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 (20vPnC) or PF-06482077
Protocol Number:	B7471010
Dates of Study:	16 August 2023 to 02 October 2023
Title of this Study:	A Study of 20vPnC in Healthy Adults in India [A Phase 3, Single-Arm, Multicenter Trial to Describe the Safety and Immunogenicity of a 20-Valent Pneumococcal Conjugate Vaccine in Pneumococcal Vaccine-Naïve Adults ≥18 Years of Age in India]
Date of this Report:	30 September 2024

– Thank You –

If you 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 called pneumococcus or *S pneumoniae*) is a kind of germ or bacteria. *S pneumoniae* can cause infections of the lung, brain lining, blood, or ear.

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

20-**valent** (vey-luhnt) **pneumococcal** (nyoo-muh-kok-uhl) **conjugate** (kon-juh-geyt)

20vPnC is an injectable vaccine that researchers think may help to prevent infections from 20 of the most common types of *S pneumoniae*.

The use of 20vPnC in this study is **investigational**, which means it is still being tested and is not approved for use in India outside of research studies. In many other countries, 20vPnC is approved for use in children and adults to prevent diseases caused by *S pneumoniae*.

What was the purpose of this study?

The main purpose of this study was to learn if 20vPnC is safe for healthy adult participants in India.

Researchers wanted to know:

- **How many participants had redness, swelling, or pain at the injection site within 7 days after vaccination with 20vPnC?**
- **How many participants had fever, tiredness, headache, joint pain, or muscle pain within 7 days after vaccination with 20vPnC?**
- **How many participants had medical problems within 1 month after vaccination with 20vPnC?**
- **How many participants had serious medical problems within 1 month after vaccination with 20vPnC?**

This study also wanted to find out if 20vPnC can help participants produce antibody responses against *S pneumoniae*.

> **Antibodies** are proteins that help the body to fight off germs. After a person gets a **vaccine**, the body makes antibodies. This is called an **antibody response**.

The results on antibody responses can be found on the websites listed on the last page of this summary.

What happened during the study?

How was the study done?

Age groups: Participants were divided into 2 groups based on their age.

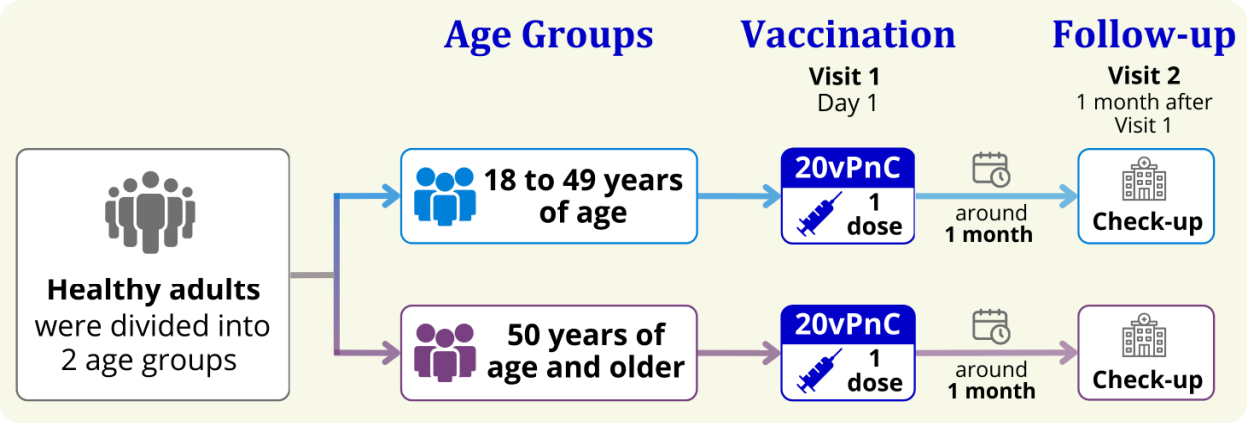
- 18 to 49 years of age
- 50 years of age and older

Visit 1: Participants in both age groups got 1 dose of 20vPnC on Day 1 of the study. The participants and researchers knew that all participants got 20vPnC in this study. This is known as an **open-label** study.

Visit 2: Around 1 month after vaccination with 20vPnC, participants had a check-up at the study site.

The study visits of both groups of participants are shown in Figure 1 below.

Figure 1. What happened during the study?



During the study:

- Researchers checked each participant's health and asked them how they were feeling.
- Researchers took blood samples from the first 50 participants in each age group before they got 20vPnC (Visit 1) and 1 month after they got 20vPnC (Visit 2). Blood samples were used to measure the level of antibodies against *S pneumoniae* before and after vaccination. This helps to see the antibody response to the vaccine.

Where did this study take place?

The Sponsor ran this study at 6 locations in India.

When did this study take place?

It began on 16 August 2023 and ended on 02 October 2023.

Who participated in this study?

The study included adults at least 18 years old who were assessed as healthy by the study doctors. Participants must not have gotten any vaccine for *S pneumoniae* before joining this study.

Out of the 405 participants in both age groups that started the study, 400 (98.8%) got 20vPnC in this study and finished the study. Out of the 400 participants:

- A total of 284 men (71%) and 116 women (29.0%) participated.
- All participants were between the ages of 19 and 88 years.

Table 1 below lists how many participants in each age group took part in the study.

Table 1. Number of participants in each age group that took part in the study

18 to 49 years of age	50 years of age and older
• Out of 200 participants that started the study, all 200 participants (100%) got 20vPnC and finished the study.	• Out of 205 participants that started the study, 200 participants (97.6%) got 20vPnC and finished the study. • 5 out of 205 participants (1.2%) stopped taking part in the study before vaccination with 20vPnC.

The reasons why the 5 participants in the 50 years of age and older group (see Table 1) stopped taking part in the study were:

- 2 participants did not meet the study requirements.
- 3 participants were not assigned to get 20vPnC because the study had already reached the planned number of participants.

How long did the study last?

Each participant was in the study for about 1 month. The entire study took about 1 month and 2 weeks to complete.

When the study ended in October 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?

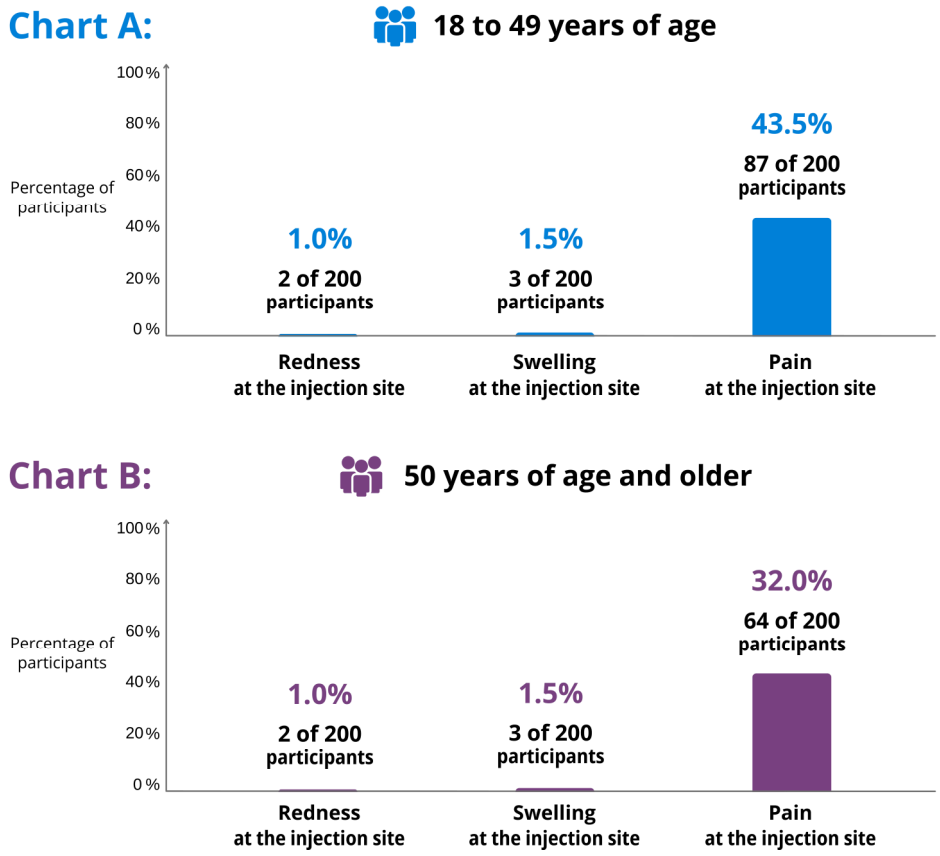
Participants recorded on their electronic diary or app in their phone if they had any reactions or symptoms listed below within 7 days after vaccination in the study.

- **Injection site reactions** of redness, swelling, or pain at the injection site on the arm
- **Symptoms** of fever, tiredness, headache, joint pain, or muscle pain

How many participants had redness, swelling, or pain at the injection site within 7 days after vaccination with 20vPnC?

The charts in Figure 2 show how many participants in each age group had redness, swelling, or pain at the injection site within 7 days after vaccination with 20vPnC. The charts also show that the most common injection site reaction in both age groups was pain at the injection site.

Figure 2. How many participants had redness, swelling, or pain at the injection site within 7 days after vaccination with 20vPnC?

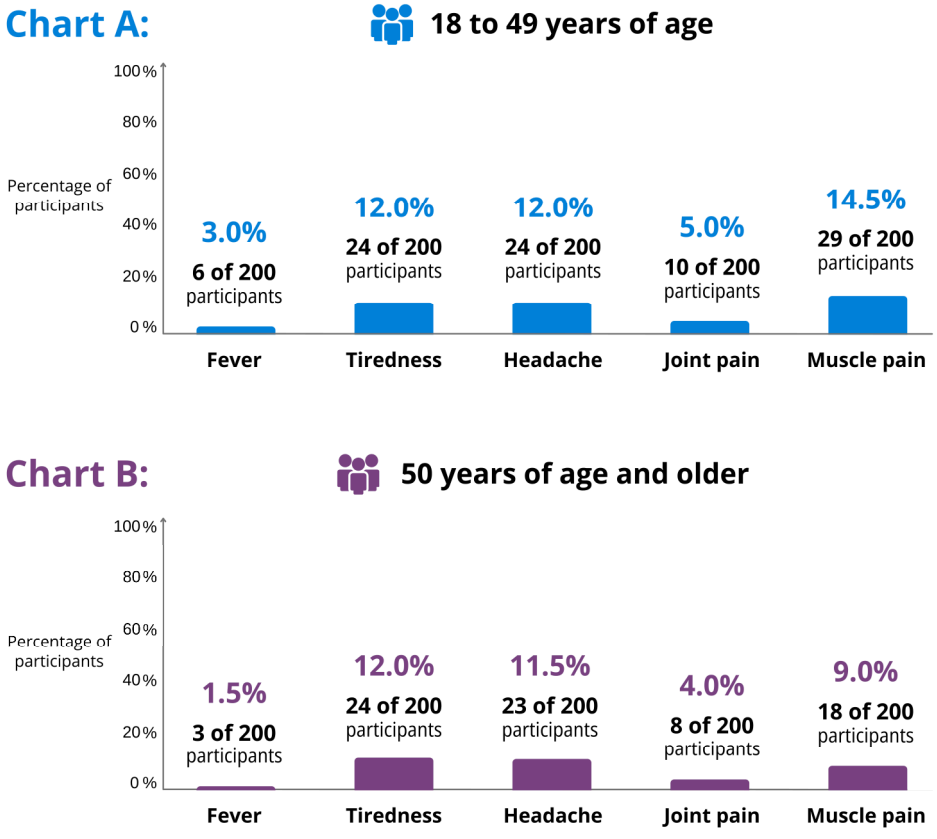


Most of these injection site reactions in both age groups were mild or moderate in severity and lasted about 1 to 3.5 days.

How many participants had fever, tiredness, headache, joint pain, or muscle pain within 7 days after vaccination with 20vPnC?

The charts in Figure 3 show how many participants in each age group had fever, tiredness, headache, joint pain, or muscle pain within 7 days after vaccination with 20vPnC. The charts also show that the most common symptoms were muscle pain in participants 18 to 49 years of age (Chart A) and tiredness in participants 50 years of age and older (Chart B).

Figure 3. How many participants had fever, tiredness, headache, joint pain, or muscle pain within 7 days after vaccination with 20vPnC?



Most of these symptoms in both age groups were mild or moderate in severity and lasted about 1 to 2 days.

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 unknown 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.

How many participants had medical problems within 1 month after vaccination with 20vPnC?

As shown in the list below, few participants in each age group had at least 1 medical problem within 1 month after vaccination with 20vPnC.

- **18 to 49 years of age:** 3 out of 200 participants (1.5%)
- **50 years of age and older:** 6 out of 200 participants (3.0%)

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

The medical problems reported by participants in this study are listed in Table 2. Table 2 also shows that the most common medical problems – those reported by at least 2 participants across both age groups – were muscle pain, skin rash, and fever.

Below are instructions on how to read Table 2.

Instructions for Understanding Table 2.

- The **1st** column of Table 2 lists the medical problems that were reported by participants in either age group during the study (within 1 month after getting 20vPnC).
- The **2nd** and **3rd** columns tell how many of the 200 participants in each age group reported each medical problem. Next to this number is the percentage of the 200 participants in each age group who reported the medical problem.
- Using these instructions, you can see how many participants in each age group reported muscle pain within 1 month after vaccination with 20vPnC.
    - **18 to 49 years of age:** 0 out of 200 participants (0%)
    - **50 years of age and older:** 2 out of 200 participants (1.0%)

Table 2. Medical problems reported by study participants within 1 month after vaccination with 20vPnC		
Medical Problem	**18 to 49 years of age (200 Participants)**	**50 years of age and older (200 Participants)**
Muscle pain	0 out of 200 participants (0%)	2 out of 200 participants (1.0%)
Skin rash	0 out of 200 participants (0%)	2 out of 200 participants (1.0%)
Fever	1 out of 200 participants (0.5%)	1 out of 200 participants (0.5%)
Feeling unwell (malaise)	0 out of 200 participants (0%)	1 out of 200 participants (0.5%)
Flu (influenza)	1 out of 200 participants (0.5%)	0 out of 200 participants (0%)
Insect bite	1 out of 200 participants (0.5%)	0 out of 200 participants (0%)

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 within 1 month after vaccination with 20vPnC?

No participant in either age group had a serious medical problem or died during the study.

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 **B7471010**

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

www.clinicaltrials.gov	Use the study identifier **NCT05875727**

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!