

# Selected Adverse Events Reported after COVID-19 Vaccination

Updated Aug. 1, 2022

### Safety of COVID-19 Vaccines

Some people have no side effects. Many people have reported side effects, such as headache, fatigue, and soreness at the injection site, that are generally mild to moderate and go away within a few days.

# What You Need to Know

- COVID-19 vaccines are safe and effective and severe reactions after vaccination are rare.
- CDC recommends COVID-19 vaccines for everyone ages 6 months and older, and boosters for everyone 5 years and older, if eligible.
- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring program in U.S. history.
- CDC, the U.S. Food and Drug Administration (FDA), and other federal agencies continue to monitor the safety of all vaccines, including COVID-19 vaccines, by reviewing data reported to the Vaccine Adverse Event Reporting System (VAERS) [2] and the Vaccine Safety Datalink (VSD).

The benefits of COVID-19 vaccination continue to outweigh any potential risks.

CDC is providing timely updates on the following adverse events of interest:

 Anaphylaxis after COVID-19 vaccination is rare and has occurred at a rate of approximately 5 cases per one million vaccine doses administered. Anaphylaxis, a severe type of allergic reaction, can occur after any kind of vaccination. If it happens, healthcare providers can effectively and immediately treat the reaction. Learn more about COVID-19 vaccines and allergic reactions, including anaphylaxis. CDC scientists have conducted detailed reviews of cases of anaphylaxis and made the information available to healthcare providers and the public:

- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine ☑
- Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US— December 14, 2020-January 18, 2021 ☐
- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine— United States, December 21, 2020-January 10, 2021
- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14-23, 2020
- Thrombosis with thrombocytopenia syndrome (TTS) after J&J/Janssen COVID-19 vaccination is rare and has occurred in approximately 4 cases per one million doses administered. TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots).

A review of reports indicates a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS. CDC scientists have conducted detailed reviews of TTS cases and made the information available to healthcare providers and the public:

- US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021 ☑
- <u>Case Series of Thrombosis with Thrombocytopenia Syndrome following COVID-19 vaccination—United States, December 2020–August 2021</u> 

  ☐
- Updates on Thrombosis with Thrombocytopenia Syndrome (TTS)
   [1.3 MB, 39 Pages]
- Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 vaccine is rare. GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. GBS has largely been reported in men ages 50 years and older.

Based on a recent analysis of data from the Vaccine Safety Datalink, the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be 21 times higher than after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). After the first 42 days, the rate of GBS was 11 times higher following J&J/Janssen COVID-19 vaccination. The analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.

Myocarditis and pericarditis after COVID-19 vaccination are rare. Myocarditis
is inflammation of the heart muscle, and pericarditis is inflammation of the outer
lining of the heart. Most patients with myocarditis or pericarditis after COVID-19
vaccination responded well to medicine and rest and felt better quickly. Most cases
have been reported after receiving Pfizer-BioNTech or Moderna (mRNA COVID-19
vaccines), particularly in male adolescents and young adults.

A review of vaccine safety data in VAERS from December 2020–August 2021 found a small but increased risk of myocarditis after mRNA COVID-19 vaccines. Over 350 million mRNA vaccines were given during the study period and CDC scientists found that rates of myocarditis were highest following the second dose of an mRNA

vaccine among males in the following age groups:

- 12–15 years (70.7 cases per one million doses of Pfizer-BioNTech)
- 16–17 years (105.9 cases per one million doses of Pfizer-BioNTech)
- 18–24 years (52.4 cases and 56.3 cases per million doses of Pfizer-BioNTech and Moderna, respectively)

Multiple studies and reviews of data from vaccine safety monitoring systems continue to show that vaccines are safe. As a result, the agency will refocus enhanced surveillance and safety monitoring efforts toward children and adolescents.

As of July 28, 2022, there have been 1,010 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 258 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 665 reports have been verified to meet CDC's working case definition for myocarditis. See below for counts of verified reports of myocarditis by age group.

5-11 years: 22 verified reports of myocarditis after 20,404,074 doses administered

12-15 years: 346 verified reports of myocarditis after 24,198,309 doses administered

16-17 years: 297 verified reports of myocarditis after 13,326,016 doses administered

As the COVID-19 vaccines are authorized for younger children, CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination and will share more information as it becomes available. Learn more about myocarditis and pericarditis, including clinical considerations, after mRNA COVID-19 vaccination.

Providers of death after COVID-19 vaccination are rare. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. More than 603 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through July 27, 2022. During this time, VAERS received 15,700 preliminary reports of death (0.0026%) among people who received a COVID-19 vaccine. CDC and FDA clinicians review reports of death to VAERS including death certificates, autopsy, and medical records.

- > Safety of COVID-19 Vaccines
- Vaccine Adverse Event Reporting System (VAERS): What Reports Mean and How VAERS Works
- > COVID-19 Vaccine Safety Publications

Last Updated Aug. 1, 2022
Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral





# Selected Adverse Events Reported after COVID-19 Vaccination

Updated Aug. 8, 2022

CDC is reviewing this page to align with updated guidance.

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- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring program in U.S. history.
- CDC, the U.S. Food and Drug Administration (FDA), and other federal agencies continue to monitor the safety of all vaccines, including COVID-19 vaccines, by reviewing data reported to the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD).

The benefits of COVID-19 vaccination continue to outweigh any potential risks.

CDC is providing timely updates on the following adverse events of interest:

 Anaphylaxis after COVID-19 vaccination is rare and has occurred at a rate of approximately 5 cases per one million vaccine doses administered. Anaphylaxis, a severe type of allergic reaction, can occur after any kind of vaccination. If it happens, healthcare providers can effectively and immediately treat the reaction. Learn more about COVID-19 vaccines and allergic reactions, including anaphylaxis.

CDC scientists have conducted detailed reviews of cases of anaphylaxis and made the information available to healthcare providers and the public:

- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine ☑
- Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US— December 14, 2020-January 18, 2021 ☐
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- Thrombosis with thrombocytopenia syndrome (TTS) after J&J/Janssen COVID-19 vaccination is rare and has occurred in approximately 4 cases per one million doses administered. TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots).

A review of reports indicates a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS. CDC scientists have conducted detailed reviews of TTS cases and made the information available to healthcare providers and the public:

- US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021 ☐
- <u>Case Series of Thrombosis with Thrombocytopenia Syndrome following COVID-19 vaccination—United States, December 2020–August 2021</u> [₹]
- Updates on Thrombosis with Thrombocytopenia Syndrome (TTS)
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- Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 vaccine is rare. GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. GBS has largely been reported in men ages 50 years and older.
  - Based on a recent analysis of data from the Vaccine Safety Datalink, the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be 21 times higher than after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). After the first 42 days, the rate of GBS was 11 times higher following J&J/Janssen COVID-19 vaccination. The analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.
- Myocarditis and pericarditis after COVID-19 vaccination are rare. Myocarditis
  is inflammation of the heart muscle, and pericarditis is inflammation of the outer
  lining of the heart. Most patients with myocarditis or pericarditis after COVID-19
  vaccination responded well to medicine and rest and felt better quickly. Most cases
  have been reported after receiving Pfizer-BioNTech or Moderna (mRNA COVID-19
  vaccines), particularly in male adolescents and young adults.

A review of vaccine safety data in VAERS from December 2020–August 2021 found a small but increased risk of myocarditis after mRNA COVID-19 vaccines. Over 350 million mRNA vaccines were given during the study period and CDC scientists

found that rates of myocarditis were highest following the second dose of an mRNA vaccine among males in the following age groups:

- 12-15 years (70.7 cases per one million doses of Pfizer-BioNTech)
- 16–17 years (105.9 cases per one million doses of Pfizer-BioNTech)
- 18–24 years (52.4 cases and 56.3 cases per million doses of Pfizer-BioNTech and Moderna, respectively)

Multiple studies and reviews of data from vaccine safety monitoring systems continue to show that vaccines are safe. As a result, the agency will refocus enhanced surveillance and safety monitoring efforts toward children and adolescents.

As of August 4, 2022, there have been 1,018 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 263 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 666 reports have been verified to meet CDC's working case definition for myocarditis. See below for counts of verified reports of myocarditis by age group.

5-11 years: 22 verified reports of myocarditis after 20,599,520 doses administered

12-15 years: 346 verified reports of myocarditis after 24,320,657 doses administered

16-17 years: 298 verified reports of myocarditis after 13,374,957 doses administered

As the COVID-19 vaccines are authorized for younger children, CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination and will share more information as it becomes available. Learn more about myocarditis and pericarditis, including clinical considerations, after mRNA COVID-19 vaccination.

Reports of death after COVID-19 vaccination are rare. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. More than 604 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through August 3, 2022. During this time, VAERS received 15,799 preliminary reports of death (0.0026%) among people who received a COVID-19 vaccine. CDC and FDA clinicians review reports of death to VAERS including death certificates, autopsy, and medical records.

- > Safety of COVID-19 Vaccines
- Vaccine Adverse Event Reporting System (VAERS): What Reports Mean and How VAERS Works
- > COVID-19 Vaccine Safety Publications

Last Updated Aug. 8, 2022 Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases



COVID-19

# Selected Adverse Events Reported after COVID-19 Vaccination

Updated Aug. 23, 2022

CDC is reviewing this page to align with updated guidance.

#### Safety of COVID-19 Vaccines

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### What You Need to Know

- COVID-19 vaccines are safe and effective and severe reactions after vaccination are rare.
- CDC recommends COVID-19 vaccines for everyone ages 6 months and older, and boosters for everyone 5 years and older, if eligible.
- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring program in U.S. history.
- CDC, the U.S. Food and Drug Administration (FDA), and other federal agencies continue to monitor the safety of all vaccines, including COVID-19 vaccines, by reviewing data reported to the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD).

The benefits of COVID-19 vaccination continue to outweigh any potential risks.

CDC is providing timely updates on the following adverse events of interest:

 Anaphylaxis after COVID-19 vaccination is rare and has occurred at a rate of approximately 5 cases per one million vaccine doses administered. Anaphylaxis, a severe type of allergic reaction, can occur after any kind of vaccination. If it happens, healthcare providers can effectively and immediately treat the reaction. Learn more about COVID-19 vaccines and allergic reactions, including anaphylaxis.

CDC scientists have conducted detailed reviews of cases of anaphylaxis and made the information available to healthcare providers and the public:

- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine ☑
- Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US— December 14, 2020-January 18, 2021 ☐
- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine— United States, December 21, 2020-January 10, 2021
- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14-23, 2020
- Thrombosis with thrombocytopenia syndrome (TTS) after J&J/Janssen COVID-19 vaccination is rare and has occurred in approximately 4 cases per one million doses administered. TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots).

A review of reports indicates a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS. CDC scientists have conducted detailed reviews of TTS cases and made the information available to healthcare providers and the public:

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- Updates on Thrombosis with Thrombocytopenia Syndrome (TTS)
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  - Based on a recent analysis of data from the Vaccine Safety Datalink, the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be 21 times higher than after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). After the first 42 days, the rate of GBS was 11 times higher following J&J/Janssen COVID-19 vaccination. The analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.
- Myocarditis and pericarditis after COVID-19 vaccination are rare. Myocarditis
  is inflammation of the heart muscle, and pericarditis is inflammation of the outer
  lining of the heart. Most patients with myocarditis or pericarditis after COVID-19
  vaccination responded well to medicine and rest and felt better quickly. Most cases
  have been reported after receiving Pfizer-BioNTech or Moderna (mRNA COVID-19
  vaccines), particularly in male adolescents and young adults.

A review of vaccine safety data in VAERS from December 2020–August 2021 found a small but increased risk of myocarditis after mRNA COVID-19 vaccines. Over 350 million mRNA vaccines were given during the study period and CDC scientists

found that rates of myocarditis were highest following the second dose of an mRNA vaccine among males in the following age groups:

- 12-15 years (70.7 cases per one million doses of Pfizer-BioNTech)
- 16-17 years (105.9 cases per one million doses of Pfizer-BioNTech)
- 18–24 years (52.4 cases and 56.3 cases per million doses of Pfizer-BioNTech and Moderna, respectively)

Multiple studies and reviews of data from vaccine safety monitoring systems continue to show that vaccines are safe. As a result, the agency will refocus enhanced surveillance and safety monitoring efforts toward children and adolescents.

As of August 18, 2022, there have been 1,021 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 262 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 669 reports have been verified to meet CDC's working case definition for myocarditis. See below for counts of verified reports of myocarditis by age group.

5-11 years: 22 verified reports of myocarditis after 20,798,557 doses administered

12-15 years: 347 verified reports of myocarditis after 24,230,069 doses administered

16-17 years: 300 verified reports of myocarditis after 13,296,922 doses administered

As the COVID-19 vaccines are authorized for younger children, CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination and will share more information as it becomes available. Learn more about myocarditis and pericarditis, including clinical considerations, after mRNA COVID-19 vaccination.

Reports of death after COVID-19 vaccination are rare. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. More than 607 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through August 17, 2022. During this time, VAERS received 16,077 preliminary reports of death (.0026%) among people who received a COVID-19 vaccine. CDC and FDA clinicians review reports of death to VAERS including death certificates, autopsy, and medical records.

- > Safety of COVID-19 Vaccines
- Yaccine Adverse Event Reporting System (VAERS): What Reports Mean and How VAERS Works
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Last Updated Aug. 23, 2022 Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases



COVID-19

# Selected Adverse Events Reported after COVID-19 Vaccination

Updated Aug. 30, 2022

CDC is reviewing this page to align with updated guidance.

#### Safety of COVID-19 Vaccines

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- Thrombosis with thrombocytopenia syndrome (TTS) after J&J/Janssen COVID-19 vaccination is rare and has occurred in approximately 4 cases per one million doses administered. TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots).

A review of reports indicates a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS. CDC scientists have conducted detailed reviews of TTS cases and made the information available to healthcare providers and the public:

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Based on a recent analysis of data from the Vaccine Safety Datalink, the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be 21 times higher than after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). After the first 42 days, the rate of GBS was 11 times higher following J&J/Janssen COVID-19 vaccination. The analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.

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vaccines), particularly in male adolescents and young adults.

A review of vaccine safety data ☐ in VAERS from December 2020–August 2021

found a small but increased risk of myocarditis after mRNA COVID-19 vaccines. Over 350 million mRNA vaccines were given during the study period and CDC scientists found that rates of myocarditis were highest following the second dose of an mRNA vaccine among males in the following age groups:

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Multiple studies and reviews of data from vaccine safety monitoring systems continue to show that vaccines are safe. As a result, the agency will refocus enhanced surveillance and safety monitoring efforts toward children and adolescents.

As of August 25, 2022, there have been 1,021 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 261 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 671 reports have been verified to meet CDC's working case definition for myocarditis. See below for counts of verified reports of myocarditis by age group.

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COVID-19

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Updated Sept. 6, 2022

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A review of vaccine safety data [4] in VAERS from December 2020–August 2021

found a small but increased risk of myocarditis after mRNA COVID-19 vaccines. Over 350 million mRNA vaccines were given during the study period and CDC scientists found that rates of myocarditis were highest following the second dose of an mRNA vaccine among males in the following age groups:

- 12–15 years (70.7 cases per one million doses of Pfizer-BioNTech)
- 16–17 years (105.9 cases per one million doses of Pfizer-BioNTech)
- 18–24 years (52.4 cases and 56.3 cases per million doses of Pfizer-BioNTech and Moderna, respectively)

Multiple studies and reviews of data from vaccine safety monitoring systems continue to show that vaccines are safe. As a result, the agency will refocus enhanced surveillance and safety monitoring efforts toward children and adolescents.

As of August 31, 2022, there have been 1,022 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 261 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 672 reports have been verified to meet CDC's working case definition for myocarditis. See below for counts of verified reports of myocarditis by age group.

5-11 years: 22 verified reports of myocarditis after 21,105,253 doses administered

12-15 years: 348 verified reports of myocarditis after 24,345,657 doses administered

16-17 years: 302 verified reports of myocarditis after 13,346,735 doses administered

As the COVID-19 vaccines are authorized for younger children, CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination and will share more information as it becomes available. Learn more about myocarditis and pericarditis, including clinical considerations, after mRNA COVID-19 vaccination.

• Reports of death after COVID-19 vaccination are rare. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. More than 610 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through August 31, 2022. During this time, VAERS received 16,257 preliminary reports of death (0.0027%) among people who received a COVID-19 vaccine. CDC and FDA clinicians review reports of death to VAERS including death certificates, autopsy, and medical records.

- > Safety of COVID-19 Vaccines
- Yaccine Adverse Event Reporting System (VAERS): What Reports Mean and How VAERS Works
- > COVID-19 Vaccine Safety Publications

Last Updated Sept. 6, 2022 Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases



COVID-19

# Selected Adverse Events Reported after COVID-19 Vaccination

Updated Sept. 12, 2022

CDC is reviewing this page to align with updated guidance.

#### Safety of COVID-19 Vaccines

Some people have no side effects. Many people have reported side effects, such as headache, fatigue, and soreness at the injection site, that are generally mild to moderate and go away within a few days.

#### What You Need to Know

- COVID-19 vaccines are safe and effective and severe reactions after vaccination are rare.
- CDC recommends COVID-19 vaccines for everyone ages 6 months and older, and boosters for everyone 5 years and older, if eligible.
- Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring program in U.S. history.
- CDC, the U.S. Food and Drug Administration (FDA), and other federal agencies continue to monitor the safety of all vaccines, including COVID-19 vaccines, by reviewing data reported to the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD).

The benefits of COVID-19 vaccination continue to outweigh any potential risks.

CDC is providing timely updates on the following adverse events of interest:

 Anaphylaxis after COVID-19 vaccination is rare and has occurred at a rate of approximately 5 cases per one million vaccine doses administered. Anaphylaxis, a severe type of allergic reaction, can occur after any kind of vaccination. If it happens, healthcare providers can effectively and immediately treat the reaction. Learn more about COVID-19 vaccines and allergic reactions, including anaphylaxis.

CDC scientists have conducted detailed reviews of cases of anaphylaxis and made the information available to healthcare providers and the public:

- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine ☑
- Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US— December 14, 2020-January 18, 2021 ☑
- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine— United States, December 21, 2020-January 10, 2021
- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14-23, 2020
- Thrombosis with thrombocytopenia syndrome (TTS) after J&J/Janssen COVID-19 vaccination is rare and has occurred in approximately 4 cases per one million doses administered. TTS is a rare but serious adverse event that causes blood clots in large blood vessels and low platelets (blood cells that help form clots).

A review of reports indicates a causal relationship between the J&J/Janssen COVID-19 vaccine and TTS. CDC scientists have conducted detailed reviews of TTS cases and made the information available to healthcare providers and the public:

- US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021 ☐
- <u>Case Series of Thrombosis with Thrombocytopenia Syndrome following COVID-19 vaccination—United States, December 2020–August 2021</u> ☐
- Updates on Thrombosis with Thrombocytopenia Syndrome (TTS)
   [1.3 MB, 39 Pages]
- Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 vaccine is rare. GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. GBS has largely been reported in men ages 50 years and older.

Based on a recent analysis of data from the Vaccine Safety Datalink, the rate of GBS within the first 21 days following J&J/Janssen COVID-19 vaccination was found to be 21 times higher than after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). After the first 42 days, the rate of GBS was 11 times higher following J&J/Janssen COVID-19 vaccination. The analysis found no increased risk of GBS after Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). CDC and FDA will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.

Myocarditis and pericarditis after COVID-19 vaccination are rare. Myocarditis
is inflammation of the heart muscle, and pericarditis is inflammation of the outer
lining of the heart. Most patients with myocarditis or pericarditis after COVID-19
vaccination responded well to medicine and rest and felt better quickly. Most cases
have been reported after receiving Pfizer-BioNTech or Moderna (mRNA COVID-19
vaccines), particularly in male adolescents and young adults.

A review of vaccine safety data [4] in VAERS from December 2020–August 2021

found a small but increased risk of myocarditis after mRNA COVID-19 vaccines. Over 350 million mRNA vaccines were given during the study period and CDC scientists found that rates of myocarditis were highest following the second dose of an mRNA vaccine among males in the following age groups:

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- 16-17 years (105.9 cases per one million doses of Pfizer-BioNTech)
- 18–24 years (52.4 cases and 56.3 cases per million doses of Pfizer-BioNTech and Moderna, respectively)

Multiple studies and reviews of data from vaccine safety monitoring systems continue to show that vaccines are safe. As a result, the agency will refocus enhanced surveillance and safety monitoring efforts toward children and adolescents.

As of September 8, 2022, there have been 1,022 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 260 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 672 reports have been verified to meet CDC's working case definition for myocarditis. See below for counts of verified reports of myocarditis by age group.

5-11 years: 22 verified reports of myocarditis after 21,196,313 doses administered

12-15 years: 348 verified reports of myocarditis after 24,377,482 doses administered

16-17 years: 302 verified reports of myocarditis after 13,362,076 doses administered

As the COVID-19 vaccines are authorized for younger children, CDC and FDA will continue to monitor for and evaluate reports of myocarditis and pericarditis after COVID-19 vaccination and will share more information as it becomes available. Learn more about myocarditis and pericarditis, including clinical considerations, after mRNA COVID-19 vaccination.

• Reports of death after COVID-19 vaccination are rare. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. More than 610 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through September 7, 2022. During this time, VAERS received 16,336 preliminary reports of death (0.0027%) among people who received a COVID-19 vaccine. CDC and FDA clinicians review reports of death to VAERS including death certificates, autopsy, and medical records.

- > Safety of COVID-19 Vaccines
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