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 for use in infants. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Medicine(s) Studied: Complementary 7-valent Pneumococcal Conjugate Vaccine, Compound Number: PF-06842433

Protocol Number: C3571002

Dates of Study: 01 June 2018 to 05 November 2020

Title of this Study: A Study of a Multivalent Pneumococcal Conjugate Vaccine Given With, or Separately From, 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants

[Final Report: A Phase 2, Randomized, Open-Label Trial to Evaluate the Safety and Immunogenicity of a Multivalent Pneumococcal Conjugate Vaccine Given With, or Separately From, 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants]

Date(s) of this Report: 02-Jun-2021

– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you and your child 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 is a bacteria that can cause serious diseases, including infections of the lung (pneumonia), brain lining (meningitis), blood (bacteremia), or ear (otitis).

These infections may be very serious in young children and older adults. *Streptococcus pneumoniae* is also known as *S pneumoniae*. There are about 100 types of *S pneumoniae*.

What is the c7vPnC vaccine?

This study is about a vaccine called the "complementary 7-valent pneumococcal conjugate vaccine", or c7vPnC. A vaccine is used to help prevent infection by helping the body to fight off germs. c7vPnC may help to prevent infections caused by *S pneumoniae*. It is called "7-valent" because it has the potential to prevent 7 common types of *S pneumoniae*.

It is referred to as "complementary" as it is expected be used with Prevnar 13®, a vaccine approved in the United States that is made up of components to prevent disease caused by 13 types of *S pneumoniae*.

When used together, c7vPnC and Prevnar 13 could have the potential to prevent disease caused by 20 different types of *S pneumoniae*.

c7vPnC is an investigational vaccine, which means that it has not been approved for general use and it is not yet known if it will protect against disease caused by *S pneumoniae*.

What was the purpose of this study?

The main purpose of this study was to learn about the safety of c7vPnC in healthy infants, when given with or separately from Prevnar 13.

Researchers wanted to know:

- How many of the infants in the study:
  - Had redness, swelling, or pain at the injection site within 7 days of each vaccination?
  - Had fever, low appetite, sleepiness, or irritability within 7 days after each vaccination?
  - Had medical problems from Dose 1 to 1 month after Dose 3, and from Dose 4 or the supplemental dose to 1 month after?
  - Had serious medical problems or any newly diagnosed chronic medical problems during the study?

What happened during the study?

How was the study done?

Researchers studied c7vPnC in a group of healthy infants to find out if infants had any health problems when given c7vPnC with or separately from Prevnar 13:

- When given both c7vPnC and Prevnar 13 at 2, 4, 6, and 12 months of age
- When given Prevnar 13 at 2, 4, 6, and 12 months of age, and c7vPnC at 3, 5, 7, and 13 months of age (every other month from Prevnar 13)

Researchers then compared the results of infants getting both c7vPnC and Prevnar 13 (given either together or separately) at 2, 4, 6, and 12 months of age to the results of infants getting Prevnar 13 at 2, 4, 6, and 12 months of age and a supplemental dose of c7vPnC at 13 months of age. In this study, Prevnar 13 was used for comparison because it is an approved and recommended vaccine for use in infants for preventing *S pneumoniae* diseases. It was given to all infants in the study.

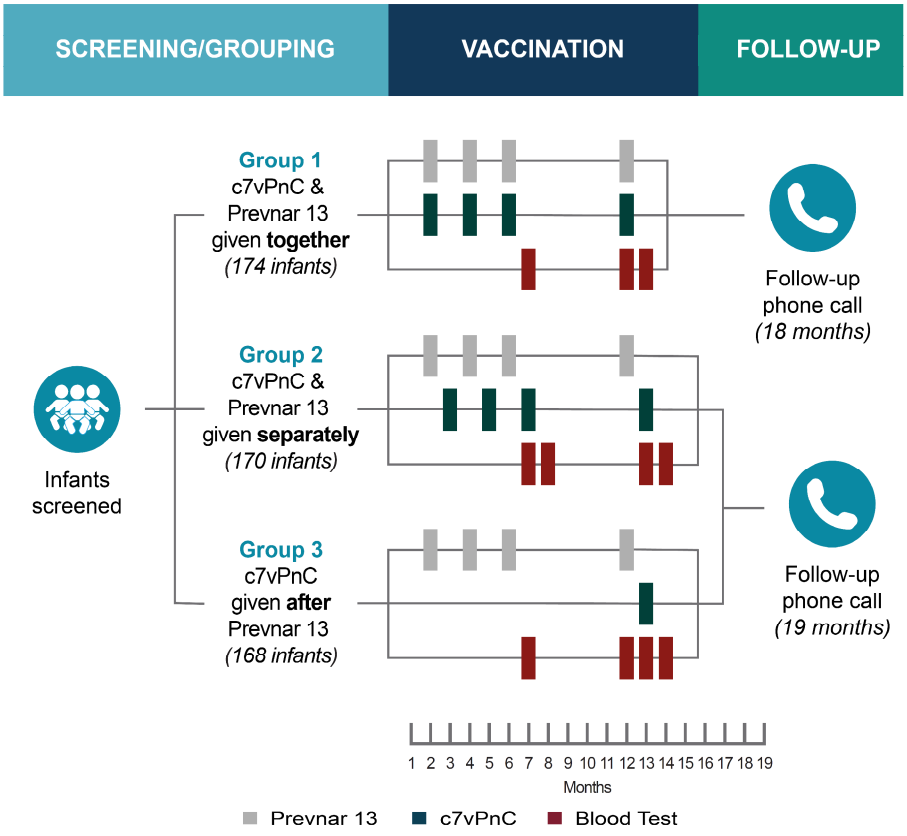
The families of the infants and the researchers knew which infants were given c7vPnC at the same time as Prevnar 13, every other month (separately) from Prevnar 13, or as a supplemental dose after the 4 doses of Prevnar 13. This is known as an "open label"

study. Infants were assigned to each group by chance alone. All infants had an equal chance of being assigned to each group.

Infants were expected to participate in 6 to 10 study visits, depending on which group they were in. At the visits, blood samples were collected, vaccines were given, and infants were checked for any medical problems. Families were also contacted over the phone about 6 months after the last vaccine, to check on the infant's health.

Infants in this study also received a Pediarix vaccine (an infant diphtheria, tetanus, pertussis, hepatitis B, poliovirus containing vaccine recommended by the American Academy of Pediatrics) with the first 3 vaccinations. They may have also received other recommended vaccines at the visits or at other times while they were enrolled in the study, which were not part of the study.

The figure below shows what happened during the study.



Where did this study take place?

The Sponsor ran this study at 39 locations in the United States.

When did this study take place?

It began 01 June 2018 and ended 05 November 2020.

Who participated in this study?

Infants were checked (screened) by the study doctors to make sure they were a good fit for the study.

This study included infants who:

- Were full term when they were born (at least 36 weeks into the pregnancy)
- Were about 2 months old when they joined the study
- Were considered to be healthy or with stable chronic disease by the study doctors
- Did not have a disease or take medicine that would be associated with a weakened immune system
- Had never received any vaccine for *S pneumoniae*

565 infants joined this study, but 2 study sites were removed from participation in the study, leaving 512 infants remaining. Of these a total of 484 infants received at least 1 vaccine dose during the study:

- A total of 244 boys were vaccinated
- A total of 240 girls were vaccinated
- All infants were between the ages of 43 and 126 days at the start of the study.

Out of the 512 infants in the study:

- 424 infants (83%) received Dose 3 of c7vPnC, and 376 infants (73%) completed their 1-month visit after Dose 3.
- 89 infants (17%) left the study before their 1-month visit after Dose 3, by their family's choice, because a doctor decided it was best for the infant to stop being in the study, or the sponsor no longer required the visit.

- 296 infants (58%) received Dose 4 and 238 infants (47%) completed their 1-month visit after Dose 4. 37 infants (7%) left the study after Dose 4 but before their 1-month visit after Dose 4.
- 88 infants (18%) received the supplemental dose and 66 infants (13%) completed their supplemental dose 1-month visit. 15 infants (3%) left the study after Dose 4 but before their supplemental dose 1-month visit.
- Overall, 389 infants (76%) completed the 6-month follow-up phone visit, and 276 infants (54%) completed all study visits.

How long did the study last?

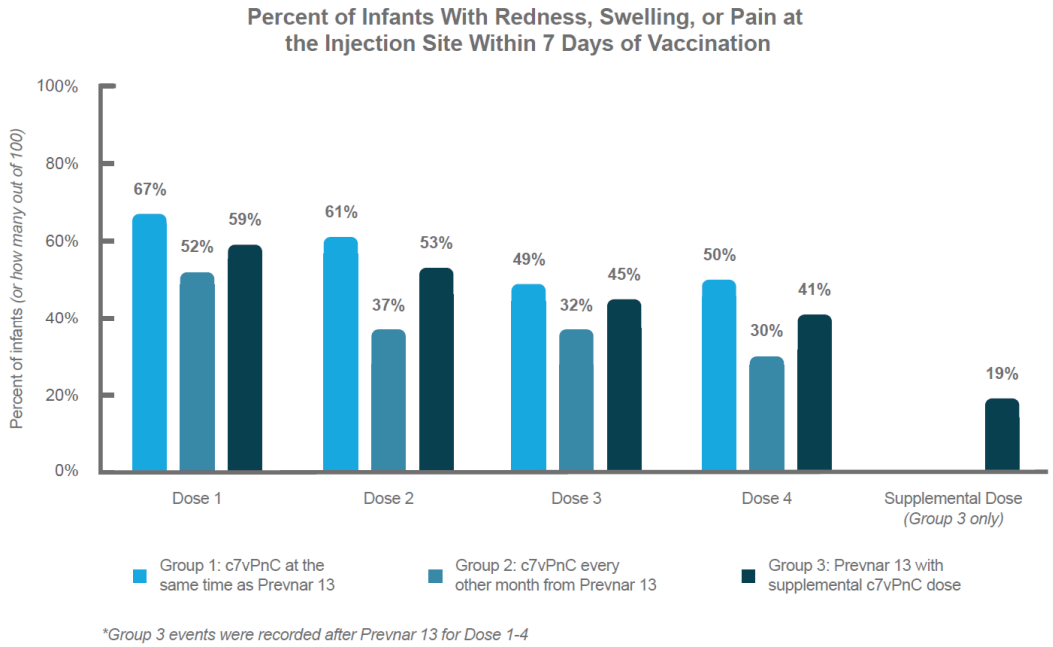
Infants were in the study for up to 17 months. The entire study took a little more than 2 years to complete.

When the study ended in 05 November 2020, 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 infants had redness, swelling, or pain at the injection site within 7 days of each vaccination?

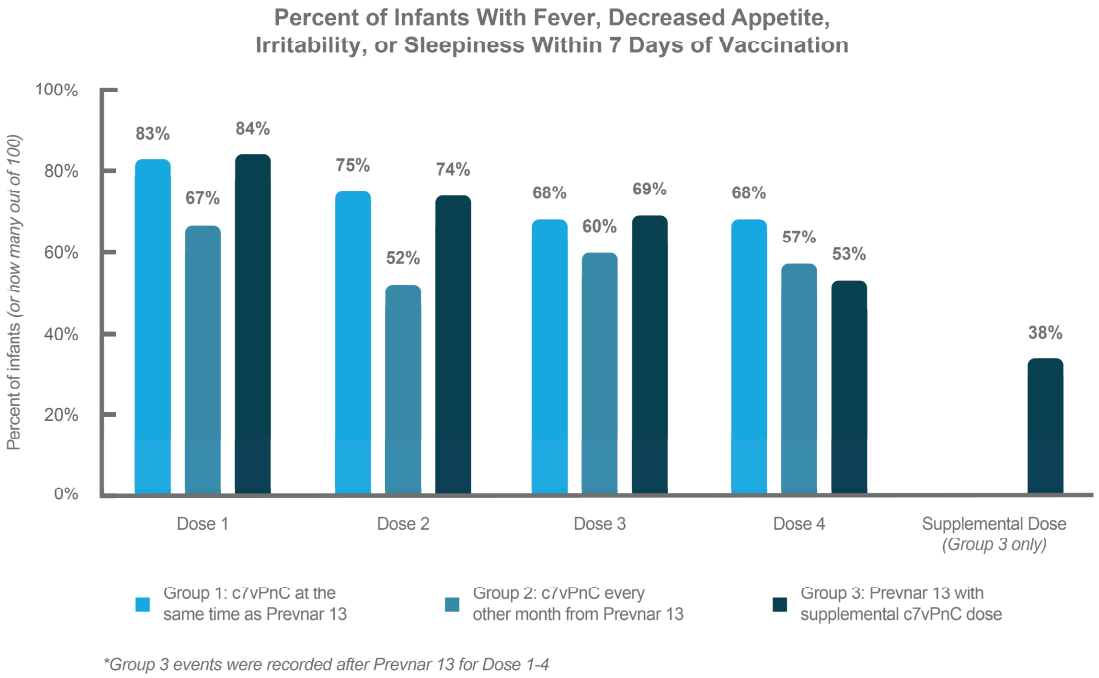
The graph below shows the percentage of infants in each vaccine group with redness, swelling, or pain at the injection site within 7 days after each vaccination. Infants in Group 2 had lower rates of redness, swelling, or pain at the injection site than infants in Groups 1 and 3. Infants in Groups 1 and 3 received other infant vaccines at the same time that they received Doses 1 to 4, but infants in Group 2 did not.



*Group 3 events were recorded after Prevnar 13 for Dose 1-4

How many infants had fever, decreased appetite, irritability, or sleepiness within 7 days after each vaccination?

The graph below shows the percentage of infants with fever, decreased appetite, irritability, or sleepiness within 7 days after each vaccination. Infants in Groups 1 and 3 received other infant vaccines at the same time that they received Doses 1 to 4, but infants in Group 2 did not.



*Group 3 events were recorded after Prevnar 13 for Dose 1-4

This does not mean that everyone in this study had these results. These are just some of the main findings of this study. Other studies may have different results.

The researchers also examined what medical problems the infants experienced during the study. This information is provided in the next section.

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, medical problems could also have been caused by a study vaccine or by another medicine the infant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across vaccine groups in many studies, doctors try to understand what effects a study vaccine might have on an infant.

In this study, by comparing infants who got the study vaccine (c7vPnC) to infants who got only Prevnar 13, researchers can understand if the safety of taking both

c7vPnC and Prevnar 13 at the same time or taking c7vPnC every other month from Prevnar 13 is similar to the safety of taking Prevnar 13 alone. There was not a similar comparison group for the infants who received the supplemental dose.

How many infants had medical problems from Dose 1 to 1 month after Dose 3, and from Dose 4 or the supplemental dose to 1 month after?

During the time period from Dose 1 to 1 month after Dose 3, the following percentage of infants had medical problems:

- 58% of infants (99 out of 171) in Group 1 who received c7vPnC at the same time as Prevnar 13
- 65% of infants (96 out of 147) who received c7vPnC every other month from Prevnar 13
- 57% of infants (94 out of 166) who received Prevnar 13 only

During the time period from Dose 4 to 1 month after Dose 4 , the following percentage of infants had medical problems:

- 24% of infants (26 out of 110) in Group 1 who received c7vPnC at the same time as Prevnar 13
- 15% of infants (13 out of 85) in Group 2 who received Dose 4 of c7vPnC 1 month after Prevnar 13
- 26% of infants (26 out of 101) in Group 3 who received Prevnar 13 only

During the time period from the supplemental dose to 1 month after the supplemental dose (Group 3 only), 18% of infants (16 out of 88) had medical problems.

The most common medical problems – those reported by at least 5% of infants – are described below in Table 1 and Table 2.

Below are instructions on how to read Tables 1-2.

Instructions for Understanding Tables 1-2.

- The **1st** column of the tables lists medical problems that were commonly reported during the study. All medical problems reported by more than 5% of infants are listed in Table 1 and Table 2.
- The **2nd** column tells how many of the infants in Group 1 (infants getting both c7vPnC and Prevnar 13 at the same time) reported each medical problem. Next to this number is the percentage of the infants in Group 1 who reported the medical problem.
- The **3rd** column tells how many of the infants in Group 2 (infants getting c7vPnC every other month from Prevnar 13) reported each medical problem. Next to this number is the percentage of the infants in Group 2 who reported the medical problem.
- The **4th** column tells how many of the infants in Group 3 (infants getting a supplemental dose of c7vPnC after all 4 doses of Prevnar 13) reported each medical problem. Next to this number is the percentage of the infants in Group 3 who reported the medical problem.
- Example: Using these instructions, in Table 1 you can see that 7 out of the 171 (4%) infants in Group 1 reported constipation between Dose 1 and 1 month after Dose 3. A total of 8 out of the 147 (5%) infants in Group 2 and 2 out of the 166 (1%) infants in Group 3 reported constipation between Dose 1 and 1 month after Dose 3.

Table 1. Commonly reported medical problems from Dose 1 to 1 month after Dose 3
(Reported in at least 5% of infants in any group)

Medical Problem	Vaccine Group 1 (171 Infants)	Vaccine Group 2 (147 Infants)	Vaccine Group 3 (166 Infants)
Any medical problem	99 out of 171 infants (58%)	96 out of 147 infants (65%)	94 out of 166 infants (57%)
Atopic dermatitis	10 out of 171 infants (6%)	4 out of 147 infants (3%)	10 out of 166 infants (6%)
Stuffy nose	10 out of 171 infants (6%)	5 out of 147 infants (3%)	5 out of 166 infants (3%)
Diaper rash	9 out of 171 infants (5%)	7 out of 147 infants (5%)	4 out of 166 infants (2%)
Cough	9 out of 171 infants (5%)	4 out of 147 infants (3%)	10 out of 166 infants (6%)
Constipation	7 out of 171 infants (4%)	8 out of 147 infants (5%)	2 out of 166 infants (1%)
Fever	5 out of 171 infants (3%)	8 out of 147 infants (5%)	6 out of 166 infants (4%)
Infection affecting the smaller airways	11 out of 171 infants (6%)	7 out of 147 infants (5%)	15 out of 166 infants (9%)
Pink eye	9 out of 171 infants (5%)	7 out of 147 infants (5%)	8 out of 166 infants (5%)
Ear ache	7 out of 171 infants (4%)	16 out of 147 infants (11%)	10 out of 166 infants (6%)
Nose, sinus, or throat infection	41 out of 171 infants (24%)	41 out of 147 infants (28%)	31 out of 166 infants (19%)

Table 2. Commonly reported medical problems from Dose 4 to 1 month after Dose 4
(Reported in at least 5% of infants in any group)

Medical Problem	Vaccine Group 1 (110 Infants)	Vaccine Group 2 (85 Infants)	Vaccine Group 3 (101 Infants)
Any medical problem	26 out of 110 infants (24%)	13 out of 85 infants (15%)	26 out of 101 infants (26%)
Upper respiratory tract infection	7 out of 110 infants (6%)	3 out of 85 infants (4%)	5 out of 101 infants (5%)

No medical problems were reported in at least 5% of the infants who received the supplemental dose (Group 3) of c7vPnC.

Did study infants 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 infants had serious medical problems or newly diagnosed chronic medical problems during the study?

4% of infants (20 out of 484) who received study vaccines had serious medical problems, including 4% of infants (7 out of 171) in Group 1, 3% of infants (4 out of 147) in Group 2, and 5% of infants (9 out of 166) in Group 3. Additionally, one infant (less than 1%) from Group 2 who did not receive any doses of c7vPnC had a serious medical problem. Serious medical problems reported in more than 1% of infants during the study included:

- Bronchiolitis (a viral infection affecting the smaller airways), occurred in 1% of infants (2 out of 171) in Group 1, 1% of infants (1 out of 147) in Group 2, and 2% of infants (3 out of 166) in Group 3.
- Pneumonia caused by a virus occurred in 1% of infants (2 out of 166) in Group 3 and no infants in Group 1 or Group 2.

6% of infants (30 out of 484) had newly diagnosed chronic medical problems during the study, including 8% of infants (13 out of 171) in Group 1, 3% of infants (5 out of 147) in Group 2, and 7% of infants (12 out of 166) in Group 3.

Researchers do not believe any of these serious medical problems or newly diagnosed chronic medical problems were related to study vaccinations. No infants died during this 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.

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

www.clinicaltrials.gov	Use the study identifier **NCT03550313**
www.clinicaltrialsregister.eu	Use the study identifier **2020-005039-59**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **C3571002**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for infants.

Again, if you participated in this study, **thank you to you and your child** for volunteering.
We do research to try to find the best ways to help infants, and you helped us to do that!