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 medication 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(s) Studied:	Nimenrix® (Meningococcal Groups A, C, W-135 and Y Conjugate Vaccine)
Protocol Number:	C0921062
Dates of Study:	09 April 2021 to 28 April 2023
Title of this Study:	Study Looking at Response to the Nimenrix Vaccine in Healthy Infants [A Phase 3b, Open-Label, Study to Evaluate the Safety and Immunogenicity of Nimenrix (Registered) in Healthy Infants, Given at 3 and 12 Months of Age]
Date(s) of this Report:	20 October 2023

– Thank You –

If your child/ward 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 *Neisseria meningitidis*?

Neisseria meningitidis (or *N. meningitidis*) is a kind of germ (bacteria). Meningococcus is its other name. There are different types of this bacteria. For example, meningococcal type A disease is caused by meningococcus A. Meningococcus A, B, C, W, and Y are the most common types.

N. meningitidis can cause infections of the blood, as well as swelling or inflammation around the brain and spinal cord. People who get this illness are at risk for brain damage, loss of limbs, hearing loss, other disabilities, and death. These risks are higher in infants, children less than 5 years old, adolescents (eg, aged between 10 and 19 years), and older adults.

What is Nimenrix?

Nimenrix is an injectable vaccine that has been licensed for use in Europe and in other countries worldwide. Nimenrix is approved for use in infants 6 weeks of age and above. Vaccines like Nimenrix may help the body's immune system defend against meningococcal types A, C, W, and Y infections.

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

What was the purpose of this study?

When infants receive Nimenrix between 6 weeks and 6 months of age, they should receive 3 doses of the vaccine; a first dose from 6 weeks of age onwards, a second one at least 2 months later, and a third dose at 12 months of age.

The researchers did this study to find out about the effects of a single dose of the vaccine in infants of 3 months of age followed by a second dose at 12 months.

The researchers wanted to know about the participant's immune response to the vaccine. They did this by measuring the amount of antibody for meningococcus A, C, W, and Y in the participants' blood.

The researchers also wanted to know about the safety of the vaccine. They did this by looking to see if there were any local reactions, systemic events, or medical problems after the vaccine was given. A local reaction is when there is redness, swelling, or pain at the injection site. The injection site is the skin area where the needle was inserted. A systemic event is when there are symptoms like fever, a decreased appetite, drowsiness, and irritability.

Researchers wanted to know:

- **Did participants given the Nimenrix vaccine have an immune response after the vaccinations?**
- **Did participants have any local reactions or systemic events after the Nimenrix vaccinations?**
- **Did participants have any medical problems or new long-term diseases or medical conditions after the Nimenrix vaccinations?**

What happened during the study?

How was the study done?

Parents or guardians of infants aged 3 months were asked if they wanted their child to participate in this study. Each participant was vaccinated with a single dose of Nimenrix at 3 months of age (Dose 1) and a second dose at 12 months of age (Dose 2).

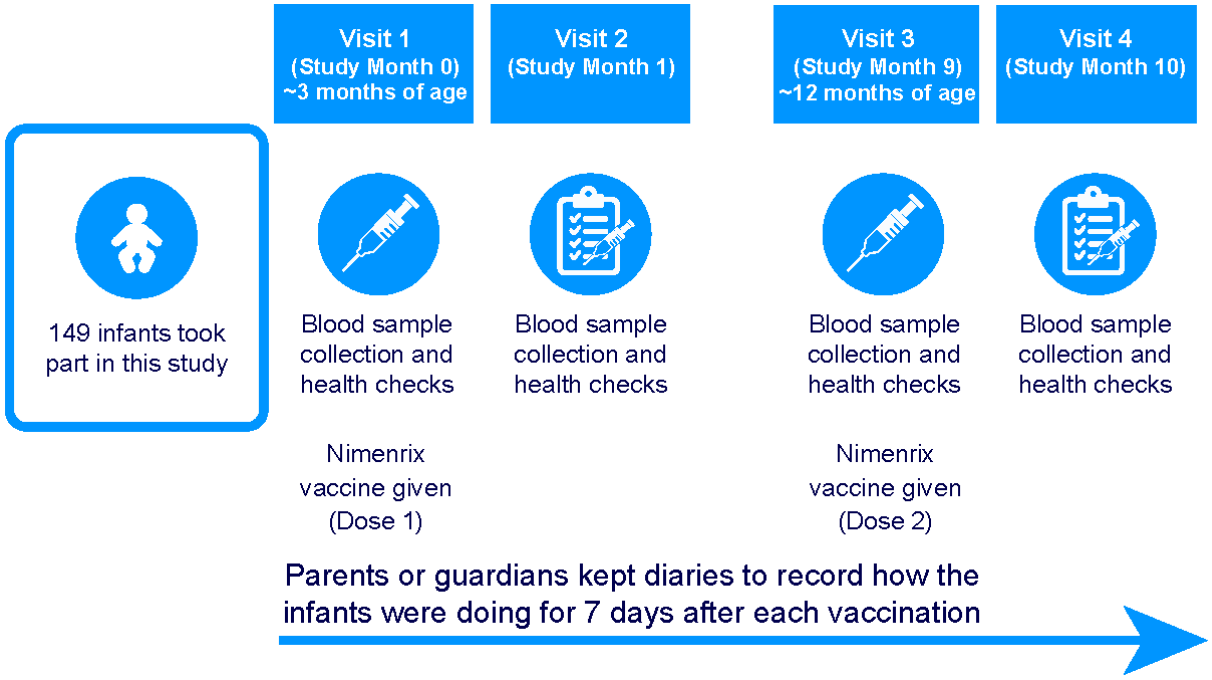
Researchers tested the effect of the vaccination schedule by looking at the immune response. They did this by collecting blood samples from all participants before Dose 1, 1 month after Dose 1, before Dose 2, and 1 month after Dose 2.

Researcher also wanted to know about the safety of the Nimenrix vaccine. They asked parents or guardians to keep a diary to record how the participants were doing within 7 days of getting Dose 1 and Dose 2. Researchers also asked about any medical problems in the 30 days after Dose 1 and Dose 2, and throughout the study.

In addition, the researchers wanted to know if any of the infants were diagnosed with a new long-term diseases or medical conditions during the study.

Figure 1 below shows what happened during the study.

Figure 1. What happened during the study?



Note: 149 infants joined the study and 147 received Dose 1 and 143 received Dose 2.

Where did this study take place?

The Sponsor ran this study at 14 locations in 3 countries in Europe (Finland, Poland, and Spain).

When did this study take place?

It began 09 April 2021 and ended 28 April 2023.

Who participated in this study?

The study included infant participants who were healthy and:

- Did not have a history of meningococcal infection(s).
- Had not been vaccinated with any meningococcal vaccine containing groups A, C, W or Y.
- Were 3 months of age when the study started.

Of the 149 participants who started the study, 147 participants received Dose 1. There were 145 participants who had data for the 30 days after Dose 1 including:

- A total of 69 boys.
- A total of 76 girls.
- All participants were around 3 months of age at the start of the study

There were 143 participants who received Dose 1 and Dose 2.

There were 6 participants who started the study but left the study before it ended. The most common reasons for not finishing the study were withdrawal by parent/guardian and lost to follow-up. Lost to follow-up means the parent or guardian stopped coming to study visits and could not be contacted by the study staff.

How long did the study last?

Study participants were in the study for about 10 months. The entire study took just over 2 years to complete.

When the study ended in April 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?

Did participants given Nimenrix have an immune response?

The researchers wanted to measure the participant's immune response to the Nimenrix vaccine. To do this, they measured the amount of antibody for meningococcus A, C, W, and Y in the participants' blood. The researchers then calculated how many participants had antibody for meningococcus A, C, W, and Y that was at or above a certain level. This level is often used in studies like this to look at the immune response. This is the main finding of the study and the results described below. Other data were collected in this study and this is included in the full study report.

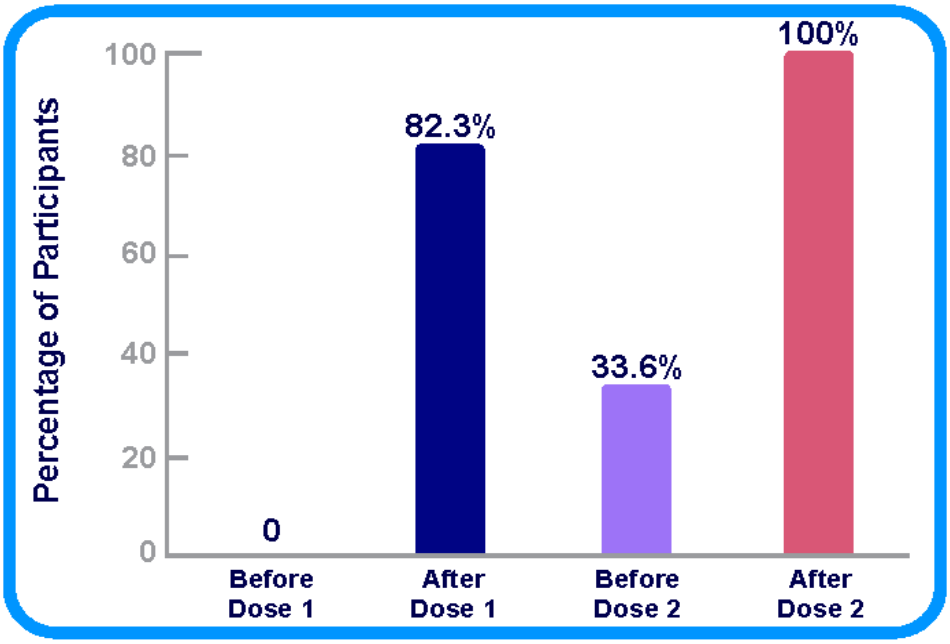
Note: Some participants had antibody for meningococcus A, C, W, and Y before they were given Dose 1. As expected, the amount of antibody was low before Dose 1 was given.

How many participants had antibody for meningococcus types A, C, W, and Y?

Meningococcus A

Available data showed that at 1 month after Dose 1, 102 out of 124 (82.3%) of participants had an immune response for meningococcus A. Before Dose 2, this was 42 out of 125 (33.6%) participants. At 1 month after Dose 2, 128 out of 128 (100%) of participants had an immune response for meningococcus A. This is shown in Figure 2.

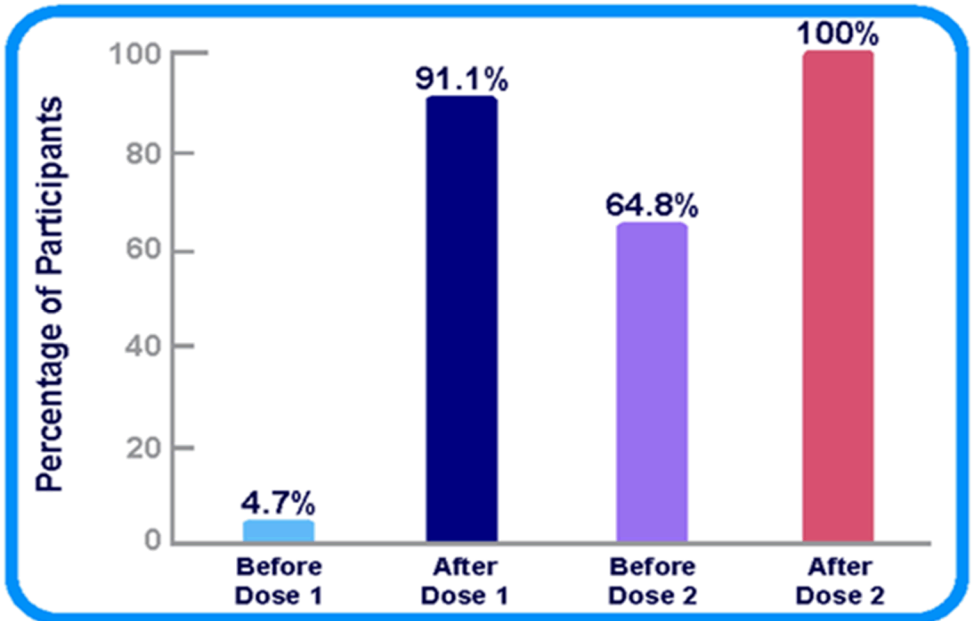
Figure 2. Percentage of participants with an immune response for meningococcus A



Meningococcus C

Available data showed that at 1 month after Dose 1, 113 out of 124 (91.1%) of participants had an immune response for meningococcus C. Before Dose 2, this was 81 out of 125 (64.8%) participants. At 1 month after Dose 2, 128 out of 128 (100%) of participants had an immune response for meningococcus C. This is shown in Figure 3.

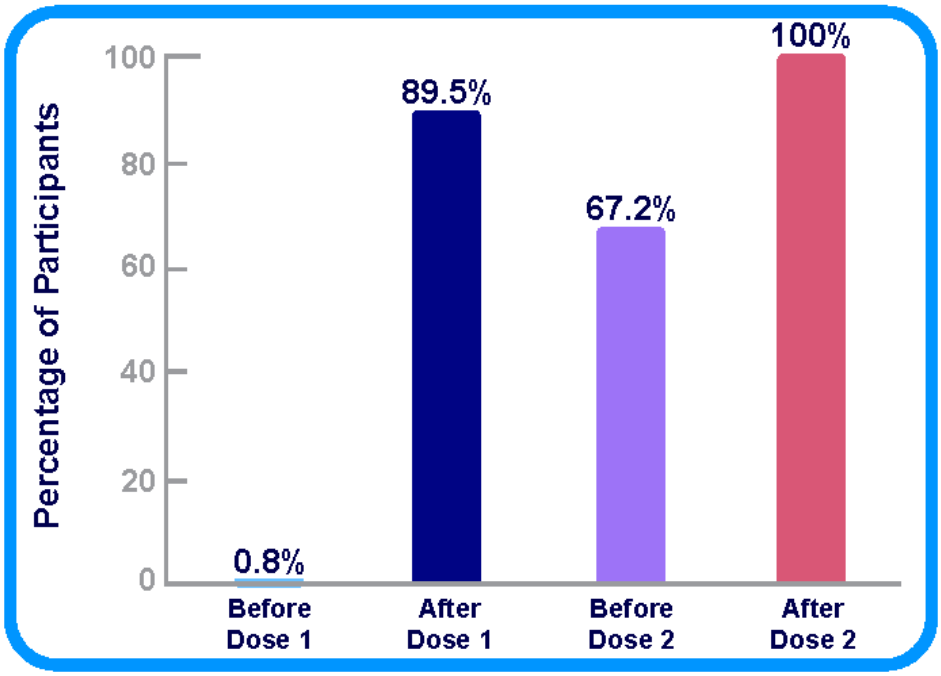
Figure 3. Percentage of participants with an immune response for meningococcus C



Meningococcus W

Available data showed that at 1 month after Dose 1, 111 out of 124 (89.5%) of participants had an immune response for meningococcus W. Before Dose 2, this was 84 out of 125 (67.2%) participants. At 1 month after Dose 2, 128 out of 128 (100%) of participants had an immune response for meningococcus W. This is shown in Figure 4.

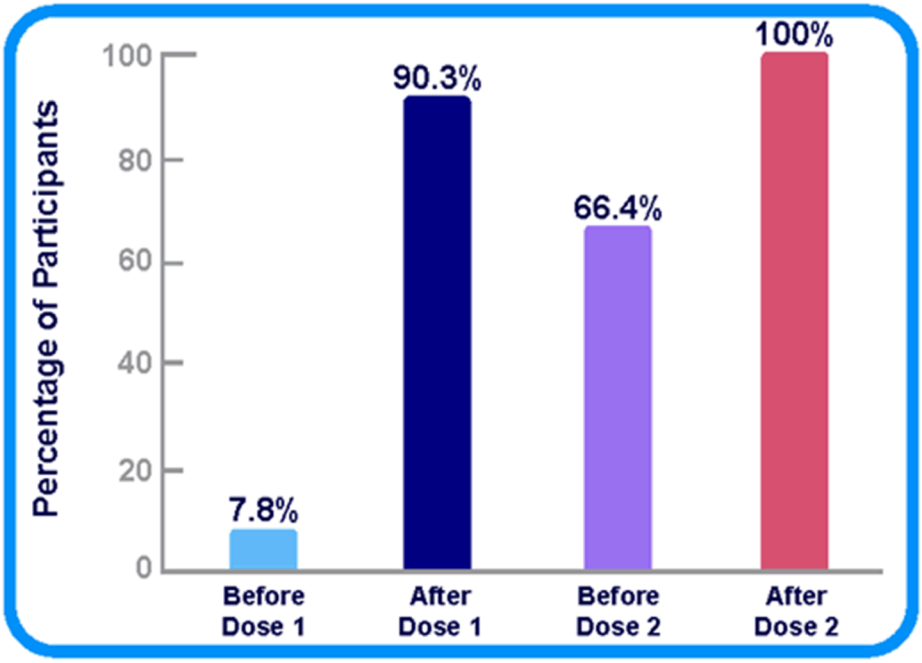
Figure 4. Percentage of participants with an immune response for meningococcus W



Meningococcus Y

Available data showed that at 1 month after Dose 1, 112 out of 124 (90.3%) of participants had an immune response for meningococcus Y. Before Dose 2, this was 83 out of 125 (66.4%) participants. At 1 month after Dose 2, 128 out of 128 (100%) of participants had an immune response for meningococcus Y. This is shown in Figure 5.

Figure 5. Percentage of participants with an immune response for meningococcus Y



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.

Did participants have any local reactions or systemic events after the vaccine?

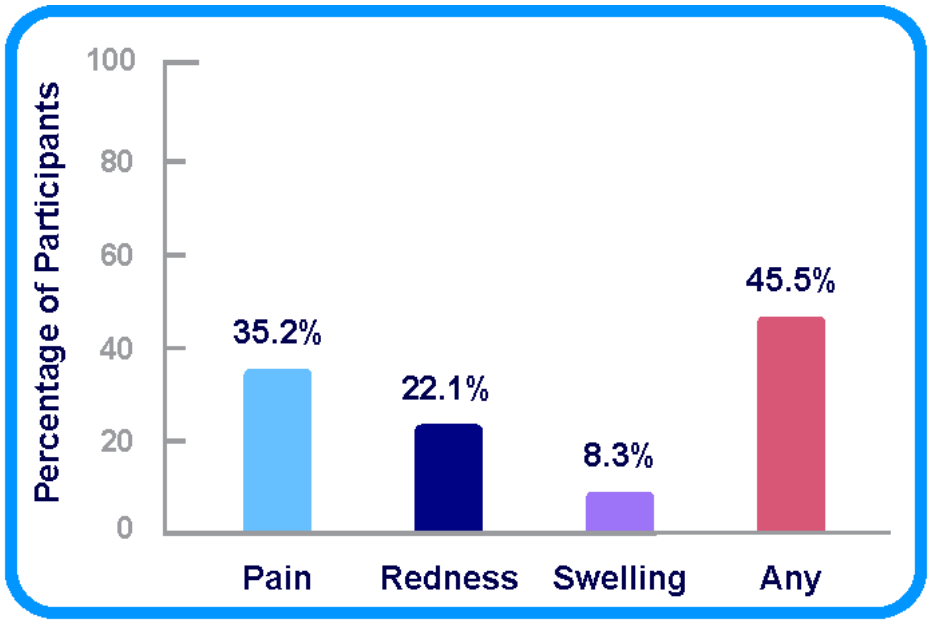
The parents or guardians kept a diary to record how the participants were doing within 7 days of Dose 1. They also did this after Dose 2. Parents or guardians recorded any effect that the vaccine might have had at the site of injection. This included local reactions like redness, swelling, and pain. They also recorded any reactions systemic events. Systemic events included things like fever, a decreased appetite, drowsiness, and irritability.

How many participants had local reactions within 7 days of the Nimenrix vaccine?

A total of 66 out of 145 (45.5%) of participants who received the Nimenrix vaccine (and had data available) had a local reaction (e.g., pain, redness or swelling at the injection site) within 7 days of Dose 1 or Dose 2. All local reactions were mild or moderate in severity.

Figure 6 below shows how many participants reported one of these local reactions after Dose 1 or Dose 2.

Figure 6. Participants with local reactions at the vaccination site within 7 days of Dose 1 or Dose 2

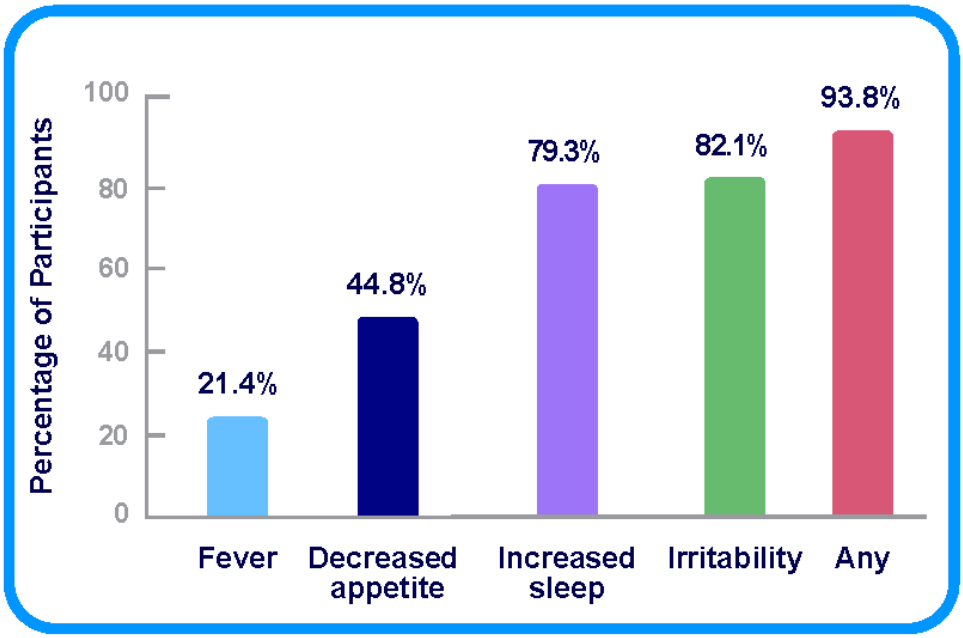


How many participants had systemic events within 7 days of the Nimenrix vaccine?

A total of 136 out of 145 (93.8%) of participants who received the Nimenrix vaccine (and had data available) had a systemic event (e.g., fever of 38ºC or 100ºF or higher, decreased appetite, increased sleep, or irritability) within 7 days of Dose 1 or Dose 2. Most systemic events were mild or moderate in severity.

Figure 7 shows how many participants reported one of these systemic events after Dose 1 or Dose 2.

Figure 7. Participants with systemic events within 7 days of Dose 1 or Dose 2



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 treatment groups in many studies, doctors try to understand what effects a study medication might have on a participant.

What medical problems did participants have during the study?

A total of 35 out of 145 (24.1%) participants in this study who received Dose 1 or Dose 2 (and had data available) had at least 1 medical problem within 30 days of the vaccination. No participants (0%) left the study because of medical problems.

The most common medical problems – those reported by 1% or more participants – are described in **Table 1** below. The majority of the reported medical problems were not thought to be related to the vaccine. Those that were thought to be related to the vaccine were systemic events that were not recorded in the diary and were reported as medical problems.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by 1% or more participants are listed.
- The **2nd** column tells how many of the participants receiving the study vaccine reported each medical problem. Next to this number is the percentage of the participants who reported the medical problem.
- Using these instructions, you can see that 7 out of the 145 (4.8%) participants reported a common cold after Dose 1 or Dose 2 of the Nimenrix vaccine.

Table 1. Commonly reported medical problems by study participants within 30 days of either vaccination

Medical Problem	Dose 1 or Dose 2 of the Nimenrix vaccine (145 Participants)
Common cold	7 out of 145 participants (4.8%)
Infection of nose and throat	7 out of 145 participants (4.8%)
Vocal cord inflammation	5 out of 145 participants (3.4%)
Fever (high temperature)	4 out of 145 participants (2.8%)

Table 1. Commonly reported medical problems by study participants within 30 days of either vaccination	
Medical Problem	**Dose 1 or Dose 2 of the Nimenrix vaccine (145 Participants)**
Infection affecting the smaller airways	2 out of 145 participants (1.4%)
Eye infection	2 out of 145 participants (1.4%)
Stomach flu	2 out of 145 participants (1.4%)
Hand-foot-and-mouth disease	2 out of 145 participants (1.4%)
Ear infection	2 out of 145 participants (1.4%)
Lung infection	2 out of 145 participants (1.4%)

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.

Ten participants (6.9%, or 10 out of 145 participants) had serious medical problems during the study. This included 8 out of 145 participants (5.5%) after Dose 1 and 2 out of 145 participants (1.4%) after Dose 2. The most common serious medical problems – those reported by more than 1% of participants – were infection of the smaller airways and infections with respiratory syncytial virus (RSV). These infections

were reported by 3 out of 145 participants (2.1%) and 2 out of 145 participants (1.4%), respectively, after Dose 1 or Dose 2.

None of these serious medical problems were thought related to the vaccine.

No participant died during the study.

How many participants were diagnosed with a new long-term disease or medical condition during the study?

Researchers wanted to know how many participants were diagnosed with a new long-term disease or medical condition during the study.

No participants were diagnosed with a new long-term disease or medical condition during the study.

Where can I learn more about this study?

If you have questions about the results of your child/ward study, please speak with the doctor or staff at your study site.

For more details on the study protocol, please visit:

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

www.clinicaltrials.gov	Use the study identifier **NCT04819113**
www.clinicaltrialsregister.eu	Use the study identifier **2020-005059-19**
www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **C0921062**

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

Again, if your child/ward 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!