# 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:** | B7471027 |
| **Dates of Study:** | 24 June 2022 to 01 June 2023 |
| **Title of this Study:** | A Study of 20vPnC in Healthy Babies Aged 12 to 23 Months Old who Got 2 Doses of Prevenar 13 Before They Were 12 Months Old<br><br>[A Phase 3, Randomized, Partially Double-Blind Trial to Evaluate the Safety and Immunogenicity of 20-valent Pneumococcal Conjugate Vaccine in Healthy Toddlers 12 Through 23 Months of Age With 2 Prior Infant Doses of Prevenar 13] |
| **Date of this Report:** | 29 November 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 child's study site.

# Why was this study done?

## What is *Streptococcus pneumoniae*?

*Streptococcus pneumoniae* (also called pneumococcus or *S pneumoniae*) is a kind of germ or bacteria. *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 to 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**.
>
> If a person reaches a specific level of antibodies after getting a vaccine, that means the vaccine is likely to offer protection against a disease.

In this study, 20vPnC was compared to the 13-valent pneumococcal conjugate vaccine (13vPnC, also known as Prevnar 13® or Prevenar 13®). 13vPnC is approved as part of the recommended vaccines in Europe, the United States, and many other countries to prevent diseases caused by *S pneumoniae* in children and adults.

- 13vPnC is made up of 13 parts (or components) that can prevent diseases caused by 13 types of *S pneumoniae*.
- 20vPnC has the same 13 parts found in 13vPnC. But, 20vPnC has 7 more parts that may widen protection against 7 additional types of *S pneumoniae*.

## What was the purpose of this study?

The main purpose of this study was to learn if 20vPnC given as 1 or 2 doses to participants is safe and produces antibody responses to *S pneumoniae*.

The participants included healthy babies aged 12 to 23 months old who got 2 doses of 13vPnC before they were 12 months old.

In this study, participants were randomly placed into 1 of 3 groups by chance:

- 2-dose 20vPnC group
- 1-dose 20vPnC group
- 1-dose 13vPnC group

**Researchers wanted to know:**

- **How many participants reached the specific level of antibodies against *S pneumoniae* 1 month after Dose 2 in the 2-dose 20vPnC group or 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?**
- **How many participants had redness, swelling, or pain at the injection site within 7 days after Dose 2 in the 2-dose 20vPnC group or within 7 days after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?**
- **How many participants had fever, loss of appetite, drowsiness, or irritability within 7 days after Dose 2 in the 2-dose 20vPnC group or within 7 days after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?**
- **How many participants had a medical problem within 1 month after Dose 2 in the 2-dose 20vPnC group or within 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?**
- **How many participants had a serious medical problem within 1 month after Dose 2 in the 2-dose 20vPnC group or within 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?**

# What happened during the study?

## How was the study done?

Study participants were randomly placed into 1 of 3 groups by chance. Which study vaccine and number of doses they got depended on the group they were assigned to.

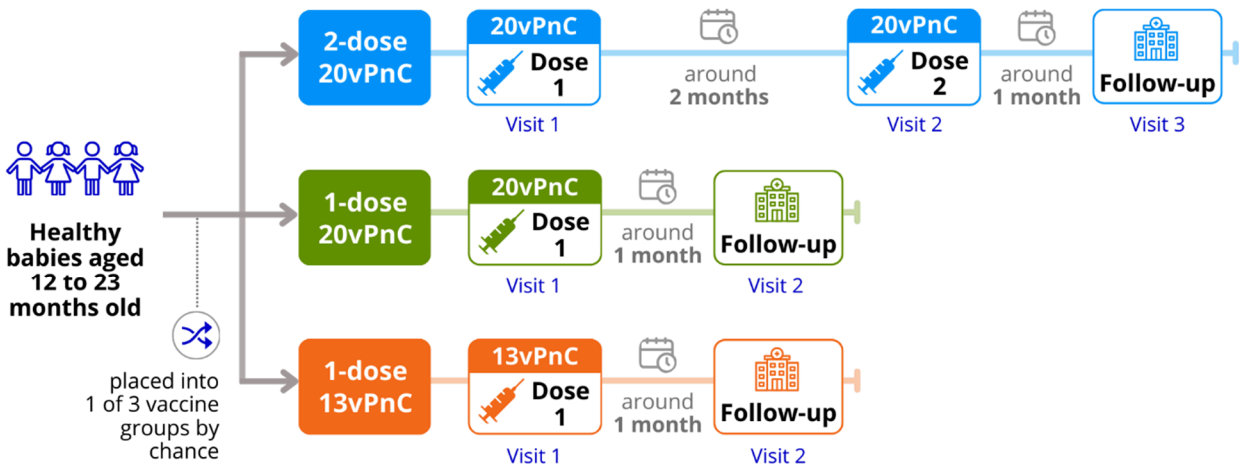
**The 3 vaccine groups in this study:**

| 2-dose 20vPnC | 1-dose 20vPnC | 1-dose 13vPnC |
|---|---|---|
| Participants in this group received 2 doses of **20vPnC**. | Participants in this group received 1 dose of **20vPnC**. | Participants in this group received 1 dose of **13vPnC**. |
| For the 2-dose 20vPnC group, the vaccine assignment was "**open-label**" or not blinded.<br>This means the participants' parents or guardians and the researchers knew that the participants in this group got 20vPnC for each dose, given 2 months apart. | For the 1-dose 20vPnC and 13vPnC groups, the vaccine assignments were "**double-blinded**".<br>This means the participants' parents or guardians and the researchers did not know if the participants in these groups got 1 dose of 20vPnC or 13vPnC. | |

This was a **"partially double-blinded"** study. This is because vaccine assignments were open-label for the 2-dose 20vPnC group and double-blinded for the 1-dose 20vPnC and 13vPnC groups.

Figure 1 below shows how the study was done.

**Figure 1. How was this study done?**




**During the study:**

- Participants had blood samples taken at the first and last visits.
- If recommended by the local or country guidance, participants may have gotten other routine vaccines on the same day of the 20vPnC or 13vPnC injection.
- Participants were checked for any medical problems they might be having.

## Where did this study take place?

The Sponsor ran this study at 31 locations in 3 countries in Europe:

Hungary Poland Spain

## When did this study take place?

It began on 24 June 2022 and ended on 01 June 2023.

## Who participated in this study?

The study included participants who:

- were from the age of 12 months to 23 months old when they joined this study.
- were assessed as healthy by the study doctors.
- got 2 doses of 13vPnC before they were 12 months old.

In total, 356 participants took part in this study.

- A total of 192 boys (53.9%) and 164 girls (46.1%) participated.
- All participants were from the age of 12 months and 23 months old at the time of the 1st dose.
- 348 participants (97.8%) finished the study, and 8 participants (2.2%) did not finish the study. The reasons for not finishing the study were: the participants' parents or guardians decided to stop their children's participation in the study before it was over, or they could not be reached for follow-up.

## How long did the study last?

Study participants were in the study for about:

- 3 months for those in the 2-dose 20vPnC group.
- 1 month for those in the 1-dose 20vPnC or 13vPnC groups.

The entire study took about 1 year to complete.

When the study ended in June 2023, 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 reached the specific level of antibodies against *S pneumoniae* 1 month after Dose 2 in the 2-dose 20vPnC group or 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?

To answer this question, researchers measured the amount of antibodies for each participant. Researchers checked how many participants had antibodies against each of the 20 types (13 plus 7 additional types) of *S pneumoniae*.

**Antibodies against 7 additional types of *S pneumoniae*:**

The table on the next page shows that, 1 month after Dose 2 in the 2-dose 20vPnC group or 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups:

- Most of the participants in the **2-dose 20vPnC and 1-dose 20vPnC groups** reached the specific level of antibodies against each of the 7 additional types of *S pneumoniae*.
- Few to almost no participants in the **1-dose 13vPnC group** reached the specific level of antibodies against each of the 7 additional types of *S pneumoniae*.

  The results in the **1-dose 13vPnC** group were low because 13vPnC does not have the 7 additional parts in 20vPnC that can make antibodies against the 7 additional types of *S pneumoniae*.

| 2-dose 20vPnC group | 1-dose 20vPnC group | 1-dose 13vPnC group |
|---|---|---|
| 93 to 102 out of 102 participants (**91.2%** to **100%**) | 59 to 106 out of 108 participants (**54.6%** to **98.1%**) | 0 to 14 out of 108 participants (**0%** to **13.0%**) |

**Antibodies against 13 types of *S pneumoniae*:**

The table below shows that, 1 month after Dose 2 in the 2-dose 20vPnC group or 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups:

Most of the participants across the 3 groups reached the specific level of antibodies against each of the 13 types of *S pneumoniae*.

| 2-dose 20vPnC group | 1-dose 20vPnC group | 1-dose 13vPnC group |
|---|---|---|
| 90 to 102 out of 102 participants (**88.2%** to **100%**) | 94 to 108 out of 108 participants (**87.0%** to **100%**) | 101 to 108 out of 108 participants (**93.5%** to **100%**) |

**What do these results mean?**

In healthy babies aged 12 to 23 months old who have gotten 2 doses of 13vPnC before they were 12 months old:

Most participants who got 1 or 2 doses of 20vPnC reached the specific level of antibodies against each of the 20 types of *S pneumoniae*. This means that 1 or 2 doses of 20vPnC produced antibody responses that can likely protect participants against diseases caused by these types of *S pneumoniae*.

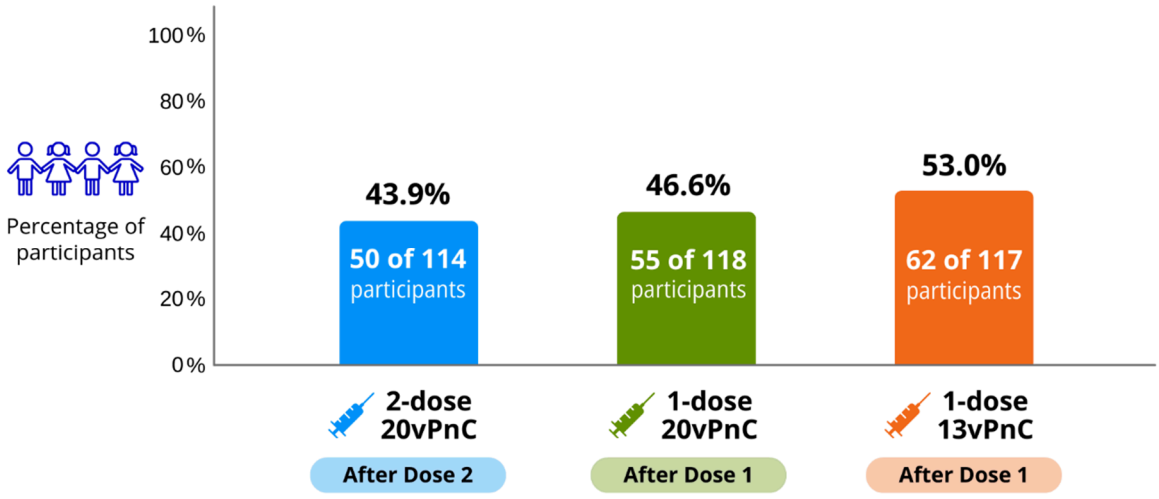
## How many participants had redness, swelling, or pain at the injection site within 7 days after Dose 2 in the 2-dose 20vPnC group or within 7 days after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?

The participants' parents or guardians kept a diary for 7 days after each dose of study vaccine to record any injection site reactions, such as redness, swelling, or pain where the vaccine was injected. Researchers looked at the results of participants with available diary records.

Figure 2 shows that, within 7 days after Dose 2 in the 2-dose 20vPnC group or within 7 days after Dose 1 in the 1-dose 20vPnC or 13vPnC groups:

Similar numbers of participants across the 3 groups had at least 1 injection site reaction of any redness, swelling, or pain.

**Figure 2. How many participants had any redness, swelling, or pain at the injection site within 7 days after Dose 2 in the 2-dose 20vPnC group or within 7 days after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?**



Most of these injection site reactions were mild or moderate in severity. These reactions lasted about 1 to 3 days.

The most common injection site reaction was:

- Pain at the injection site in the 2-dose 20vPnC group.
- Redness at the injection site in the 1-dose 13vPnC and 20vPnC groups.

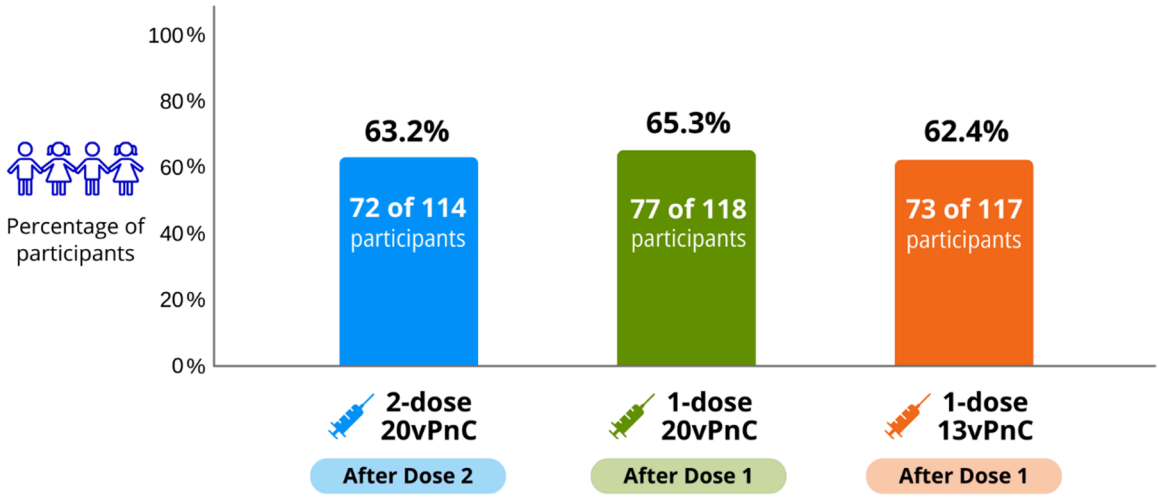
## How many participants had fever, loss of appetite, drowsiness, or irritability within 7 days after Dose 2 in the 2-dose 20vPnC group or within 7 days after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?

The participants' parents or guardians kept a diary for 7 days after each dose of study vaccine to record any symptoms, such as fever, loss of appetite, drowsiness, or irritability. Researchers looked at the results of participants with available diary records.

Figure 3 shows that, within 7 days after Dose 2 in the 2-dose 20vPnC group or within 7 days after Dose 1 in the 1-dose 20vPnC or 13vPnC groups:

Similar numbers of participants across the 3 groups had at least 1 symptom of any fever, loss of appetite, drowsiness, or irritability.

**Figure 3. How many participants had any fever, loss of appetite, drowsiness, or irritability within 7 days after Dose 2 in the 2-dose 20vPnC group or within 7 days after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?**




Most of these symptoms were mild or moderate in severity. These symptoms lasted about 1 to 2 days.

Irritability was the most common of these symptoms across the 3 groups.

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 an underlying disease 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.

Researchers looked at the records of all participants who got at least 1 dose of 20vPnC or 13vPnC in this study.

None of the participants in any of the 3 vaccine groups left the study because of medical problems they had during the study.

No participant died during the study.

## How many participants had a medical problem within 1 month after Dose 2 in the 2-dose 20vPnC group or 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?

The table on the next page shows that, within 1 month after Dose 2 in the 2-dose 20vPnC group or within 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups:

Similar numbers of participants across the 3 groups had at least 1 medical problem.

| 2-dose 20vPnC group (from Dose 2 to 1 month after Dose 2 of 20vPnC) | 1-dose 20vPnC group (from Dose 1 to 1 month after Dose 1 of 20vPnC) | 1-dose 13vPnC group (from Dose 1 to 1 month after Dose 1 of 13vPnC) |
|---|---|---|
| 26 out of 116 participants (**22.4%**) | 29 out of 118 participants (**24.6%**) | 30 out of 117 participants (**25.6%**) |

Table 1 describes the most common medical problems seen in participants within 1 month after Dose 2 in the 2-dose 20vPnC group and within 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups. These medical problems were seen in 4 or more participants in at least 1 vaccine group.

Below are instructions on how to read Table 1.

### Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported within 1 month after Dose 2 in the 2-dose 20vPnC group and within 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups. All medical problems seen in 4 or more participants in at least 1 vaccine group are listed.
- The **2nd** column tells how many of the 116 participants in the **2-dose 20vPnC** group had each medical problem. Next to this number is the percentage of the 116 participants in this group who had the medical problem.
- The **3rd** column tells how many of the 118 participants in the **1-dose 20vPnC** group had each medical problem. Next to

this number is the percentage of the 118 participants in this group who had the medical problem.

- The **4th** column tells how many of the 117 participants in the **1-dose 13vPnC** group had each medical problem. Next to this number is the percentage of the 117 participants in this group who had the medical problem.
- For example, using these instructions, you can see how many participants were reported with infection of the nose, sinuses, or throat:
    - 9 out of 116 participants (7.8%) in the **2-dose 20vPnC** group.
    - 13 out of 118 participants (11.0%) in the **1-dose 20vPnC** group.
    - 9 out of 117 participants (7.7%) in the **1-dose 13vPnC** group.

**Table 1. Commonly reported medical problems within 1 month after Dose 2 in the 2-dose 20vPnC group or within 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups**

| Medical Problem | 2-dose 20vPnC (116 Participants) From Dose 2 to 1 month after Dose 2 | 1-dose 20vPnC (118 Participants) From Dose 1 to 1 month after Dose 1 | 1-dose 13vPnC (117 Participants) From Dose 1 to 1 month after Dose 1 |
|---|---|---|---|
| **Infection of the nose, sinuses, or throat** | 9 out of 116 participants (7.8%) | 13 out of 118 participants (11.0%) | 9 out of 117 participants (7.7%) |
| **Stomach flu** | 5 out of 116 participants (4.3%) | 2 out of 118 participants (1.7%) | 2 out of 117 participants (1.7%) |
| **Ear infection** | 2 out of 116 participants (1.7%) | 4 out of 118 participants (3.4%) | 2 out of 117 participants (1.7%) |
| **Infection of the tiny airways of the lungs** | 0 out of 116 participants (0%) | 4 out of 118 participants (3.4%) | 3 out of 117 participants (2.6%) |

# 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 a serious medical problem within 1 month after Dose 2 in the 2-dose 20vPnC group or within 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups?

The table below shows that, within 1 month after Dose 2 in the 2-dose 20vPnC group or within 1 month after Dose 1 in the 1-dose 20vPnC or 13vPnC groups:

Few participants across the 3 groups had at least 1 serious medical problem.

| **2-dose 20vPnC group** **(from Dose 2 to 1 month after Dose 2 of 20vPnC)** | **1-dose 20vPnC group** **(from Dose 1 to 1 month after Dose 1 of 20vPnC)** | **1-dose 13vPnC group** **(from Dose 1 to 1 month after Dose 1 of 13vPnC)** |
|---|---|---|
| 1 out of 116 participants (**0.9%**) | 1 out of 118 participants (**0.8%**) | 1 out of 117 participants (**0.9%**) |
| This participant had an **infection of the lower lung airways** and a **skin rash**. | This participant had a **skin injury or burn** after hot water was accidentally spilled on the participant. | This participant had a whistling sound, called **wheezing,** while breathing. |

Researchers do not believe any of these serious medical problems were related to 20vPnC or 13vPnC.

## Where can I learn more about this study?

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

For more details on your study protocol, please visit:

| | |
|---|---|
| www.pfizer.com/research/research_clinical_trials/trial_results | Use the protocol number **B7471027** |

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

| | |
|---|---|
| www.clinicaltrials.gov | Use the study identifier **NCT05408429** |
| www.clinicaltrialsregister.eu | Use the study identifier **2021-006624-41** |

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 and 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!