



## 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 study participants. The results of this study might be different than the results of other studies that the researchers review.

**Sponsor:** Pfizer Inc.

**Vaccine Studied:** 20-valent pneumococcal conjugate vaccine (called 20vPnC or PF-06482077)

**Protocol Number:** B7471014

**Dates of Study:** 04 December 2020 to 06 April 2022

**Title of this Study:** A study of 20vPnC vaccine in healthy children – if it was safe and produced antibody responses against a germ called *Streptococcus pneumoniae*

[A Phase 3, Single-Arm Trial to Evaluate the Safety and Immunogenicity of a 20-Valent Pneumococcal Conjugate Vaccine in Healthy Children 15 Months Through 17 Years of Age]

**Date(s) of this Report:** 24 August 2022

### — Thank You —

If you and 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?

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### What is *Streptococcus pneumoniae*?

*Streptococcus pneumoniae* (or *S pneumoniae*) is a kind of germ (bacteria). Pneumococcus is its other name. *S pneumoniae* has more than 100 types, but only a few types cause serious diseases.

*S pneumoniae* can cause infections of the lungs, brain lining, blood, and ear. These infections may be serious in young children.

### What is a vaccine and an antibody response?

A vaccine can help prevent an infection or a disease. It works by helping the body fight off germs.

Antibodies are proteins that fight infections and help prevent diseases. After a person gets a vaccine, the body's response includes making antibodies. This is called an antibody response.

### What is 20-valent pneumococcal conjugate vaccine (20vPnC)?

Valent (vey-luhnt)  
Pneumococcal (nyoo-muh-kok-uhl)  
Conjugate (kon-juh-geyt)

20vPnC is an injectable study vaccine. It was not approved for general use at the time of this study. 20vPnC has the same 13 components as the 13-valent pneumococcal conjugate vaccine (13vPnC or Prevnar<sup>®</sup> 13), but 20vPnC has 7 more components that may give a wider protection. 13vPnC is approved in the United States to prevent *S pneumoniae* diseases in children and adults.

Researchers think 20vPnC can help prevent 20 of the most common types of *S pneumoniae* that cause infections.

### What was the purpose of this study?

This study aimed to find out if 20vPnC was safe in healthy children, and if it produced antibody responses against *S pneumoniae*.

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## Researchers wanted to know:

1. Did children have an antibody response against *S pneumoniae* at 1 month after they got 20vPnC?
  2. How many children had redness, swelling, or pain at the injection site after they got 20vPnC?
  3. How many of the younger children had fever, loss of appetite, drowsiness, or irritability after they got 20vPnC?
  4. How many of the older children had fever, tiredness, headache, or muscle or joint pain after they got 20vPnC?
  5. How many children were diagnosed with a new long-term disease or medical condition during the study?
  6. What medical problems did the children have during the study?
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## What happened during the study?

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### How was the study done?

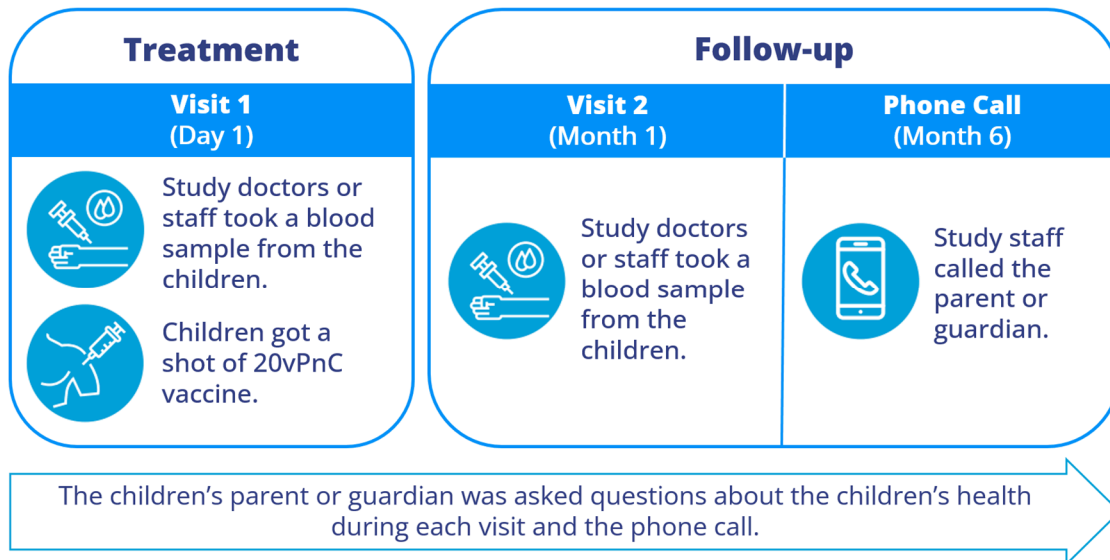
Researchers tested 20vPnC on a group of children who joined the study. The children visited the study site at least 2 times during the study.

- On Visit 1, the study doctors or staff took a blood sample from the children before they got 20vPnC. Then, the children got 1 shot of 0.5 milliliter (mL) of 20vPnC.
- Visit 2 happened at 1 month after the children got 20vPnC. During this visit, the study doctors or staff took another blood sample from the children.
- Six (6) months after the children got 20vPnC, the children's parent or guardian got a follow-up phone call.

During each visit and the phone call, the children's parent or guardian was asked questions about the children's health.

The figure below shows what happened during the study.

Figure 1. What happened during the study?



## Where did this study take place?

The Sponsor ran this study at 40 locations in the United States.

## When did this study take place?

It began 04 December 2020 and ended 06 April 2022.

## Who participated in this study?

The study included children who were assessed as healthy by study doctors. Healthy children ages 15 months to 17 years old could join the study.

Of the 839 children who started the study, 831 children got 20vPnC.

- There were 446 boys and 385 girls.
- The children were between the ages of 15 months and 17 years old.

In this study, children were sorted by age group. The 4 age groups were:

- 15 months to below 24 months old
- 2 years to below 5 years old
- 5 years to below 10 years old
- 10 years to below 18 years old

Overall, 819 children finished the study. Twenty (20) children did not finish the study. The most common reasons were because:

- Their parent or guardian could not be reached for follow-up.
- They left the study by their own, parent, or guardian's choice.

## How long did the study last?

The children were in the study for about 6 months. The entire study took about 16 months to finish.

When the study ended in April 2022, 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?

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The researchers measured the amount of antibodies against *S pneumoniae* in the children's blood samples. They compared the amount of antibodies before and after getting 20vPnC.



### Did the children have an antibody response against *S pneumoniae* at 1 month after they got 20vPnC?

At 1 month after getting 20vPnC, researchers saw a rise in antibodies against *S pneumoniae* among the children in all 4 age groups. They found out that the children had antibody responses against *S pneumoniae*.

Parents or guardians kept a diary to record how the children felt within 7 days of getting 20vPnC.

Researchers checked the records of 823 children who had diary entries.



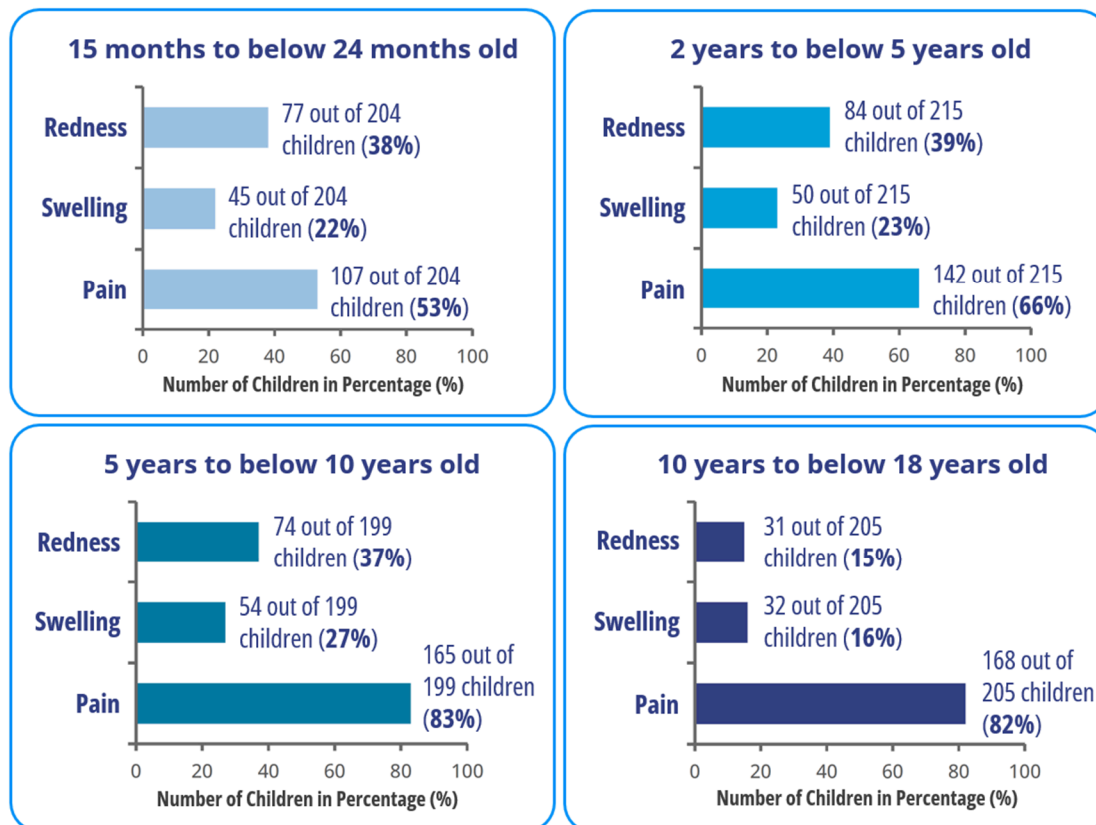
## How many children had redness, swelling, or pain at the injection site after they got 20vPnC?

The list below shows how many children in each age group had redness, swelling, or pain at the injection site (or the skin area where the needle was injected) within 7 days of getting 20vPnC.

- 15 months to below 24 months old: 129 out of 204 children (63%)
- 2 years to below 5 years old: 151 out of 215 children (70%)
- 5 years to below 10 years old: 172 out of 199 children (86%)
- 10 years to below 18 years old: 172 out of 205 children (84%)

The charts below in **Figure 2** show that pain at the injection site was the most common reaction in all age groups.

**Figure 2. How many children had redness, swelling, or pain at the injection site within 7 days of getting 20vPnC?**



Researchers looked at 2 sets of symptoms based on the children’s age group: younger children (15 months to below 24 months old) and older children (2 years to below 18 years old).

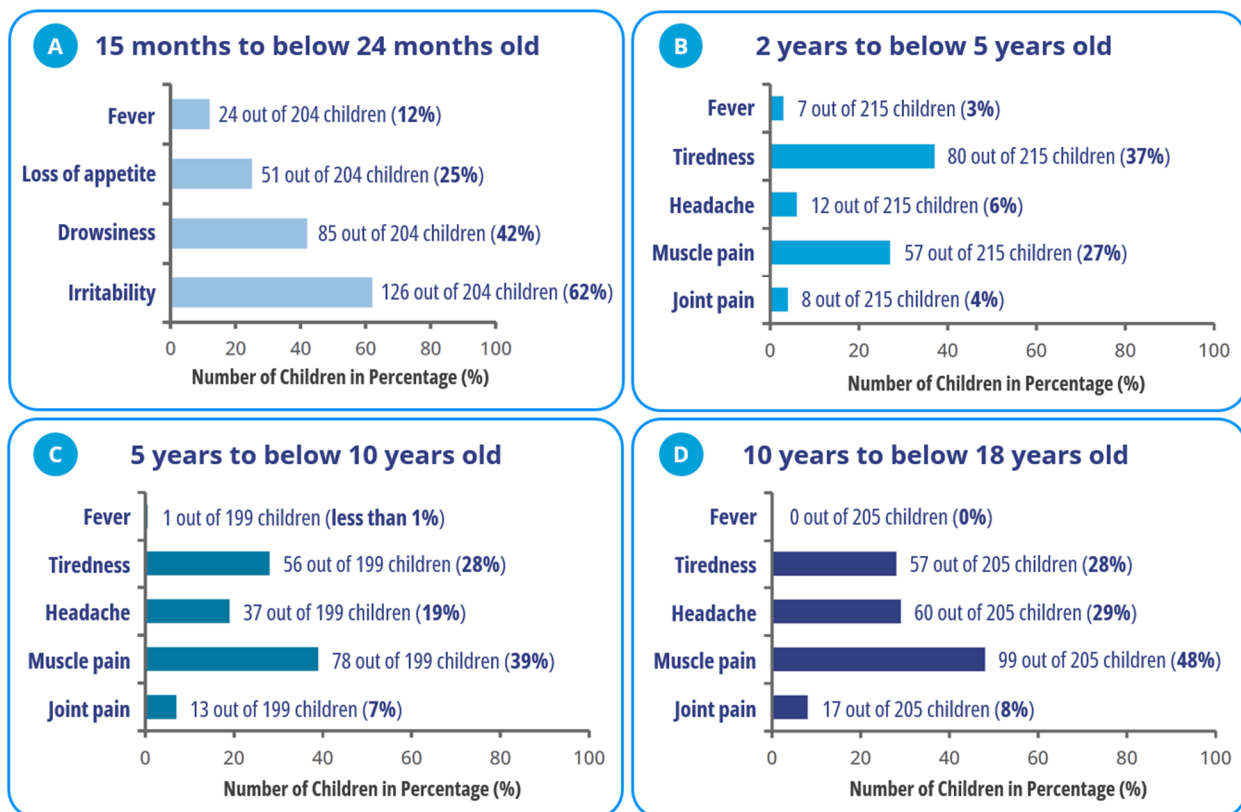


### How many of the younger children had fever, loss of appetite, drowsiness, or irritability after they got 20vPnC?

Researchers looked at the records of younger children (15 months to below 24 months old) who had diary entries. They found out that 153 out of 204 children (75%) had fever, loss of appetite, drowsiness, or irritability within 7 days of getting 20vPnC.

Chart “A” in **Figure 3** below shows that irritability was the most common symptom in children 15 months to below 24 months old.

**Figure 3. How many children had fever and other symptoms within 7 days of getting 20vPnC?**







### How many of the older children had fever, tiredness, headache, or muscle or joint pain after they got 20vPnC?

Researchers looked at the records of older children (2 years to below 18 years old) who had diary entries. The list below shows how many children had fever, tiredness, headache, or muscle or joint pain within 7 days of getting 20vPnC.

- 2 years to below 5 years old: 108 out of 215 children (50%)
- 5 years to below 10 years old: 116 out of 199 children (58%)
- 10 years to below 18 years old: 140 out of 205 children (68%)

Charts “B”, “C”, and “D” in **Figure 3** above show the most common symptoms by age group.

- Tiredness in children 2 years to below 5 years old
- Muscle pain in children 5 years to below 18 years old

The reactions at the injection site (redness, swelling, or pain) and fever seen with 20vPnC in this study were found to be similar to those seen with 13vPnC in the same age groups.



### How many children were diagnosed with a new long-term disease or medical condition during the study?

Researchers wanted to know how many children were diagnosed with a new long-term disease or medical condition during the study (within 6 months of getting 20vPnC). Researchers looked at the records of 831 children who got 20vPnC.

The list below shows how many children were diagnosed with a new long-term disease or medical condition within 6 months of getting 20vPnC.

- 15 months to below 24 months old: 7 out of 209 children (3%)
- 2 years to below 5 years old: 1 out of 216 children (less than 1%)
- 5 years to below 10 years old: 1 out of 201 children (less than 1%)
- 10 years to below 18 years old: 2 out of 205 children (1%)

Most of the new long-term diseases or medical conditions were allergic in nature.



## What medical problems did the children have during the study?

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

Researchers looked at the records of 831 children who got 20vPnC.

No child left the study because of medical problems.



### How many children had medical problems within 1 month of getting 20vPnC?

The list below shows how many children had a medical problem within 1 month of getting 20vPnC.

- 15 months to below 24 months old: 50 out of 209 children (24%)
- 2 years to below 5 years old: 17 out of 216 children (8%)
- 5 years to below 10 years old: 13 out of 201 children (7%)
- 10 years to below 18 years old: 9 out of 205 children (4%)

The table below describes the most common medical problems – those reported by at least 2% of children in any age group.

Below are instructions on how to read Table 1.

#### Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists the most common medical problems reported during the study. It lists all medical problems reported by at least 2% of children in any age group.
- The **2nd** to **5th** columns tell how many of the children in each age group had a medical problem. Next to this number is the percentage of children in each age group who had the medical problem.
- Using these instructions, you can see that 6 out of the 209 children (3%) who were 15 months to below 24 months old had an ear infection. None of the children who were 2 years to below 18 years old had an ear infection.

**Table 1. Most common medical problems in the study**

Medical Problem	15 months to below 24 months old (209 children)	2 years to below 5 years old (216 children)	5 years to below 10 years old (201 children)	10 years to below 18 years old (205 children)
Ear infection	6 out of 209 children (3%)	0 out of 216 children (0%)	0 out of 201 children (0%)	0 out of 205 children (0%)
Infection of the nose, sinuses, or throat (cold)	4 out of 209 children (2%)	1 out of 216 children (less than 1%)	1 out of 201 children (less than 1%)	0 out of 205 children (0%)
Cold caused by a virus	4 out of 209 children (2%)	1 out of 216 children (less than 1%)	0 out of 201 children (0%)	0 out of 205 children (0%)
Recent onset of ear infection	4 out of 209 children (2%)	0 out of 216 children (0%)	0 out of 201 children (0%)	0 out of 205 children (0%)

## Did the children have any serious medical problems?

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

No child died during the study.



### How many children had a serious medical problem during the study (within 6 months of getting 20vPnC)?

Five (5) children had a serious medical problem within 6 months of getting 20vPnC.

- 15 months to below 24 months old: 2 out of 209 children (1%)
- 10 years to below 18 years old: 3 out of 205 children (2%)

None of the serious medical problems were considered by study doctors as related to 20vPnC. No child 2 years to below 10 years old had a serious medical problem.

## Where can I learn more about this study?

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If you 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](http://www.pfizer.com/research/research_clinical_trials/trial_results)

Use the protocol number **B7471014**

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

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)  
[www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu)

Use the study identifier **NCT04642079**

Use the study identifier **2019-003308-11**

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

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