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 study participants. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Vaccine(s) Studied: 20-valent Pneumococcal Conjugate Vaccine (20vPnC)

Protocol Number: B7471009

Dates of Study: 14 June 2021 to 13 May 2022

Title of this Study: 20-valent Pneumococcal Conjugate Vaccine Safety and Immunogenicity Study in Pneumococcal Vaccine-Naïve Adults 60 Years of Age and Older in Japan, Korea, and Taiwan

[Final Report: A Phase 3, Randomized, Double-Blind, Third-Party-Unblinded Trial to Evaluate the Safety and Immunogenicity of a 20-Valent Pneumococcal Conjugate Vaccine in Pneumococcal Vaccine-Naïve Adults 60 Years of Age and Older in Japan, Korea, and Taiwan]

Date(s) of this Report: 24 April 2023

– 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 is a type of 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 older adults. *Streptococcus pneumoniae* is also known as *S. pneumoniae* or pneumococcus.

What is a vaccine and an antibody response?

A vaccine can help prevent an infection or a disease. It works by helping the body fight off germs.

Antibodies are proteins that fight infections and help prevent diseases. After a person gets a vaccine, the body's response includes making antibodies. This is called an antibody response.

What is the 20-valent pneumococcal conjugate vaccine?

Valent (vey-luhnt)
Pneumococcal (nyoo-muh-kok-uhl)
Conjugate (kon-juh-geyt)

The "20-valent pneumococcal conjugate vaccine", or 20vPnC, may help to prevent infections caused by *S. pneumoniae*. It is called "20-valent" because 20vPnC contains components which may help to prevent 20 common types of *S. pneumoniae*. 20vPnC is an investigational vaccine and it was not approved for general use in Japan, Korea, or Taiwan at the time of this study.

Other vaccines used in this study were the "13-valent pneumococcal conjugate vaccine", or 13vPnC, which may help to prevent 13 of the most common types of *S. pneumoniae* (in this study report, the 13 types that are in both 13vPnC and 20vPnC are called "matched types"); and the "pneumococcal polysaccharide vaccine", or PPSV23.

What was the purpose of this study?

The main purpose of this study was to learn about the safety and the antibody responses of 20vPnC in participants 60 years and older from Japan, Korea, and Taiwan.

Researchers wanted to know:

1. For the 13 matched types found in both 20vPnC and 13vPnC, did participants who received 20vPnC have antibody responses that were within a range considered to be comparable to those who received 13vPnC?
2. For the 7 additional types found in both 20vPnC and PPSV23, did participants who received 20vPnC have antibody responses that were considered to be within a range comparable to antibody responses against the 7 additional types in those who received PPSV23?
3. What percentage of participants had redness, swelling, or pain at the injection site within 10 days after vaccination with 20vPnC or 13vPnC?
4. What percentage of participants had fever, headache, tiredness, muscle pain, or joint pain within 7 days after vaccination with 20vPnC or 13vPnC?
5. What percentage of participants had medical problems within 1 month after vaccination with 20vPnC or 13vPnC?
6. What percentage of participants had serious medical problems within 1 month after vaccination with 20vPnC or 13vPnC?

What happened during the study?

How was the study done?

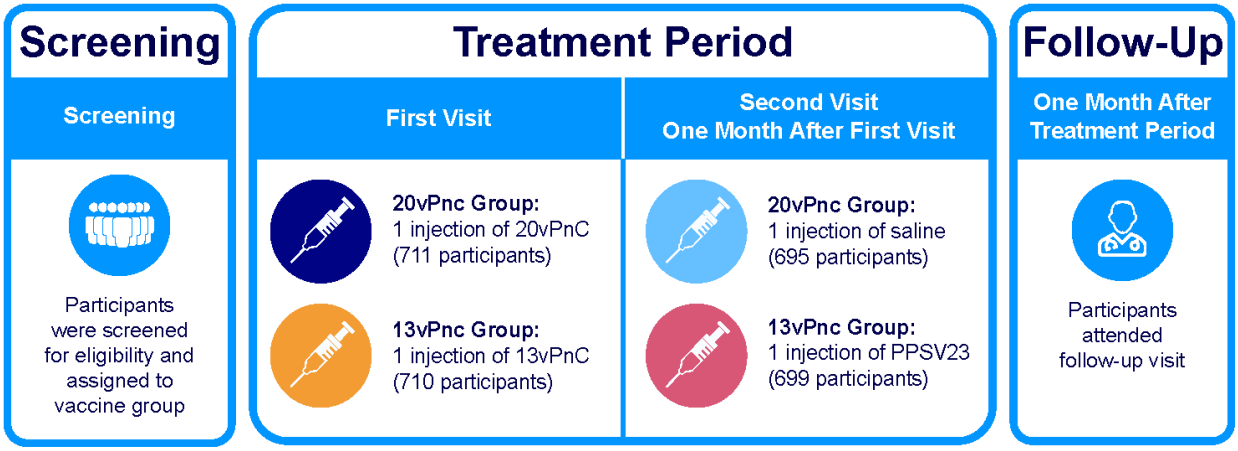
Researchers studied 2 groups of study participants. Group 1 received an injection of 20vPnC, followed by an injection of saline (a mix of salt and water) 1 month later. Group 2 received an injection of 13vPnC, followed by an injection of PPSV23 1 month later. The saline injections were given so that the participants and researchers did not know who was in each vaccine group. This is known as a "double-blinded" study to make sure that the study results were not influenced in any way. Study participants were first separated according to age (60 to 64 years, 65 years and older) and then assigned to each group by chance alone.

- 20vPnC Group : 711 out of 713 (99.7%) participants that joined the study received 20vPnC, and 695 (97.5%) received a dose of saline 1 month later.
- 13vPnC Group : 710 out of 712 (99.7%) participants that joined the study received a 13vPnC and 699 (98.2%) received a dose of PPSV23 1 month later.

Participants were in the study for about 2 months and were expected to attend 3 study visits during this time. At these visits, participants had their blood drawn, received study injections, and were monitored for any medical problems.

Figure 1 below shows what happened during the study.

Figure 1. What Happened During The Study?



Study doctors took a sample of blood from the participants at each visit

Where did this study take place?

The Sponsor ran this study at 28 locations in Japan, Korea, and Taiwan.

When did this study take place?

It began 14 June 2021 and ended 13 May 2022.

Who participated in this study?

The study included men and women 60 years and older from Japan, Korea, or Taiwan. Study participants were examined by the study doctor and determined to be appropriate for study participation, had never received a vaccine for *S. pneumoniae,* and were not allergic to any of the ingredients in the study vaccines. Participants aged 60 to 64 years in Japan were also required to have a pre-existing, stable chronic medical condition with an increased risk for pneumococcal disease, such as chronic heart disease, chronic lung disease, chronic kidney disease, chronic liver diseases, or diabetes.

- A total of 791 men (56%) participated
- A total of 630 women (44%) participated

- All participants were between the ages of 60 and 85 years

A total of 1425 participants joined the study, and 1421 participants (more than 99%) received at least 1 study vaccine. 1391 participants (98%) completed the study. A total of 34 participants (2%) left the study early for the following reasons:

- 15 participants (1%) chose to leave the study early
- 10 participants (1%) had a medical problem
- 4 participants (less than 1%) were withdrawn from the study due to an unplanned variation from the study design
- 1 participant (less than 1%) left the study due to study doctor decision
- 1 participant (less than 1%) left the study due to a vaccination error (this participant did not have a medical problem associated with the error)
- 1 participant (less than 1%) no longer qualified to be in the study
- 2 participants (less than 1%) left the study early for other reasons

How long did the study last?

Study participants were in the study for about 2 months. The entire study took about 11 months to complete.

Throughout the course of the study the sponsors reviewed safety data. After the study ended in May 2022, and after antibody testing was completed, the Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

For the 13 matched types found in both 13vPnC and 20vPnC, did participants who received 20vPnC have

antibody responses that were within a range considered to be comparable to those who received 13vPnC?

The researchers measured the amount of antibodies against the 13 matched types of *S. pneumoniae* in participants' blood 1 month after being vaccinated with 20vPnC or 13vPnC. The researchers found that antibody levels for each of the 13 components in participants who received 20vPnC were within a range considered to be comparable to those in participants who received 13vPnC. Therefore, the participants who received 20vPnC had antibody responses against the 13 matched types of *S. pneumoniae* that were comparable to the participants who received 13vPnC.

For the 7 additional types found in both 20vPnC and PPSV23, did participants who received 20vPnC have antibody responses that were considered to be within a range comparable to antibody responses against the 7 additional types in those who received PPSV23?

The researchers measured the amount of antibodies against the 7 additional types of *S. pneumoniae* in participants' blood 1 month after being vaccinated with 20vPnC or PPSV23. For 6 of the 7 additional types, the researchers found that antibody levels in participants who received 20vPnC were within a range considered to be comparable to those in participants who received PPSV23. Therefore, the participants who received 20vPnC had antibody responses against 6 of the 7 additional types that were comparable to the participants who received PPSV23 for these 6 types, and in fact had higher average antibody levels.

For 1 of 7 additional types, the researchers found that antibody level in participants who received 20vPnC was just below the range considered to be comparable to those in participants who received PPSV23. However, the researchers still expected 20vPnC to produce an adequate antibody response for this type. Based on these

results, the researchers have decided that the results are not likely the result of chance.

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?

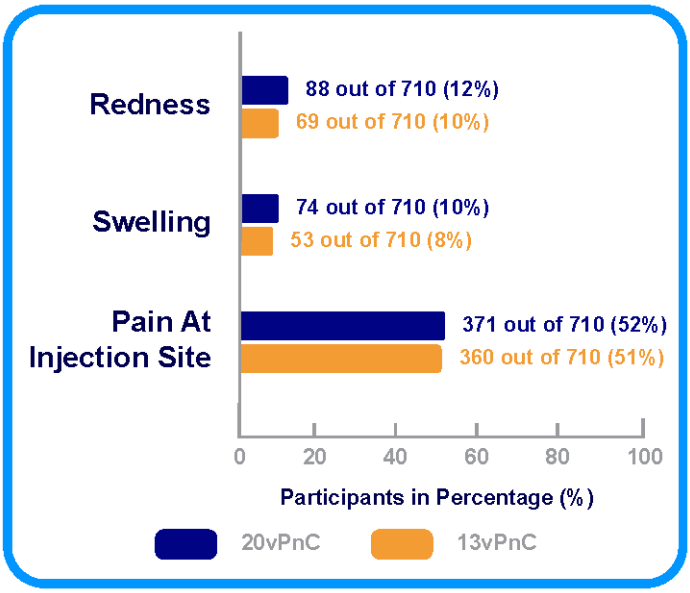
The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study vaccine or by 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.

What percentage of participants had redness, swelling, or pain at the injection site within 10 days after vaccination with 20vPnC or 13vPnC?

393 out of 710 (55%) participants who received 20vPnC had redness, swelling, or pain at the injection site within 10 days after vaccination. 375 out of 710 (53%) participants who received 13vPnC had redness, swelling, or pain at the injection site within 10 days after vaccination.

The charts below in **Figure 2** show that pain at the injection site was the most common reaction. Most of the reported reactions were mild or moderate in severity level.

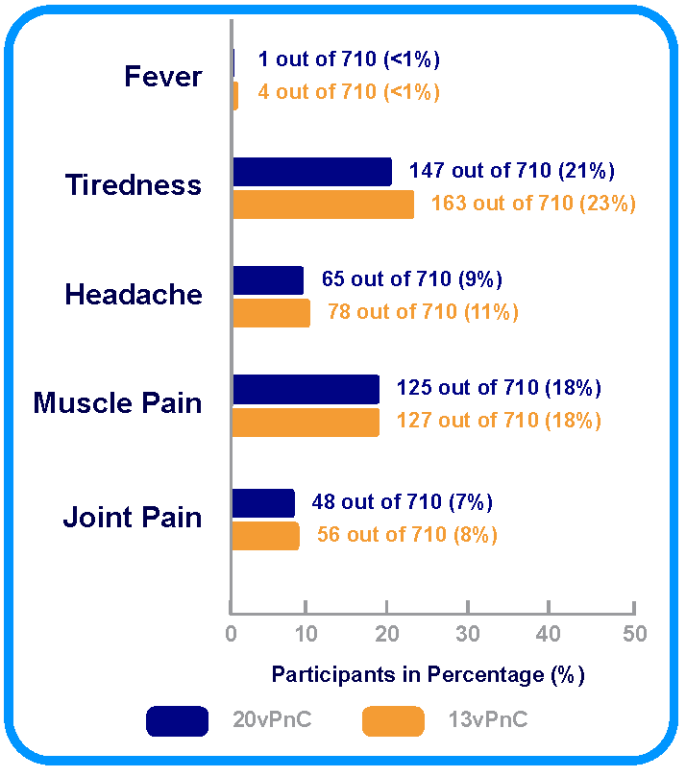
Figure 2. Participants With Redness, Pain, or Swelling at Injection Site Within 10 Days After Vaccination With 20vPnC or 13vPnC



What percentage of participants had fever, headache, tiredness, muscle pain, or joint pain within 7 days after vaccination with 20vPnC or 13vPnC?

233 out of 710 (33%) participants who received 20vPnC had fever, headache, tiredness, muscle pain, or joint pain within 7 days after vaccination. 235 out of 710 (33%) participants who received 13vPnC had fever, headache, tiredness, muscle pain, or joint pain within 7 days after vaccination. The charts below in **Figure 3** show that tiredness was the most frequent of these symptoms. Most of the reported symptoms were mild or moderate in severity level.

Figure 3. Participants With Fever, Headache, Tiredness, Muscle Pain, or Joint Pain Within 7 Days After Vaccination With 20vPnC or 13vPnC



What percentage of participants had medical problems within 1 month after vaccination with 20vPnC or 13vPnC?

40 out of 711 (6%) participants who received 20vPnC had at least 1 medical problem within 1 month after vaccination. 42 out of 710 (6%) participants who received 13vPnC had at least 1 medical problem within 1 month after vaccination.

10 (1%) participants left the study because of medical problems.

The most common medical problems within 1 month after vaccination with 20vPnC or 13vPnC, those reported by at least 1% of participants in any group – are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table.

- The **1st** column of Table 1 lists medical problems that were commonly reported by study participants within 1 month after vaccination. All medical problems reported by less than or equal to 1% of participants in any group are listed.
- The **2nd** column tells how many of the 711 participants vaccinated with 20vPnC reported each medical problem. Next to this number is the percentage of the 711 participants vaccinated with 20vPnC who reported the medical problem.
- The **3rd** column tells how many of the 710 participants vaccinated with 13vPnC reported each medical problem. Next to this number is the percentage of the 710 participants vaccinated with 13vPnC who reported each medical problem.
- Using these instructions, you can see that 8 out of the 711 (1%) participants vaccinated with 20vPnC reported a positive COVID-19 test. 4 out of the 710 (less than 1%) participants vaccinated with 13vPnC reported a positive COVID-19 test.

Table 1. Commonly reported medical problems by study participants within 1 month after vaccination		
Medical Problem	**20vPnC (711 Participants Vaccinated)**	**13vPnC (710 Participants Vaccinated)**
Positive COVID-19 test	8 out of 711 participants (1%)	4 out of 710 participants (less than 1%)
COVID-19 infection	8 out of 711 participants (1%)	4 out of 710 participants (less than 1%)

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.

What percentage of participants had serious medical problems within 1 month after vaccination with 20vPnC or 13vPnC?

3 out of 711 (less than 1%) participants who received 20vPnC had at least 1 serious medical problem within 1 month after vaccination. 4 out of 710 (less than 1%) participants who received 13vPnC had at least 1 serious medical problem within 1 month after vaccination. No single serious medical problem happened in at least 1% of participants in either group. 1 participant who received 13vPnC had serious medical problems that were considered to be related to study vaccine by the study doctor. No participants (0%) 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.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results

Use the protocol number **B7471009**

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

www.clinicaltrials.gov

Use the study identifier **NCT04875533**

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

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