V-safe active surveillance for COVID-19 vaccine safety

Version 5
April 18, 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 2nd 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 18, 2022	Modified protocol language to add section about v-safe program evaluation Added Attachments 4-6 for the three evaluation activities

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.

Table of Contents

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

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.

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, and archival of a final data set for data sharing purposes. The archive will include the protocol, statistical programs, human subjects review documents, statistical output, analytical data sets, and manuscripts. It will clearly identify the permanent storage location for these files.

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

Analysis plan

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

(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?

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)

☐ 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? (A*sked 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)

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

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

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(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?

(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 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)
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(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?

(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)
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(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?

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

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 company contracted with CDC to hear your thoughts and opinions about the v-safe program, an after COVID-19 vaccination program created by the Centers for Disease Control and Prevention. I will be guiding our discussion today and will 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 project 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?
    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)*

5) If applicable, was it easy for you to enter your 2nd dose 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)*

6) If applicable, was it easy for you to enter for booster dose 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)*

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 evaluating 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? (select one)
    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
5. *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 v-safe information
        5. We include 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*> _____

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

    c. *(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*> _____

d. *(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*> _____

6. *(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*> _____

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!"

B. Health Department survey

Survey intro text:
"CDC is evaluating 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:

8. Are you a(n):
    a. MD
    b. NP
    c. RN
    d. PA
    e. Immunization Manager
    f. Other_____

9. 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

10. 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*>_____

11. 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*> _____

12. 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 includes some v-safe information
    5. We include 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 health department 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 health department 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> _____

13. *(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> _____

14. 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 evaluating 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 _____

15. 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)*

16. 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 _____

17. 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 _____

18. 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 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 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>_____

19. *(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> _____

20. 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"

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 survey!"