Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study vaccine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor:	Pfizer Inc.
Vaccine Studied:	Abrysvo®, also known as respiratory syncytial virus stabilized prefusion F subunit (RSVpreF) vaccine
Protocol Number:	C3671016
Dates of Study:	22 June 2023 to 29 February 2024
Title of this Study:	A Study to Learn About the Safety and Immune Activity of RSVpreF in Children 2 Years to Under 18 Years of Age [A Phase 1, Open-Label, Age-Descending, Dose-Finding Study to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus Prefusion F Subunit Vaccine (RSVpreF) in Children 2 to <18 Years of Age]
Date of this Report:	14 October 2024

– Thank You –

If you or your child participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is respiratory syncytial virus (RSV)?

Respiratory syncytial [sin-SISH-ul] virus (RSV) is a common and contagious virus that affects the lungs. Symptoms of RSV infection are similar to a bad cold, such as cough, fever, sore throat, and runny nose.

RSV infection is the leading cause of lower respiratory tract illness among infants and young children worldwide. It can also cause severe illness in those with long-term medical conditions like lung diseases such as asthma. People with serious RSV infection may have trouble breathing and may need to be hospitalized.

> A **long-term medical condition** is any health issue that lasts for a long time or needs ongoing medical care.

What is the RSV stabilized prefusion F subunit (RSVpreF) vaccine?

RSV stabilized prefusion F subunit (RSVpreF) is an injectable vaccine that may help the body's immune system to protect against RSV disease. It contains proteins found in the virus that may stimulate the body's response to make antibodies. Antibodies are proteins that fight off infections. There is no live virus in RSVpreF.

RSVpreF has been approved by health agencies in the United States (US) and other countries for use in pregnant people to protect their infants from RSV. RSVpreF is also approved for use in older adults to protect them from RSV. The use of RSVpreF in children in this study was investigational, which means it is not approved by health agencies for use outside of research studies.

Researchers think that vaccination with RSVpreF may also help to protect children against RSV disease.

What was the purpose of this study?

The main purpose of this study was to learn about the safety of RSVpreF in children 2 years to under 18 years of age who may or may not have a long-term medical condition that makes them high-risk for RSV disease.

In this summary, children who took part in the study are referred to as "participants."

Researchers wanted to know:

- **How many participants had injection site pain, redness, or swelling within 7 days after vaccination with RSVpreF?**
- **How many participants had fever, tiredness, headache, muscle pain, joint pain, vomiting, or diarrhea within 7 days after vaccination with RSVpreF?**
- **How many participants had medical problems within 1 month after vaccination with RSVpreF?**
- **How many participants had serious medical problems during the study?**
- **How many participants were diagnosed with a new long-term medical condition during the study?**

What happened during the study?

How was the study done?

Participants were divided into 2 age groups in this study:

- **Younger** age group: 2 years to under 5 years of age
- **Older** age group: 5 years to under 18 years of age

Depending on when they joined the study, participants in either age group got 1 shot of RSVpreF vaccine given as either **120 micrograms (mcg)** or **60 mcg**.

This study was open-label. This means that participants, their parents/guardians, and the researchers knew that participants got RSVpreF (and its dose) in this study.

Vaccination:

First, participants in the **older** age group (5 years to under 18 years of age) were given RSVpreF **120 mcg**. After researchers made sure there were no safety concerns with this dose in the **older** age group, participants in the **younger** age group (2 years to under 5 years of age) were given RSVpreF **60 mcg**.

After researchers made sure there were no safety concerns with participants of either age group given RSVpreF, another group of participants in the **younger** age group were given RSVpreF **120 mcg**.

Some participants in the **older** age group were given RSVpreF **60 mcg**.

Follow-up:

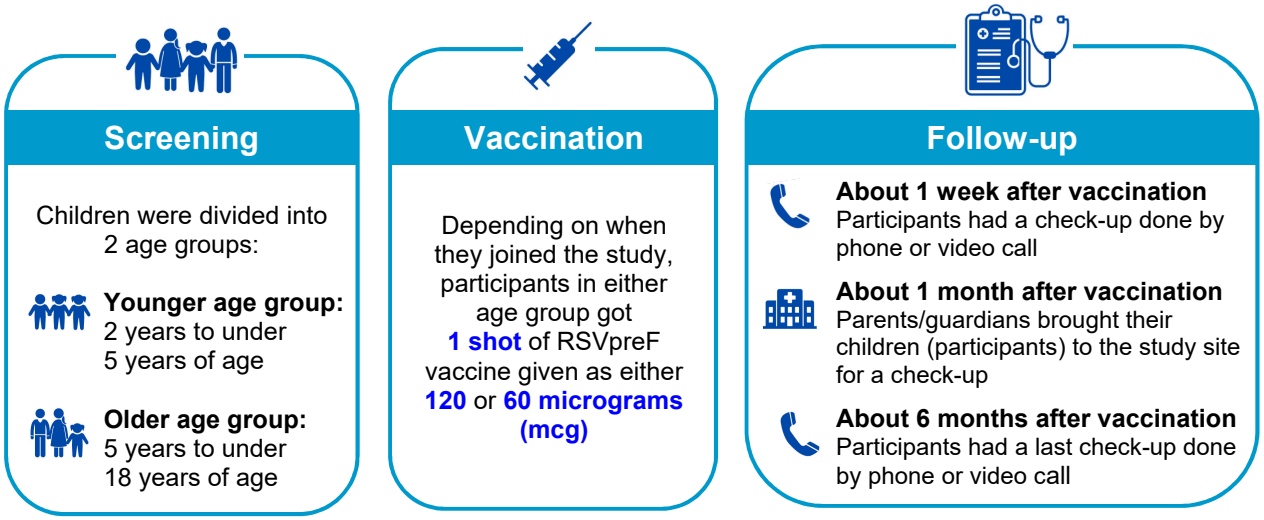
The participants, accompanied by their parents/guardians, had up to 3 health checks after getting their study vaccine:

- About 1 week after vaccination, participants had a check-up done by phone or video call.
- About 1 month after vaccination, parents/guardians brought their children (participants) to the study site for a check-up.
- About 6 months after vaccination, participants had a last check-up done by phone or video call.

During the study, researchers checked how participants were feeling and asked about medicines they might be taking. Researchers also took samples of blood from participants for testing. This was done to measure the antibody levels against RSV before and after their vaccination in this study.

Figure 1 shows how the study was done.

Figure 1. What happened in the study?



Where did this study take place?

The Sponsor ran this study at 16 locations in the US.

When did this study take place?

It began on 22 June 2023 and ended on 29 February 2024.

Who participated in this study?

The study included children 2 years to under 18 years of age. They must have been **healthy** according to the study doctors or must have had a **long-term medical condition** that makes them high-risk for RSV disease.

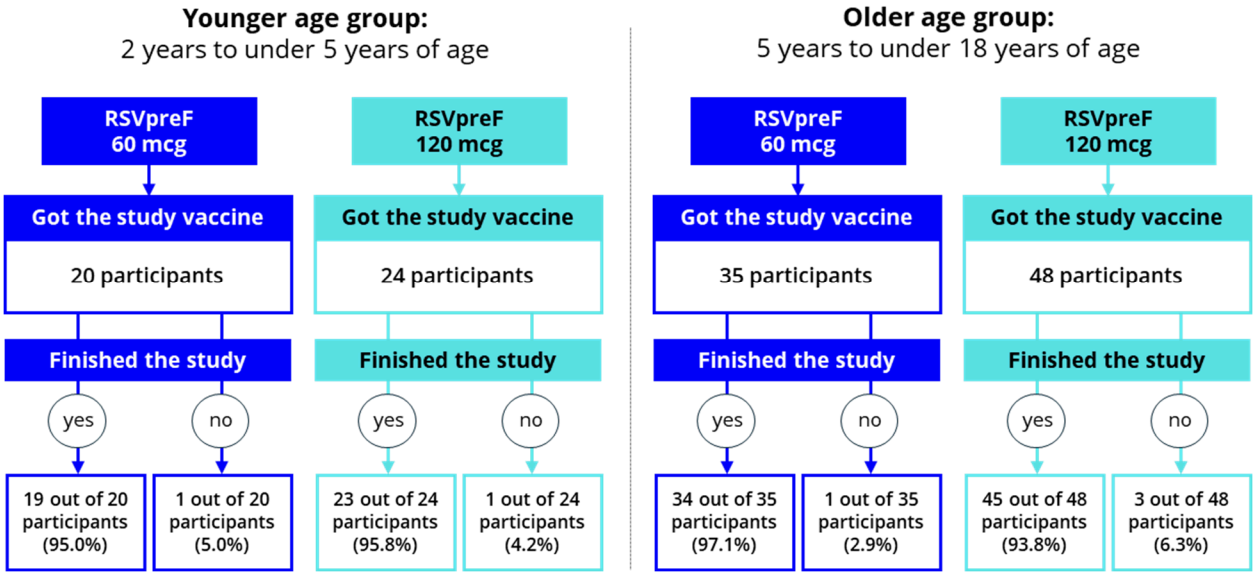
- Children **2 years to under 5 years of age** must have had an RSV infection in the past as confirmed from a blood test.
- Children **5 years to under 18 years of age** were assumed to have had RSV infection in the past and did not need a blood test.

Of the 136 participants who were screened to see if they could join the study, 8 participants did not meet the requirements to join the study. Overall, 127 participants got RSVpreF and 1 participant did not get RSVpreF in this study.

Of the 127 participants who got RSVpreF, 69 (54.3%) were boys and 58 (45.7%) were girls.

Figure 2 shows how many participants in each group took part in the study.

Figure 2. Number of participants who took part in the study



A total of 6 participants across the 2 age groups did not finish the study (see Figure 2). The reason was because their parents/guardians could not be contacted for the participants' follow-up checks.

How long did the study last?

Each participant was in the study for about 6 months. The entire study took about 8 months to complete.

When the study ended in February 2024, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

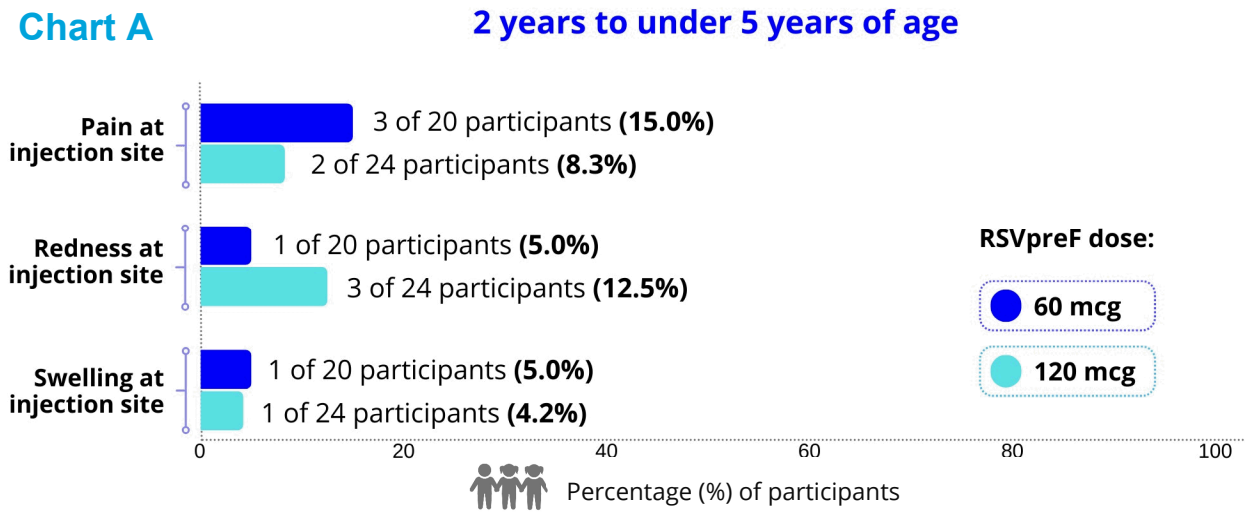
How many participants had injection site pain, redness, or swelling within 7 days after vaccination with RSVpreF?

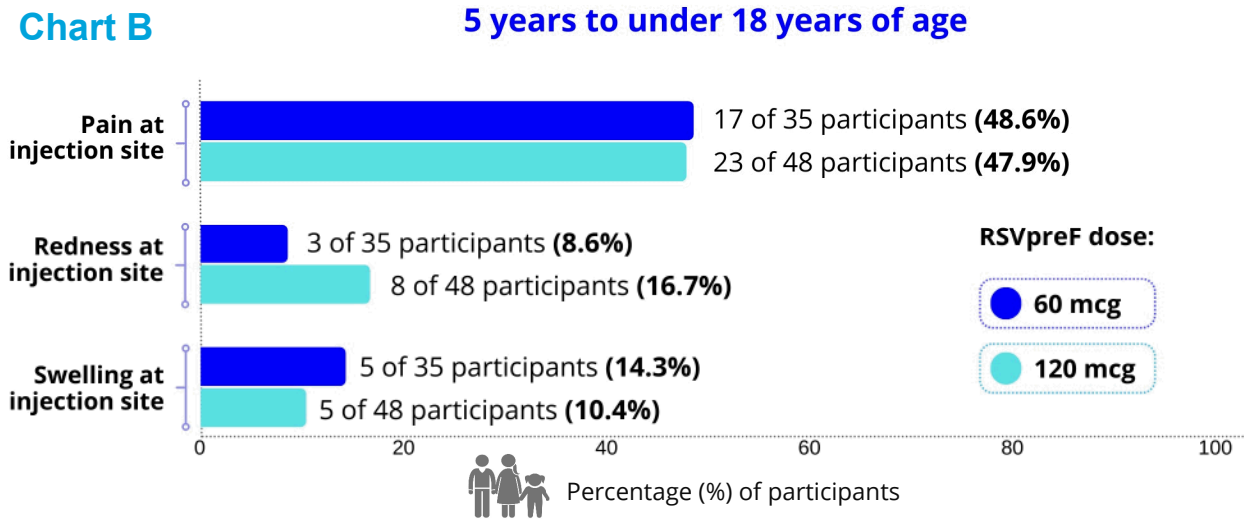
To answer this question, researchers checked the participants' electronic diary records if they had any injection site pain, redness, or swelling (also called **injection site reactions**) within 7 days after vaccination.

The charts in Figure 3 show that, in both dose groups, a higher number of participants 5 years to under 18 years of age (**Chart B**) had injection site reactions than those 2 years to under 5 years of age (**Chart A**). The most common injection site reactions were:

- **Injection site pain** in participants 2 years to under 5 years of age who got RSVpreF 60 mcg and **injection site redness** in those who got RSVpreF 120 mcg (**Chart A**)
- **Injection site pain** in participants 5 years to under 18 years of age in both dose groups (**Chart B**)

Figure 3. How many participants had injection site reactions within 7 days after vaccination with RSVpreF?





How many participants had fever, tiredness, headache, muscle pain, joint pain, vomiting, or diarrhea within 7 days after vaccination with RSVpreF?

To answer this question, researchers checked the participants' electronic diary records if they had any fever, tiredness, headache, muscle pain, joint pain, vomiting, or diarrhea (also called **systemic reactions**) within 7 days after vaccination.

The charts in Figure 4 show that, in both dose groups, a higher number of participants 5 years to under 18 years of age (**Chart B**) had systemic reactions than those 2 years to under 5 years of age (**Chart A**). The most common systemic reaction was **tiredness** in both age and dose groups.

Figure 4. How many participants had systemic reactions within 7 days after vaccination with RSVpreF?

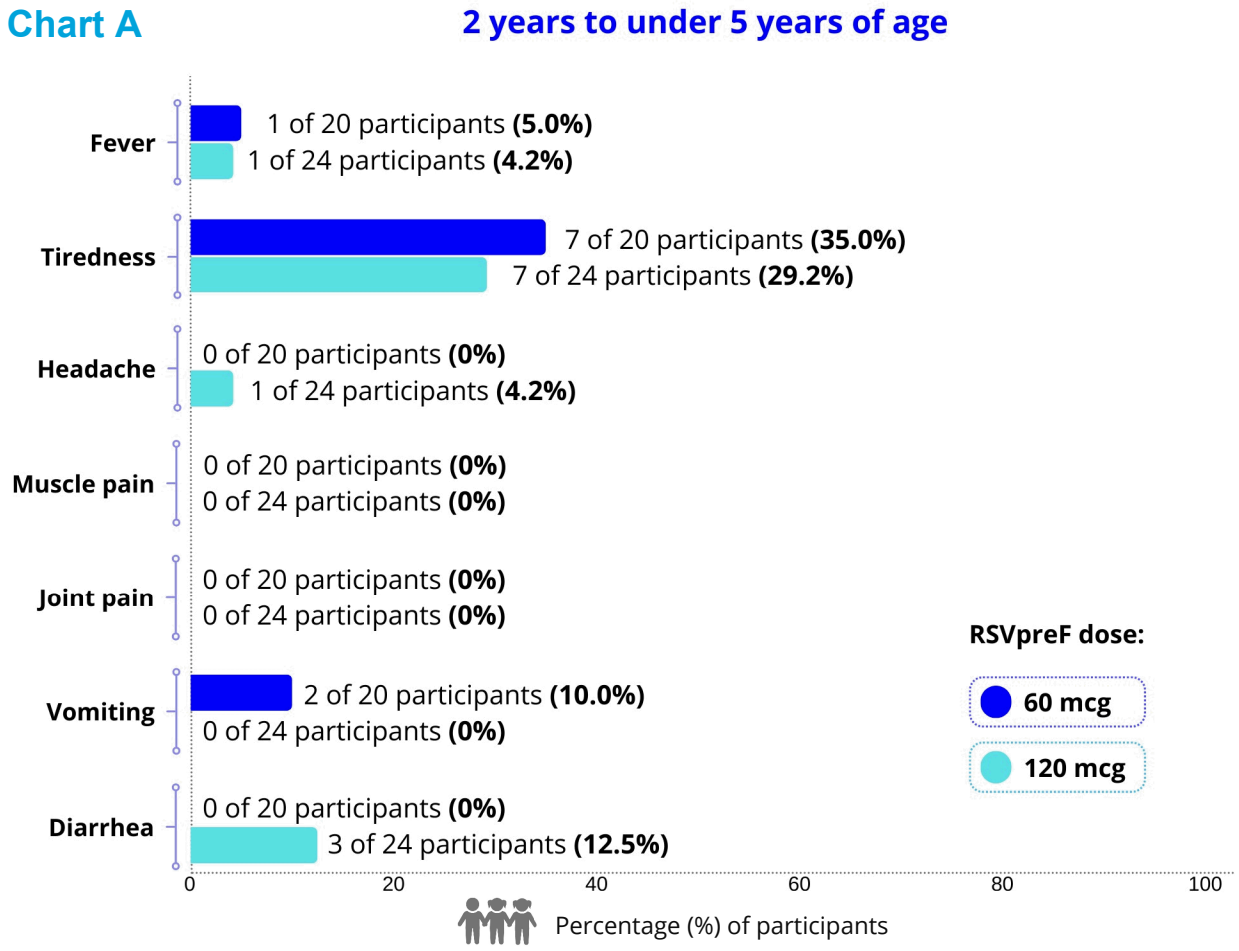
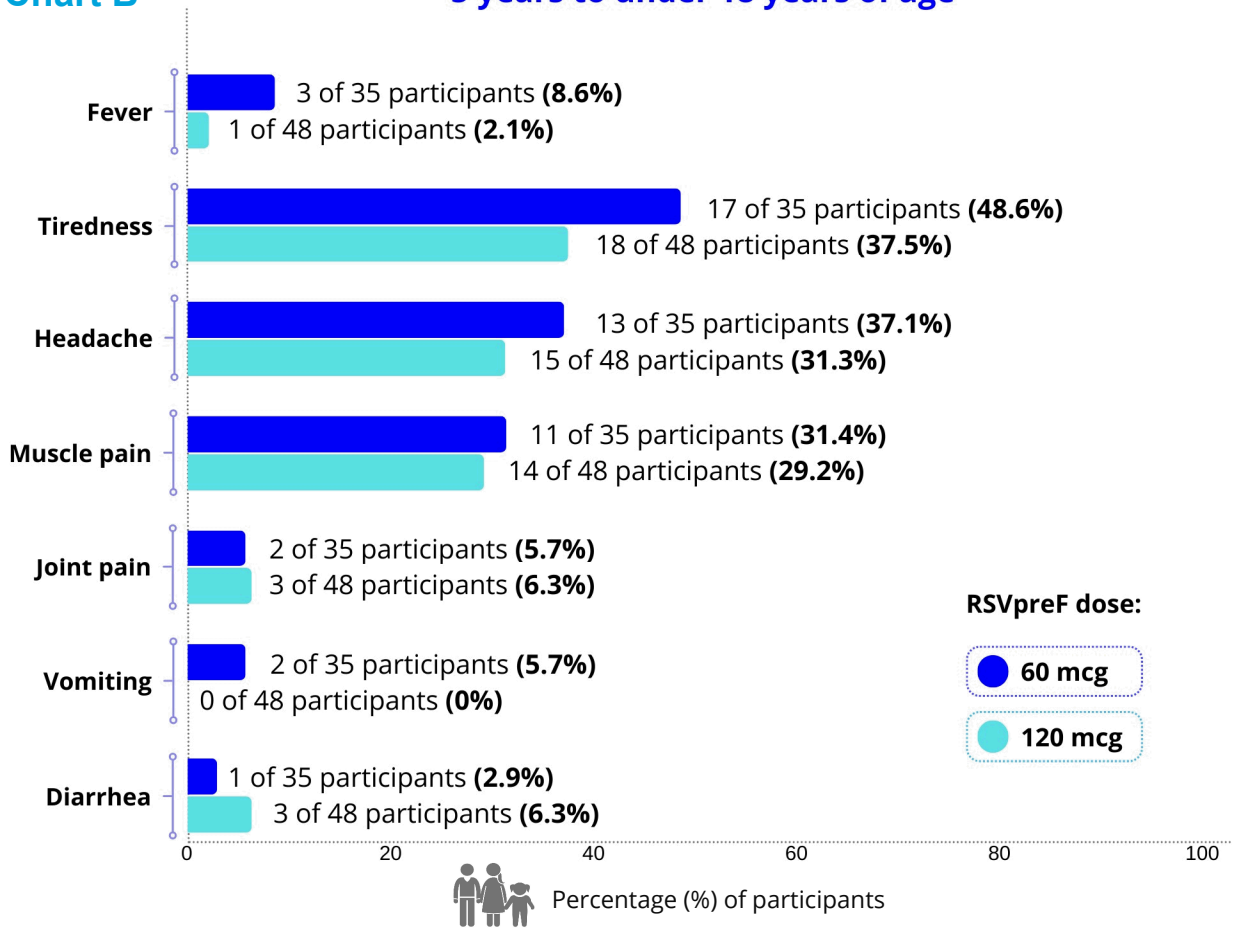


Chart B **5 years to under 18 years of age**



This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

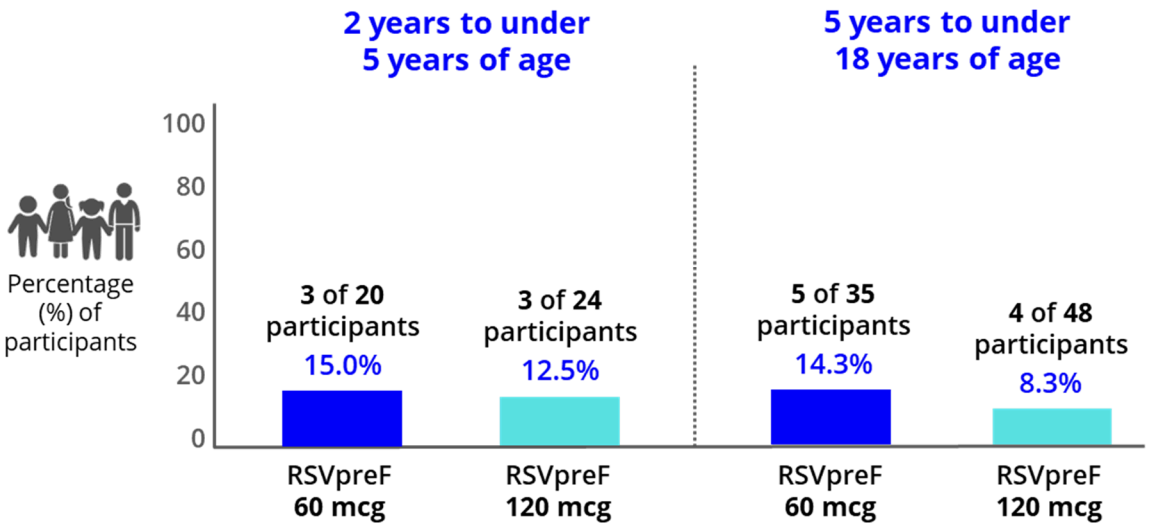
What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by other health problems or by chance). Or, medical problems could also have been caused by a study vaccine or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many vaccine groups in many studies, doctors try to understand what effects a study vaccine might have on a participant.

How many participants had medical problems within 1 month after vaccination with RSVpreF?

The results are shown in Figure 5 below for participants 2 years to under 5 years of age and those 5 years to under 18 years of age.

Figure 5. How many participants had medical problems within 1 month after vaccination with RSVpreF?



No participant in either age group left the study because of medical problems they had during the study.

The most common medical problems within 1 month after vaccination with RSVpreF – seen in at least 2 participants overall – are listed in Figure 6. **Chart A** lists the common medical problems reported in participants 2 years to under 5 years. **Chart B** lists the common medical problems reported in participants 5 years to under 18 years.

Figure 6. Commonly reported medical problems by participants within 1 month after vaccination with RSVpreF

Chart A

2 years to under 5 years of age

RSVpreF 60 mcg	RSVpreF 120 mcg
• 1 out of 20 participants (5%) had an **illness from unknown virus** • 1 out of 20 participants (5%) had a **fever** • 1 out of 20 participants (5%) had **croup**, a respiratory infection that causes swelling of the voice box and windpipe	• 1 out of 24 participants (4.2%) had an **illness from unknown virus** • 1 out of 24 participants (4.2%) had a **fever**

Chart B

5 years to under 18 years of age

RSVpreF 60 mcg	RSVpreF 120 mcg
• 1 out of 35 participants (2.9%) had an **illness from unknown virus** • 1 out of 35 participants (2.9%) had a **food allergy**	• 1 out of 48 participants (2.1%) had **croup**, a respiratory infection that causes swelling of the voice box and windpipe • 1 out of 48 participants (2.1%) had a **food allergy**

Did study participants have any serious medical problems?

A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

How many participants had serious medical problems during the study?

No participant **2 years to under 5 years** of age had serious medical problems during the study.

In the **5 years to under 18 years** age group, 2 participants had serious medical problems during the study. Of these 2 participants:

- 1 out of 35 participants (2.9%) who got **RSVpreF 60 mcg** had an asthma attack.
- 1 out of 48 participants (2.1%) who got **RSVpreF 120 mcg** had a food allergy.

Researchers did not think any of the serious medical problems were caused by the study vaccine.

No participant died during the study.

How many participants were diagnosed with a new long-term medical condition during the study?

No participant was diagnosed with a new long-term medical condition during the study.

Where can I learn more about this study?

If you or your child have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number C3671016

The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier **NCT05900154**

Please remember that researchers look at the results of many studies to find out which vaccines can work and are safe for patients.

Again, if you or your child participated in this study, **thank you** for volunteering. We do research to try to find the best ways to help patients, and you helped us to do that!