. Information on how to request a consultation is available at the [Clinical Immunization Safety Assessment \(CISA\) Project](#).

¹ VAERS (managed by CDC and FDA) is a passive surveillance system that is used to detect possible vaccine safety problems and also monitors for vaccination errors. VAERS reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable and VAERS is not designed to determine if a vaccine caused a health problem. VAERS data are updated frequently and may change. VAERS reports that meet [certain criteria are classified as serious](#).

² Calculated using the National Immunization Survey Adult COVID Module (NIS-ACM) nirsevimab coverage data, Vaccine Safety Datalink RSV maternal vaccination coverage

data, and CDC Wonder birth data through December 2023. Several assumptions were applied (number of eligible persons, application of coverage estimates to eligible cohort, and no child-parent dyad receiving both immunizations).

For More Information:

Healthcare Provider Toolkit: [Healthcare Provider Toolkit: Preventing vaccine administration errors](#)

RSV vaccination for pregnant people: [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](#)

RSV antibody immunization for infants: [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](#)

Kathy Kudish, DVM, MSPH

Immunization Program Manager and Deputy State Public Health Veterinarian
CT Department of Public Health, Email: Kathy.kudish@ct.gov

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