

V-safe active surveillance for COVID-19 vaccine safety

Version 3
May 20, 2021

Protocol Change History

| Version | Date | Change |
|---------|--------------|--|
| 1 | Dec 8, 2021 | N/A – Original |
| 2 | Jan 28, 2021 | Added race and ethnicity question to survey (Attachment 1) Modified Attachment 1 to clarify timepoints that include pregnancy questions |
| 3 | May 12, 2021 | Modified protocol and survey language to reflect enhancement to v-safe that allows registration of dependents and completion of surveys for dependents Revised language to reflect revision of CDC follow-up calls to be specific to medically attended health events Additional language to reflect enhancements to the v-safe platform (ability to delete account on participant request, text reminders for 2 nd dose) Minor edits to reflect current survey language and completion messages viewed at end of survey |

Protocol summary

V-safe is an active surveillance program to monitor the safety of COVID-19 vaccines during the period when the vaccines are authorized for use under Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and possibly early after vaccine licensure. V-safe is a new smartphone-based system that uses text messaging to initiate web-based survey monitoring in the form of periodic health check-ins to assess for potential adverse events following vaccination. CDC will use the follow-up capability of the existing Vaccine Adverse Event Reporting System (VAERS) call center to conduct active telephone follow-up on recipients reporting a significant, medically attended health impacts during v-safe health check-ins. The purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions.

Background and significance

Coronavirus disease 2019 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Following the emergence of COVID-19 in China in late 2019, the first confirmed U.S. cases were detected in January 2020. With rapid human-to-human transmission occurring, the United States declared a public health emergency in February 2020, followed by a national emergency in March 2020 (1). As of November 18, 2020, there have been 11,300,635 cases of COVID-19 disease in the United States and 247,834 deaths (2). A key U.S. pandemic response initiative is Operation Warp Speed, a public-private partnership established in May 2020, with a goal to develop and deliver safe and effective COVID-19 vaccine(s) to the U.S. population by early 2021 (3).

Post-authorization/post-approval vaccine safety monitoring is a federal government responsibility, with the Centers for Disease Control and Prevention (CDC) and the FDA sharing most of the responsibility along with other federal agencies involved in healthcare delivery (e.g., Veterans Affairs, Department of Defense, Indian Health Service). Initial safety assessment begins in early vaccine development and expands during phased clinical trials in humans. Clinical trials are effective at identifying and characterizing common adverse events, such as local and systemic reactions. However, even large clinical trials, like the COVID-19 vaccine

clinical trials that are enrolling tens of thousands of volunteers, might not be large enough to detect rare adverse events (for example, those occurring at rates of <1 per 100,000 people vaccinated). Furthermore, for some clinical trials of COVID-19 vaccines, the follow-up period to monitor for possible adverse events with delayed onset may not be completed for all subjects prior to issuance of an EUA or licensure. Additionally, exclusion criteria for clinical trials may limit generalizability of safety and efficacy findings to special populations, such as those with certain chronic illnesses or pregnant women (4). For these reasons, robust post-authorization/approval safety monitoring of COVID-19 vaccines is a public health priority.

To meet the safety data needs for COVID-19 vaccine pharmacovigilance during the post-authorization/approval period, CDC will implement v-safe, a smartphone-based system that uses text messaging to initiate web-based surveys to monitor for adverse events following vaccination. The surveillance process triggers active telephone follow-up on vaccinated individuals reporting a significant, medically attended health impact during v-safe health check-ins.

Goals and objectives

Goals

- Characterize the safety profile of COVID-19 vaccines.
- Rapidly monitor and identify potential safety problems associated with COVID-19 vaccines that would impact policy or regulatory decisions.

Objectives

- Characterize the local and systemic reactogenicity of COVID-19 vaccines during the first week post-vaccination (days 0-7).
- Identify and characterize clinically important adverse events following COVID-19 vaccination during a 6-week post-vaccination follow-up period.

- Monitor the long(er)-term (3, 6, and 12 months post-vaccination) safety of COVID-19 vaccines.

Methods

Surveillance population

All people in the United States who receive a COVID-19 vaccination will be eligible to enroll in v-safe for the duration of the v-safe program. Surveys will be available in English, Spanish, Simplified Chinese, Vietnamese, and Korean languages.

Enrollment criteria:

- Participants must have received a COVID-19 vaccination.
- Participants or their parent/guardian must possess a smartphone with a valid US telephone number. More than one individual may use the same smartphone/telephone number (i.e., shared smartphone).

Enrollment

The v-safe program will commence when COVID-19 vaccines are authorized or approved for use and become available to the U.S. population. Vaccination may occur at a mass vaccination clinic, an occupational health clinic, a public health clinic, a healthcare provider's office, a pharmacy, or other setting. At the time of vaccination, the healthcare provider will briefly describe the v-safe program using a prescribed script. In addition, the healthcare provider will provide the vaccinated patient with an information sheet that includes a brief description of the program, a URL and a scannable QR code, and enrollment instructions.

Vaccinated individuals can enroll in v-safe immediately following vaccination or at a later date; surveys will be timed appropriately based on vaccination date(s). For vaccine recipients whose vaccination information is captured in CDC's Vaccine Administration Management System (VAMS), VAMS will send recipients a reminder text message about v-safe 24 hours after vaccination (5). For vaccine recipients receiving a 2-dose vaccine, v-safe will send a text reminder to participants that they should schedule their second dose. Participation in v-safe is

voluntary and people can opt out at any time by texting “STOP” when v-safe sends a reminder text message; people can also start v-safe again by texting “UNSTOP.”

Once a vaccinated individual decides to enroll in v-safe, the individual will either scan his/her mobile phone camera over the QR code on the information sheet or type in the v-safe URL to access the v-safe registration website.

Registration information includes:

- First name
- Last name
- Mobile phone number
- Date of birth
- Sex
- Zip code

If registering in v-safe on behalf of a dependent, the original registrant will also be asked to supply the following:

- First name of dependent
- Last name of dependent
- Date of birth of dependent
- Sex of dependent
- Zip code of dependent
- Relationship to dependent (child or adolescent, adult friend or relative, other)

The registration system will ask the participant to verify their phone number by sending a text message with a verification code. The participant will enter the texted code to verify their identity. After that, the participant will be asked to record information on their first COVID-19 vaccination (or that of their dependent), including the vaccine manufacturer and the vaccination date. If the v-safe participant does not know this information, they are encouraged to refer to the vaccination record card they received or to contact their healthcare provider.

Once a participant has registered and provided information on their COVID-19 vaccination, they will be prompted to take an initial v-safe health check-in survey for themselves or their dependent. The survey will be dependent on the vaccination date and dose number (if applicable)

entered during registration. Subsequently, text messages will be sent to their smartphone with a link to a web-based survey at 2:00 pm (local time based on zip code entered at registration) on the schedule listed below. Surveys for all timepoints are included in Attachment 1.

Electronic health check-in schedule

The schedule for electronic health check-ins is as follows:

1. Day 0 (day of vaccination)
2. Daily on days 1-7 (the 1st week post-vaccination)
3. Weekly starting day 14 (2nd week post-vaccination) to up to day 42 (6th week post-vaccination) if no 2nd dose of COVID-19 vaccine is received
 - a. If participant receive a 2nd COVID-19 vaccine dose during the post-vaccination follow-up period, the process will reset to day 0 for the 2nd dose and continue through steps 1-3 above based on time since the 2nd dose.
4. At 3, 6, and 12 months post-vaccination following 2nd dose vaccination or following first dose if no 2nd dose is received

Daily surveys expire at midnight on the day of the survey and weekly surveys expire at midnight on the last day of the week before the next weekly survey period. The day 42 survey will expire on day 48 at midnight. Monthly surveys will be available for 6 full days following receipt of the survey, expiring at midnight. A participant cannot go back and complete surveys for timepoints prior to their registration (i.e., surveys will be prospective from the time of enrollment). In addition, a participant cannot revise their survey once it has been submitted. After submission, the participant is told that depending on his/her answers, someone from CDC might call to follow up.

Active telephone follow-up

If, during any v-safe health check-in, a participant reports a significant, medically-attended health impact event for themselves or their dependent, including but not exclusive to requiring care in a hospital or emergency room setting, VAERS call center staff will be informed and active telephone follow-up will be initiated to check on the patient and take a VAERS report if appropriate. [VAERS](#) is an existing national spontaneous reporting system that is co-managed by FDA and CDC. It serves as an early warning system for adverse events following vaccination (6).

VAERS call center staff will be notified of participants who have reported a significant health impact event via a data set that will be created from the v-safe survey system. The data set will include the following variables:

- Unique v-safe id
- First name
- Last name
- Phone number
- Sex
- Age
- Zip code
- First name of guardian, if applicable
- Last name of guardian, if applicable
- Relationship to guardian, if applicable
- Flagged health impact question
- Flagged health impact response(s) survey number (dose/survey [i.e., Dose2D0])

Using this information, the VAERS call center staff will call participants identified in the data set and complete a VAERS report (located at <https://vaers.hhs.gov>) by phone if appropriate.

Data collection, quality, and management

V-safe data will be collected, managed, and housed on a secure server by Oracle. Through Health and Human Services (HHS), Oracle has donated IT services to any agency conducting COVID-19 related activities. Oracle is providing IT support for v-safe. All data will be stored, processed, and transmitted in accordance with the Federal Information Security Modernization Act (FISMA) and based on NIST standards. Data will be housed in *Oracle Cloud Infrastructure (OCI) U.S. Government Cloud tenancy*; the OCI U.S. government tenancy is Federal Risk and Authorization Management Program (FEDRAMP) approved (7).

Per Oracle's internal policies, Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, will have access to aggregate deidentified data for reporting. CDC will have "read" access to the individualized survey data, including PII, provided by Oracle. On a continuous basis (either daily or weekly), these survey data will be accessible to CDC through downloads from the secure server. The v-safe system employs strict security measures appropriate for the level of sensitivity of the data. Data received by CDC will be stored on an internal secure CDC/ISO server and access will be limited to authorized personnel.

Oracle will create a data set for the VAERS call center that includes those participants who reported having a health impact event that requires call follow-up. CDC-badged contractors will access these data in order to provide call center representatives with information needed to follow up with participants (see "Active telephone follow-up" above). The VAERS call center staff is employed specifically for v-safe follow-up and is associated with the overall VAERS contractor.

VAERS reports will be obtained during active telephone follow-up with v-safe participants and will be processed, handled, stored, and accessed in accordance with existing approved VAERS procedures and policies.

Data from all components of v-safe, as well as VAERS reports obtained through the call center, may be combined into a master data set behind the CDC firewall using unique identification numbers assigned at registration.

Preapproved CDC investigators and data managers, including CDC contractors, will be the only individuals with access to the full data (v-safe, linked VAERS reports). All electronic documents, data sets, and files relevant to the project will be stored on network folders with restricted access on CDC computers. The v-safe team at CDC will be primarily responsible for data management activities, including data extraction, documentation, and archival of a final data set for data sharing purposes. The archive will include the protocol, statistical programs, human

subjects review documents, statistical output, analytical data sets, and manuscripts. It will clearly identify the permanent storage location for these files.

A final data set at the end of the v-safe program with deidentified aggregate data will be made available for external data requests or through Freedom of Information Act (FOIA) requests.

Analysis plan

Descriptive analyses will be conducted using the data collected through surveys on a weekly basis during the surveillance period. Participation rates over time will also be calculated.

For v-safe participants who have a VAERS report submitted through the VAERS call center, additional analyses will be conducted. Rates of serious events as well as adverse events of special interest (AESI) following COVID-19 vaccination will be generated using VAERS reports solicited via v-safe to define the numerator and v-safe participants as the denominator (Attachment 2). VAERS reports that are considered serious or AESI will be reviewed by medical staff at CDC. Case definitions (Brighton Collaboration or other standard definitions as appropriate) will be applied to the AESIs. Reporting rates for each AESI will be calculated and compared to established background rates. If at any time rates observed in v-safe exceed what is expected from background rates, further investigation will occur within other vaccine safety monitoring systems, including VAERS and Vaccine Safety Datalink (7).

VAERS monitoring for all COVID-19 reports will include VAERS reports solicited from v-safe participants. Reports obtained from v-safe participants during call center outreach will be coded so that they can be distinguished from other VAERS reports and analyzed separately from other VAERS reports if needed.

Human subjects considerations and confidentiality

This protocol will require human subjects determination at CDC since CDC is the lead site and surveillance data will include collection of PII. No PII will be included in any v-safe analyses, manuscripts, or data sets shared through external data requests. Participation is completely voluntary and individuals self-enroll. Participants can elect to stop text notifications at any time

and their data will be used for those surveys completed prior to opting out. Participants who request to be removed entirely from the system will be inactivated in v-safe so that their registration record is deleted, and their health survey data will not be included in future analyses. As an analysis of data collected for non-research purposes, this activity presents minimal risk to subjects, and use of patient data for this purpose will not adversely affect subjects' rights or welfare.

Duration

The anticipated duration of the v-safe program is at least one year of active enrollment, based on anticipated length of emergency use authorizations for COVID-19 vaccines. The decision to discontinue v-safe or to modify v-safe procedures to scale back active telephone follow-up will be made in consultation with the CDC COVID-19 Vaccine Task Force leadership and FDA.

Limitations and challenges

Limitations and challenges for v-safe surveillance include:

- Enrollment and registration will initially be a manual process and will be dependent on healthcare providers sharing information about the system with vaccine recipients. Enrollment might be limited. While VAMS will help promote v-safe enrollment through automated text message reminders, not all jurisdictions will use VAMS, and VAMS text messaging capabilities may not be rolled out until several weeks/months after vaccine becomes available.
- Accurate capture of vaccine manufacturer information will depend on accurate self-report, at least initially. Vaccine recipients are expected to receive vaccination record cards specifying the vaccine they received, which might help to improve accuracy of these data.

- Vaccinated people who choose to participate in v-safe might be different from those who decline; therefore, rates of side effects and adverse events generated from v-safe might not be generalizable to the full population of vaccine recipients.
- V-safe allows people to enter late in the post-vaccination monitoring period. The group of individuals who enroll in v-safe late might be heterogeneous—those who simply neglected to enroll early, those who chose to enroll only after experiencing a clinically important adverse event, and others. Data collected from these individuals may need to be analyzed separately from data from those who enrolled early.
- The information provided by v-safe participants at 3, 6, and 12 months after vaccination might be impacted by recall bias.
- Participants will likely be lost to follow-up at later time points, reducing participant numbers and likely creating biases in v-safe analyses of safety out to 12 months.
- Because v-safe relies on vaccine recipients reporting their own experiences after vaccination, v-safe is not conducive to capturing the adverse event of death following vaccination.

Dissemination

Data from v-safe will be important in the beginning phases of the COVID-19 vaccination program. Regular updates will be provided to advisory committees and data review groups. It is anticipated that v-safe data will be shared with the scientific community and with the public through manuscripts and public reports.

References

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2. CDC. CDC COVID Data Tracker. Available at https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days.
3. Slaoui M, Hepburn M. Developing Safe and Effective Covid Vaccines—Operation Warp Speed’s Strategy and Approach. *N Engl J Med* 2020; 383:1701–1703.
4. Su JR, Duffy J, Shimabukuro TT (2019). Chapter 1: Vaccine Safety. In Poland GA (Ed.) and Whitaker JA (Assoc. Ed.), *Vaccinations*. St. Louis, MO: Elsevier.
5. https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf
6. Shimabukuro TT, Nguyen M, Martin D, DeStefano F. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*. 2015; 33(36): 4398–4405.
7. <https://www.gsa.gov/technology/government-it-initiatives/fedramp>)?

8. McNeil MM, Gee J, Weintraub E, et al. The Vaccine Safety Datalink: successes and challenges monitoring vaccine safety. *Vaccine*. 2014; 32(42):5390–8.

Attachment 1: V-safe health check-in surveys

Note: language to be used for dependents is italicized. Pregnancy questions are only asked for those 18 years of age or older.

Day 0 - Dose 1

Text message invitation:

Hi <NAME>. It's time for your first v-safe check-in. <URL for survey>

Hi <NAME>. *It's time for the first v-safe check-in for <DEPENDENT NAME>. <URL for survey>*

Survey:

Hi <NAME>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Fever check

Since your/their vaccination, have you/they had a fever or felt feverish?

☐ Yes ☐ No

(If Yes) Do you know your/their highest temperature reading from today?

- ☐ Yes- in degrees Fahrenheit
- ☐ Yes- in degrees Celsius
- ☐ No- don't remember the reading
- ☐ No- didn't take my/their temperature

Enter your/their highest temperature reading from today (degrees Fahrenheit)

Enter your/their highest temperature reading from today (degrees Celsius)

Symptom check

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limit of your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

Have you/they had any of these symptoms today where you/they got the shot (injection site)?

select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

How would you rate your/their symptoms:

- | | | | |
|-----------------------|-------------------------------|-----------------------------------|---------------------------------|
| (If checked Pain) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Redness) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Swelling) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |

- ☐ Chills
- ☐ Headache
- ☐ Joint pain
- ☐ Muscle or body aches
- ☐ Fatigue or tiredness
- ☐ Nausea
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Abdominal pain
- ☐ Rash, not including the immediate area around the injection site
- ☐ None

(If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
 (If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
 (If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
 (If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
 (If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
 (If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
 (If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
 (If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
 (If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
 (If checked Rash, not including the immediate area around the injection site) ☐ Mild
☐ Moderate ☐ Severe

- ☐ Be unable to work or attend school?
- ☐ Be unable to do *your/their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If “Get care...” checked) What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?
(*This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1.*)

- ☐ Yes ☐ No ☐ Don't know

Race/Ethnicity

(*This is only asked once; once data are captured, questions will not display on future surveys*)

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

Thanks for completing today's check-in.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

If you had/*there were* symptoms or health problems following your/*the* COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report the experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

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We'll be in touch tomorrow.

Days 1-7 post vaccination - Dose 1

Text message invitation:

Hi, <NAME>. It's time for your daily v-safe check-in. <URL for survey>

Hi <NAME>. It's time for the daily v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder (day 7 only):

Hi <NAME>, Please remember to do your daily v-safe check-in. <URL for survey>

Hi <NAME>. Please remember to do the daily v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

Hi <NAME>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Fever check

Have you/they had a fever or felt feverish TODAY?

☐ No ☐ Yes

(If Yes) Do you know your/their highest temperature reading from today?

- ☐ Yes- in degrees Fahrenheit
- ☐ Yes- in degrees Celsius
- ☐ No- don't remember the reading
- ☐ No- didn't take my/their temperature

Enter your/their highest temperature reading from today (degrees Fahrenheit)

Enter your/their highest temperature reading from today (degrees Celsius)

Symptom check

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limit your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

Have you/they had any of these symptoms at or near the injection site today?

Check all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

How would you rate your/their symptoms:

| | | | |
|-----------------------|-------------------------------|-----------------------------------|---------------------------------|
| (If checked Pain) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Redness) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Swelling) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Itching) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |

Have you/*they* experienced any of these symptoms today?

Select all that apply:

- ☐ Chills
- ☐ Headache
- ☐ Joint pain
- ☐ Muscle or body aches
- ☐ Fatigue or tiredness
- ☐ Nausea
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Abdominal pain
- ☐ Rash, not including the immediate area around the injection site
- ☐ None

Any other symptoms or health conditions you want to report _____

Symptoms:

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limit your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

How would you rate your/*their* symptoms:

- (If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Rash, not including the immediate area around the injection site) ☐ Mild
☐ Moderate ☐ Severe

Health impact

Did any of the/*their* symptoms or health conditions you reported today cause you/*them* to (Select all that apply):

- ☐ Be unable to work or attend school?
- ☐ Be unable to do your/*their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If "Get care..." checked) What type of healthcare visit did you/*they* have? (check all that apply)

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- ☐ Telehealth, virtual health, or email health consultation
 - ☐ Outpatient clinic or urgent care clinic visit
 - ☐ Emergency room or emergency department visit
 - ☐ Hospitalization
 - ☐ Other, describe:
-

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?

(This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1.)

- ☐ Yes ☐ No ☐ Don't know

Race/Ethnicity

(This is only asked once; once data are captured, questions will not display on future surveys)

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

Thanks for completing today's check-in.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

If you had/*there were* symptoms or health problems following your/*the* COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch tomorrow. (For Day 7 survey, "tomorrow" is replaced with "for your next check-in".)

Day 14 (2 weeks) post vaccination - Dose 1

Text message invitation:

Hi <NAME>. It's time for your weekly v-safe check-in. <URL for survey>

Hi <NAME>. It's time for the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:

Hi <NAME>. Please remember to do your weekly v-safe check-in. <URL for survey>

Hi <NAME>. Please remember to do the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

Hi <NAME>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your/*their* last check-in, have you/*they* experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe:

(if Yes) Did any of the/*their* symptoms or health conditions cause you/*them* to (check all that apply):

- ☐ Be unable to work or attend school?
- ☐ Be unable to do your/*their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If "Get care..." checked) What type of healthcare visit did you/*they* have? (check all that apply)

☐ Telehealth, virtual health, or email health consultation

- ☐ Outpatient clinic or urgent care clinic visit
 - ☐ Emergency room or emergency department visit
 - ☐ Hospitalization
 - ☐ Other, describe:
-

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐ No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?

(This is only asked once for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)

☐ Yes ☐ No ☐ Don't know

Race/Ethnicity

(This is only asked once; once data are captured, questions will not display on future surveys)

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

Thanks for completing today's check-in.

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Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).
We'll be in touch next week.

Alternate onscreen completion message for Pfizer and Novavax recipients:

Thanks for completing today's check-in.
Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.
You'll need to get your 2nd COVID-19 vaccine next week./*The 2nd COVID-19 vaccine will be needed next week*. Please remember to make an appointment if you have not done so already!
(Alternate language if ≥ 18 days replaces "next week" with "shortly")
After you/*they* receive your/*their* 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.
If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).
We'll be in touch for your/*the* next check-in.

Day 21 (3 weeks) post vaccination - Dose 1

Text message invitation:

Hi <NAME>. It's time for your weekly v-safe check-in. <URL for survey>

Hi <NAME>. It's time for the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:

Hi <NAME>. Please remember to do your weekly v-safe check-in. <URL for survey>

Hi <NAME>. Please remember to do the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

For Pfizer/Novavax recipients:

Hi <name>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

Did you/they get your/their 2nd COVID-19 vaccination?

☐ Yes ☐ No

(If YES) Thank you.

(Survey will end and will be directed to enter Dose 2 information:)

Thank you for letting us know that you/they received your/their 2nd COVID-19 vaccine.

Please click the View My Account button below to view your/their account and register your/their 2nd COVID-19 vaccine.

For Moderna/AstraZeneca/Janssen-Johnson&Johnson/Pfizer/Novavax recipients who did not get dose 2:

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your/their last check in, have you/they experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(If Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you/them to (check all that apply):

☐ Be unable to work or attend school?

- ☐ Be unable to do your/*their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional
- ☐ None of the above

(If “Get care...” checked) What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
 - ☐ Outpatient clinic or urgent care clinic visit
 - ☐ Emergency room or emergency department visit
 - ☐ Hospitalization
 - ☐ Other, describe:
-

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐ No

(If Yes) When were you/*they* diagnosed? _____ (mm/dd/yyyy)

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?

(This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)

☐ Yes ☐ No ☐ Don't know

Since your/*their* last COVID-19 vaccination, have you/*they* had a home or laboratory pregnancy test that was positive? *(Asked if participant answered no to above pregnancy question in this or previous survey)*

☐ Yes
☐ No

Race/Ethnicity

(This is only asked once; once data are captured, questions will not display on future surveys)

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

For Janssen/Johnson & Johnson recipients:

Thanks for completing today's check-in.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch next week.

For Moderna/AstraZeneca:

Thanks for completing today's check-in.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

You'll need to get your 2nd COVID-19 vaccine next week./*The 2nd COVID-19 vaccine is due next week.* Please remember to make an appointment if you have not done so already! (Alternate language if ≥ 25 days replaces “next week” with “shortly”)

After you/*they* receive your/*their* 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.

If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch for your/*their* next check-in.

For Pfizer/Novavax recipients who did not receive dose 2:

Thanks for completing today's check-in.

Depending on your/*the* answers, CDC may call you to check on you/*may call*.

It is time to get your/*the* 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!

After you/*they* receive your/*their* 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.

If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch for your/*their* next check-in.

Day 28 (4 weeks) post vaccination - Dose 1

Text message invitation:

Hi <NAME>. It's time for your weekly v-safe check-in. <URL for survey>

Hi <NAME>. It's time for the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:

Hi <NAME>. Please remember to do your weekly v-safe check-in. <URL for survey>

Hi <NAME>. Please remember to do the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

For all Moderna/AstraZeneca/Pfizer/Novavax recipients who did not previously report Dose 2:

Hi <NAME>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

Did you/they get your/their 2nd COVID-19 vaccination?

☐ Yes ☐ No

(If YES) Thank you.

Survey will end and will be directed to enter Dose 2 information.

Thank you for letting us know that you/they received your/their 2nd COVID-19 vaccine.
Please click the View My Account button below to view your/their account and register your/their 2nd COVID-19 vaccine.

For Janssen/Johnson & Johnson and all 2 dose vaccine recipients who report 'No' above

Hi <name>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your/their last check-in, have you/they experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(If Yes) Please describe the symptoms or health conditions:

(if Yes) Did any of these symptoms or health conditions cause you/*them* to (check all that apply):

- ☐ Be unable to work or attend school?
- ☐ Be unable to do your/*their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If “Get care...” checked) What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
 - ☐ Outpatient clinic or urgent care clinic visit
 - ☐ Emergency room or emergency department visit
 - ☐ Hospitalization
 - ☐ Other, describe:
-

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐ No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?

(This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)

☐ Yes ☐ No ☐ Don't know

Race/Ethnicity

(This is only asked once; once data are captured, questions will not display on future surveys)

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* racial group(s)? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

For Janssen/Johnson & Johnson recipients:

Thanks for completing today's check-in.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch next week.

For Pfizer/Novavax/Moderna/AstraZeneca recipients who did not receive dose 2:

Thanks for completing today's check-in.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

It is time to get your/*the* 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!

After you/*they* receive your/*their* 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.

If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch for your next check-in.

Day 35 (5 weeks) post vaccination - Dose 1

Text message invitation:

Hi <NAME>. It's time for your weekly v-safe check-in. <URL for survey>

Hi <NAME>. It's time for the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:

Hi <NAME>. Please remember to do your weekly v-safe check-in. (link to personalized survey)

Hi <NAME>. Please remember to do the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

For all Moderna/AstraZeneca/Pfizer/Novavax who did not previously report receipt of Dose 2:

Hi <NAME>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

Did you/they get your/their 2nd COVID-19 vaccination?

☐ Yes ☐ No

(If YES) Thank you.

Survey will end and will be directed to enter Dose 2 information.

Thank you for letting us know that you/they received your/their 2nd COVID-19 vaccine. Please click the View My Account button below to view your/their account and register your/their 2nd COVID-19 vaccine.

For Janssen/Johnson & Johnson and all 2 dose recipients who report 'No' above

Hi <NAME>.

Hi there.

Let's start today's health check-in .

Let's start today's health check-in for <DEPENDENT NAME>.

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your/their last check-in, have you/they experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you/*them* to (check all that apply):

- ☐ Be unable to work or attend school?
- ☐ Be unable to do your/*their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If “Get care...” checked) What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
 - ☐ Outpatient clinic or urgent care clinic visit
 - ☐ Emergency room or emergency department visit
 - ☐ Hospitalization
 - ☐ Other, describe:
-

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

- ☐ Yes ☐ No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?

(This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)

- ☐ Yes ☐ No ☐ Don't know

Race/Ethnicity

(This is only asked once; once data are captured, questions will not display on future surveys)

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

For Janssen/Johnson & Johnson recipients:

Thanks for completing today's check-in.

Depending on your/*the* answers, someone from CDC may call you to check on you/*may call*.

If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch next week.

For Pfizer/Novavax/Moderna/AstraZeneca recipients who did not receive dose 2:

Thanks for completing today's check-in.

Your contributions are helping CDC monitor the safety of COVID-19 vaccines.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

It is time to get your/*the* 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!

After you/*they* receive your/*their* 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.

If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch for your next check-in.

Day 42 (6 weeks) post vaccination - Dose 1

Text message invitation:

Hi <NAME>. It's time for your 6-week v-safe check-in. <URL for survey>

Hi <NAME>. It's time for your 6-week v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:

Hi <NAME>. Please remember to do your 6-week v-safe check-in. <URL for survey>

Hi <NAME>. Please remember to do the 6-week v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

For all Moderna/AstraZeneca/Pfizer/Novavax who did not previously report receipt of Dose 2:

Hi <name>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

Did you/they get your/their 2nd COVID-19 vaccination?

☐ Yes ☐ No

(If YES) Thank you.

Survey will end and will be directed to enter Dose 2 information

Thank you for letting us know that you/they received your/their 2nd COVID-19 vaccine.

Please click the View My Account button below to view your/their account and register your/their 2nd COVID-19 vaccine.

For Janssen/Johnson & Johnson and all 2 dose recipients who report 'No' above

Hi <name>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your/their last check-in, have you/they experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you/*them* to (check all that apply):

- ☐ Be unable to work or attend school?
- ☐ Be unable to do your/*their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If “Get care...” checked) What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit
- ☐ Hospitalization
- ☐ Other, describe:

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

- ☐ Yes ☐ No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

How would you describe your/*their* current state of health?

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

How is your/*their* health now compared to your/*their* health before your/*their* last COVID-19 vaccination?

- ☐ Better
- ☐ About the same
- ☐ Worse

(If Worse) Do you believe your/*their* health problems might be related to your/*their* COVID-19 vaccination?

- ☐ Yes

☐ No

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?

(This is only asked for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)

☐ Yes ☐ No ☐ Don't know

Since your/*their* last COVID-19 vaccination, have you/*they* had a home or laboratory pregnancy test that was positive?*(Asked if participant answered no to above pregnancy question in this or previous survey)*

☐ Yes

☐ No

Race/Ethnicity

(This is only asked once; once data are captured, questions will not display on future surveys)

What is your/*their* ethnic group?

☐ Hispanic or Latino

☐ Not Hispanic or Latino

☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

☐ American Indian or Alaska Native

☐ Asian

☐ Black or African American

☐ Native Hawaiian or other Pacific Islander

☐ White

☐ Other

☐ Unknown or prefer not to say

Onscreen completion thank you message:

For Janssen/Johnson & Johnson recipients:

Thanks for completing today's check-in.

Your contributions are helping CDC monitor the safety of COVID-19 vaccines.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

Take care and stay safe.

We'll be in touch in a few months.

For Pfizer/Novavax/Moderna/AstraZeneca recipients who did not receive dose 2:

Thanks for completing today's check-in.

Your contributions are helping CDC monitor the safety of COVID-19 vaccines.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

It is time to get your/*the* 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!

After you/*they* receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your/*their* vaccination information.

If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

Take care and stay safe. We'll be in touch in a few months.

Day 0 – Dose 2

Text message invitation:

Hi <NAME>. It's time for your first v-safe check-in. <URL for survey>

Hi <NAME>. *It's time for the first v-safe check-in for <DEPENDENT NAME>. <URL for survey>*

Survey:

Hi <NAME>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Fever check

Since your/their second COVID-19 vaccination, have you/they had a fever or felt feverish?

☐ No ☐ Yes

(If Yes) Do you know your/their highest temperature reading from today?

- ☐ Yes- in degrees Fahrenheit
- ☐ Yes- in degrees Celsius
- ☐ No- don't remember the reading
- ☐ No- didn't take my/their temperature

Enter your/their highest temperature reading from today (degrees Fahrenheit)

Enter your/their highest temperature reading from today (degrees Celsius)

Symptom check

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limit of your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

Have you/they had any of these symptoms where you/they got the shot (injection site)?

Select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

How would you rate your/their symptoms:

| | | | |
|-----------------------|-------------------------------|-----------------------------------|---------------------------------|
| (If checked Pain) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Redness) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Swelling) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Itching) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |

Have you/*they* experienced any of these symptoms today?

Select all that apply.

- ☐ Chills
- ☐ Headache
- ☐ Joint pain
- ☐ Muscle or body aches
- ☐ Fatigue or tiredness
- ☐ Nausea
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Abdominal pain
- ☐ Rash, not including the immediate area around the injection site
- ☐ None

Any other symptoms or health conditions you want to report _____

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms cause some limitation of your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

How would you rate your/*their* symptoms:

- (If checked Chills) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Headache) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Joint pain) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Muscle or body aches) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Fatigue or tiredness) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Nausea) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Vomiting) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Diarrhea) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Abdominal pain) ☐ Mild ☐ Moderate ☐ Severe
- (If checked Rash, not including the immediate area around the injection site) ☐ Mild
☐ Moderate ☐ Severe

Health impact

Did any of the/*their* symptoms or health conditions you reported TODAY cause you/*them* to
(Select all that apply):

- ☐ Be unable to work to attend school?
- ☐ Be unable to do your/*their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If “Get care...” checked) What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
 - ☐ Outpatient clinic or urgent care clinic visit
 - ☐ Emergency room or emergency department visit
 - ☐ Hospitalization
 - ☐ Other, describe:
-

Were you/*they* pregnant at the time of your/*their* second COVID-19 vaccination? (*This is only asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2*)

☐ Yes ☐ No ☐ Don't know

Race/Ethnicity

(*This is only asked once; once data are captured, questions will not display on future surveys*)

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

Thanks for completing today's check-in.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

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If you had/*there were* symptoms or health problems following your/*the* COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#). We'll be in touch tomorrow.

Days 1-7 post vaccination – Dose 2

Text message invitation:

Hi <NAME>. It's time for your daily v-safe check-in. <URL for survey>

Hi <NAME>. It's time for the daily v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder (day 7 only):

Hi <NAME>. Please remember to do your daily v-safe check-in. <URL for survey>

Hi <NAME>. Please remember to do the daily v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

Hi <NAME>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Fever check

Have you/they had a fever or felt feverish TODAY?

☐ No ☐ Yes

(If Yes) Do you know your/their highest temperature reading from today?

- ☐ Yes- in degrees Fahrenheit
- ☐ Yes- in degrees Celsius
- ☐ No- don't remember the reading
- ☐ No- didn't take my/their temperature

Enter your/their highest temperature reading from today (degrees Fahrenheit)

Enter your/their highest temperature reading from today (degrees Celsius)

Symptom check

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limit your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

Have you/they had any of these symptoms where you/they got the shot (injection site)?

Check all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

How would you rate your/their symptoms:

| | | | |
|-----------------------|-------------------------------|-----------------------------------|---------------------------------|
| (If checked Pain) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Redness) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Swelling) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Itching) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |

Have you/*they* experienced any of these symptoms today?

Select all that apply:

- ☐ Chills
- ☐ Headache
- ☐ Joint pain
- ☐ Muscle or body aches
- ☐ Fatigue or tiredness
- ☐ Nausea
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Abdominal pain
- ☐ Rash, not including the immediate area around the injection site
- ☐ None

Any other symptoms or health conditions you want to report _____

Symptoms:

Symptoms can be classified as:

Mild = you notice symptoms, but they aren't a problem

Moderate = symptoms that limit your normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

How would you rate your/*their* symptoms:

| | | | |
|---|-------------------------------|-----------------------------------|---------------------------------|
| (If checked Chills) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Headache) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Joint pain) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Muscle or body aches) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Fatigue or tiredness) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Nausea) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Vomiting) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Diarrhea) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Abdominal pain) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |
| (If checked Rash, not including the immediate area around the injection site) | <input type="checkbox"/> Mild | <input type="checkbox"/> Moderate | <input type="checkbox"/> Severe |

Health impact

Did any of the/*their* symptoms or health conditions you reported today cause you/*them* to (Select all that apply):

- ☐ Be unable to work or attend school?
- ☐ Be unable to do your/*their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?

☐ None of the above

(If “Get care...” checked) What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
 - ☐ Outpatient clinic or urgent care clinic visit
 - ☐ Emergency room or emergency department visit
 - ☐ Hospitalization
 - ☐ Other, describe:
-

Were you/*they* pregnant at the time of your/*their* second COVID-19 vaccination? (*This is only asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2*)

☐ Yes ☐ No ☐ Don't know

Race/Ethnicity

(*This is only asked once; once data are captured, questions will not display on future surveys*)

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

Thanks for completing today's check-in.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

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If you had/*there were* symptoms or health problems following your/*the* COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch tomorrow. (For Day 7 survey, "tomorrow" is replaced with "for your next check-in".

Days 14, 21, 28, 35 (2, 3, 4, 5 weeks) post vaccination – Dose 2

Text message invitation:

Hi <NAME>. It's time for your weekly v-safe check-in. <URL for survey>

Hi <NAME>. It's time for the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:

Hi <NAME>. Please remember to do your weekly v-safe check-in. <URL for survey>

Hi <NAME>. Please remember to do the weekly v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

Hi <NAME>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your/*their* last check-in, have you/*they* experienced any new symptoms or worsening health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions:

(if Yes) "Did any of these symptoms or health conditions cause you/*them* to (check all that apply):"

- ☐ Be unable to work or attend school?
- ☐ Be unable to do your/*their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If "Get care..." checked) "What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit

- ☐ Hospitalization
 - ☐ Other, describe:
-

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐ No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

Were you/*they* pregnant at the time of your/*their* second COVID-19 vaccination? (*This is only asked for the initial survey taken for Dose 2; if yes then no more pregnancy questions asked for Dose 2*)

☐ Yes ☐ No ☐ Don't know

Since your last COVID-19 vaccination, have you/*they* had a home or laboratory pregnancy test that was positive? (*Asked at Day 21 if participant answered no to above pregnancy question in this or previous survey*)

☐ Yes
☐ No

Race/Ethnicity

(*This is only asked once; once data are captured, questions will not display on future surveys*)

What is your/*their* ethnic group?

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

Thanks for completing today's check-in.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

We'll be in touch next week.

Day 42 (6 weeks) post vaccination – Dose 2

Text message invitation:

Hi <NAME>. It's time for your 6 week v-safe check-in. <URL for survey>

Hi <NAME>. It's time for your 6-week v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:

Hi <NAME>. Please remember to do your weekly v-safe check-in. <URL for survey>

Hi <NAME>. Please remember to do the 6-week v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

Hi <NAME>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since your/*their* last check-in, have you/*they* experienced any new or worsening symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) “Did any of these symptoms or health conditions cause you/*them* to (check all that apply):

- ☐ Be unable to work or attend school?
- ☐ Be unable to do your/*their* normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If “Get care...” checked) What type of healthcare visit did you/*they* have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit

- ☐ Emergency room or emergency department visit
 - ☐ Hospitalization
 - ☐ Other, describe:
-

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

- ☐ Yes ☐ No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

How would you describe your/*their* current state of health?

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor

How is your/*their* health now compared to your/*their* health before your/*their* last COVID-19 vaccination?

- ☐ Better
- ☐ About the same
- ☐ Worse

(If Worse) Do you believe your/*their* health problems might be related to your/*their* COVID-19 vaccination?

- ☐ Yes
- ☐ No

Were you/*they* pregnant at the time of your/*their* COVID-19 vaccination?

(This is only asked for the initial survey taken for Dose 2; if yes, then no more pregnancy questions asked for Dose 2)

- ☐ Yes ☐ No ☐ Don't know

Since your/*their* last COVID-19 vaccination, have you/*they* had a home or laboratory pregnancy test that was positive?

(Asked if participant answered no to above pregnancy question in this or previous survey)

- ☐ Yes
- ☐ No

Race/Ethnicity

(This is only asked once; once data are captured, questions will not display on future surveys)

What is your/*their* ethnic group?

- ☐ Hispanic or Latino

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- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

Thanks for completing today's check-in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.

Depending on your/*the* answers, someone from CDC may call to check on you/*may call*.

If you had/*there were* symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

Take care and stay safe. We'll be in touch in a few months.

3, 6, and 12 month post vaccination – Dose 1 or Dose 2

Text message invitation:

Hi <NAME>. We hope you are doing well! It's time for a v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Text message reminder:

Hi <NAME>. Please remember to do your v-safe check-in. <URL for survey>
Hi <NAME>. Please remember to do the v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey

Hi <NAME>.

Hi there.

Let's start today's health check-in.

Let's start today's health check-in for <DEPENDENT NAME>.

How are you/they feeling today? 😊

☐ Good ☐ Fair ☐ Poor

Since we last contacted you, have you/they experienced any new symptoms or health conditions?

☐ Yes ☐ No

(if Yes) Please describe the symptoms or health conditions.

(if Yes) Did any of these symptoms or health conditions cause you/they to (check all that apply):

- ☐ Be unable to work or attend school?
- ☐ Be unable to do your/their normal daily activities?
- ☐ Get care from a doctor or other healthcare professional?
- ☐ None of the above

(If "Get care..." checked) What type of healthcare visit did you/they have? (check all that apply)

- ☐ Telehealth, virtual health, or email health consultation
- ☐ Outpatient clinic or urgent care clinic visit
- ☐ Emergency room or emergency department visit

☐ Hospitalization

☐ Other, describe:

Since your/*their* last check-in, did you/*they* have a positive COVID-19 test or were you/*they* told by a health care provider that you/*they* had COVID-19?

☐ Yes ☐ No

(if Yes) When were you/*they* diagnosed? _____(mm/dd/yyyy)_

Since your/*their* last check-in, have you/*they* had a home or laboratory pregnancy test that was positive?

☐ Yes

☐ No

How would you describe your/*their* current state of health?

☐ Excellent

☐ Good

☐ Fair

☐ Poor

How is your/*their* health now compared to your/*their* health before your/*their* last COVID-19 vaccination?

☐ Better

☐ About the same

☐ Worse

(If Worse) Do you believe your/*their* health problems might be related to your/*their* COVID-19 vaccination?

☐ Yes

☐ No

Since your/*their* last COVID-19 vaccination, have you/*they* had a home or laboratory pregnancy test that was positive? (*Asked if participant answered no to above pregnancy question in this or previous survey*)

☐ Yes

☐ No

Race/Ethnicity

(*This is only asked once; once data are captured, questions will not display on future surveys*)

What is your/*their* ethnic group?

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- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown or prefer not to say

What is your/*their* race? (select one or more)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Other
- ☐ Unknown or prefer not to say

Onscreen completion thank you message:

3/6 Month:

Thanks for completing today's check in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.

Depending on your answers, someone from CDC may call to check on you/*may call*.

If you/*they* had symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#).

Take care and stay safe. We'll be in touch in a few months.

12 Month:

Congratulations! You have completed your/*the* final v-safe check-in.

Depending on your answers, someone from CDC may call to check on you/*may call*.

If you/*they* had symptoms or health problems following COVID-19 vaccination that concern you, please contact your/*a* healthcare provider. You can also report your/*the* experience to the Vaccine Adverse Event Reporting System (VAERS).

Thank you for participating in v-safe! Your contributions are helping CDC monitor the safety of COVID-19 vaccines.

Take care and stay safe.

Attachment 2: Adverse Events of Special Interest

| Prespecified Medical Conditions |
|--|
| Acute myocardial infarction |
| Anaphylaxis |
| Coagulopathy |
| COVID-19 Disease |
| Death* |
| Guillain-Barré syndrome |
| Kawasaki disease |
| Multisystem Inflammatory Syndrome in children ¹ |
| Multisystem Inflammatory Syndrome in adults ² |
| Myocarditis/Pericarditis |
| Narcolepsy/Cataplexy |
| Pregnancy and Prespecified Conditions |
| Seizures/Convulsions |
| Stroke |
| Transverse Myelitis |

* Capture of deaths through v-safe will be limited.