

V-safe active surveillance for COVID-19 vaccine safety

Version 6
October 21, 2022

Protocol Change History

Version	Date	Change
1	Dec 8, 2020	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
4	Mar 10, 2022	Corrected Version 1 date in change history from Dec 8, 2021 to Dec 8, 2020 Modified protocol language and added new surveys to reflect revised daily surveys to be used for non-verbal children Revised language to include capture of data for vaccines co-administered with COVID-19 vaccine Revised language to reflect capture of data for additional doses beyond primary series, prepare for additional vaccine manufacturers, and reflect duration of program Revised language to further describe analyses conducted in v-safe
5	Apr 12, 2022	Modified protocol language to add section about v-safe program evaluation Added Attachments 4-6 for the three evaluation activities

6	October 21, 2022	Modified protocol language to add details about a public use dataset in the data management plan
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Note: protocol updates include revisions as needed to reflect updates to the v-safe system; sections (such as Background and Significance) are not updated to reflect current state of pandemic response.

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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 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 implemented 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, including primary series and booster doses.
- 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 commenced when COVID-19 vaccines were authorized for use and became available to the U.S. population on December 14, 2020. 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 about their COVID-19 vaccines received to date (or that of their dependent), including the vaccine manufacturer(s) and the vaccination date(s). The participant will also be asked if any other vaccines were administered at the time of COVID-19 vaccination and, if there were, to specify the type of vaccine(s). 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 vaccine(s), 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 (daily surveys for participants ages 3 years and over, weekly and monthly surveys for all participants) and Attachment 2 (daily surveys for non-verbal participants age <3 years).

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 other dose of COVID-19 vaccine is received
 - a. If participant receives another COVID-19 vaccine dose during the post-vaccination follow-up period, the process will reset to day 0 for the most recent dose and continue through steps 1-3 above based on time since the most recent dose.
4. At 3, 6, and 12 months post-vaccination following most recent dose vaccine or following first dose if no other dose is received
 - a. If participant receives another COVID-19 vaccine dose during the post-vaccination follow-up period, the process will reset to day 0 for the most recent dose and continue through steps 1-4 based on time since the most recent dose

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 medically-attended health impact 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])
- Days since (allows identification of number of days since last dose)
- Vaccine manufacturer

- Dose number
- Reported date
- Preferred language
- Time zone
- Pregnancy indicator
- Source for medically-attended care

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. A small number of select employees of the contractor 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. The VAERS call center staff will provide a cumulative dataset to CDC on a weekly basis containing information on completed call outreach and allowing CDC staff to link VAERS reports completed during outreach with v-safe participant records.

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 secure network locations with restricted access on CDC computers. The v-safe team at CDC will be primarily responsible for data management activities, including data extraction, documentation, archival of a final data set, and a public use 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 data set with deidentified individual-level data will be created and posted twice a year to data.cdc.gov or through Freedom of Information Act (FOIA) requests. Data shared externally will go through a systematic process to remove PII and be cleared through the relevant clearance processes.

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.

Analyses for specific cohorts, as defined by age, vaccine manufacturer, dose, or special

population status (for example, pregnant persons) will be executed as needed and/or requested by pandemic response leadership and advisory committees.

For v-safe participants who have a VAERS report submitted through the VAERS call center, additional analyses will be conducted by VAERS, using the VAERS Standard Operating Procedures for COVID (8). 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 3). 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 (9).

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 2-3 years 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 is 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. 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 throughout 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.

v-safe Program Evaluation

To better understand factors related to participation in v-safe, a multi-component evaluation strategy has been developed. This includes surveys and cognitive interviews to address: (1) Knowledge, attitudes, and perceptions of COVID-19 vaccine recipients and user testing of the v-safe registration process; (2) Promotion efforts and barriers to promotion of v-safe among COVID-19 vaccine providers, and (3) Motivating factors for participating in v-safe among current v-safe participants. The evaluation activities are described in more detail below. The information gathered from these evaluation activities will inform future strategies to improve v-safe promotion and participation.

1. Knowledge, Attitudes, & Perceptions (KAP) and user testing of v-safe registration process

The purpose of this activity is to understand knowledge, attitudes, and perceptions (KAP) and usability of the revised v-safe landing page and registration process. Cognitive individual interviews lasting 30-45 minutes each among a total of 30 COVID-19 vaccine recipients and parents of children who have received or intend to receive COVID-19 vaccine will be conducted by user insight researchers from Tanaq Government Services LLC (Tanaq) using a discussion

guide approved by CDC (see **Attachment 4**). Participants will be 18 years of age or older, English speaker, and own a smartphone. During the interview, participants will be asked open-ended questions about their knowledge, attitudes, and perceptions of v-safe and be asked to complete registration of v-safe on their smartphone using dummy data (fake names, birth dates, and mock-COVID-19 vaccination dates). Researchers will ask follow-up questions related to the v-safe registration process so that future modifications to the v-safe registration platform can address particular areas of difficulty for registrants, if needed.

KAP interview data will be analyzed using category-based thematic analysis techniques and frequencies of responses to the user testing survey data will be reported. The data will be shared with CDC via an interim and final report. No PII will be collected. User testing will occur through the v-safe user testing environment where no PII will be collected as participants will enter dummy data (fake names, birth dates, and vaccination data) in order to test the revised v-safe registration page. Tanaq will analyze both quantitative and qualitative data and share results with CDC.

2. Promotion efforts/barriers to promotion of v-safe

The purpose of this evaluation activity is to assess promotional efforts for and barriers to promotion of v-safe among a convenience sample of U.S. healthcare providers, pharmacists, and health department staff. CDC will share an email including a link for an online REDCap survey in English that will be sent to CDC partner groups, including AMA, AAP, AAFP, ANA, NAPNAP, CDC COVID-19 vaccine state awardees, and CDC Pharmacy Partner groups. These partner groups will share this information, which will include the REDCap survey link, to their membership for voluntary participation. The survey will be open for two weeks with no reminders. Participants will be 18 years of age or older. See **Attachment 5** for full surveys. Data will be collected and housed in the CDC REDCap Anonymous/Survey Environment (<https://airc.cdc.gov>). No PII will be collected, and all responses will be anonymous. Data access will be limited to authorized personnel. Survey responses will be analyzed and described by CDC staff to inform CDC on promotional practices and barriers related to v-safe promotion so that future v-safe promotional interventions can be implemented.

3. *v-safe participant surveys on motivators for registration*

The purpose of this evaluation activity is to assess current v-safe participant motivations for signing up for v-safe. A survey link distributed by Oracle from the v-safe system via text will be sent to a sample of current v-safe participants 18 years of age or older who registered themselves or their dependents during March 1 – April 1, 2021, May 11 – June 12, 2021 (vaccine recommendation for 12-15-year-olds), and Nov 2 – Dec 1, 2021 (vaccine recommendation for 5-11-year-olds). The link will be open for 6 days, and one reminder text will be sent 4 days after the initial text. See **Attachment 6** for full survey.

As with the standard v-safe survey data, these data will be collected, managed, and housed on a secure server by Oracle. See the *Data collection, quality, and management section in this protocol for full details.* Survey responses will be analyzed and described to inform CDC on motivators for v-safe participation to better cater future v-safe promotional interventions for improved uptake.

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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. See Attachment 2 for non-verbal surveys on days 0-7 for children age <3 years.

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) Mild Moderate Severe

(If checked Redness) Mild Moderate Severe

- (If checked Swelling) Mild Moderate Severe
(If checked Itching) Mild Moderate 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 that limit 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 or attend school?
- Be unable to do your/*their* normal daily activities?
- Get care from a doctor or other healthcare professional?

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- 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*.

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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 the experience to the [Vaccine Adverse Event Reporting System \(VAERS\)](#). 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, Novavax, and Sanofi 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/Sanofi 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/Sanofi 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?

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- 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)

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- 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/Sanofi 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/Sanofi 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/Sanofi 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/Sanofi 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/Sanofi 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/Sanofi 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?

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- 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 \(VAERS\)](#).

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Take care and stay safe.

We'll be in touch in a few months.

For Pfizer/Novavax/Moderna/AstraZeneca/Sanofi 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 and additional/booster doses

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 and additional/booster doses

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) Mild Moderate Severe
(If checked Redness) Mild Moderate Severe
(If checked Swelling) Mild Moderate Severe
(If checked Itching) Mild Moderate 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?

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- 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:

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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”).

Days 14, 21, 28, 35 (2, 3, 4, 5 weeks) post vaccination – Dose 2 and additional/booster doses

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 and additional/booster doses

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
- 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 or additional/booster doses

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

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- 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?

- 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

V-safe health check-in non-verbal children surveys

Note: language is for parents/guardians to complete for children younger than 3 years

Day 0 - Dose 1

Text message invitation:

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

Survey:

Hi there.

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

How are they feeling today? 😊

Good Fair Poor

Fever check

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

Yes No

(If Yes) Do you know 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 their highest temperature reading from today (degrees Fahrenheit)

Enter 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 their normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

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

select all that apply: Pain Redness Swelling/hardness Groin or underarm swelling/tenderness None

How would you rate their symptoms:

(If checked Pain) Mild (discomfort to touch) Moderate (may cry when limb moved) Severe (refuses to move limb)

(If checked Redness) Mild Moderate Severe

(If checked Swelling/hardness) Mild Moderate Severe

(If checked Groin or underarm swelling/tenderness) Mild Moderate
Severe

Have they experienced any of these symptoms today?

Select all that apply.

- Sleepiness
- Irritability/crying
- Loss of appetite
- Vomiting
- Diarrhea
- Rash, not including the immediate area around the injection site
- None

Any other symptoms or health conditions you want to report _____

How would you rate their symptoms:

(If checked Sleepiness) Mild (sleepier than usual) Moderate (not interested in surroundings or sleeps through meals) Severe (sleeps most of the time or difficult to wake)

(If checked Irritability/crying) Mild (lasts <1 hour or easily consolable)
Moderate (lasts 1-3 hours or requires increased attention) Severe (lasts >3 hours or inconsolable)

(If checked Loss of appetite) Mild (eats less than normal for 1-2 meals)
Moderate (missed 1-2 meals completely) Severe (missed >2 meals or refuses to eat)

(If checked Vomiting) Mild (1-2 episodes per day) Moderate (>2 episodes per day) Severe (got an IV for fluids)

(If checked Diarrhea and age <1 year) Mild (liquid stools, same number as normal)
 Moderate (liquid stools, increased number) Severe (liquid stools, got an IV for fluids)

(If checked Diarrhea and age 1-2 years) Mild (increase of 2-3 loose stools per day)
 Moderate (increase of 4-5 loose stools per day) Severe (increase of 6 or more loose stools per day or got an IV for fluids)

(If checked Rash, not including the immediate area around the injection site) Mild (covering <10% of body) Moderate (covering 10-30% of body) Severe (covering >30% of body)

Health impact

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

- Be unable to attend daycare/school?
- Be unable to do 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:
-

Race/Ethnicity

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

What is their ethnic group?

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

What is 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 *the* answers, someone from CDC may call.

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

We'll be in touch tomorrow.

Days 1-7 post vaccination – Dose 1

Text message invitation:

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 the daily v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

Hi there.

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

How are they feeling today? 😊

Good Fair Poor

Fever check

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

Yes No

(If Yes) Do you know 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 their highest temperature reading from today (degrees Fahrenheit)

Enter 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 their normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

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

select all that apply: Pain Redness Swelling/hardness Groin or underarm swelling/tenderness None

How would you rate their symptoms:

- (If checked Pain) Mild (discomfort to touch) Moderate (may cry when limb moved) Severe (refuses to move limb)
(If checked Redness) Mild Moderate Severe
(If checked Swelling/hardness) Mild Moderate Severe
(If checked Groin or underarm swelling/tenderness) Mild Moderate Severe

Have they experienced any of these symptoms today?

Select all that apply.

- Sleepiness
- Irritability/crying
- Loss of appetite
- Vomiting
- Diarrhea
- Rash, not including the immediate area around the injection site
- None

Any other symptoms or health conditions you want to report _____

How would you rate their symptoms:

- (If checked Sleepiness) Mild (sleepier than usual) Moderate (not interested in surroundings or sleeps through meals) Severe (sleeps most of the time or difficult to wake)
(If checked Irritability/crying) Mild (lasts <1 hour or easily consolable) Moderate (lasts 1-3 hours or requires increased attention) Severe (lasts >3 hours or inconsolable)
(If checked Loss of appetite) Mild (eats less than normal for 1-2 meals) Moderate (missed 1-2 meals completely) Severe (missed >2 meals or refuses to eat)
(If checked Vomiting) Mild (1-2 episodes per day) Moderate (>2 episodes per day) Severe (got an IV for fluids)
(If checked Diarrhea and age <1 year) Mild (liquid stools, same number as normal) Moderate (liquid stools, increased number) Severe (liquid stools, got an IV for fluids)
(If checked Diarrhea and age 1-2 years) Mild (increase of 2-3 loose stools per day) Moderate (increase of 4-5 loose stools per day) Severe (increase of 6 or more loose stools per day or got an IV for fluids)
(If checked Rash, not including the immediate area around the injection site) Mild (covering <10% of body) Moderate (covering 10-30% of body) Severe (covering >30% of body)

Health impact

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

- Be unable to attend daycare/school?

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- Be unable to do 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:
-

Race/Ethnicity

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

What is their ethnic group?

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

What is 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 the answers, someone from CDC may call.

If you there were symptoms or health problems following the COVID-19 vaccination that concern you, please contact a healthcare provider. You can also report 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 the next check-in".)

Day 0 – Dose 2 and additional/booster doses

Text message invitation:

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

Survey:

Hi there.

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

How are they feeling today? 😊

Good Fair Poor

Fever check

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

Yes No

(If Yes) Do you know 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 their highest temperature reading from today (degrees Fahrenheit)

Enter 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 their normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

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

select all that apply: Pain Redness Swelling/hardness Groin or underarm swelling/tenderness None

How would you rate their symptoms:

- (If checked Pain) Mild (discomfort to touch) Moderate (may cry when limb moved) Severe (refuses to move limb)
(If checked Redness) Mild Moderate Severe
(If checked Swelling/hardness) Mild Moderate Severe
(If checked Groin or underarm swelling/tenderness) Mild Moderate Severe

Have they experienced any of these symptoms today?

Select all that apply.

- Sleepiness
- Irritability/crying
- Loss of appetite
- Vomiting
- Diarrhea
- Rash, not including the immediate area around the injection site
- None

Any other symptoms or health conditions you want to report _____

How would you rate their symptoms:

- (If checked Sleepiness) Mild (sleepier than usual) Moderate (not interested in surroundings or sleeps through meals) Severe (sleeps most of the time or difficult to wake)
(If checked Irritability/crying) Mild (lasts <1 hour or easily consolable) Moderate (lasts 1-3 hours or requires increased attention) Severe (lasts >3 hours or inconsolable)
(If checked Loss of appetite) Mild (eats less than normal for 1-2 meals) Moderate (missed 1-2 meals completely) Severe (missed >2 meals or refuses to eat)
(If checked Vomiting) Mild (1-2 episodes per day) Moderate (>2 episodes per day) Severe (got an IV for fluids)
(If checked Diarrhea and age <1 year) Mild (liquid stools, same number as normal) Moderate (liquid stools, increased number) Severe (liquid stools, got an IV for fluids)
(If checked Diarrhea and age 1-2 years) Mild (increase of 2-3 loose stools per day) Moderate (increase of 4-5 loose stools per day) Severe (increase of 6 or more loose stools per day or got an IV for fluids)
(If checked Rash, not including the immediate area around the injection site) Mild (covering <10% of body) Moderate (covering 10-30% of body) Severe (covering >30% of body)

Health impact

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

- Be unable to attend daycare/school?

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- Be unable to do 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:
-

Race/Ethnicity

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

What is their ethnic group?

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

What is 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 the answers, someone from CDC may call.

If you there were symptoms or health problems following the COVID-19 vaccination that concern you, please contact a healthcare provider. You can also report 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 the next check-in".)

Days 1-7 post vaccination – Dose 2 and additional/booster doses

Text message invitation:

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 the daily v-safe check-in for <DEPENDENT NAME>. <URL for survey>

Survey:

Hi there.

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

How are they feeling today? 😊

Good Fair Poor

Fever check

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

Yes No

(If Yes) Do you know 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 their highest temperature reading from today (degrees Fahrenheit)

Enter 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 their normal daily activities

Severe = symptoms make normal daily activities difficult or impossible

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

select all that apply: Pain Redness Swelling/hardness Groin or underarm swelling/tenderness None

How would you rate their symptoms:

(If checked Pain) Mild (discomfort to touch) Moderate (may cry when limb moved) Severe (refuses to move limb)

(If checked Redness) Mild Moderate Severe

(If checked Swelling/hardness) Mild Moderate Severe

(If checked Groin or underarm swelling/tenderness) Mild Moderate Severe

Have they experienced any of these symptoms today?

Select all that apply.

- Sleepiness
- Irritability/crying
- Loss of appetite
- Vomiting
- Diarrhea
- Rash, not including the immediate area around the injection site
- None

Any other symptoms or health conditions you want to report _____

How would you rate their symptoms:

(If checked Sleepiness) Mild (sleepier than usual) Moderate (not interested in surroundings or sleeps through meals) Severe (sleeps most of the time or difficult to wake)

(If checked Irritability/crying) Mild (lasts <1 hour or easily consolable) Moderate (lasts 1-3 hours or requires increased attention) Severe (lasts >3 hours or inconsolable)

(If checked Loss of appetite) Mild (eats less than normal for 1-2 meals) Moderate (missed 1-2 meals completely) Severe (missed >2 meals or refuses to eat)

(If checked Vomiting) Mild (1-2 episodes per day) Moderate (>2 episodes per day) Severe (got an IV for fluids)

(If checked Diarrhea and age <1 year) Mild (liquid stools, same number as normal) Moderate (liquid stools, increased number) Severe (liquid stools, got an IV for fluids)

(If checked Diarrhea and age 1-2 years) Mild (increase of 2-3 loose stools per day) Moderate (increase of 4-5 loose stools per day) Severe (increase of 6 or more loose stools per day or got an IV for fluids)

(If checked Rash, not including the immediate area around the injection site) Mild (covering <10% of body) Moderate (covering 10-30% of body) Severe (covering >30% of body)

Health impact

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

- Be unable to attend daycare/school?
- Be unable to do 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:

Race/Ethnicity

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

What is their ethnic group?

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

What is 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 the answers, someone from CDC may call.

If you there were symptoms or health problems following the COVID-19 vaccination that concern you, please contact a healthcare provider. You can also report 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 the next check-in".)

Attachment 3

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.

Attachment 4

V-safe program evaluation: Knowledge, Attitudes, & Perceptions (KAP) and User Testing

Discussion Guide Outline

Introduction

Welcome and thank you for taking the time to join this conversation. My name is _____. I work for a private research company, and I'll be guiding our discussion today. We're interested in hearing your thoughts and opinions about the v-safe program, an after COVID-19 vaccination program created by the Centers for Disease Control and Prevention. We'll ask you to complete a few tasks and have a conversation about it. Our discussion should take no more than 60 minutes. Before we begin, I want to go over a couple of things:

- We invited you here today because we want to hear what *you* think and feel about v-safe. There are no right or wrong answers to any of the questions, and any thoughts or opinions you share are greatly valued and appreciated. Our whole purpose for being here is to hear what you think, so please feel comfortable sharing your point of view. You may represent what a lot of other people think.
- There may be times I ask you to clarify or talk more about what you just said. This is just to make sure I understood and accurately capture what you think, not because I'm challenging your point of view. We want to make sure you have the chance to share your ideas precisely.
- I didn't design or make anything that we will discuss today. So nothing you say will offend me or hurt my feelings. Please feel free to openly share your thoughts and give me your honest opinions.
- We appreciate the time you have taken out of your busy day to be here and want to be respectful of that, so I may interrupt you so that we stay on track.
- Your participation is voluntary, and you can choose to leave this interview at any time. If I ask any questions you don't want to answer, you don't have to answer them.
- There are some other people listening who are working with me on this and interested in hearing from you as well. Someone is helping me take notes so that I can fully focus on our conversation and be respectful of your time. At the end of the discussion, they might have a couple clarifying questions for us to make sure they captured everything we discussed today accurately.

We don't want to miss any of your comments, so I'd like to record our conversation. Only the research staff will have access to this recording and no personally identifiable information will be used in connection with the recording, so please speak freely and honestly. Do you agree to be recorded? **[Obtain verbal agreement]**

- Nothing you say during our conversation will be tied back to you. Your name and any identifying information will not be used in any of our reports, and all information from this discussion will be summarized anonymously.
- Lastly, I am not an expert on COVID vaccines. You may have questions that I cannot answer about the vaccine. At the end of this discussion, I will have additional information and resources available for you.

Do you have any questions before we begin?

Vaccine Status

1. [For parent participants] Please tell me about the ages of your children and if they are vaccinated against COVID-19 or not. [Identify which child the parent plans to have vaccinated in the next month.]
2. [For adult participants] Please tell me about your COVID-19 status. Have you received any COVID-19 vaccine shots? How many? [Identify which shot the person plans to receive in the next month or has recently received.]

Knowledge, Attitudes, Perceptions of v-safe

The participant is handed the v-safe information sheet.

1. Have you previously heard of v-safe?
2. After reading the information sheet, what are your first impressions about v-safe?
3. Is this something you would consider signing up for? Why or why not?
4. What do you think you or your family would get out of using v-safe (why is v-safe good for you?)
5. What, if any, concerns would you have about using v-safe?

Ask participant to pull out their smartphone and log into v-safe on their phone using the UAT URL included on the information sheet. Please tell the participant for confidentiality purposes, we will be providing you with a name, birthdate, and vaccination data to enter (for themselves and for the child/dependent they are registering). This information will be shared on the screen for ease of reference by the interviewer.

Once the participant is done, the following questions will be asked:

- 1) Tell us about your experience registering and verifying your account:
 - a. I had no problems
 - b. Confusing but I figured it out
 - c. I had to ask for help

Please explain why you chose this response (*open ended*)

- 2) When you got to the registration page, could you easily determine which option to choose?
 - a. Yes
 - b. No
 - i. If No, please explain (*open ended*)

- 3) Tell us your experience entering your demographic information
 - a. I had no problems
 - b. Confusing but I figured it out
 - c. I had to ask for help

Please explain why you chose this response (*open ended*)

- 4) Tell us your experience entering your vaccination information. We know that for some people, you will be registering for v-safe for a 2nd or booster dose. Was it easy for you to enter your first dose information?
- I had no problems
 - Confusing but I figured it out
 - I had to ask for help

Please explain why you chose this response (*open ended*)

- 5) If applicable, was it easy for you to enter your 2nd dose information
- I had no problems
 - Confusing but I figured it out
 - I had to ask for help

Please explain why you chose this response (*open ended*)

- 6) If applicable, was it easy for you to enter for booster dose information
- I had no problems
 - Confusing but I figured it out
 - I had to ask for help

Please explain why you chose this response (*open ended*)

- 7) Could anything be changed to make this process feel more trustworthy?
- 8) Please share any additional comments on the process of registering and entering your vaccination information.
- 9) Do you have any suggestions on how to increase awareness for others to enroll into v-safe after COVID-19 vaccination?

That's all the questions I have for you today. Is there anything else you'd like to share? If you have more questions about the COVID-19 vaccines, please visit the web site I shared in the chat.

Attachment 5

v-safe program evaluation: Promotion efforts/barriers to promotion of v-safe partner group surveys

A. Pharmacy group survey

Survey intro language:

CDC is conducting research on current promotional efforts and barriers for promotion of the v-safe After Vaccination Health Checker, an essential part of the safety monitoring efforts for COVID-19 vaccines. This survey is being led by CDC's Immunization Safety Office. The responses we collect from this survey will help us improve outreach efforts and future participation in v-safe. The survey should only take about 5-10 minutes. Your responses are completely anonymous. If you have any questions about the survey, please contact eocevent523@cdc.gov. We thank you for your participation!

Survey questions:

1. Are you a(n):
 - a. Pharmacist
 - b. Pharmacy-technician
 - c. MD
 - d. NP
 - e. RN
 - f. PA
 - g. Other <enter text> _____

2. For what age groups does your pharmacy offer COVID vaccine? Select all that apply.
 - i. Adults
 - ii. Teens
 - iii. Current recommended pediatric populations
 - iv. Will offer to younger age groups (under 5 years of age), once recommended

3. Are you aware of **v-safe: the after-vaccination health checker**?
 - a. Yes
 - b. No (skip to question 5)
 - 3a. (If "yes"), how did you first find out about v-safe?
 - i. Partner organization
 - ii. CDC
 - iii. Friend
 - iv. Internet
 - v. Health department
 - vi. Tribal organizations
 - vii. Patient/vaccine recipient asked about it during vaccination visit
 - viii. I found out about v-safe when I was vaccinated

ix. Other *<enter text>* _____

4. Is **v-safe** promoted through your pharmacy?

- a. Yes
- b. No

4a. *(If yes)*, How is v-safe promoted? Select all that apply.

- 1. I/we ask that vaccine administrators promote it verbally at the time of vaccination
- 2. Staff promote it during the observation period
- 3. We provide the CDC **v-safe** information sheet as part of the COVID-19 information packet at the vaccination visit
- 4. We provide the Emergency Use Authorization documentation to the patient at the vaccination visit, which already includes some information
- 5. We have included v-safe information in our own information packet at the vaccination visit
- 6. V-safe posters on walls
- 7. We send information about v-safe electronically
- 8. Other *<enter text>* _____

ii. *If yes to 7. “We send information about v-safe electronically”,* what do you send electronically to vaccine recipients?

- 1. **V-safe** registration URL: vsafe.cdc.gov
- 2. CDC’s **v-safe** webpage: www.cdc.gov/v-safe
- 3. CDC’s **v-safe** information sheet
- 4. Information sheet about **v-safe** created by our pharmacy
- 5. EUA documentation that mentions **v-safe**
- 6. Other *<enter text>* _____

c. *(If “yes” my pharmacy promotes v-safe)*, What additional materials from CDC would help you and your pharmacy promote **v-safe**? *<enter text>*

d. *(If “yes” my pharmacy promotes v-safe)*, What have you heard reported to you as barriers for vaccine recipients and/or parents/guardians of vaccine recipients to enroll into **v-safe**? Select all that apply.

- 1. Patients/parents of vaccine recipients do not read the information my pharmacy provides about **v-safe**
- 2. Patients/parents of vaccine recipients do not have time to respond to surveys
- 3. Patients/parents of vaccine recipients at my pharmacy do not have smartphones
- 4. Patients/parents of patients do not want to share personal information

5. Patients/parents of patients are concerned about sharing information with CDC (or government)
 6. It's not important
 7. It's difficult to use
 8. Answering surveys will take too much time
 9. Other *<enter text>* _____
- e. (If "no" my pharmacy does not promote v-safe), What are the barriers in your pharmacy to promote **v-safe**? Select all that apply.
1. **V-safe** is not actively promoted by a verbal recommendation to vaccine recipients/parents of vaccine recipients
 2. Not enough time to promote **v-safe** during the vaccination visit
 3. Not everyone in my pharmacy is aware of **v-safe**
 4. Our pharmacy chain does not allow for **v-safe** promotion
 5. We do not have the resources to print the **v-safe** information sheet
 6. We do not have the resources to print **v-safe** posters
 7. I have heard negative feedback about **v-safe**
 8. Other *<enter text>* _____
5. (If you are not aware of v-safe) Where do you receive information about CDC's COVID-19 vaccine safety programs? Select all that apply.
- a. My state health department
 - b. My pharmacy chain's headquarters/coordinators of the COVID-19 vaccination program
 - c. Professional groups, like AAP, AMA, etc.
 - d. CDC.gov
 - e. Other resources on the internet
 - f. Social media
 - g. Other *<enter text>* _____
6. Any other comments you want to tell us about **v-safe**: *<enter text>*

End of survey text: "Thank you for completing this valuable survey!"

B. Health Department survey

Survey intro text:

"CDC is conducting research on current promotional efforts and barriers for promotion of the v-safe After Vaccination Health Checker, an essential part of the safety monitoring efforts for COVID-19 vaccines. This survey is being led by CDC's Immunization Safety Office. The responses we collect from this survey will help us improve outreach efforts and future participation in v-safe. The survey should only take about 5-10 minutes. Your responses are

completely anonymous. If you have any questions about the survey, please contact eocevent523@cdc.gov. We thank you for your participation!”

Survey Questions:

1. Are you a(n):
 - a. MD
 - b. NP
 - c. RN
 - d. PA
 - e. Immunization Manager
 - f. Other _____

2. For what age groups does your health department offer COVID-19 vaccine?
 - i. Adults
 - ii. Teens
 - iii. Current recommended pediatric populations
 - iv. Will offer to younger age groups (under 5 years of age), once recommended

3. Describe the settings where your health departments offer COVID-19 vaccines? Select all that apply.
 - a. Health department clinic
 - b. School vaccination clinic for students and families
 - c. Faith-based vaccination clinic
 - d. Concerts
 - e. Sporting events
 - f. Special vaccination clinics
 - g. Other <enter text> _____

4. Are you aware of **v-safe: the after-vaccination health checker**?
 - a. Yes
 - b. No (skip to Question 6)
 - i. (If yes) How did you find out about v-safe?
 1. Partner organization
 2. Friend
 3. Internet
 4. Health department
 5. Tribal organizations
 6. Patient/vaccine recipient asked about it during vaccination visit
 7. I found out about v-safe when I was vaccinated
 8. Other <enter text> _____

5. Does your health department promote **v-safe** at COVID-19 vaccination clinic sites?

- a. Yes
- b. No
 - i. *(If yes)* How is v-safe promoted? Select all that apply.
 - 1. I/we ask that vaccine administrators promote **v-safe** verbally at the time of vaccination
 - 2. Staff promote **v-safe** during the observation period
 - 3. We provide the CDC **v-safe** information sheet as part of the COVID-19 information packet at the vaccination visit
 - 4. We provide the Emergency Use Authorization documentation to the patient at the vaccination visit, which already includes some **v-safe** information
 - 5. We have included our own **v-safe** information sheet in the information packet at the vaccination visit
 - 6. V-safe posters on walls
 - 7. We send information about v-safe electronically
 - a. *(If yes to send information electronically)* What do you send electronically to vaccine recipients?
 - i. **V-safe** registration URL: vsafe.cdc.gov
 - ii. CDC's **v-safe** webpage: www.cdc.gov/v-safe
 - iii. CDC's **v-safe** information sheet
 - iv. Information sheet about **v-safe** created by our office
 - v. EUA documentation that mentions **v-safe**
 - vi. Other <enter text> _____
 - ii. *(If yes v-safe is promoted)* What additional materials from CDC would help you and your practice promote **v-safe**? <enter text> _____
 - iii. *(If yes v-safe is promoted)* What have you heard reported to you as barriers for vaccine recipients and/or parents/guardians of vaccine recipients to enroll into **v-safe**? Select all that apply.
 - 10. Patients/parents of patients do not read the information my practice provides about **v-safe**
 - 11. Patients/parents of patients do not have time to respond to surveys
 - 12. Patients/parents of patients at my practice do not have smartphones
 - 13. Patients/parents of patients do not want to share personal information
 - 14. Patients/parents of patients are concerned about sharing information with CDC (or government)
 - 15. It's not important
 - 16. It's difficult to use
 - 17. Answering surveys will take too much time
 - 18. Other <enter text> _____

- iv. *(If no v-safe is not promoted)*, What are barriers for your health department/COVID-19 vaccination clinic sites to promote **v-safe**? Select all that apply.
 1. **V-safe** is not actively promoted by a verbal recommendation to vaccine recipients/parents of vaccine recipients
 2. Not enough time to promote **v-safe** in the clinic workflow
 3. Not everyone in my practice is aware of **v-safe**
 4. We do not have the resources to print the **v-safe** information sheet
 5. We do not have the resources to print **v-safe** posters
 6. I/we have heard negative feedback about **v-safe**
 7. Other <enter text> _____

6. *(If you are not aware of v-safe)* Where do you receive information about CDC's COVID-19 vaccine safety programs?
 - a. My state health department
 - b. Professional groups, like AAP, AMA, etc.
 - c. CDC.gov
 - d. Other resources on the internet
 - e. Social media
 - f. Other <enter text> _____

7. Any other comments you want to tell us about **v-safe**:

End of survey text: "Thank you for completing this valuable survey!"

C. Provider Survey

Survey intro language:

"CDC is conducting research on current promotional efforts and barriers for promotion of the v-safe After Vaccination Health Checker, an essential part of the safety monitoring efforts for COVID-19 vaccines. This survey is being led by CDC's Immunization Safety Office. The responses we collect from this survey will help us improve outreach efforts and future participation in v-safe. The survey should only take about 5-10 minutes. Your responses are completely anonymous. If you have any questions about the survey, please contact eocevent523@cdc.gov. We thank you for your participation!"

Survey questions:

1. Are you a(n):
 - a. MD
 - b. NP
 - c. RN
 - d. PA
 - e. Other _____

2. Does your practice offer COVID-19 vaccine?
 - a. If yes, to whom do you offer COVID vaccine (check all that apply)?
 - i. Adults
 - ii. Teens
 - iii. Current recommended pediatric populations
 - iv. Will offer to younger age groups (under 5 years of age), once recommended
 - b. If no, does your practice plan on offering COVID-19 vaccines?
 - i. Yes (*continue*)
 - ii. No (*stop*)
 - iii. Unsure (*continue*)

3. Describe the type of practice where you offer/will offer COVID-19 vaccines?
 - a. Family Medicine
 - b. Adult
 - c. Pediatrics
 - d. Urgent care
 - e. Specialist
 - f. Health department
 - g. Other _____

4. Are you aware of **v-safe: the after-vaccination health checker**?
 - a. Yes
 - b. No (skip to question 6)
 - i. (If **yes**) How did you first find out about v-safe?
 1. Partner organization
 2. CDC
 3. Friend
 4. Internet
 5. Health department
 6. Tribal organizations
 7. Patient/vaccine recipient asked about it during vaccination visit
 8. I found out v-safe when I was vaccinated
 9. Other _____

5. Is **v-safe** being promoted in your practice?
 - a. Yes
 - b. No
 - i. (*If yes*), How is v-safe promoted in your practice?
 1. I promote it verbally
 2. Vaccine administrators promote it verbally at time of vaccination
 3. Staff promote it during the observation period
 4. We provide the CDC **v-safe** information sheet as part of the COVID-19 information packet at the vaccination visit

5. We provide the Emergency Use Authorization COVID-19 vaccine documentation to the patient at the vaccination visit, which already includes **v-safe** information
 6. We have included **v-safe** information in our own information packet at the vaccination visit
 7. V-safe posters on walls
 8. We send information about **v-safe** electronically
 9. Other _____
- ii. *(If yes to 'We send information about v-safe electronically')* What do you send electronically to patients?
- a. **V-safe** registration URL: vsafe.cdc.gov
 - b. CDC's **v-safe** webpage: www.cdc.gov/v-safe
 - c. CDC's **v-safe** information sheet
 - d. Information sheet about **v-safe** created by our office
 - e. EUA documentation that mentions **v-safe**
 - f. Other _____
- iii. *(If yes to your practice promotes v-safe)* What additional materials from CDC would help you and your practice promote **v-safe**? <enter text>
- iv. *(If yes your practice promotes v-safe)*, What have you heard reported to you as barriers for vaccine recipients and/or parents/guardians of vaccine recipients to enroll into **v-safe**? Select all that apply.
19. Patients/parents of patients do not read the information my practice provides about **v-safe**
 20. Patients/parents of patients do not have time to respond to surveys
 21. Patients/parents of patients at my practice do not have smartphones
 22. Patients/parents of patients do not want to share personal information
 23. Patients/parents of patients are concerned about sharing information with CDC (or government)
 24. It's not important
 25. It's difficult to use
 26. Answering surveys will take too much time
 27. Other <enter text> _____
- v. *(If no, v-safe is not promoted in my practice)*, What do you think are the reasons why v-safe is not promoted in your practice?
1. Staff do not have time to actively promote **v-safe** by a verbal recommendation to vaccine recipients/parents of vaccine recipients
 2. Not everyone in my practice is aware of **v-safe**
 3. We do not have the resources to print the **v-safe** information sheet
 4. We do not have the resources to print **v-safe** posters
 5. I have heard negative feedback about **v-safe**

6. Other <enter text> _____

6. *(If you are not aware of v-safe)*, Where do you receive information about CDC's COVID-19 vaccine safety programs?

- a. My state health department
- b. Professional groups, like AAP, AMA, etc.
- c. CDC.gov
- d. Other resources on the internet
- e. Social media
- f. Other <enter text> _____

7. Any other comments you want to tell us about v-safe: <enter text>

End of survey text: "Thank you for completing this valuable survey!"

Attachment 6

v-safe Program Evaluation: v-safe participant survey on motivators for enrollment into v-safe

Text invite language:

“Hi _____, Thanks for your v-safe check-ins. We have a quick survey to get your thoughts about v-safe. Link to participate: ”

Main survey:

Intro text: “Hi _____, thanks for your interest in participating in this survey about v-safe. We would like to understand why you registered for v-safe.”

Questions

1. How did you first find out about v-safe? Select one.
 - a. Friend or family member
 - b. v-safe poster or information sheet
 - c. From my vaccine provider
 - i. (if c. ‘From my vaccine provider’ selected) How did you find out from your vaccine provider?
 1. Verbal recommendation
 2. Mentioned in a text message, email, or on their website
 3. Other
 - d. CDC’s website
 - e. State/city/county health department website
 - f. Social media
 - i. (if f. ‘Social media’ selected) On which social media platform did you first find out about v-safe?
 1. Facebook
 2. Instagram
 3. Twitter
 4. LinkedIn
 5. YouTube
 6. TikTok
 7. Other (open-ended text box)
 - g. Other (open-ended text box)
2. (If signed up a dependent) What type of dependent did you sign up for v-safe? Select all that apply.
 - a. Child under 18 years old.
 - b. Family member or friend that is elderly.
 - c. Family member or friend with a disability.
 - d. Family member or friend that does not own/have regular access to a cell phone.
 - e. Other (open-ended text box)
3. What was your main reason for enrolling in v-safe? Select one.

- a. Vaccine site or provider encouraged participation
 - b. Friend or family member encouraged participation
 - c. Important to share how people feel after COVID vaccination
 - d. Participation is a civic duty.
 - e. Participation may help future COVID-19 vaccine recipients.
 - f. To track my/my dependent's health history after COVID-19 vaccination.
 - g. Due to experiencing previous adverse reactions to vaccines.
 - h. Because CDC calls participants that report seeking medical care after vaccination.
 - i. To be included in the v-safe pregnancy registry.
 - j. To help health care workers.
 - k. Concern about the safety of COVID-19 vaccines.
 - l. Other (open-ended text box)
4. How was your experience signing up for v-safe?
- a. Very easy
 - b. Somewhat easy
 - c. About as easy as I expected
 - d. Somewhat difficult
 - e. Very difficult
5. Does v-safe contact you:
- a. Too much
 - b. Just enough
 - c. Not enough
- 5a. (if a. 'Too much' selected) How much contact would you prefer? Select all that apply.
- a. Fewer surveys in the first week
 - b. Fewer surveys in weeks 2 through 6
 - c. Fewer surveys after 6 weeks
- 5b. (if c. 'Not enough' selected)
- a. More surveys in weeks 2 through 6
 - b. More surveys after 6 weeks
6. Which of the following did you enjoy most about v-safe?
- a. The sign-up process was easy
 - b. Being asked "how do you feel today"

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- c. Automatic reminders to get additional doses
 - d. Health check-ins were short and simple
7. Would you encourage others to sign-up for v-safe based on your own experience?
- a. Yes
 - b. No
- 4a. (If a. 'Yes' selected), What materials would help you encourage others to sign up?
- a. Social media posts
 - b. Web links to CDC materials
 - c. None, I would make verbal recommendations
8. Would you sign up for v-safe if it was offered for a different vaccine?
- a. Yes
 - b. No
9. This is our favorite question to ask! How are you feeling today?
- a. Good 😊
 - b. Fair 😐
 - c. Poor 😞

Survey completion message:

“Thank you for completing this valuable survey!”