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:	20-valent pneumococcal conjugate vaccine (called 20vPnC or PF-06482077)
Protocol Number:	B7471013
Dates of Study:	21 May 2020 to 31 August 2022
Title of this Study:	A Study of the Safety of 20vPnC in Healthy Infants [A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety of a 20-valent Pneumococcal Conjugate Vaccine in Healthy Infants]
Date(s) of this Report:	04 January 2023

— 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?

What is *Streptococcus pneumoniae*?

Streptococcus pneumoniae (also known as pneumococcus or *S pneumoniae*) is a kind of germ. *S pneumoniae* has more than 100 types, but only a few types cause serious diseases.

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

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

20vPnC is an injectable vaccine that was tested in this study. Researchers think that 20vPnC can help prevent 20 of the most common types of *S pneumoniae* that cause infections.

> A vaccine can help the body prevent an infection or a disease.
>
> After a person gets a vaccine, the body makes antibodies, which are proteins that fight off infections. This is called an antibody response.

In this study, 20vPnC was compared to 13-valent pneumococcal conjugate vaccine (13vPnC).

- 13vPnC is also known as Prevnar 13® or Prevenar 13®. It is approved in the United States, Europe, and many other countries to prevent diseases caused by *S pneumoniae* in infants and adults. 13vPnC is made up of 13 parts (or components) to prevent diseases caused by 13 types of *S pneumoniae*.
- 20vPnC has the same parts found in 13vPnC. But, 20vPnC has 7 more parts that may give wider protection against 7 additional types of *S pneumoniae*.

What was the purpose of this study?

The purpose of this study was to learn if 20vPnC was safe when given in 4 doses to healthy infants.

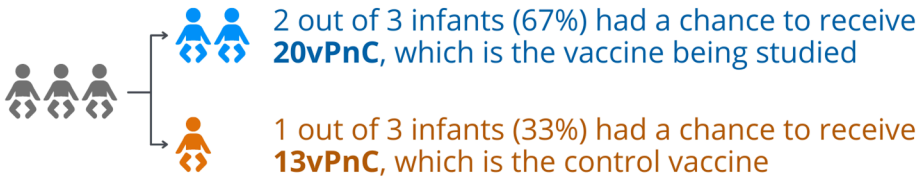
Researchers wanted to know:

1. **What percentage of infants had redness, swelling, or pain at the injection site after each dose of 20vPnC or 13vPnC?**
2. **What percentage of infants had fever, loss of appetite, drowsiness, or irritability after each dose of 20vPnC or 13vPnC?**
3. **What percentage of infants had a medical problem at any time from the 1st dose to 1 month after the 3rd dose of 20vPnC or 13vPnC?**
4. **What percentage of infants had a medical problem at any time from the 4th dose to 1 month after the 4th dose of 20vPnC or 13vPnC?**
5. **What percentage of infants had a serious medical problem during the study?**
6. **What percentage of infants were diagnosed with a new long-term medical condition during the study?**

What happened during the study?

How was the study done?

The infants were assigned to 1 of 2 vaccine groups by chance. This study was designed to include twice as many infants given 20vPnC as those given 13vPnC.



The infants' parents or guardians and the researchers did not know which vaccine (20vPnC or 13vPnC) was given to the infants during the study. This is known as a "double-blind" study.

This study looked at 2 groups of infants to learn about the safety of 20vPnC.

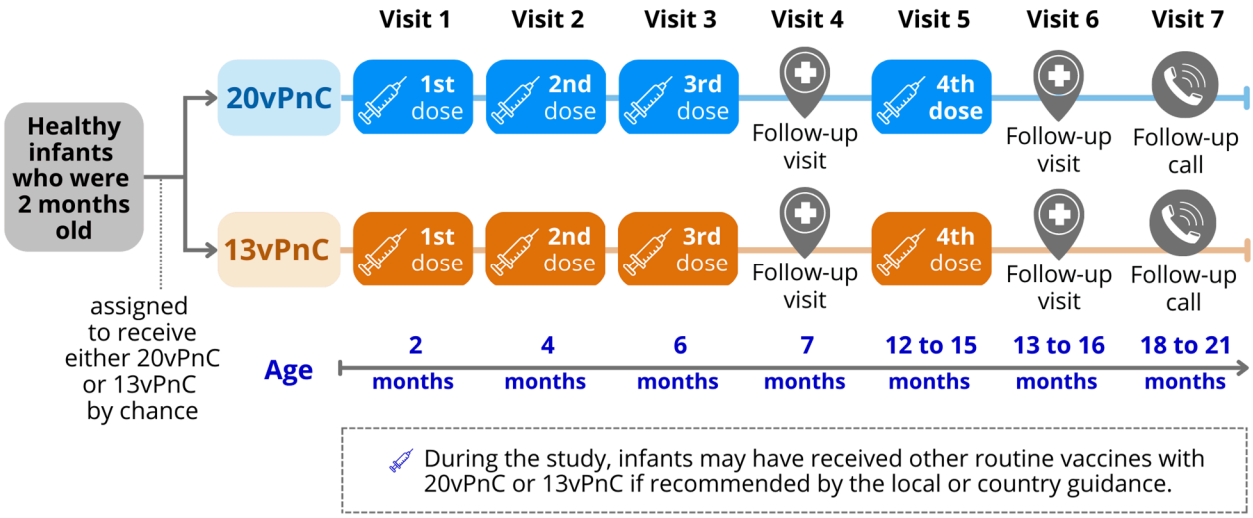
- **20vPnC Group** (test group): Researchers tested 20vPnC on a group of infants. 20vPnC is the vaccine being studied.
- **13vPnC Group** (control group): 13vPnC was given to a group of infants. In this study, 13vPnC was the control vaccine because it is commonly given in infants to prevent diseases caused by *S pneumoniae*.

> Participants in a control group do not receive the vaccine being studied.

Researchers then compared the results of infants given 20vPnC to the results of infants given 13vPnC.

Figure 1 shows that infants received either 20vPnC or 13vPnC at Visits 1, 2, 3, and 5. They received the same vaccine (20vPnC or 13vPnC) for up to 4 doses.

Figure 1: What happened during the study?



Throughout the study, the parents or guardians were asked about their infants' health.

- During Visits 4 and 6, the parents or guardians brought their infants to the study site for a follow-up visit 1 month after the 3rd dose and 1 month after the 4th dose.
- During Visit 7, the parents or guardians were asked about their infants over a phone call about 6 months after the 4th dose.

Where did this study take place?

The Sponsor ran this study at 83 locations in 10 countries.

- Argentina
- Canada
- Chile
- Czech Republic
- Finland
- Germany
- Greece
- Hungary
- Spain
- United States of America (including Puerto Rico)

When did this study take place?

It began on 21 May 2020 and ended on 31 August 2022.

Who participated in this study?

The study included infants who:

- were assessed as healthy by the study doctors.
- were born after at least 34 weeks of pregnancy.
- were about 2 months old, or between 42 to 98 days old (or 6 to 14 weeks old), when they joined this study.
- had not received any other vaccine for *S pneumoniae* before joining this study.

Out of the 1511 infants who took part in this study, 7 infants were assigned to a vaccine group but did not receive a vaccine.

Overall, 1504 infants received at least the 1st dose of 20vPnC or 13vPnC. Out of 1504 infants, 1000 were assigned to receive 20vPnC, and 504 were assigned to receive 13vPnC. Of the infants assigned to receive 13vPnC, 1 infant received 20vPnC as the 1st dose. The results of this infant are not included in this summary.

The results of 1503 infants are included in this summary.

- Out of 1503 infants, 761 (51%) were boys and 742 (49%) were girls.
- At the time of the 1st dose, the average age of infants was 65 days old.

Overall, 1357 out of 1511 infants (90%) completed all the study visits. A total of 150 out of 1511 infants (10%) did not finish the study. The most common reasons were that their parents or guardians could not be contacted for follow-up, and their parents or guardians decided for them to leave the study before it was over.

How long did the study last?

Infants were in the study for about 16 to 19 months. The entire study took about 2 years and 3 months to complete.

When the study ended in August 2022, the Sponsor conducted their final review of the information collected and analyzed the data. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

In this study, researchers found that the safety results of 20vPnC were similar to those of 13vPnC. Similar to 13vPnC, 20vPnC was shown to have an acceptable safety profile when given in 4 doses to infants.

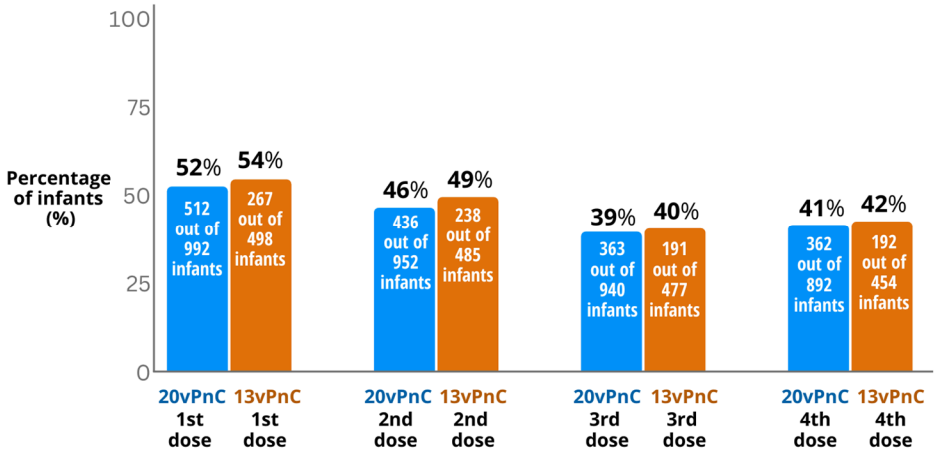
The answers to Questions 1 to 6 below describe these results.

1 What percentage of infants had redness, swelling, or pain at the injection site after each dose of 20vPnC or 13vPnC?

Parents or guardians kept a diary to record how the infants felt within 7 days after each dose of 20vPnC or 13vPnC. They checked for any reaction at the skin area where 20vPnC or 13vPnC was injected (or injection site reaction). Researchers looked at the diary records collected for infants.

Figure 2 shows that the percentages of infants with at least 1 injection site reaction (any redness, swelling, or pain at the injection site) within 7 days after each dose were similar in the 20vPnC and 13vPnC groups.

Figure 2: What percentage of infants had at least 1 injection site reaction (any redness, swelling, or pain at the injection site) within 7 days after each dose of 20vPnC or 13vPnC?



Not shown in Figure 2:

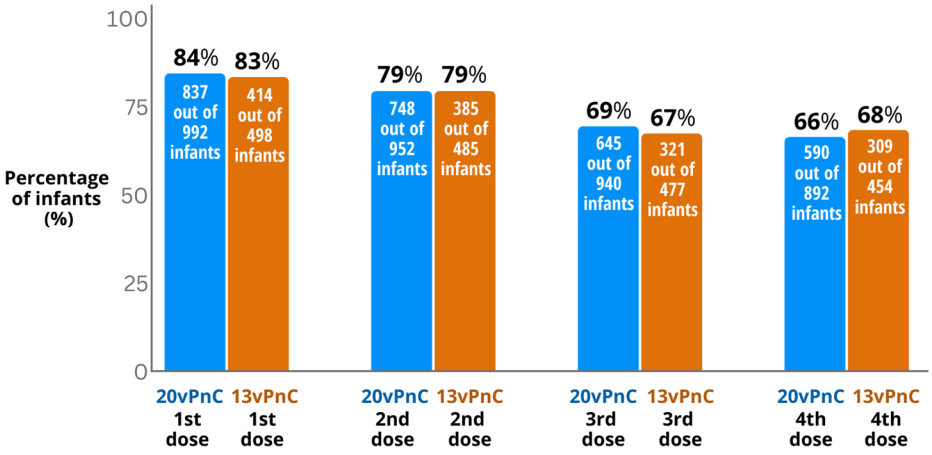
Most of these injection site reactions were mild or moderate in severity. These reactions generally went away after about 1 to 2 days. The most common single reaction after any dose of 20vPnC or 13vPnC was pain at the injection site.

2 What percentage of infants had fever, loss of appetite, drowsiness, or irritability after each dose of 20vPnC or 13vPnC?

Parents or guardians kept a diary to record their infants' symptoms within 7 days after each dose of 20vPnC or 13vPnC. Researchers looked at the diary records collected for infants.

Figure 3 shows that the percentages of infants with at least 1 symptom (any fever, loss of appetite, drowsiness, or irritability) within 7 days after each dose were similar in the 20vPnC and 13vPnC groups.

Figure 3: What percentage of infants had at least 1 symptom (any fever, loss of appetite, drowsiness, or irritability) within 7 days after each dose of 20vPnC or 13vPnC?



Not shown in Figure 3:

Most of these symptoms were mild or moderate in severity. These symptoms generally went away after about 1 to 2 days. The most common single symptom after any dose of 20vPnC or 13vPnC was irritability.

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 of 20vPnC may have different results.

What medical problems did infants have during the study?

The researchers recorded any medical problems the infants had during the study. Infants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, the medical problems could have been caused by the study vaccine, another vaccine, or a medicine the infant 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 an infant.

Overall, 3 infants in the 20vPnC group stopped taking part in the study because of a medical problem they had during the study. As a result, they did not receive the remaining doses of 20vPnC. None of the infants in the 13vPnC group stopped taking part in the study because of a medical problem.

3 What percentage of infants had a medical problem at any time from the 1st dose to 1 month after the 3rd dose of 20vPnC or 13vPnC?

Researchers looked at the records of 1503 infants who received at least the 1st dose of 20vPnC or 13vPnC.

The percentages of infants with a medical problem that happened at any time from the **1st dose** to **1 month after the 3rd dose** were similar in the 20vPnC and 13vPnC groups.

- 296 out of 1000 infants (**30%**) in the 20vPnC group.
- 139 out of 503 infants (**28%**) in the 13vPnC group.

Table 1 shows the most common medical problems that happened at any time from the 1st dose to 1 month after the 3rd dose of 20vPnC or 13vPnC. These medical problems were seen in at least 2% of infants in any group.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column lists the most common medical problems that happened at any time from the 1st dose to 1 month after the 3rd dose. The table lists all medical problems seen in at least 2% of infants in any group who received at least the 1st dose of 20vPnC or 13vPnC.
- The **2nd** column tells how many of the 1000 infants in the 20vPnC group had each medical problem. Next to this number is the percentage of the 1000 infants in the 20vPnC group who had the medical problem.
- The **3rd** column tells how many of the 503 infants in the 13vPnC group had each medical problem. Next to this number is the percentage of the 503 infants in the 13vPnC group who had the medical problem.
- For example, using these instructions, you can see that 41 out of 1000 infants (4%) in the 20vPnC group had an infection of the nose, sinuses, or throat. A total of 15 out of 503 infants (3%) in the 13vPnC group had an infection of the nose, sinuses, or throat.

Table 1. What were the most common medical problems that happened at any time from the 1st dose to 1 month after the 3rd dose of 20vPnC or 13vPnC?		
Medical Problem	**20vPnC (1000 Infants)**	**13vPnC (503 Infants)**
Infection of the nose, sinuses, or throat	41 out of 1000 infants (4%)	15 out of 503 infants (3%)
Swelling of the nasal (nose) **passages and throat** (also known as **a cold**)	28 out of 1000 infants (3%)	6 out of 503 infants (1%)
"Eczema" (a dry and itchy skin condition)	21 out of 1000 infants (2%)	8 out of 503 infants (2%)
Viral infection of the small airways in the lungs	15 out of 1000 infants (2%)	10 out of 503 infants (2%)
"Atopic dermatitis" (a type of eczema)	23 out of 1000 infants (2%)	6 out of 503 infants (1%)

4 What percentage of infants had a medical problem at any time from the 4th dose to 1 month after the 4th dose of 20vPnC or 13vPnC?

Researchers looked at the records of 1384 infants who received all 4 doses of 20vPnC or 13vPnC.

The percentages of infants with a medical problem that happened at any time from the **4th dose** to **1 month after the 4th dose** were similar in the 20vPnC and 13vPnC groups.

- 139 out of 923 infants (**15%**) in the 20vPnC group.
- 73 out of 461 infants (**16%**) in the 13vPnC group.

The list below shows the most common medical problems that happened at any time from the 4th dose to 1 month after the 4th dose of 20vPnC or 13vPnC. These medical problems were seen in at least 2% of infants in any group.

- **Infection of the nose, sinuses, or throat** was seen in:
  - 19 out of 923 infants (**2%**) in the 20vPnC group.
  - 14 out of 461 infants (**3%**) in the 13vPnC group.
- **Swelling of the nasal (nose) passages and throat** (also known as a **cold**) was seen in:
  - 21 out of 923 infants (**2%**) in the 20vPnC group.
  - 5 out of 461 infants (**1%**) in the 13vPnC group.

Did infants have any serious medical problems?

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

5 What percentage of infants had a serious medical problem during the study?

Researchers looked at the records of 1503 infants who received at least the 1st dose of 20vPnC or 13vPnC.

The percentages of infants with a serious medical problem during the study (at any time from the **1st dose** to **6 months after the 4th dose**) were low and similar for the 20vPnC and 13vPnC groups.

- 44 out of 1000 infants (**4%**) in the 20vPnC group.
- 28 out of 503 infants (**6%**) in the 13vPnC group.

Each serious medical problem happened in 1% of infants or fewer in any group. Most of these serious medical problems included hospital care for infections, which are commonly seen in this age group. The study doctors did not consider any of the serious medical problems to be related to 20vPnC or 13vPnC.

No infant died during the study.

Did infants have any new long-term medical conditions?

6 What percentage of infants were diagnosed with a new long-term medical condition during the study?

Researchers looked at the records of 1503 infants who received at least the 1st dose of 20vPnC or 13vPnC.

The percentages of infants diagnosed with a new long-term medical condition during the study (at any time from the **1st dose** to **6 months after the 4th dose**) were low and similar for both 20vPnC and 13vPnC groups.

- 28 out of 1000 infants (**3%**) in the 20vPnC group.
- 14 out of 503 infants (**3%**) in the 13vPnC group.

The most common new long-term medical conditions were: "eczema" (a dry and itchy skin condition), "atopic dermatitis" (a type of eczema), and allergies to food or milk. These medical conditions are commonly seen in this age group.

Where can I learn more about this study?

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	Use the protocol number **B7471013**

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

www.clinicaltrials.gov	Use the study identifier **NCT04379713**
www.clinicaltrialsregister.eu	Use the study identifier **2019-003307-35**

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 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!