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:	B7471012
Dates of Study:	09 September 2020 to 18 February 2023
Title of this Study:	A Study to Learn if 3 Doses of the 20vPnC Vaccine Were Safe in Healthy Infants and if 20vPnC Produced Antibody Responses Against a Germ Called *Streptococcus pneumoniae* [A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a 20-valent Pneumococcal Conjugate Vaccine Given as a Series of 2 Infant Doses and 1 Toddler Dose in Healthy Infants]
Date(s) of this Report:	22 December 2022; 30 August 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 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.

In this study, 20vPnC was compared to the 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 children 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 contained in 13vPnC. But, 20vPnC has 7 more parts for wider protection against 7 additional types of *S pneumoniae*.

What was the purpose of this study?

This study had 2 cohorts (or groups of people):

Cohort A	Participants in this group were healthy infants from Europe and Australia. Cohort A is also called the "Primary Study Population".
Cohort B	Participants in this group were healthy infants from Russia.

Cohort A had a much larger group of participants than Cohort B.

The main purposes of this study were:

- **For both Cohorts A and B:**

  This study aimed to find out if 20vPnC was safe when given in 3 doses to participants (healthy infants).

- **For Cohort A:** Researchers wanted to know if 20vPnC produced antibody responses to *S pneumoniae* that were comparable to those seen with 13vPnC.

- **For Cohort B:** Researchers wanted to measure the antibody responses to *S pneumoniae* in participants who got 20vPnC and in participants who got 13vPnC. No statistical comparison was done because of the small number of participants in Cohort B.

The results for each cohort are described separately in this summary.

Researchers wanted to know:

For Cohort A:

1. Did infants who received 3 doses of 20vPnC have antibody responses to the study vaccine that were within a range considered comparable to those who received 3 doses of 13vPnC?
2. Was the percentage of infants with a specific level of antibodies to the study vaccine after the 2nd dose of 20vPnC within a range considered comparable to the percentage of infants after the 2nd dose of 13vPnC?
3. Did infants who received the 2nd dose of 20vPnC have antibody responses to the study vaccine that were within a range considered comparable to those who received the 2nd dose of 13vPnC?
4. Did infants who received routine vaccines with 20vPnC have antibody responses to these routine vaccines that were within a range considered comparable to those who received routine vaccines with 13vPnC?

For Cohort B:

5. What were the antibody responses after receiving 3 doses of 20vPnC or 3 doses of 13vPnC?
6. What were the antibody responses after receiving 2 doses of 20vPnC or 2 doses of 13vPnC?
7. What percentage of infants were found with a specific level of antibodies after the 2nd dose of 20vPnC or 13vPnC?

For Cohorts A and B:

8. What percentage of infants had redness, swelling, or pain at the injection site after each dose of 20vPnC or 13vPnC?
9. What percentage of infants had fever, loss of appetite, drowsiness, or irritability after each dose of 20vPnC or 13vPnC?
10. What percentage of infants had a medical problem at any time from the 1st dose to 1 month after the 2nd dose of 20vPnC or 13vPnC?
11. What percentage of infants had a medical problem at any time from the 3rd dose to 1 month after the 3rd dose of 20vPnC or 13vPnC?
12. What percentage of infants had a serious medical problem during the study?
13. 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?

Study Vaccines – for Cohorts A and B

The infants received either 20vPnC or 13vPnC. They received the same study vaccine (20vPnC or 13vPnC) for all 3 doses.

- Researchers tested 20vPnC on a group of infants. Researchers then compared the results of infants given 20vPnC to the results of another group of infants given 13vPnC.
- The infants were assigned to 1 of 2 vaccine groups by chance. 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.

Routine or Recommended Vaccines

Cohorts A and B:

With each of the 3 doses of 20vPnC or 13vPnC, infants also received a dose of a routine vaccine. This routine combination vaccine and its key germ targets are:

- Diphtheria, tetanus, and pertussis (DTP)
- Hepatitis B virus (HBV)
- Poliovirus
- Haemophilus influenzae type b (Hib)

Cohort A:

With the 3rd dose of 20vPnC or 13vPnC, infants also received a dose of routine vaccines if recommended by the local or country guidance. These routine vaccines and their key germ targets are:

- Measles, mumps, and rubella (MMR)
- Chickenpox

Cohort B:

Outside of the study, the infants in this group may have received MMR and chickenpox routine vaccines as recommended by guidance in Russia.

Study Visits

Cohorts A and B:

During each visit, the parents or guardians were asked how the infants were feeling.

Blood samples were taken during Visits 3, 4, and 5.

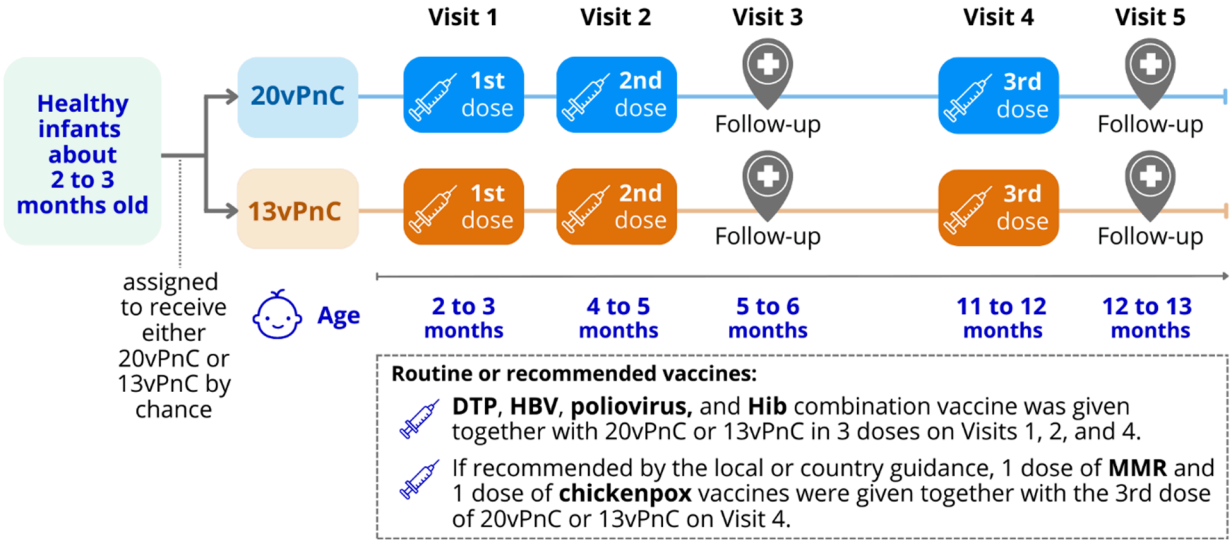
Cohort A:

Some infants also had blood samples taken during Visits 1 and 2.

Figures below show what happened in **Cohort A** (Figure 1) and **Cohort B** (Figure 2).

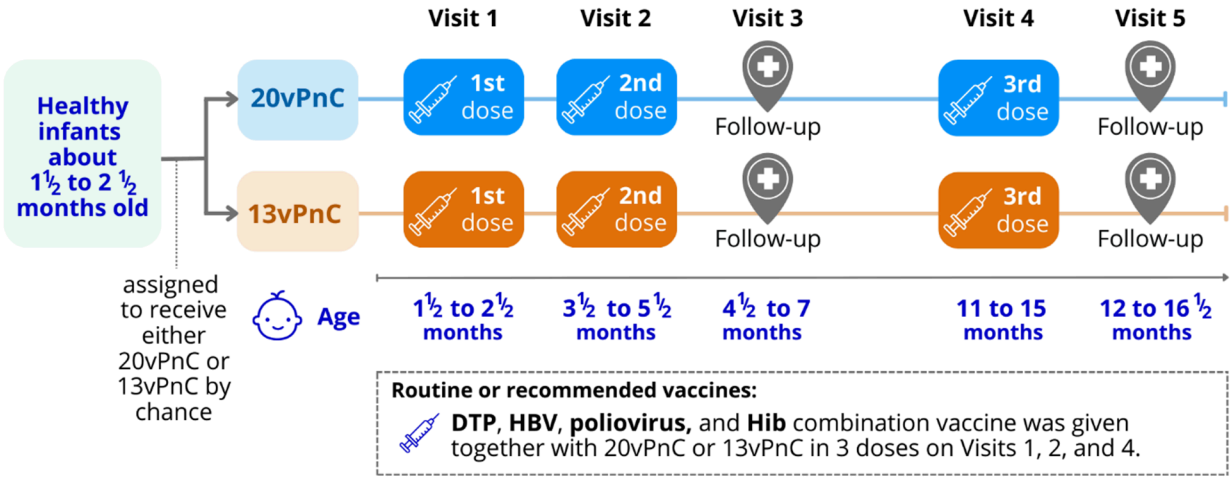
Cohort A:

Figure 1. What happened in Cohort A during the study?



Cohort B:

Figure 2. What happened in Cohort B during the study?



Where did this study take place?

The Sponsor ran this study at:

- 59 locations in Europe and Australia − for Cohort A.
- 4 locations in Russia − for Cohort B.

When did this study take place?

For the Cohort A infants in Europe and Australia, the study began on 09 September 2020, and it ended on 22 April 2022.

For the Cohort B infants in Russia, the study began on 30 November 2021, and it ended on 18 February 2023.

Who participated in this study?

This study included infants who:

- were born after more than 36 weeks of pregnancy.
- were between 6 and 16 weeks (or 42 and 112 days) old when they joined this study (Cohort A).
- were between 6 and 10 weeks (or 42 and 70 days) old when they joined this study (Cohort B).
- were assessed as healthy by the study doctors.
- had not gotten any vaccine for *S pneumoniae* or specific routine vaccines for infants (DTP, HBV, poliovirus, and Hib) before joining this study.

Cohort A:

A total of 1207 infants joined this study from Europe and Australia. Overall, 1204 infants received at least the 1st dose of a study vaccine (20vPnC or 13vPnC), and 3 infants did not receive a study vaccine.

Out of the 1204 infants who received at least the 1st dose of a study vaccine:

- 610 (51%) were boys, and 594 (49%) were girls.
- The infants' average age was 69 days old at the time of the 1st dose.

Out of the 1207 infants who started the study:

- 1173 (97%) infants finished the study.
- 34 (3%) infants did not finish the study. The most common reason was that their parents or guardians decided for them to leave the study before it was over.

Cohort B:

A total of 51 infants joined this study from Russia. All of them received at least the 1st dose of a study vaccine (20vPnC or 13vPnC).

- 23 (45%) were boys, and 28 (55%) were girls.
- The infants' average age was 64 days old at the time of the 1st dose.

Out of the 51 infants who started the study:

- 47 (92%) infants finished the study.
- 4 (8%) infants did not finish the study. The reason for this was either:
    - The parents or guardians of 2 (4%) infants (1 from each vaccine group) decided for them to leave the study before it was over.
    - Two (4%) infants (1 from each vaccine group) no longer met the study requirements.

It was planned to sign up 60 infants in Cohort B, but enrollment was stopped after 51 infants were signed up. This was because of an unexpected event related to global security, which was not caused by the COVID-19 pandemic.

How long did the study last?

Cohort A:

The infants were in the study for about 11 months. The study sites in Europe and Australia took about 1 year and 7 months to complete. This is because each infant started the study at different times.

Cohort B:

The infants were in the study for about 10 to 14 months. The study sites in Russia took about 1 year and 2 months to complete. This is because each infant started the study at different times.

Cohorts A and B:

When the last study visit took place for the Cohort A infants in Europe and Australia in April 2022, the Sponsor began performing antibody testing and then reviewing the information collected. The Sponsor then created a report of the results. A summary of that report was created in December 2022. This is a summary of that report.

When the last study visit took place for the Cohort B infants in Russia in February 2023, the Sponsor reviewed the new information collected. The Sponsor then created a report of the results. The results from Cohort B were added to this summary in August 2023.

This is a summary of the reports for Cohorts A and B.

What were the results of the study?

Cohort A: Questions 1 to 4

To answer Questions 1 to 3 below, researchers checked the infants' antibody responses to 20 types of *S pneumoniae*. To find out, researchers measured the levels of antibodies to these types of *S pneumoniae*.

- For the 13 parts found in both 20vPnC and 13vPnC, researchers compared the levels of antibodies to the 13 types of *S pneumoniae* for the 20vPnC group to those seen in the 13vPnC group.
- Researchers compared the levels of antibodies to 7 additional types of *S pneumoniae* for the 20vPnC group to the lowest among the 13 types of *S pneumoniae* for the 13vPnC group.

Antibody responses between the vaccine groups in Cohort A were compared statistically.

1. Did infants who received 3 doses of 20vPnC have antibody responses to the study vaccine that were within a range considered comparable to those who received 3 doses of 13vPnC? – Cohort A

The infants who received all 3 doses of 20vPnC had antibody responses to almost all 20 types of *S pneumoniae* that were within a range considered comparable to those seen in infants who received all 3 doses of 13vPnC.

- The levels of antibodies to all but 1 of the 13 types of *S pneumoniae* after infants received 3 doses of 20vPnC were within a range considered comparable to those seen after infants received 3 doses of 13vPnC.

  Of the 13 types of *S pneumoniae*, the level of antibodies to 1 type after infants received 3 doses of 20vPnC was slightly lower than the range to be considered comparable to those seen after infants received 3 doses of 13vPnC.

- The levels of antibodies to all of the 7 additional types of *S pneumoniae* after infants received 3 doses of 20vPnC were within a range considered comparable to the lowest seen among the 13 types of *S pneumoniae* after infants received 3 doses of 13vPnC.

2. Was the percentage of infants with a specific level of antibodies to the study vaccine after the 2nd dose of 20vPnC within a range considered comparable to the percentage of infants after the 2nd dose of 13vPnC? – Cohort A

After the 2nd dose (out of the 3 total doses) of 20vPnC or 13vPnC:

- The percentages of infants with a specific level of antibodies to some of the 13 types of *S pneumoniae* after the 2nd dose of 20vPnC were within a range considered comparable to those after the 2nd dose of 13vPnC.
- For the rest of the 13 types of *S pneumoniae*, the percentages of infants with a specific level of antibodies were lower after the 2nd dose of 20vPnC compared to those after the 2nd dose of 13vPnC.
- The percentages of infants with a specific level of antibodies to most of the 7 additional types of *S pneumoniae* after the 2nd dose of 20vPnC were within a range considered comparable to the lowest seen among the 13 types of *S pneumoniae* after the 2nd dose of 13vPnC.

3. Did infants who received the 2nd dose of 20vPnC have antibody responses to the study vaccine that were within a range considered comparable to those who received the 2nd dose of 13vPnC? – Cohort A

After the infants' 2nd dose of 20vPnC (out of the 3 total doses), antibody responses to most of the 20 types of *S pneumoniae* were within a range considered comparable to those seen in infants after the 2nd dose (out of the 3 total doses) of 13vPnC.

- The levels of antibodies to most of the 13 types of *S pneumoniae* after infants received the 2nd dose of 20vPnC were within a range considered comparable to those seen after infants received the 2nd dose of 13vPnC.
- The levels of antibodies to all of the 7 additional types of *S pneumoniae* after infants received the 2nd dose of 20vPnC were within a range considered comparable to the lowest seen among the 13 types of *S pneumoniae* after infants received the 2nd dose of 13vPnC.

4. Did infants who received routine vaccines with 20vPnC have antibody responses to these routine vaccines that were within a range considered comparable to those who received routine vaccines with 13vPnC? – Cohort A

Together with a study vaccine (20vPnC or 13vPnC), the infants received routine vaccines. These routine vaccines and their key germ targets are:

- DTP, HBV, poliovirus, and Hib combination vaccine
- MMR vaccine
- Chickenpox vaccine

To answer this question, the researchers looked at the infants' blood to measure the levels of antibodies that show a response to the routine vaccines.

Antibody responses to routine vaccines were within a range considered comparable between infants who received 20vPnC and those who received 13vPnC.

- Infants who received DTP, HBV, poliovirus, and Hib routine vaccines together with 20vPnC for 3 doses had antibody responses to these routine vaccines that were within a range considered comparable to those seen in infants who received routine vaccines with 13vPnC.
- Infants who received 1 dose of MMR and 1 dose of chickenpox routine vaccines together with the 3rd dose of 20vPnC had antibody responses to these routine vaccines that were within a range considered comparable to those seen in infants who received routine vaccines together with the 3rd dose of 13vPnC.

Summary of Antibody Responses in Cohort A:

The researchers have decided that the results for Cohort A are not likely due to chance. This means that, in this study, 3 doses of 20vPnC produced antibody responses that are likely to protect infants against diseases caused by *S pneumoniae*.

Cohort B: Questions 5 to 7

To answer Questions 5 to 7 below, researchers checked the infants' antibody responses to 13 and 7 additional types of *S pneumoniae*. Antibody responses for Cohort B were not compared statistically because of the small number of participants in this group.

The amount of antibodies was measured using a unit called microgram per milliliter (also called µg/mL).

5. What were the antibody responses after receiving 3 doses of 20vPnC or 3 doses of 13vPnC? – Cohort B

The amount of antibodies to 13 types of *S pneumoniae* seen after infants received all 3 total doses of the study vaccine ranged from:

- 0.84 µg/mL to 6.63 µg/mL in infants who received 3 doses of 20vPnC.
- 0.57 µg/mL to 5.63 µg/mL in infants who received 3 doses of 13vPnC.

The amount of antibodies to 7 additional types of *S pneumoniae* seen after infants received all 3 doses of study vaccine ranged from:

- 0.17 µg/mL to 4.90 µg/mL in infants who received 3 doses of 20vPnC.
- 0.02 µg/mL to 0.09 µg/mL in infants who received 3 doses of 13vPnC.

The results for the 13vPnC group were low and as expected because 13vPnC does not have the 7 additional types of *S pneumoniae*.

6. What were the antibody responses after receiving 2 doses of 20vPnC or 2 doses of 13vPnC? – Cohort B

The amount of antibodies to 13 types of *S pneumoniae* seen after infants received their 2nd dose (out of 3 total doses) of the study vaccine ranged from:

- 0.07 µg/mL to 1.56 µg/mL in infants after their 2nd dose of 20vPnC.
- 0.27 µg/mL to 3.32 µg/mL in infants after their 2nd dose of 13vPnC.

The amount of antibodies to 7 additional types of *S pneumoniae* seen after infants received their 2nd dose of study vaccine ranged from:

- 0.06 µg/mL to 1.19 µg/mL in infants after their 2nd dose of 20vPnC.
- 0.02 µg/mL to 0.16 µg/mL in infants after their 2nd dose of 13vPnC.

  The results for the 13vPnC group were low and as expected because 13vPnC does not have the 7 additional types of *S pneumoniae*.

7. What percentage of infants were found with a specific level of antibodies after the 2nd dose of 20vPnC or 13vPnC? – Cohort B

The percentages of infants with a specific level of antibodies to the 13 types of *S pneumoniae* after the 2nd dose (out of the 3 total doses) of the study vaccine ranged from:

- 21% to 96% of infants who received the 2nd dose of 20vPnC.
- 59% to 96% of infants who received the 2nd dose of 13vPnC.

The percentages of infants with a specific level of antibodies to the 7 types of *S pneumoniae* after the 2nd dose (out of the 3 total doses) of the study vaccine ranged from:

- 13% to 83% of infants who received the 2nd dose of 20vPnC.
- 15% to 33% of infants who received the 2nd dose of 13vPnC.

  The results for the 13vPnC group were generally as expected because 13vPnC does not have the 7 additional types of *S pneumoniae*. Some infants in the 13vPnC group who had a specific level of antibodies to these 7 additional types of *S pneumoniae* may be due to antibodies they got from their mothers.

Summary of Antibody Responses in Cohort B:

The interpretation of available results for Cohort B is limited because of the very small number of participants in this group.

In this study, Cohort B infants were shown to have antibody responses after they received 20vPnC. The antibody responses were generally similar to other 20vPnC studies done in infants, which have shown that 20vPnC may offer protection against diseases caused by *S pneumoniae*.

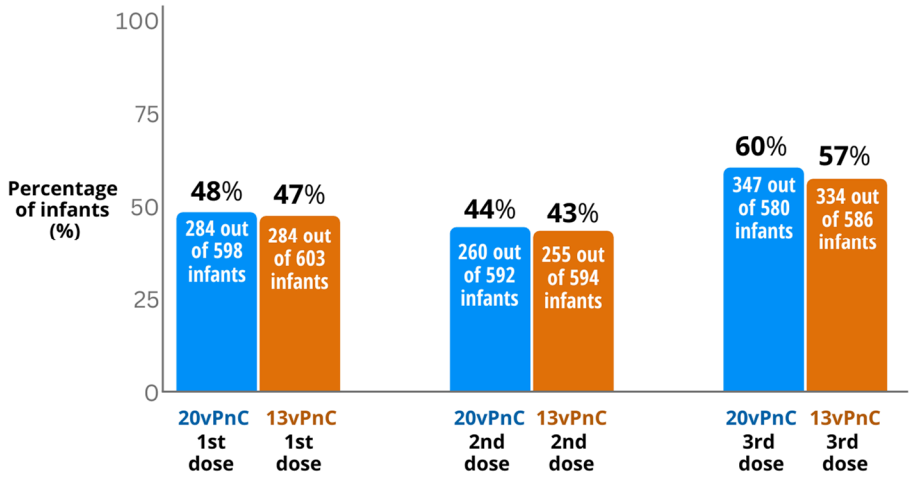
8. What percentage of infants had redness, swelling, or pain at the injection site after each dose of 20vPnC or 13vPnC? − Cohorts A and B

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 the study vaccine was injected (or injection site reaction). Researchers looked at the diary records collected for infants.

Cohort A:

Figure 3 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 3. 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? – Cohort A



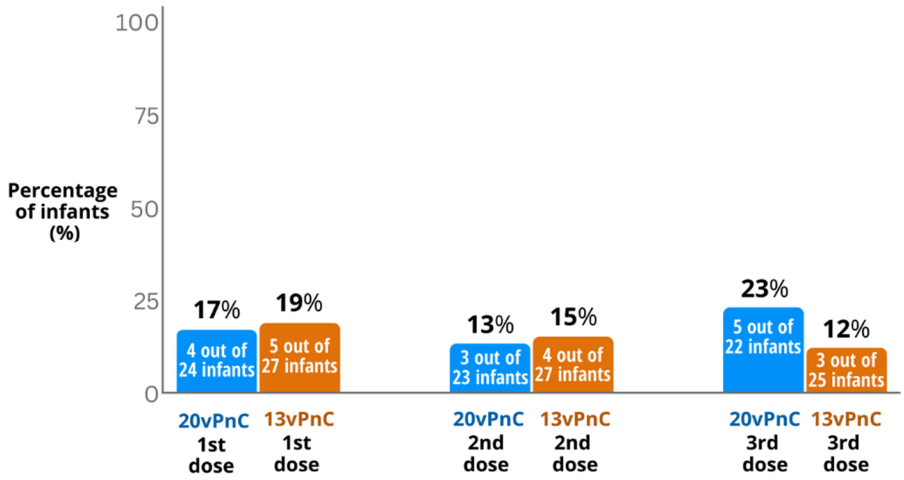
Not shown in Figure 3:

Most of these injection site reactions were mild or moderate in severity. These reactions generally went away after about 1 to 3 days. The most common single reaction after the 1st and 3rd doses of 20vPnC or 13vPnC was pain at the injection site. The most common single reaction after the 2nd dose of 20vPnC or 13vPnC was redness at the injection site.

Cohort B:

Figure 4 shows that, in general, 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 4: 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? – Cohort B



Not shown in Figure 4:

Most of these injection site reactions were mild or moderate in severity. These reactions generally went away after about 1 to 5 days. The most common of these reactions after the 1st dose of 20vPnC or 13vPnC were redness and pain at the injection site. The most common of these reactions after the 2nd and 3rd doses of 20vPnC or 13vPnC was pain at the injection site.

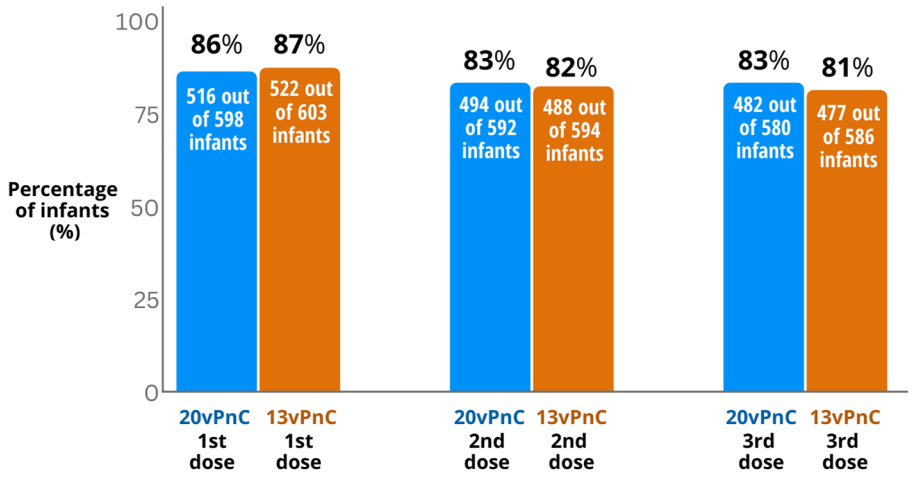
9. What percentage of infants had fever, loss of appetite, drowsiness, or irritability after each dose of 20vPnC or 13vPnC? – Cohorts A and B

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.

Cohort A:

Figure 5 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 5: 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? – Cohort A



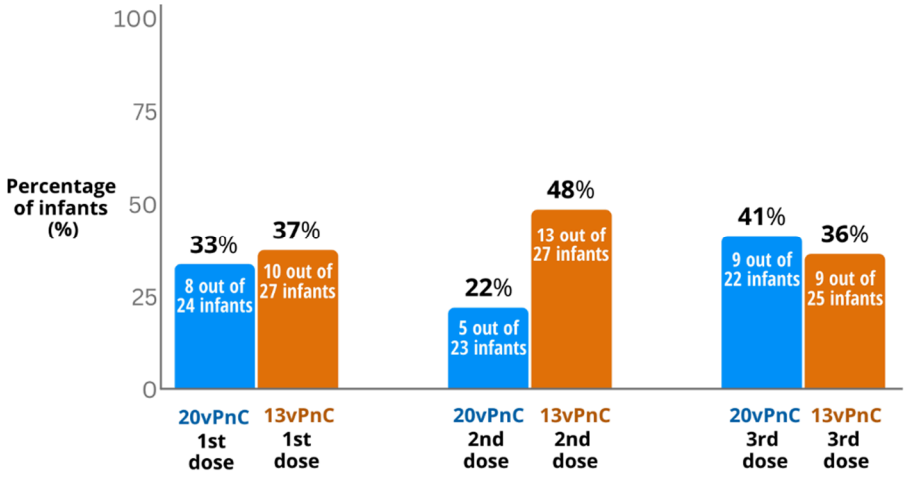
Not shown in Figure 5:

Most of these symptoms were mild or moderate in severity. These symptoms generally went away after about 1 to 3 days. The most common of these symptoms after each dose of 20vPnC or 13vPnC (Doses 1 to 3) were irritability and drowsiness.

Cohort B:

Figure 6 shows that, in general, 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 6: 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? – Cohort B



Not shown in Figure 6:

Most of these symptoms were mild or moderate in severity. These symptoms generally went away after about 1 to 5 days. The most common of these symptoms after the 1st dose of 20vPnC or 13vPnC was drowsiness. The most common of these symptoms after the 2nd and 3rd doses of 20vPnC or 13vPnC was irritability.

Cohorts A and B:

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 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.

Cohort A:

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.

Cohort B:

No infant in either of the 20vPnC or 13vPnC group stopped taking part in the study because of a medical problem they had during the study.

10. What percentage of infants had a medical problem at any time from the 1st dose to 1 month after the 2nd dose of 20vPnC or 13vPnC? – Cohorts A and B

Cohort A:

Researchers looked at the records of 1204 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 2nd dose were similar in the 20vPnC and 13vPnC groups.

- 83 out of 601 infants (14%) in the 20vPnC group.
- 87 out of 603 infants (14%) 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 2nd dose of 20vPnC or 13vPnC. These medical problems were seen in at least 2% of infants in either vaccine group.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of the table lists the most common medical problems during a time period of this study. The table lists all medical problems seen in at least 2% of infants in either vaccine group.
- The **2nd** column shows how many of the 601 infants, including the percentage of the 601 infants, in the 20vPnC group had each medical problem.
- The **3rd** column shows how many of the 603 infants, including the percentage of the 603 infants, in the 13vPnC group had each medical problem.
- For example, you can see in Table 1 that 9 out of the 601 infants (2%) who received 20vPnC had an eye infection. None of the 603 infants (0%) who received 13vPnC had an eye infection.

Table 1. What were the most common medical problems that happened at any time from the 1st dose to 1 month after the 2nd dose of 20vPnC or 13vPnC? − Cohort A

Medical Problem	20vPnC (601 Infants)	13vPnC (603 Infants)
Eye infection	9 out of 601 infants (2%)	0 out of 603 infants (0%)
Swelling of the nose and throat (also known as **a cold**)	8 out of 601 infants (1%)	12 out of 603 infants (2%)
Infection of the nose, sinuses, and throat	8 out of 601 infants (1%)	12 out of 603 infants (2%)
Itchy and dry skin condition called "eczema"	9 out of 601 infants (2%)	9 out of 603 infants (2%)

Cohort B:

Researchers looked at the records of 51 infants who received at least the 1st dose of 20vPnC or 13vPnC.

Few infants had a medical problem that happened at any time from the 1st dose to 1 month after the 2nd dose of 20vPnC or 13vPnC:

- 2 out of 24 infants (8%) in the 20vPnC group.
    - 1 out of 24 infants (4%) had colic (crying for a lot longer than usual).
    - 1 out of 24 infants (4%) had hives (an itchy skin reaction) from a food allergy.
- 1 out of 27 infants (4%) in the 13vPnC group had thrush (a yeast infection of the mouth).

11. What percentage of infants had a medical problem at any time from the 3rd dose to 1 month after the 3rd dose of 20vPnC or 13vPnC? – Cohorts A and B

Cohort A:

Researchers looked at the records of 1182 infants who received all 3 doses of 20vPnC or 13vPnC.

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

- 91 out of 588 infants (16%) in the 20vPnC group.
- 98 out of 594 infants (17%) in the 13vPnC group.

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

Instructions on how to read Table 2 are similar to those for Table 1, but the time periods and the total number of infants are different.

Table 2. What were the most common medical problems that happened at any time from the 3rd dose to 1 month after the 3rd dose of 20vPnC or 13vPnC? – Cohort A		
Medical Problem	**20vPnC (588 Infants)**	**13vPnC (594 Infants)**
Swelling of the nose and throat (also known as **a cold**)	12 out of 588 infants (2%)	10 out of 594 infants (2%)
Infection of the middle ear	5 out of 588 infants (1%)	10 out of 594 infants (2%)
Infection of the nose, sinuses, and throat	13 out of 588 infants (2%)	26 out of 594 infants (4%)

Cohort B:

Researchers looked at the records of 47 infants who received all 3 doses of 20vPnC or 13vPnC.

One (1) out of 22 infants (5%) in the 20vPnC group had a medical problem that happened at any time from the 3rd dose to 1 month after the 3rd dose of 20vPnC. This infant had an infection of the nose, sinuses, and throat.

None of the 25 infants (0%) in the 13vPnC group had any medical problem from the 3rd dose to 1 month after the 3rd dose of 13vPnC.

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.

12. What percentage of infants had a serious medical problem during the study? − Cohorts A and B

Cohort A:

Researchers looked at the records of 1204 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 1 month after the 3rd dose) were similar in the 20vPnC and 13vPnC groups.

- 34 out of 601 infants (6%) in the 20vPnC group.
- 40 out of 603 infants (7%) in the 13vPnC group.

No specific serious medical problem was seen in 1% or more infants in either vaccine group.

One (1) infant who received 20vPnC had a serious medical problem of fever and blood test that showed signs of an overactive immune system 7 days after the 1st dose.

- This infant also had groin swelling and pain on the opposite side of the 20vPnC injection.
- The study site doctor thought this serious medical problem could be related to either the study vaccine or the routine vaccine. The infant received the 2nd and 3rd doses of 20vPnC with no repeat of the medical problem.

No infant died during the study.

Cohort B:

No infant in either of the 20vPnC or 13vPnC group had a serious medical problem at any time during the study (from the 1st dose to 1 month after the 3rd dose of 20vPnC or 13vPnC).

No infant died during the study.

Did participants have any new long-term medical conditions?

13. What percentage of infants were diagnosed with a new long-term medical condition during the study? – Cohorts A and B

Cohort A:

Researchers looked at the records of 1204 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 1 month after the 3rd dose) were low and similar in the 20vPnC and 13vPnC groups.

- 6 out of 601 infants (1%) in the 20vPnC group.
- 6 out of 603 infants (1%) in the 13vPnC group.

The most common new long-term medical condition was an itchy and dry skin condition called “eczema”. This medical condition is commonly seen in this age group.

Cohort B:

No infant in either of the 20vPnC or 13vPnC group had any new long-term medical conditions 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 **B7471012**

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

www.clinicaltrials.gov	Use the study identifier **NCT04546425**
www.clinicaltrialsregister.eu	Use the study identifier **2019-003306-27**

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!