Plain Language Clinical Study

Summary

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: B7471024

Dates of Study: 16 September 2022 to 20 September 2025

Title of this Study: A Study to Describe the Safety and Immunogenicity of 20vPnC in Infants in India and Taiwan

[A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a 20-Valent Pneumococcal Conjugate Vaccine Given in a Series of 3 Infant Doses and 1 Toddler Dose in Infants in India and Taiwan]

Date of this Report: 26 June 2026

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

Pfizer

– Thank You –

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

This summary will describe the study results. Do you have any questions about the study or the results? If so, 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* can cause infections of the lung, brain lining, blood, or ear.

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.

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*.

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

What was the purpose of this study?

The main goals of this study were to learn about the safety of 20vPnC and to learn if it may produce immune responses in healthy infants against diseases caused by *S pneumoniae*. The study was done in Taiwan and India.



When a person first gets a vaccine, a protective **immune response** is triggered in the body. This means that the body's immune system is activated to make **antibodies**.

- **Antibodies** are proteins that can fight off infections and help prevent disease.
- An **immune response** is the body's ability to find and fight off germs that cause disease.

Researchers wanted to know:

- **How safe was 20vPnC when given to healthy infants in Taiwan and India?**
- **Did 20vPnC produce immune responses after Dose 4 when given to healthy infants in India?**
- **What medical problems did participants have during the study?**

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

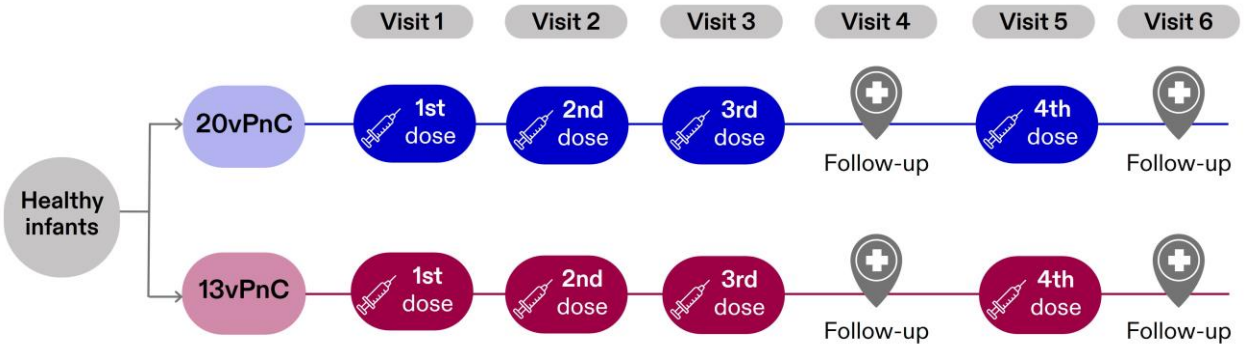
What happened during the study?

How was the study done?

The infants were assigned to receive either 20vPnC or 13vPnC by chance. They got 4 doses of the same vaccine (20vPnC or 13vPnC) during the study. The infants' parents or guardians and the researchers did not know which study vaccine (20vPnC or 13vPnC) was given to the infants during the study. This is known as a "double-blind" study.

Figure 1 shows how the study was done.

Figure 1. Study plan



During a regular check of the study data while the study was still ongoing, the researchers found some administrative issues at one of the study clinics. Specifically, the clinic staff did not keep records correctly and did not give the study vaccines according to the study plan. To make sure the final study results were completely accurate and reliable, the researchers did not include any of the information from the 100 participants at this 1 clinic in the main results.

Researchers then did extra checks to see if leaving out this clinic's data changed what they learned from the study. Researchers found that removing this data did not change the overall results. It did not change how safe the vaccine is or how well it helps the body builds antibodies against the bacteria (the immune response). All of the results shown in this summary did not include the information from this 1 clinic.

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

Where did this study take place?

The Sponsor ran this study in Taiwan and India.

When did this study take place?

It began on 16 September 2022 and ended on 20 September 2025.

Who participated in this study?

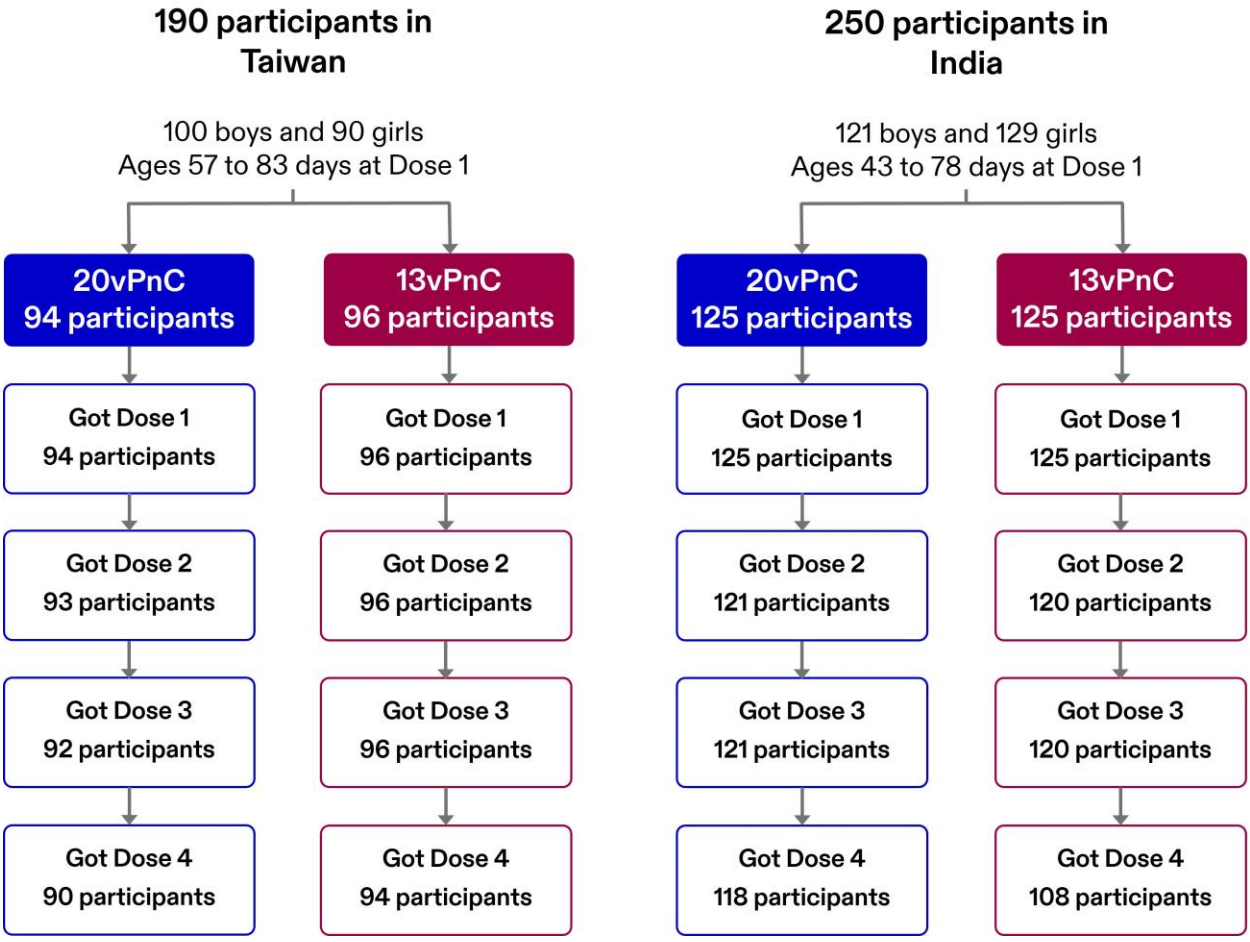
The study included infants who were born after at least 36 weeks of pregnancy and:

- Between 56 days and 84 days (or about 8 to 12 weeks) old at study entry for infants in Taiwan
- Between 42 days and 84 days (or about 6 to 12 weeks) old at study entry for infants in India

Figure 2 shows the number of participants who joined the study.

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

Figure 2. Study participants



A total of 8 out of 190 participants (4%) in Taiwan who received the vaccine did not finish the study. The most common reason was because they no longer met the study requirements to continue taking part in the study.

A total of 26 out of 250 participants (10%) in India who received the vaccine did not finish the study. The most common reason was because the participant's parent or guardian decided not to continue participating in the study.

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

How long did the study last?

Study participants were in the study for about 1 year and 3 months (or about 15 months). The entire study took about 3 years to complete. The study was completed as planned.

When the study ended in September 2025, 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 safe was 20vPnC when given to healthy infants in Taiwan and India?

To answer this question, researchers looked at all the information collected on the participants' health throughout the study. Researchers then compared the safety results of infants who got 20vPnC to the results of infants who got 13vPnC.



Researchers found that 20vPnC was as safe as 13vPnC when given to healthy infants in Taiwan and India.

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

Did 20vPnC produce immune responses after Dose 4 when given to healthy infants in India?

To answer this question, researchers checked the infants' antibody responses to 20 types of *S pneumoniae* at **1 month after Dose 4** of vaccination.



Researchers found that at 1 month after 4 doses, 20vPnC produce immune responses that can help protect infants in India against 20 types of *S pneumoniae*.

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.

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

How many participants had any local reaction within 7 days after each dose of vaccine?

"**Local reactions**" include redness, swelling, and pain at the injection site (area on the arm where the vaccine was injected).

Participants in Taiwan

The charts below show how many participants in Taiwan had any local reaction within 7 days after each dose of vaccine.

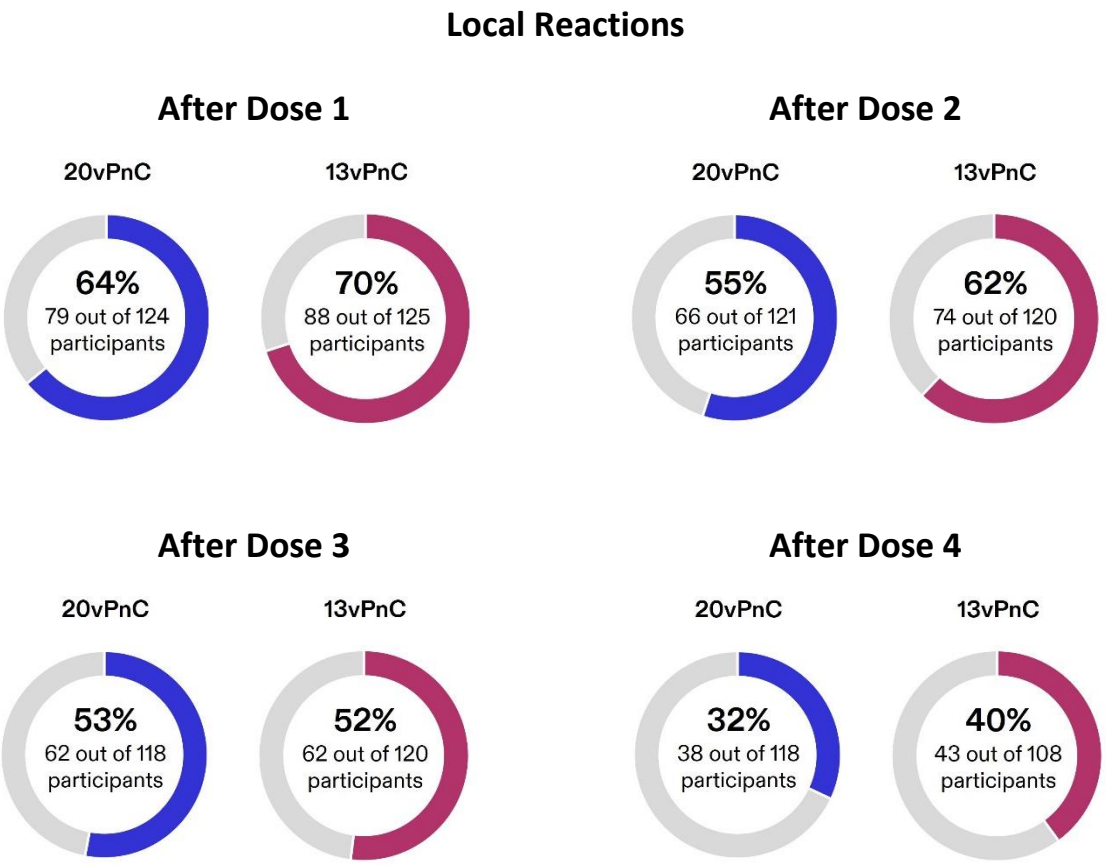


The most common local reaction in both vaccine groups after each dose was swelling. Most local reactions were mild or moderate in severity.

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

Participants in India

The charts below show how many participants in India had any local reaction within 7 days after each dose of vaccine:



The most common local reaction in both vaccine groups after each dose was pain at the injection site. Most local reactions were mild or moderate in severity.

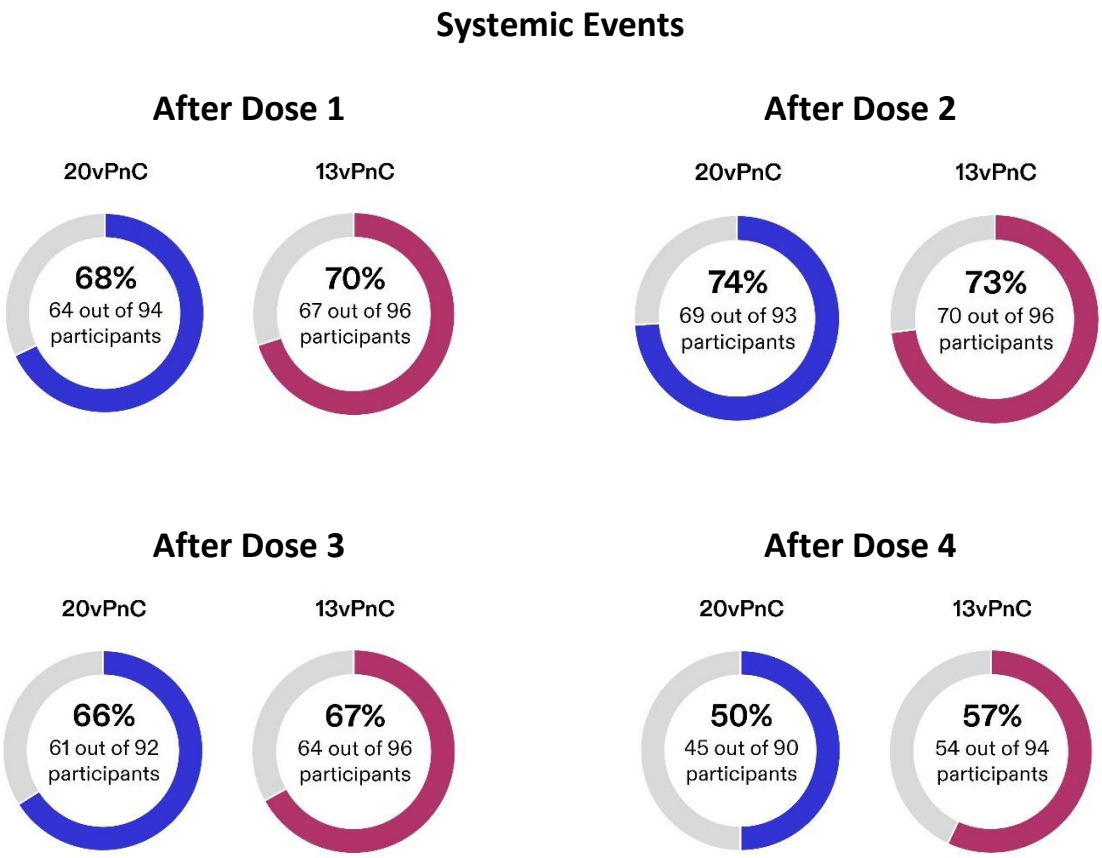
090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

How many participants had any systemic event within 7 days after each dose of vaccine?

"**Systemic events**" are reactions that affect the whole body like fever, loss of appetite, feeling drowsy, and feeling irritable.

Participants in Taiwan

The charts below show how many participants in Taiwan had any systemic event within 7 days after each dose of vaccine:

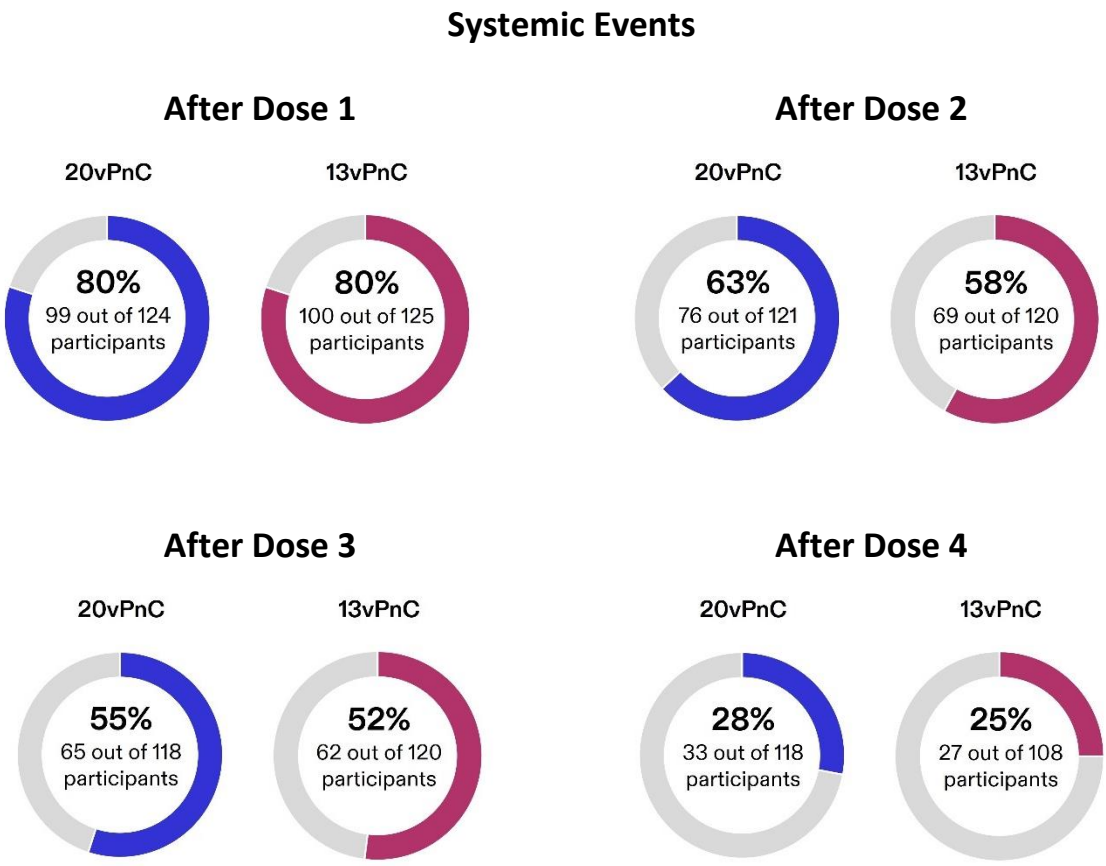


The most common systemic events in both vaccine groups after each dose were feeling irritable and feeling drowsy. Most systemic events were mild or moderate in severity.

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

Participants in India

The charts below show how many participants in India had any systemic event within 7 days after each dose of vaccine:



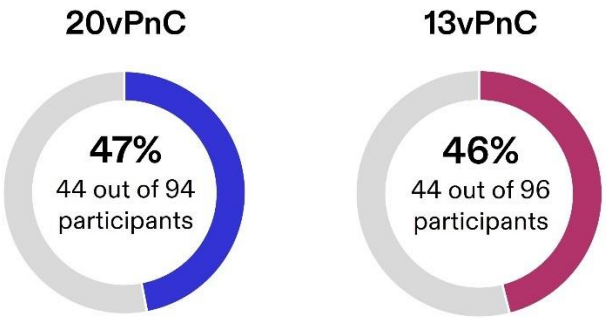
The most common systemic events in both vaccine groups after each dose were feeling irritable and feeling drowsy. Most systemic events were mild or moderate in severity.

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

How many participants had any medical problem from Dose 1 to 1 month after Dose 3 of vaccine?

Participants in Taiwan

The charts below show how many participants in Taiwan had any medical problem from Dose 1 to 1 month after Dose 3 of vaccine.



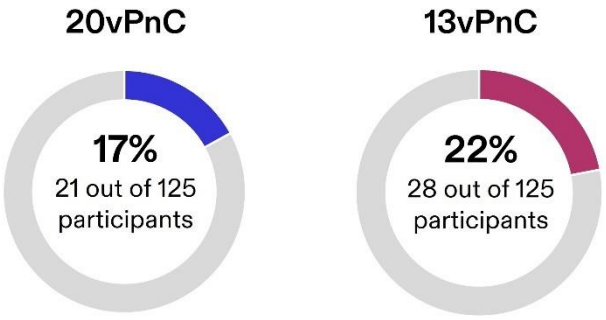
The most common medical problems from Dose 1 to 1 month after Dose 3 of vaccine – reported by at least 10% of participants in any group – are as follows:

- **COVID-19 infection**
  - 10 out of 94 participants (11%) who got 20vPnC
  - 10 out of 96 participants (10%) who got 13vPnC
- **Common cold**
  - 9 out of 94 participants (10%) who got 20vPnC
  - 11 out of 96 participants (12%) who got 13vPnC
- **Tested positive for COVID-19**
  - 6 out of 94 participants (6%) who got 20vPnC
  - 10 out of 96 participants (10%) who got 13vPnC

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

Participants in India

The charts below show how many participants in India had any medical problem from Dose 1 to 1 month after Dose 3 of vaccine.



The most common medical problem from Dose 1 to 1 month after Dose 3 of vaccine – reported by at least 10% of participants in any group – was **nose and throat infection** in:

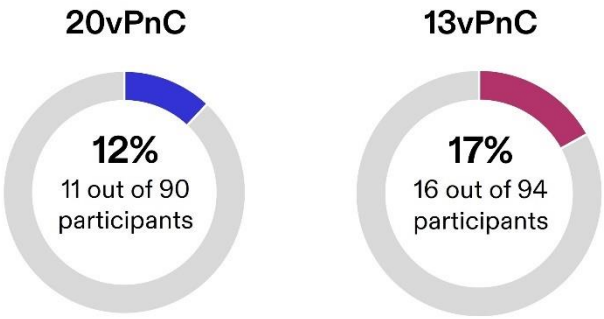
- 11 out of 125 participants (9%) who got 20vPnC
- 15 out of 125 participants (12%) who got 13vPnC

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

How many participants had any medical problem from Dose 4 to 1 month after Dose 4 of vaccine?

Participants in Taiwan

The charts below show how many participants in Taiwan had any medical problem from Dose 4 to 1 month after Dose 4 of vaccine.



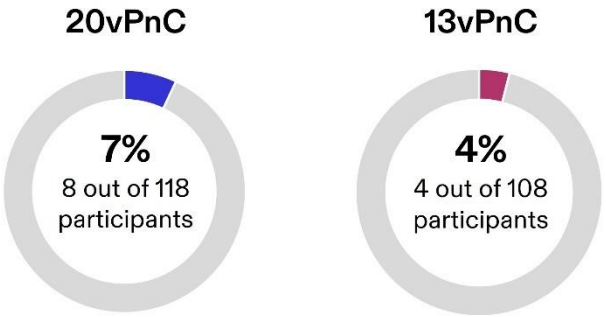
The most common medical problem from Dose 4 to 1 month after Dose 4 of vaccine – reported by at least 10% of participants in any group – was **common cold** in:

- 5 out of 90 participants (6%) who got 20vPnC
- 11 out of 94 participants (12%) who got 13vPnC

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

Participants in India

The charts below show how many participants in India had any medical problem from Dose 4 to 1 month after Dose 4 of vaccine.



The most common medical problem from Dose 4 to 1 month after Dose 4 of vaccine – reported by at least 2% of participants in any group – was **runny or stuffy nose caused by a virus** in:

- 3 out of 118 participants (3%) who got 20vPnC
- 0 out of 108 participants (0%) who got 13vPnC

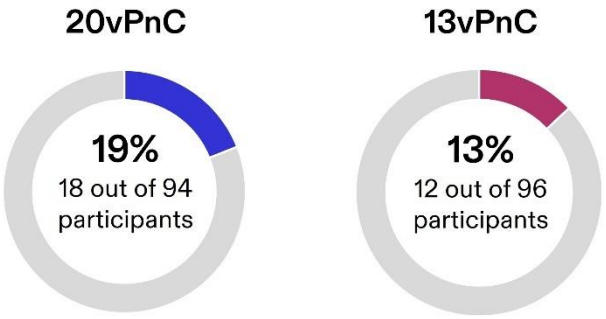
090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

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.

Participants in Taiwan

The charts below show how many participants in Taiwan had any serious medical problem after Dose 1 of vaccine.



The most common serious medical problem after Dose 1 of vaccine – reported by at least 5% of participants in any group – was **viral infection of the small airways in the lung** in:

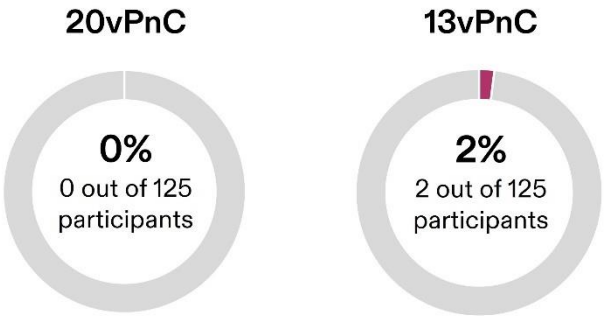
- 5 out of 94 participants (5%) who got 20vPnC
- 0 out of 96 participants (0%) who got 13vPnC

Researchers do not believe any of the serious medical problems reported by participants were related to the vaccine.

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

Participants in India

The charts show below show how many participants in India had any serious medical problem after Dose 1 of vaccine.



Of the 2 participants in the 13vPnC group who had serious medical problems, 1 had diarrhea and 1 had a viral lung infection. Researchers do not believe any of these serious medical problems were related to the vaccine.

No participants died during the study.

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

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 **B7471024**

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

www.clinicaltrials.gov	Use the study identifier **NCT05512819**

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 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!

090177e1a67240ea\Approved\Approved On: 29-Jun-2026 01:44 (GMT)

Pfizer