

COVID-19 Booster Dose Update

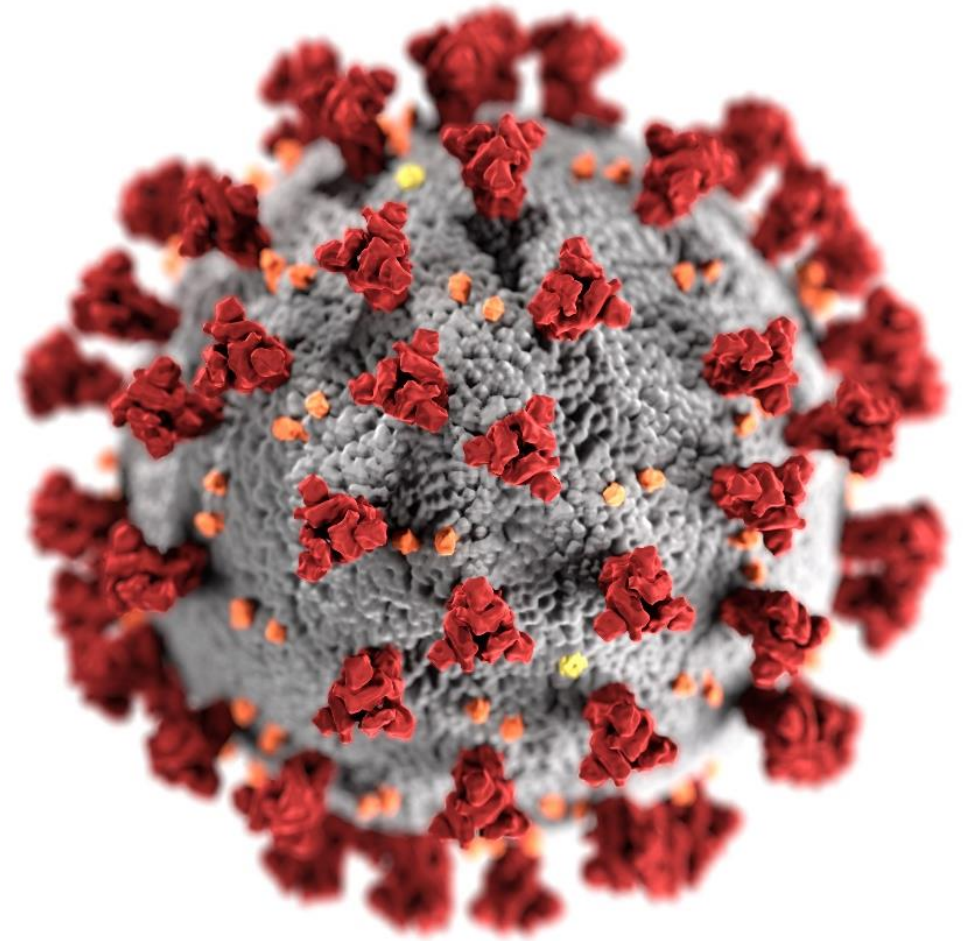
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cdc.gov/coronavirus

Timeline

August 18, 2021:

U.S. Department of Health and Human Services (HHS) announced a plan to begin issuing COVID-19 booster doses in fall 2021, contingent upon recommendations from the Food and Drug Administration (FDA) and CDC's Advisory Committee on Immunization Practices (ACIP).¹

¹<https://www.hhs.gov/about/news/2021/08/18/joint-statement-hhs-public-health-and-medical-experts-covid-19-booster-shots.html>

September 22, 2021:

FDA amended its emergency use authorization (EUA) for Pfizer-BioNTech's COVID-19 vaccine to allow use of a single booster dose in specific populations.²

²<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

September 23, 2021:

ACIP recommended certain populations receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine.²

September 24, 2021:

CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed ACIP's recommendation for a booster dose of the Pfizer-BioNTech COVID-19 vaccine in certain populations and also recommended a booster dose for those in high-risk occupational and institutional settings.³

³<https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations.html>



High and equitable COVID-19 vaccination coverage with a COVID-19 vaccine primary series remains the highest priority and is fundamental to reducing COVID-related morbidity and mortality.

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>



THE COVID-19 VACCINE:

**As essential
as you are.**

Add one more layer of protection
to keep you and your family safe.

I GOT
MY COVID-19
VACCINE!



Learn how you can get a COVID-19 vaccine.
cdc.gov/coronavirus/vaccines

Interim Recommendations for Booster Doses



Only certain populations initially vaccinated with the Pfizer-BioNTech vaccine can get a booster dose at this time.



<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#Populations>

CDC recommends who should receive a booster dose

- People aged 65 years and older and adults 50–64 years with underlying medical conditions should get a booster dose of the Pfizer-BioNTech vaccine at least 6 months after their primary series.
- Residents aged 18 years and older of long-term care settings should get a booster dose of the Pfizer-BioNTech vaccine at least 6 months after their primary series.

CDC recommends **people in the following groups SHOULD receive a booster dose of Pfizer-BioNTech's COVID-19 Vaccine at least 6 months** after completion of their 2-dose Pfizer series:

- People ages 65 years and older
- Adults 18+ living in long-term care settings
- People ages 50–64 with underlying medical conditions



CDC recommends who may receive a booster dose

- People aged 18–49 years with underlying medical conditions may get a booster dose of the Pfizer-BioNTech vaccine at least 6 months after their primary series based on their individual benefits and risks.
- People aged 18–64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may get a booster dose of the Pfizer-BioNTech vaccine at least 6 months after their primary series based on their individual risks and benefits.

CDC recommends **people in the following groups MAY receive a booster dose of Pfizer-BioNTech's COVID-19 Vaccine at least 6 months** after completion of their 2-dose Pfizer series based on their individual benefits and risks:

- People ages 18–49 with underlying medical conditions
- People ages 18–64 at increased risk for COVID-19 exposure because of the setting they work or live in



Frequently Asked Questions about Booster Doses



When can I get a COVID-19 vaccine booster dose if I am NOT in one of the recommended groups?

Additional populations may be recommended to receive a booster dose as more data become available. The COVID-19 vaccines approved and authorized in the United States continue to be effective at reducing risk of severe disease, hospitalization, and death. Experts are looking at all available data to understand how well the vaccines are working for different populations. This includes looking at how new variants, like Delta, affect vaccine effectiveness.



<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#FAQs>



What should people who received Moderna or Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccine do?

- At this time, the Pfizer-BioNTech booster dose authorization only applies to people whose primary series was Pfizer-BioNTech vaccine.
- People in the recommended groups who got the Moderna or J&J/Janssen vaccine may need a booster dose in the future.
- With safety and effectiveness data in hand, CDC will keep the public informed with a timely plan for Moderna and J&J/Janssen booster doses.



What is the status of booster doses for people who received Moderna or J&J/Janssen vaccines?

- More data on the effectiveness and safety of Moderna and J&J/Janssen booster doses are expected after FDA's Vaccines and Related Biological Products Advisory Committee Meeting on October 14 and 15.¹
 - **October 14:** Committee to discuss EUA for a booster dose of the ModernaTX Inc. COVID-19 vaccine.
 - **October 15:** Committee to discuss EUA for a booster dose of the Janssen Biotech Inc. COVID-19 vaccine.
- Safety and immunogenicity information to support mixing and matching vaccine brands is not yet available.



¹ <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-14-15-2021-meeting-announcement>

If we need a booster dose, does that mean that the vaccines aren't working?

No. COVID-19 vaccines are working well to prevent severe illness, hospitalization, and death, even against the widely circulating Delta variant. However, public health experts are starting to see reduced protection, especially among certain populations, against mild and moderate disease.



<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#FAQs>

What's the difference between a booster dose and an additional dose?

Sometimes people who are moderately to severely immunocompromised do not build enough (or any) protection when they first get a vaccination. When this happens, getting another dose of the vaccine can sometimes help them build more protection against the disease. CDC recommends moderately to severely immunocompromised people consider receiving an **additional (third) dose** of an mRNA COVID-19 vaccine at least 28 days after the completion of the initial 2-dose mRNA COVID-19 vaccine series. In contrast, a **booster dose** refers to another dose of a vaccine that is given to someone who built enough protection after vaccination, but then that protection decreased over time (this is called waning immunity).



What's the difference between a booster dose and an additional dose?

Additional Dose

Booster Dose



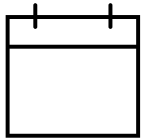
- Recommended for moderately and severely immunocompromised people

- Who **SHOULD** get it: People ages 65+, those living in long-term care settings, and people ages 50–64 with underlying conditions
- Who **MAY** get it: People ages 18–49 with underlying conditions and people ages 18–64 who live and/or work in high-risk settings, based on individual risk and benefit



- Pfizer-BioNTech and Moderna only

- Pfizer-BioNTech only



- At least 28 days after the completion of the primary 2-dose mRNA COVID-19 vaccine series

- At least 6 months after the completion of the primary 2-dose Pfizer-BioNTech COVID-19 vaccine series

Am I still considered fully vaccinated if I don't get a booster dose?

Yes. Everyone is still considered fully vaccinated two weeks after their second dose in a 2-shot series, such as the Pfizer-BioNTech or Moderna vaccines, or two weeks after a single-dose vaccine, such as the J&J/Janssen vaccine.



<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#FAQs>

Can COVID-19 booster doses be co-administered with other vaccines?

- COVID-19 vaccines may be administered without regard to timing of other vaccines. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.¹
 - If multiple vaccines are administered at a single visit, administer each injection in a different injection site.¹
- Extensive experience with non-COVID-19 vaccines indicates immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.²



¹ <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Coadministration>

² https://emergency.cdc.gov/coca/calls/2021/callinfo_090921.asp

Implications for Vaccine Confidence and Demand Providers



Topline Booster Dose Messages from HHS

The following people who got the Pfizer-BioNTech primary series can go get their booster dose, starting at least 6 months after their second shot.

- Who **SHOULD** get it: People 65+, those living in long-term care settings, and people 50–64 with underlying conditions
 - Who **MAY** get it: People 18–49 with underlying conditions and people 18–64 who live and/or work in high-risk settings, based on individual risk and benefit
- This is the first group of people eligible, and FDA and CDC will continue to evaluate data over the coming weeks and make determinations for additional populations going forward, including people who got the Moderna or J&J/Janssen primary vaccine series.
 - HHS will always follow the direction of scientists and public health experts and we will always be transparent with what we know, as soon as we know it.
 - HHS is ready to distribute booster doses to all those eligible, free of charge, at tens of thousands of pharmacies, doctors' offices, and healthcare providers across the country.
 - Getting any dose of the vaccine is easier than ever. Go to [vaccines.gov](https://www.vaccines.gov) to learn more and find a vaccine near you.



Content from a presentation given by the White House COVID-19 Response Team during “Made to Save Public Health Office Hours,” September 28, 2021.



HHS Guidelines for Booster Dose Messaging

1. To increase uptake, we need to provide clear and simple information on eligibility and communicate how easy it is to get a shot.
2. We do not need to persuade most people to get booster doses at this time, but we do need to make people aware of eligibility.
3. We need to continue efforts to increase vaccine confidence among the unvaccinated, including answering questions about booster doses.



Content from a presentation given by the White House COVID-19 Response Team during “Made to Save Public Health Office Hours,” September 28, 2021.



HHS Guidelines for Booster Dose Messaging

HHS is relying on partners to:

- Proactively reach out to appropriate community members to alert them of **eligibility and ease of access**.
 - No insurance or ID required
 - Walk-ins and appointments available at local pharmacies if provider is unable to administer
- Ensure patients who are vaccinated but not yet eligible for a booster dose understand that more recommendations will be coming.
- Increase confidence among the unvaccinated.



Content from a presentation given by the White House COVID-19 Response Team during “Made to Save Public Health Office Hours,” September 28, 2021.



HHS Resources about COVID-19 Booster Doses


WHAT TO KNOW ABOUT
COVID-19 Vaccine Boosters

COVID-19 vaccines continue to be highly effective at preventing severe illness, hospitalization, and death due to COVID-19, including from the Delta variant. But protection appears to decrease over time, and some groups have an increased risk of getting and spreading COVID. As a result, some people are now eligible for a booster shot.

Who Is Eligible for a Booster

You are eligible to get a booster shot if it's been at least 6 months since you got the second dose of a Pfizer-BioNTech vaccine and are:

- 65 years or older;
- A long-term care resident or staff member;
- 18+ and have an underlying medical condition, including asthma, diabetes, and obesity; or
- 18+ and work or live in high-risk settings, including health care workers, teachers, and grocery store workers.




If you received a Moderna or Johnson & Johnson's Janssen vaccine, you are not eligible for a booster yet. Updates will be provided as soon as possible.

For more information about boosters, or if you have questions about your eligibility, visit cdc.gov/coronavirus or talk to a health care provider.

How to Find Vaccines

You have three ways to find vaccines near you:

- Go to vaccines.gov
- Text your ZIP code to 438829
- Call 1-800-232-0233



WE CAN DO THIS

COVID-19 Vaccine Boosters for Employees in High-Risk Settings

COVID-19 vaccines continue to be highly effective at preventing severe illness, hospitalization, and death due to COVID-19, including from the Delta variant. But protection appears to decrease over time, and some people are at increased risk of getting and spreading COVID-19 because of where they work. As a result, some people are now eligible for a booster shot.

Who Is Eligible for a Booster

You are eligible to get a booster shot if it's been at least 6 months since you got the second dose of a Pfizer-BioNTech vaccine, are at least 18 years old, and work in certain high-risk settings. Examples include:

- First responder (such as firefighter or police officer)
- Health care worker
- Education staff (such as teacher, support staff, or daycare worker)
- Food and agriculture worker
- Factory worker
- Corrections worker
- U.S. Postal Service worker
- Public transportation worker
- Grocery store worker

If your workplace is not listed above, your health care provider can help you decide if a booster is right for you.

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Content last reviewed: September 29, 2021

For more information, visit cdc.gov/coronavirus

WHAT TO KNOW ABOUT
COVID-19 Vaccine Boosters for People With Underlying Medical Conditions

COVID-19 vaccines continue to be highly effective at preventing severe illness, hospitalization, and death due to COVID-19, including from the Delta variant. But protection appears to decrease over time, and people with underlying medical conditions are at increased risk of severe illness from COVID-19. As a result, some people are now eligible for a booster shot.

Who Is Eligible for a Booster


You are eligible to get a booster shot if it's been at least 6 months since you got the second dose of a Pfizer-BioNTech vaccine, are at least 18 years old, and are at increased risk for severe COVID-19 because of an underlying medical condition, such as:

- Cancer
- Chronic kidney disease
- Chronic lung diseases, including COPD (chronic obstructive pulmonary disease), asthma, interstitial lung disease, cystic fibrosis, and pulmonary hypertension
- Dementia or other neurological conditions
- Type 1 or 2 diabetes
- Down syndrome
- Heart conditions (such as heart failure, coronary artery disease, cardiomyopathies, or hypertension)
- HIV infection
- Liver disease
- Overweight and obesity
- Pregnancy
- Sickle cell disease or thalassemia
- Smoking, current or former
- Solid organ or blood stem cell transplant
- Stroke or cerebrovascular disease, which affects blood flow to the brain
- Substance use disorders

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WE CAN DO THIS

Eligibility for COVID-19 Vaccine Boosters

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<https://wecandothis.hhs.gov/covid-19-vaccine-booster-shot-resources>



Lessons from the Ad Council's COVID-19 Vaccine Education Initiative on Promoting the Primary Vaccine Series

GUIDING MESSAGING PRINCIPLES

- Lead with the “new news.”
- Ideal tone is empathetic, urgent, authentic, and respectful.
- Respect people’s independence and urge them to make an informed decision.
- Position vaccines as a way to help people protect both themselves and their loved ones.
- Acknowledge that there is a lot of information on COVID-19 and the vaccines.
- Build trust by being honest and transparent.
- When sharing a key message, provide a reason to believe.
- Convey messages through personal and relatable stories, and/or visualizations.
- Framing around loss or negatives is best done through storytelling.

MESSAGES TO AVOID

- Positioning getting a vaccine as “the right thing to do.”
- Language around “getting back to moments missed.”
- Overpromising that getting a vaccine will “flip the switch” and end the pandemic.



More Ways to Take Action



Recent Reports

The following reports seek to identify emerging issues of misinformation, disinformation, and places where intervention efforts can positively increase vaccine confidence across the United States.

[Report 15 | September 27, 2021](#)  [6 pages]

[Rapid Report – Announcement of Booster Dose Program of mRNA COVID-19 Vaccines for U.S. Adults | August 26, 2021](#)  [8 pages]

Sign up for updates! <https://www.cdc.gov/vaccines/covid-19/vaccinate-with-confidence.html>



Resources

- [Who Is Eligible for a COVID-19 Vaccine Booster Shot? | CDC](#)
- [Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots | HHS.gov](#)
- [Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC](#)
- [CDC Statement on ACIP Booster Recommendations | CDC Online Newsroom | CDC](#)
- [ACIP September 22-23, 2021 Meeting Videos | Immunization Practices | CDC](#)
- [Slides: CDC Awardee COVID-19 Vaccination Planning Meeting](#)
- [Ensuring COVID-19 Vaccine Safety in the US | CDC](#)
- [CDC COVID Data Tracker](#)
- [COVID-19 Vaccination Clinical and Professional Resources | CDC](#)
- [Communication Resources for COVID-19 Vaccines | CDC](#)
- [Talking with Patients about COVID-19 Vaccination | CDC](#)
- [Vaccinate with Confidence | CDC](#)
- [COVID-19 Vaccine Confidence | CDC](#)
- [Rapid COVID-19 State of Vaccine Confidence Insights Report \(cdc.gov\)](#)
- [Vaccines for COVID-19 | CDC](#)
- [Pfizer and BioNTech Initiate Rolling Submission of Supplemental Biologics License Application to U.S. FDA for Booster Dose of COMIRNATY® in Individuals 16 and Older | Pfizer](#)
- [Moderna Announces Submission of Initial Data to U.S. FDA for Its COVID-19 Vaccine Booster | Moderna, Inc. \(modernatx.com\)](#)
- [Johnson & Johnson Announces Data to Support Boosting its Single-Shot COVID-19 Vaccine | Johnson & Johnson \(jnj.com\)](#)
- [Webinar September 9, 2021 - 2021-2022 Influenza Vaccination Recommendations and Guidance on Coadministration with COVID-19 Vaccines \(cdc.gov\)](#)
- [Resources About COVID-19 Vaccine Boosters | WECANDOTHIS.HHS.GOV](#)
- [COVID-19 Vaccine Education Initiative \(adcouncil.org\)](#)

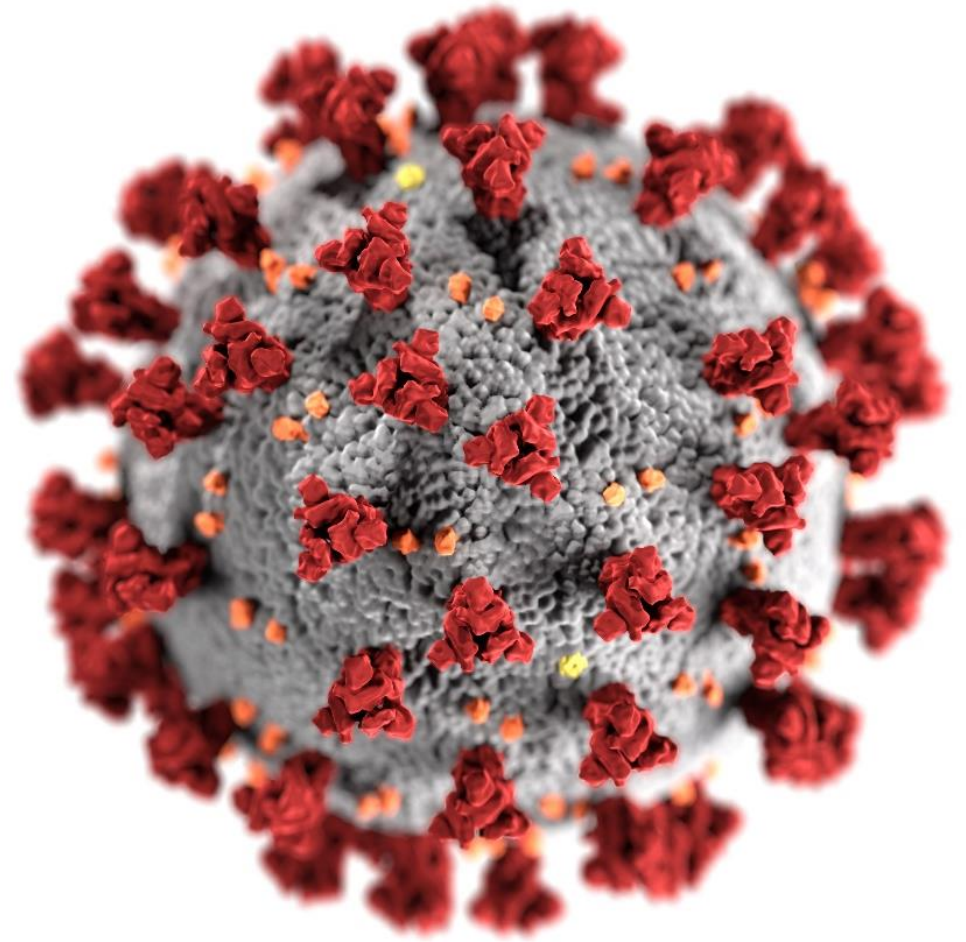


Thank you!



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



BACKUP SLIDES



Frequently Asked Questions about Booster Doses



What are the risks to getting a booster dose?

So far, reactions reported after getting the Pfizer-BioNTech booster dose were similar to that of the 2-shot primary series. Fatigue and pain at the injection site were the most commonly reported side effects, and overall, most side effects were mild to moderate. However, as with the 2-shot primary series, serious side effects are rare, but may occur.



<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#FAQs>

COVID-19 Booster Dose Safety Data



CDC Vaccine Safety Monitoring

- COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**
- Strong, complementary systems are in place—both new and established

v-safe

VAERS

VSD

CISA Project



Full list of U.S. COVID-19 vaccine safety monitoring systems

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>



<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-22/06-COVID-Hause-508.pdf>

VAERS accepts reports from everyone

Regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event

Key strengths

- Rapidly detects potential safety problems
- Can detect rare adverse events

Key limitations

- Inconsistent quality and completeness of information
- Reporting biases
- Generally, cannot determine cause and effect



Most frequently reported adverse events to VAERS following dose 3 of mRNA COVID-19 vaccination, by seriousness

Serious (n=131)

Rank	Adverse Event*	n (%)
1	Extra dose administered	40 (31)
2	Fever	27 (21)
3	Dyspnea	23 (18)
4	Death	18 (14)
5	Fatigue	14 (11)

Non-serious (n=2,432)

Rank	Adverse Event*	n (%)
1	Extra dose administered	945 (39)
2	Fever	323 (13)
3	Headache	274 (11)
4	Fatigue	269 (11)
5	No adverse event	243 (10)

Includes data collected during December 14, 2020–September 17, 2021 for persons 12+ years of age. Per federal law, includes reports of hospitalization, prolongation of existing hospitalization, life threatening condition, permanent disability, congenital deformity or birth defect, or death.

* Not mutually exclusive



<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-22/06-COVID-Hause-508.pdf>

Reports of death to VAERS following dose 3 of mRNA COVID-19 vaccination

- Median age = 76 years (range: 47–93)
- Median time from 3rd dose to death = 1 day (range: day of vaccination – 12)

Preliminary Impression of Cause of Death*	Reports
Respiratory and/or cardiac arrest	7
Unable to assess	4
Pulmonary embolism	2
Sepsis	1
Accident/trauma	1
Cancer	1
COVID-19 pneumonia	1
Total	18

Includes data collected during December 14, 2020–September 17, 2021

* Based upon physician review of initial report and available documentation, including death certificates



Active safety monitoring for COVID-19 vaccines

v-safe is a CDC smart-phone based monitoring program for COVID-19 vaccine safety

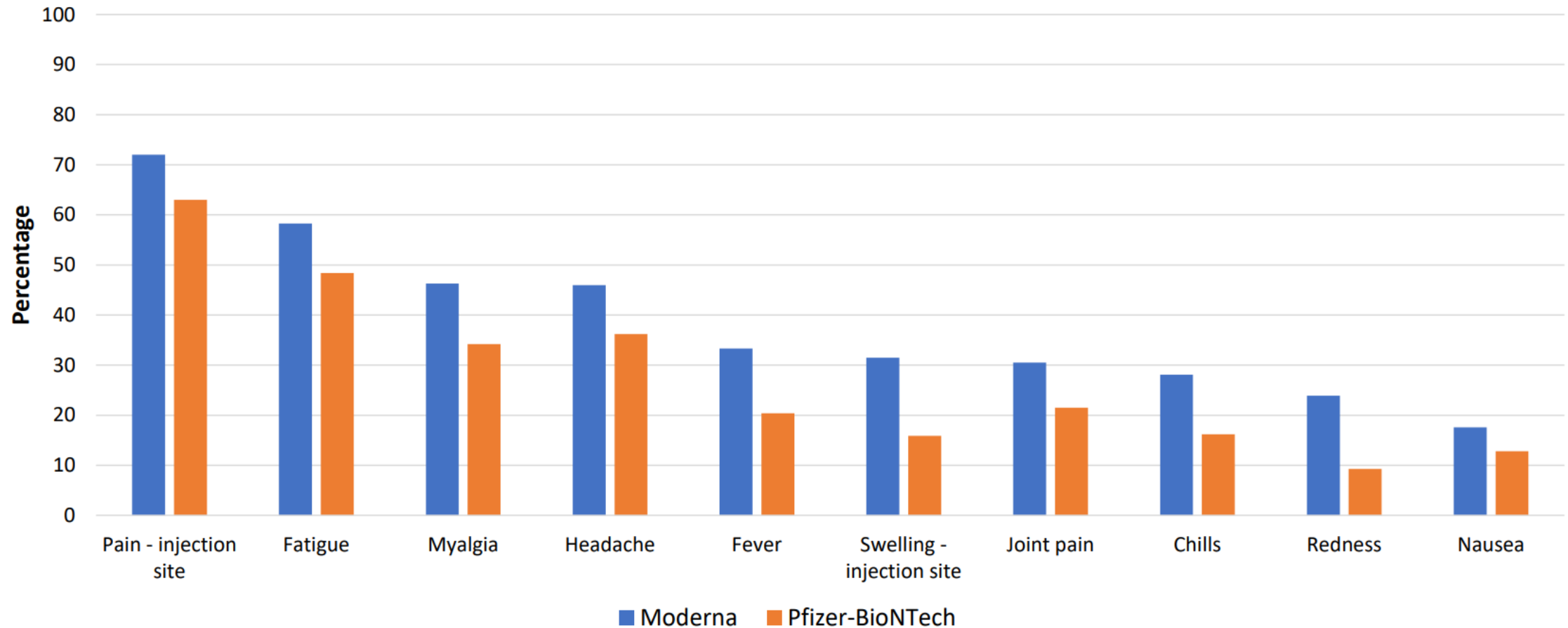
- Uses text messaging and web surveys to check in with vaccine recipients after vaccination
- Can register at any time: after 1st, 2nd, or 3rd dose
- Solicits participants' reports on how they feel after COVID-19 vaccination
 - Local injection site reactions
 - Systemic reaction
 - Health impacts (unable to perform normal daily activities, missed school or work, or received care)



<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-22/06-COVID-Hause-508.pdf>



Most common solicited reactions reported at least once 0–7 days after dose 3 of Moderna or Pfizer-BioNTech vaccine

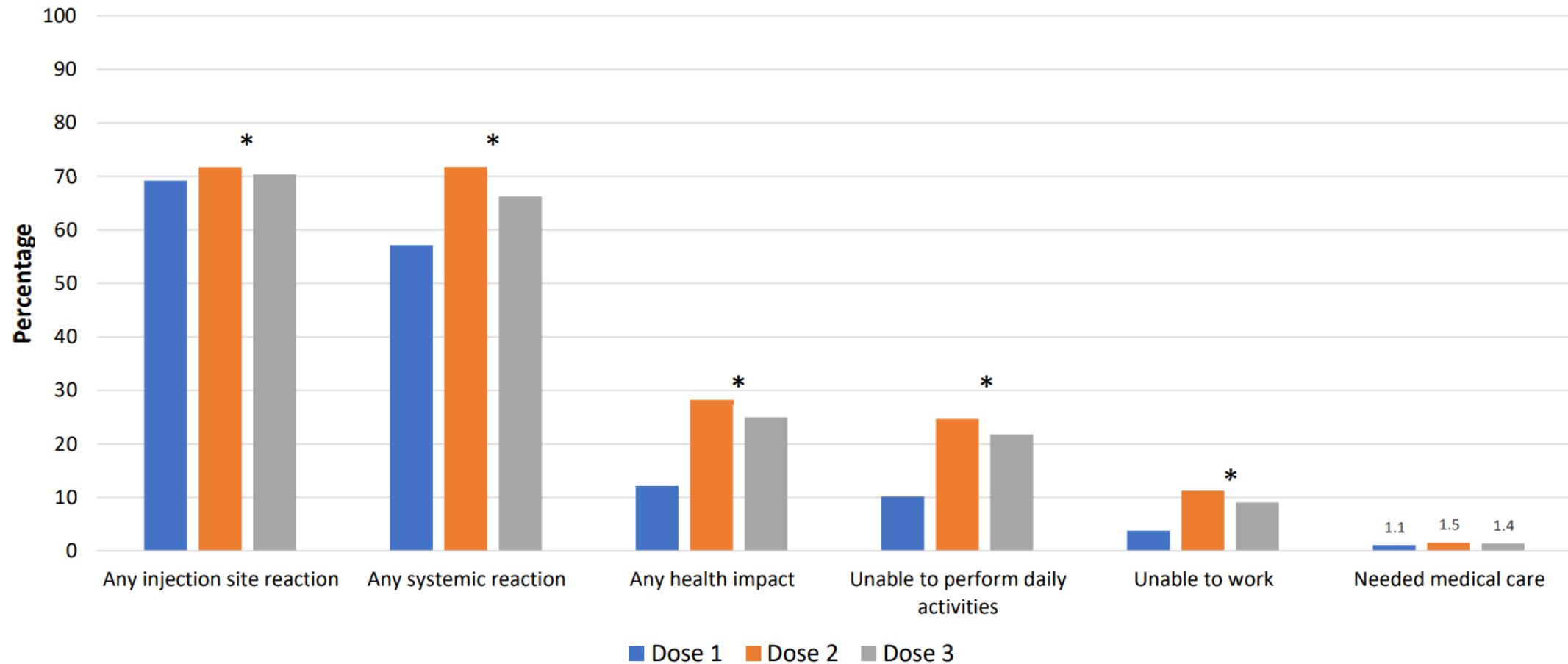


Includes 21,413 participants who completed at least one survey in the first week after additional dose, data collected during August 12–September 19, 2021



<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-22/06-COVID-Hause-508.pdf>

Comparison of reactions and health impact events reported at least once in days 0–7 after Pfizer-BioNTech vaccination, by dose



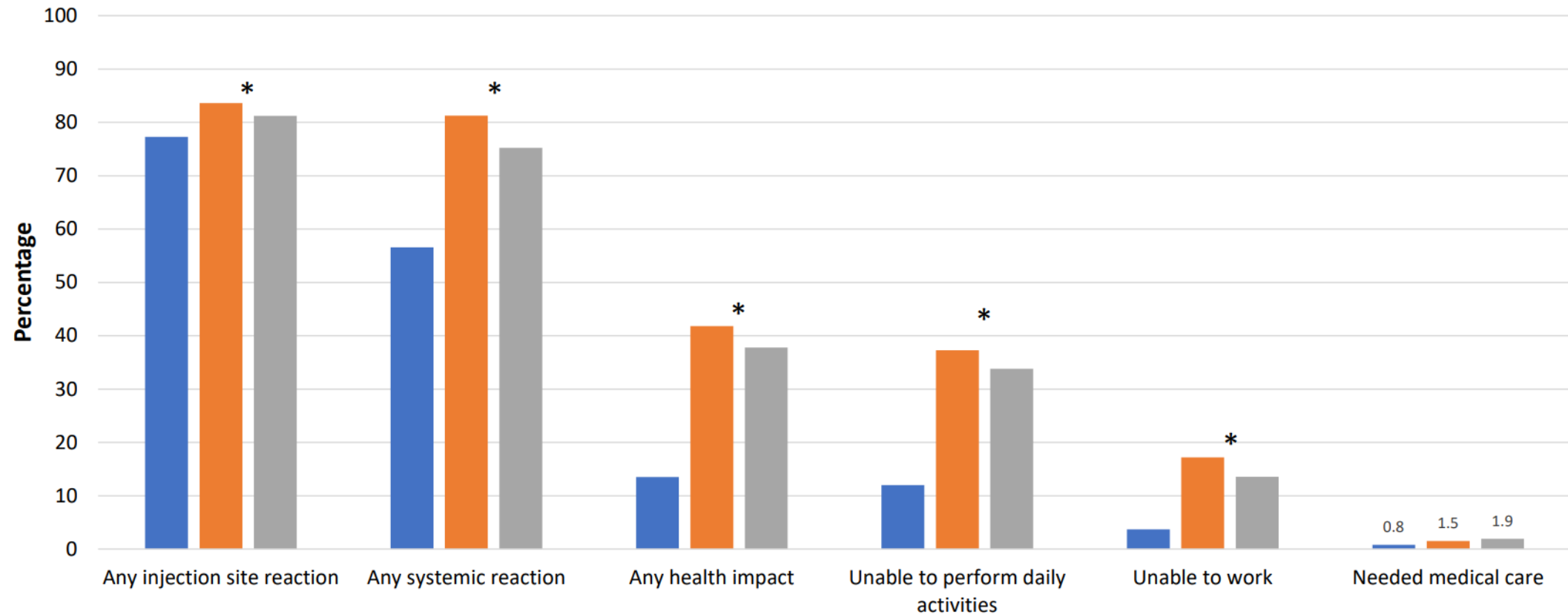
Includes 6,267 participants who completed at least one survey in the first week after each dose, data collected during August 12–September 19, 2021

* Odds of reporting an event following dose 2 and 3 compared using multivariable generalized estimating equations model that accounted for the correlation between registrants and adjusted for demographic variables; p-values less than 0.05 were considered statistically significant.

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-22/06-COVID-Hause-508.pdf>



Comparison of reactions and health impact events reported at least once in days 0–7 after Moderna vaccination, by dose



Includes 6,242 participants who completed at least one survey in the first week after each dose, data collected during August 12–September 19, 2021

* Odds of reporting an event following dose 2 and 3 compared using multivariable generalized estimating equations model that accounted for the correlation between registrants and adjusted for demographic variables; p-values less than 0.05 were considered statistically significant



<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-22/06-COVID-Hause-508.pdf>

Limitations of early safety monitoring for an additional COVID-19 vaccine dose

- V-safe population likely not representative of the vaccinated U.S. population
- Additional dose recipients likely included immunocompromised and non- immunocompromised persons
 - V-safe does not include information about immune status
 - Immunocompromised persons might have different reactogenicity than immunocompetent persons
- Data available now are insufficient
 - To determine patterns of adverse events after receipt of an additional dose from a manufacturer different from the primary series
 - To identify rare adverse events
- Complete medical review of deaths following vaccination reported to VAERS is dependent on availability of medical records, death certificates, and autopsy reports, which may be delayed or not available



Summary

- No unexpected patterns of adverse events were identified
- 95% of VAERS reports following dose 3 of COVID-19 vaccination were nonserious
- Over 21,000 v-safe registrants reported an additional dose
 - Most reported a primary mRNA vaccine series followed by dose 3 from the same manufacturer
 - Local and systemic reactions were reported slightly less frequently following dose 3 than dose 2
 - Similar to Pfizer-BioNTech phase 3 clinical trial (included 306 persons)¹

¹ <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission>



For More Information...

Where Can You Get More Information?



COVID-19



Your Health

Vaccines

Cases & Data

Work & School

Healthcare Workers

Health Depts

Science

More

CDC now recommends that people aged 65 years and older, residents in long-term care settings, and people aged 50–64 years with [underlying medical conditions](#) **should** receive a booster shot of Pfizer-BioNTech's COVID-19 Vaccine at least 6 months after completing their Pfizer-BioNTech primary series. Other groups **may** receive a booster shot based on their individual risk and benefit. [Learn more.](#)

Vaccines for COVID-19

COVID-19 vaccines are safe, effective, and free! After you've been fully vaccinated, you can [participate in many of the activities that you did](#) prior to the pandemic. [Key Things to Know](#)

YOUR VACCINATION

WHEN FULLY VACCINATED

BOOSTER SHOT



<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>