



Selected Adverse Events Reported after COVID-19 Vaccination

Updated Dec. 21, 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 everyone ages 6 months and older get vaccinated as soon as possible to protect against COVID-19 and its potentially severe complications.
- Although mRNA vaccines (Pfizer-BioNTech or Moderna COVID-19 vaccines) are preferred, Johnson & Johnson's Janssen COVID-19 vaccine may be considered in some situations.
- 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 COVID-19 vaccines.
- Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS) ☑ .
- VAERS accepts reports of any adverse event following vaccination.

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

- 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 ☑

 - 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 December 15, 2022, there have been 1,054 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 246 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 702 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: 23 verified reports of myocarditis after 22,752,091 doses administered

12-15 years: 365 verified reports of myocarditis after 25,531,993 doses administered

16-17 years: 314 verified reports of myocarditis after 13,973,909 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 660 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through December 14, 2022. During this time, VAERS received 18,007 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. Continued monitoring has identified nine deaths causally associated with J&J/Janssen COVID-19 vaccination. CDC and FDA continue to review reports of death following COVID-19 vaccination and update information as it becomes available.

Related Pages

- > 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 Dec. 21, 2022 Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases





Selected Adverse Events Reported after COVID-19 Vaccination

Updated Jan. 9, 2023

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 everyone ages 6 months and older get vaccinated as soon as possible to protect against COVID-19 and its potentially severe complications.
- Although mRNA vaccines (Pfizer-BioNTech or Moderna COVID-19 vaccines) are preferred, Johnson & Johnson's Janssen COVID-19 vaccine may be considered in some situations.
- 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 COVID-19 vaccines.
- Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS) \square .
- VAERS accepts reports of any adverse event following vaccination.

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

- 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 [2] 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 January 5, 2023, there have been 1,050 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 248 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 705 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: 23 verified reports of myocarditis after 22,988,430 doses administered

12-15 years: 368 verified reports of myocarditis after 25,684,954 doses administered

16-17 years: 314 verified reports of myocarditis after 14,056,891 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 665 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through January 4, 2023. During this time, VAERS received 18,533 preliminary reports of death (0.0028%) 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. Continued monitoring has identified nine deaths causally associated with J&J/Janssen COVID-19 vaccination. CDC and FDA continue to review reports of death following COVID-19 vaccination and update information as it becomes available.

Related Pages

- > 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 Jan. 9, 2023 Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases





Selected Adverse Events Reported after COVID-19 Vaccination

Updated Jan. 13, 2023

CDC's Vaccine Safety Datalink (VSD) met the statistical criteria to prompt additional investigation into whether there was a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. To date, no other safety systems have shown a similar signal and multiple subsequent analyses have not validated this signal. **No change is recommended in COVID-19 vaccination practice.**

Read More

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 everyone ages 6 months and older get vaccinated as soon as possible to protect against COVID-19 and its potentially severe complications.
- Although mRNA vaccines (Pfizer-BioNTech or Moderna COVID-19 vaccines) are preferred, Johnson & Johnson's Janssen COVID-19 vaccine may be considered in some situations.
- 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 COVID-19 vaccines.
- Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS) \square .
- VAERS accepts reports of any adverse event following vaccination.

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

- 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 ☑
- Case Series of Thrombosis with Thrombocytopenia Syndrome following COVID-19 vaccination—United States, December 2020–August 2021
- 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 January 5, 2023, there have been 1,050 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 248 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 705 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: 23 verified reports of myocarditis after 22,988,430 doses administered

12-15 years: 368 verified reports of myocarditis after 25,684,954 doses administered

16-17 years: 314 verified reports of myocarditis after 14,056,891 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 665 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through January 4, 2023. During this time, VAERS received 18,533 preliminary reports of death (0.0028%) 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. Continued monitoring has identified nine deaths causally associated with J&J/Janssen COVID-19 vaccination. CDC and FDA continue to review reports of death following COVID-19 vaccination and update information as it becomes available.

Related Pages

- > 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 Jan. 13, 2023 Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases





Selected Adverse Events Reported after COVID-19 Vaccination

Updated Jan. 19, 2023

CDC's Vaccine Safety Datalink (VSD) met the statistical criteria to prompt additional investigation into whether there was a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. To date, no other safety systems have shown a similar signal and multiple subsequent analyses have not validated this signal. **No change is recommended in COVID-19 vaccination practice.**

Read More

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 everyone ages 6 months and older get vaccinated as soon as possible to protect against COVID-19 and its potentially severe complications.
- Although mRNA vaccines (Pfizer-BioNTech or Moderna COVID-19 vaccines) are preferred, Johnson & Johnson's Janssen COVID-19 vaccine may be considered in some situations.
- 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 COVID-19 vaccines.
- Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS) ☑ .
- VAERS accepts reports of any adverse event following vaccination.

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

- 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 ☑
- Case Series of Thrombosis with Thrombocytopenia Syndrome following COVID-19 vaccination—United States, December 2020–August 2021 ☑
- 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 January 12, 2023, there have been 1,050 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 246 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 706 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: 23 verified reports of myocarditis after 23,059,773 doses administered
- 12-15 years: 369 verified reports of myocarditis after 25,724,061 doses administered

_ 16-17 years: 314 verified reports of myocarditis after 14,080,121 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 666 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through January 11, 2023. During this time, VAERS received 18,649 preliminary reports of death (0.0028%) 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. Continued monitoring has identified nine deaths causally associated with J&J/Janssen COVID-19 vaccination. CDC and FDA continue to review reports of death following COVID-19 vaccination and update information as it becomes available.

Related Pages

- > 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 Jan. 19, 2023 Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases





Selected Adverse Events Reported after COVID-19 Vaccination

Updated Jan. 23, 2023

CDC's Vaccine Safety Datalink (VSD) met the statistical criteria to prompt additional investigation into whether there was a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. To date, no other safety systems have shown a similar signal and multiple subsequent analyses have not validated this signal. **No change is recommended in COVID-19 vaccination practice.**

Read More

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 everyone ages 6 months and older get vaccinated as soon as possible to protect against COVID-19 and its potentially severe complications.
- Although mRNA vaccines (Pfizer-BioNTech or Moderna COVID-19 vaccines) are preferred, Johnson & Johnson's Janssen COVID-19 vaccine may be considered in some situations.
- 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 COVID-19 vaccines.
- Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS) ☑ .
- VAERS accepts reports of any adverse event following vaccination.

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

- 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 ☐
- Case Series of Thrombosis with Thrombocytopenia Syndrome following COVID-19 vaccination—United States, December 2020–August 2021 ☐
- 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 January 19, 2023, there have been 1,056 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 246 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 708 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: 23 verified reports of myocarditis after 23,124,868 doses administered
- 12-15 years: 370 verified reports of myocarditis after 25,762,928 doses administered

 16-17 years: 315 verified reports of myocarditis after 14,101,756 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 667 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through January 18, 2023. During this time, VAERS received 18,769 preliminary reports of death (0.0028%) 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. Continued monitoring has identified nine deaths causally associated with J&J/Janssen COVID-19 vaccination. CDC and FDA continue to review reports of death following COVID-19 vaccination and update information as it becomes available.

Related Pages

- > 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 Jan. 23, 2023 Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases





Selected Adverse Events Reported after COVID-19 Vaccination

Updated Jan. 30, 2023

CDC's Vaccine Safety Datalink (VSD) met the statistical criteria to prompt additional investigation into whether there was a safety concern for ischemic stroke in people ages 65 and older who received the Pfizer-BioNTech COVID-19 Vaccine, Bivalent. To date, no other safety systems have shown a similar signal and multiple subsequent analyses have not validated this signal. **No change is recommended in COVID-19 vaccination practice.**

Read More

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 everyone ages 6 months and older get vaccinated as soon as possible to protect against COVID-19 and its potentially severe complications.
- Although mRNA vaccines (Pfizer-BioNTech or Moderna COVID-19 vaccines) are preferred, Johnson & Johnson's Janssen COVID-19 vaccine may be considered in some situations.
- 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 COVID-19 vaccines.
- Adverse events described on this page have been reported to the Vaccine Adverse Event Reporting System (VAERS) ☑ .
- VAERS accepts reports of any adverse event following vaccination.

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

- 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 ☐
- Case Series of Thrombosis with Thrombocytopenia Syndrome following COVID-19 vaccination—United States, December 2020–August 2021 ☐
- 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 January 26, 2023, there have been 1,060 preliminary reports in VAERS among people younger than age 18 years under review for potential cases of myocarditis and pericarditis. Of these, 247 remain under review. Through confirmation of symptoms and diagnostics by provider interview or review of medical records, 710 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: 23 verified reports of myocarditis after 23,178,311 doses administered
- 12-15 years: 371 verified reports of myocarditis after 25,791,756 doses administered

_ 16-17 years: 316 verified reports of myocarditis after 14,117,149 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 668 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through January 26, 2023. During this time, VAERS received 18,977 preliminary reports of death (0.0028%) 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. Continued monitoring has identified nine deaths causally associated with J&J/Janssen COVID-19 vaccination. CDC and FDA continue to review reports of death following COVID-19 vaccination and update information as it becomes available.

Related Pages

- > 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 Jan. 30, 2023 Source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases