V-safe active surveillance for COVID-19 vaccine safety

Protocol summary

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

Background and significance

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

Post-authorization/post-approval vaccine safety monitoring is a federal government responsibility, with the Centers for Disease Control and Prevention (CDC) and the FDA sharing most of the responsibility along with other federal agencies involved in healthcare delivery (e.g., Veterans Affairs, Department of Defense, Indian Health Service). Initial safety assessment

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

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

Goals and objectives

Goals

- Characterize the safety profile of COVID-19 vaccines.

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

Objectives

- Characterize the local and systemic reactogenicity of COVID-19 vaccines during the first week post-vaccination (days 0-7).

- Identify and characterize clinically important adverse events following COVID-19 vaccination during a 6-week post-vaccination follow-up period.

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

Methods

Surveillance population

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

Enrollment criteria:

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

Enrollment

The v-safe program will commence when COVID-19 vaccines are authorized or approved for use and become available to the U.S. population. Vaccination may occur at a mass vaccination clinic, an occupational health clinic, a public health clinic, a healthcare provider's office, a pharmacy, or other setting. At the time of vaccination, the healthcare provider will briefly describe the v-safe program using a prescribed script (Attachment 1). 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. If they do not enroll immediately, they can decide to participate in v-safe at any time up to 42 days following the first vaccination. 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). 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

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

Once a participant has registered and provided information on their COVID-19 vaccination, they will be prompted to take an initial v-safe health check-in survey. 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.

Electronic health check-in schedule

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

1. Day 0 (day of vaccination)

2. Daily on days 1-7 (the 1st week post-vaccination)

3. Weekly starting day 14 (2nd week post-vaccination) to up to day 42 (6th week post-vaccination) if no 2nd dose of COVID-19 vaccine is received

    a. If participant receive a 2nd COVID-19 vaccine dose during the post-vaccination follow-up period, the process will reset to day 0 for the 2nd dose and continue through steps 1-3 above based on time since the 2nd dose.

4. At 3, 6, and 12 months post-vaccination following 2nd dose vaccination or following first dose if no 2nd dose is received

Daily surveys expire at midnight on the day of the survey and weekly surveys expire at midnight on the last day of the week before the next weekly survey period. The day 42 survey will expire on day 48 at midnight. Monthly surveys will be available for 6 full days following receipt of the survey, expiring at midnight. A participant can enroll in v-safe up to 42 days during the post-vaccination follow-up period after the first dose, but cannot go back and complete surveys that have expired (i.e., it 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 health impact event, defined as per the survey: a) missed work, and/or b) unable to do normal daily activities, and/or c) got care from a doctor or other healthcare professional, VAERS call center staff will be informed and active telephone follow-up will be initiated to check on the patient and take a VAERS report if appropriate. VAERS is an existing national spontaneous reporting system that is co-managed by FDA and CDC. It serves as an early warning system for adverse events following vaccination (6).

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

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

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

Data collection, quality, and management

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

Per Oracle's internal policies, Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, will have access to aggregate deidentified data for reporting. CDC will have "read" access to the individualized survey data, including PII, provided by Oracle. On a continuous basis (either daily or weekly), these survey data will be accessible to CDC through downloads from the CDC IT contractor's 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 heath impact event. CDC-badged contractors will access these data in order to provide call center representatives with information needed to follow up with participants (see "Active telephone follow-up" above). The VAERS call center staff is employed specifically for v-safe follow-up and is associated with the overall VAERS contractor.

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

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

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

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

Analysis plan

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

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

VAERS monitoring for all COVID-19 reports will include VAERS reports solicited from v-safe participants. Reports obtained from v-safe participants 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 opt out of v-safe at any time and their data will be used for the time they were considered an active participant. 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 approximately 6-8 months of active enrollment. The decision to discontinue v-safe or to modify v-safe procedures to scale back active telephone follow-up will be made in consultation with the CDC COVID-19 Vaccine Task Force leadership and FDA.

Limitations and challenges

Limitations and challenges for v-safe surveillance include:

- Enrollment and registration will initially be a manual process and will be dependent on healthcare providers sharing information about the system with vaccine recipients. Enrollment might be limited. While VAMS will help promote v-safe enrollment 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, at least initially. Vaccine recipients are expected to receive vaccination record cards specifying the vaccine they received, which might help to improve accuracy of these data.

- Vaccinated people who choose to participate in v-safe might be different from those who decline; therefore, rates of side effects and adverse events generated from v-safe might not be generalizable to the full population of vaccine recipients.

- V-safe allows people to enter late in the post-vaccination monitoring period. The group of individuals who enroll in v-safe late might be 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.

- Participants will likely be lost to follow-up at later time points, reducing participant numbers and likely creating biases in v-safe analyses of safety out to 12 months.

- Because v-safe relies on vaccine recipients reporting their own experiences after vaccination, v-safe is not conducive to capturing the adverse event of death following vaccination.

Dissemination

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

References

1. *The American Journal of Managed Care*. A Timeline of COVID-19 Developments in 2020. Available at https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020.

2. CDC. CDC COVID Data Tracker. Available at https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days.

3. Slaoui M, Hepburn M. Developing Safe and Effective Covid Vaccines—Operation Warp Speed's Strategy and Approach. *N Engl J Med* 2020; 383:1701–1703.

4. Su JR, Duffy J, Shimabukuro TT (2019). Chapter 1: Vaccine Safety. In Poland GA (Ed.) and Whitaker JA (Assoc. Ed.), *Vaccinations*. St. Louis, MO: Elsevier.

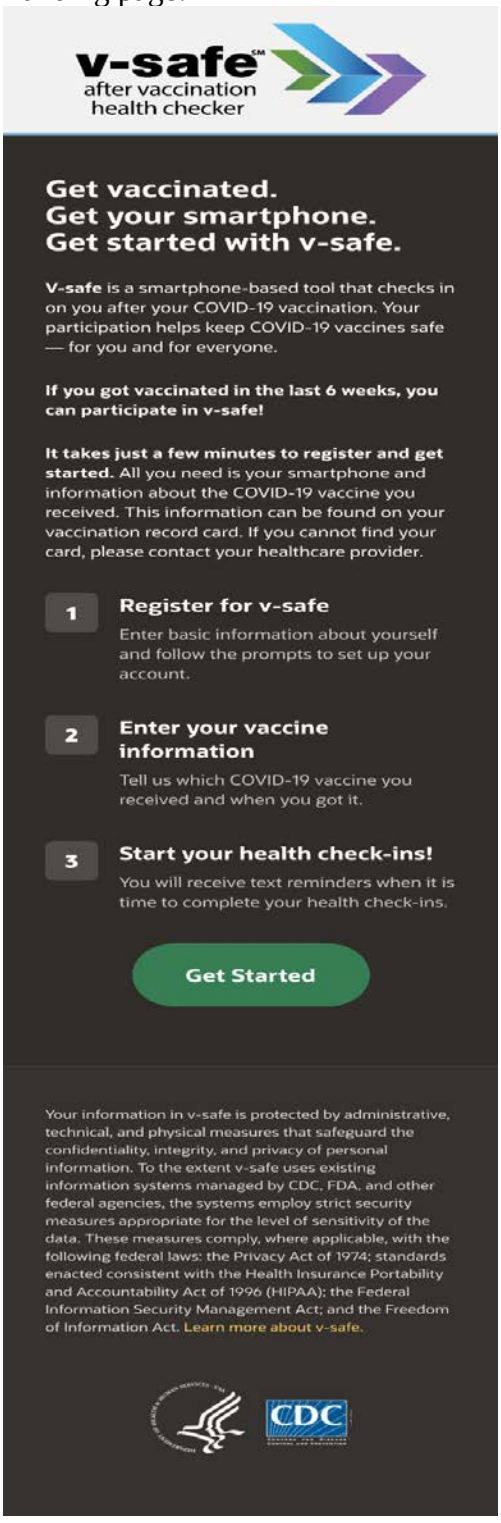
5. https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

6. Shimabukuro TT, Nguyen M, Martin D, DeStefano F. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*. 2015; 33(36): 4398–4405.

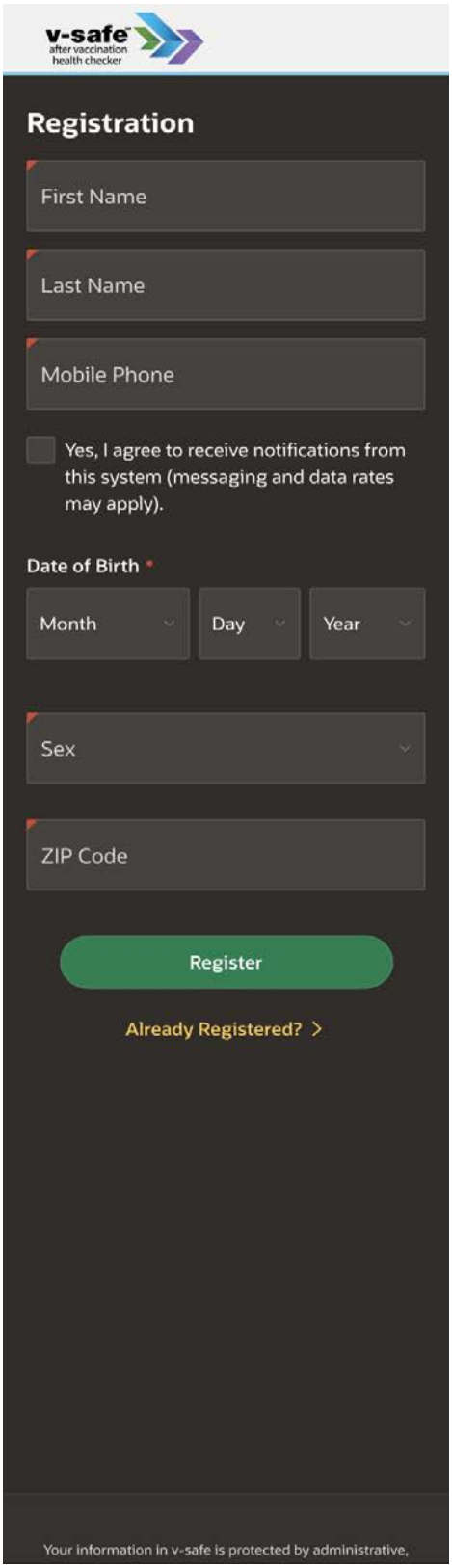
7. *https://www.gsa.gov/technology/government-it-initiatives/fedramp)?*

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

Attachment 1: V-safe survey script
Registration and my account:
Landing page:

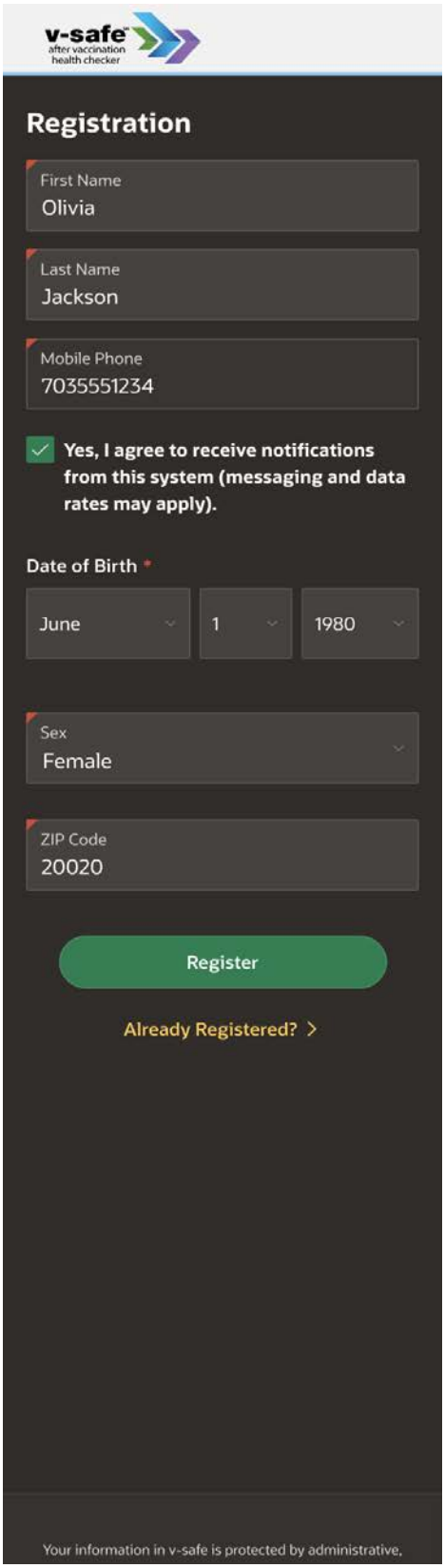


Registration page

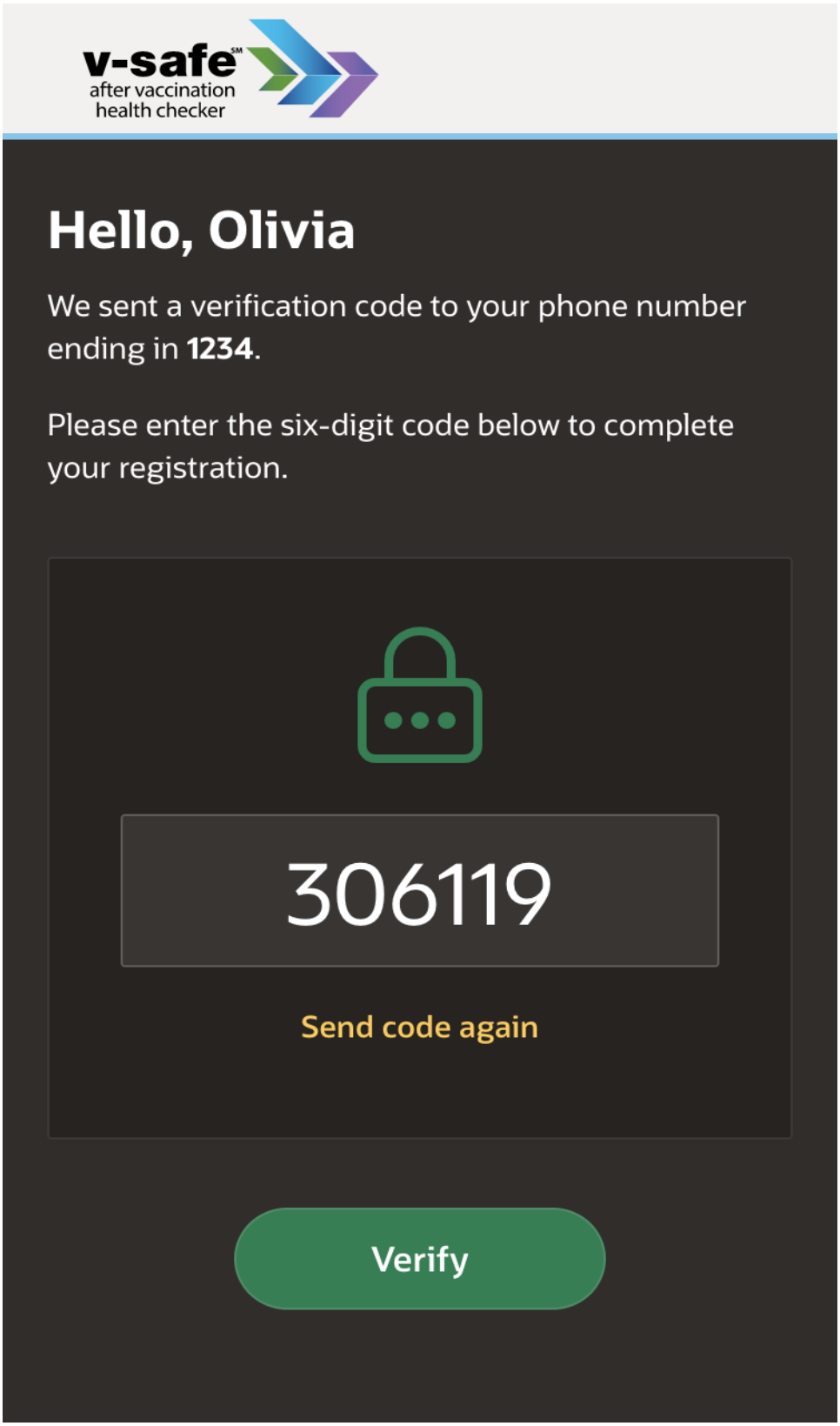


v-safe protocol: Nov 19, 2020

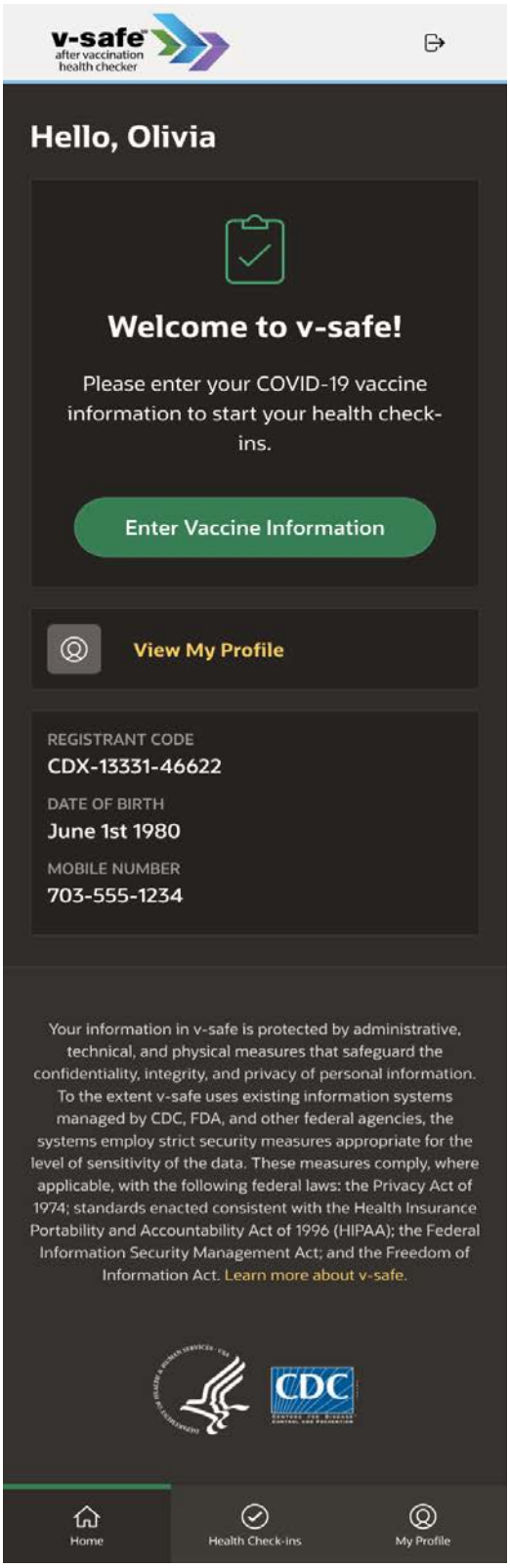
Registration completed:



Verification:

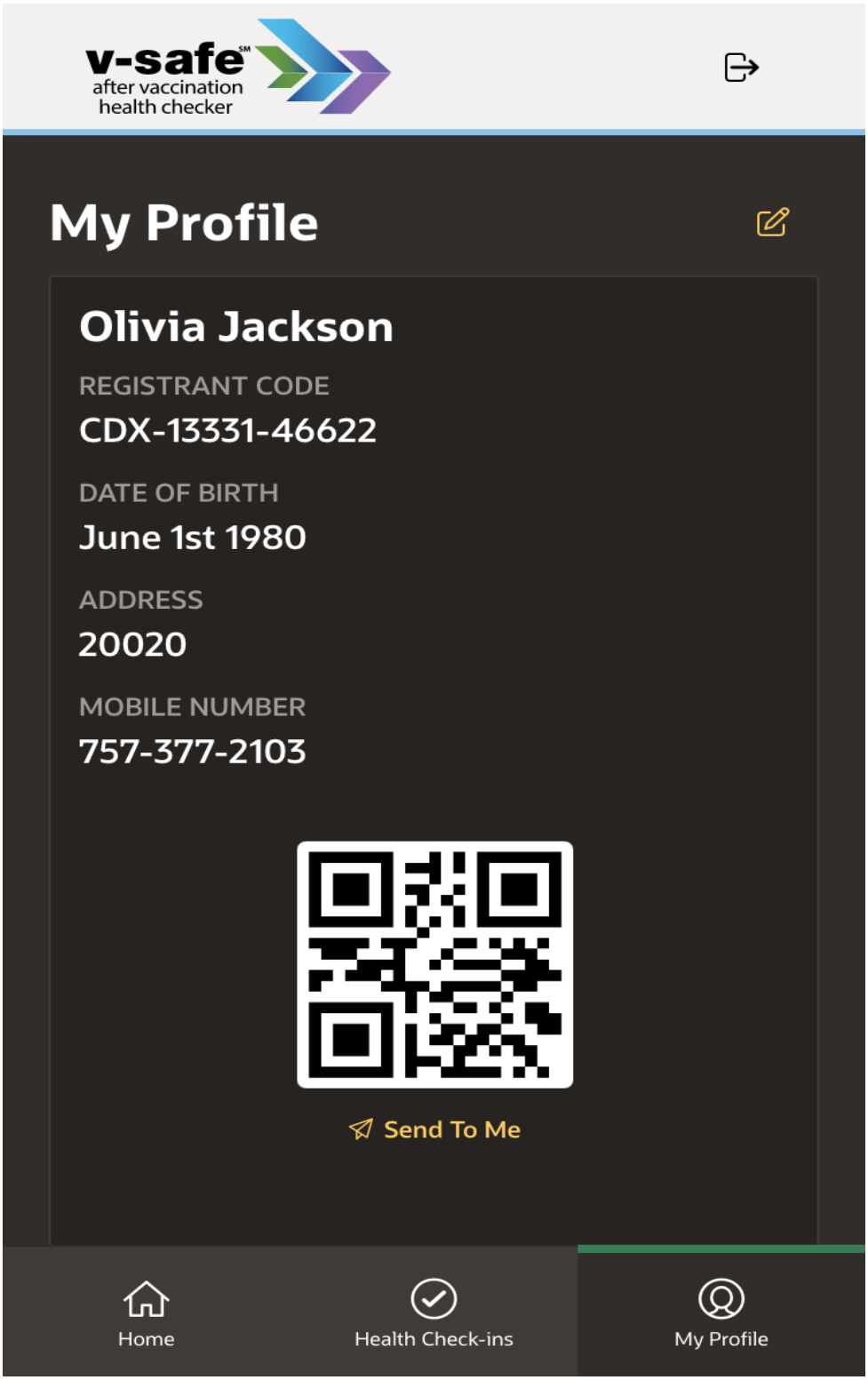


Account:


v-safe
after vaccination health checker
Hello, Olivia
Welcome to v-safe!
Please enter your COVID-19 vaccine information to start your health check-ins.
Enter Vaccine Information
View My Profile
REGISTRANT CODE
CDX-13331-46622
DATE OF BIRTH
June 1st 1980
MOBILE NUMBER
703-555-1234
Your information in v-safe is protected by administrative, technical, and physical measures that safeguard the confidentiality, integrity, and privacy of personal information. To the extent v-safe uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the level of sensitivity of the data. These measures comply, where applicable, with the following federal laws: the Privacy Act of 1974; standards enacted consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act; and the Freedom of Information Act. Learn more about v-safe.
CDC
Home
Health Check-ins
My Profile

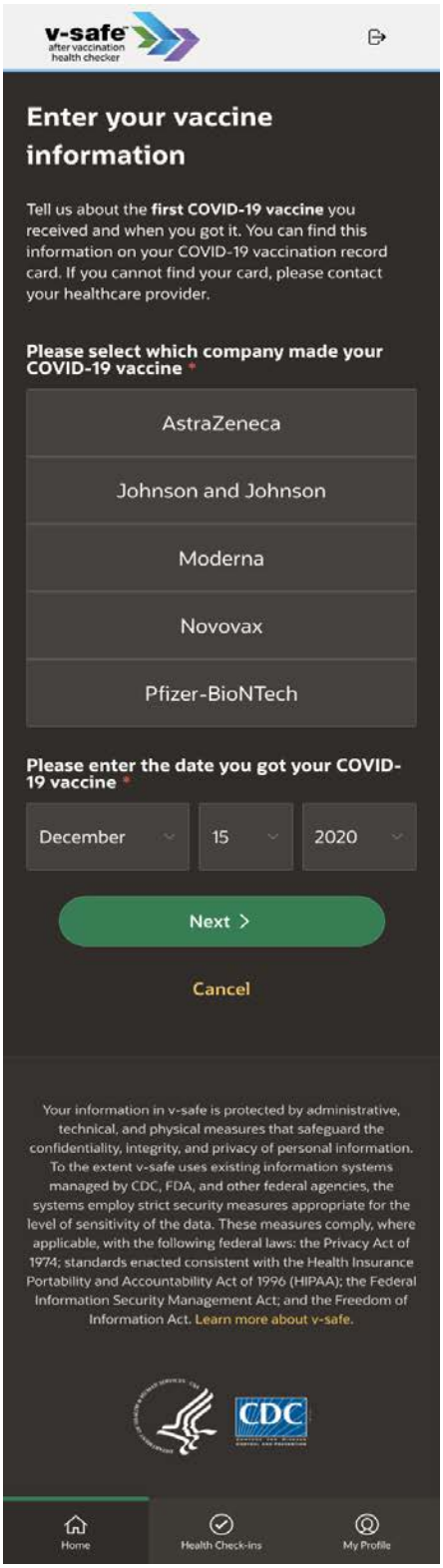
v-safe protocol: Nov 19, 2020

My profile:



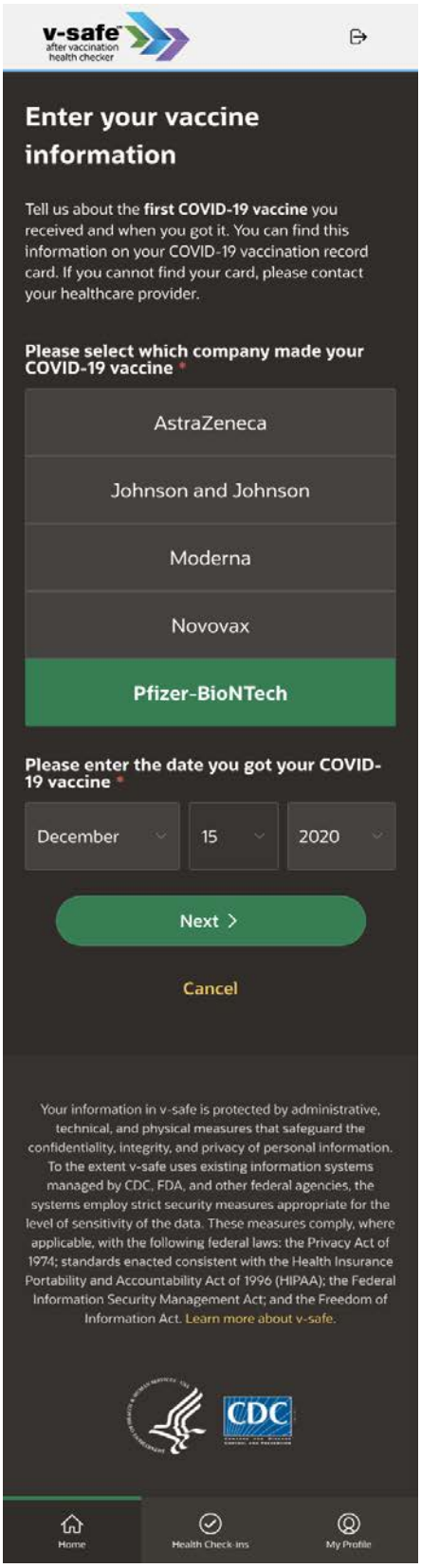
v-safe protocol: Nov 19, 2020

Enter vaccine:



v-safe protocol: Nov 19, 2020

Enter vaccine- completed:



v-safe protocol: Nov 19, 2020

Confirm vaccine:

V-safe Dose 1 surveys through Day 42

DAY 0- Dose 1:

Text message invitation::
Hi <NAME>. It's time for your first v-safe check-in. (*link to personalized v-safe survey)*

Survey:
Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Since your vaccination, have you had a fever or felt feverish?
☐ Yes ☐ No

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit): _____
Enter your 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 had any of these symptoms at or near the injection site?
select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐None

How would you rate your 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 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

(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 symptoms or health conditions you reported TODAY cause you to (select all that apply):

☐ Be unable to work?

☐ Be unable to do your 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 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 pregnant at the time of your COVID-19 vaccination?
(*This is only asked for the only initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*

☐ ☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch tomorrow.

Days 1-7 post vaccination

Text message & reminder:

Invitation text: Hi, <name>. It's time for your daily v-safe check-in. (*link to personalized survey)*

Reminder text (for Day 7 survey only): Hi <name>, Please remember to do your daily v-safe check-in. ((*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Have you had a fever or felt feverish TODAY?
☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit)
Enter your 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 had any of these symptoms at or near the injection site today?
Check all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching ☐ None

(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 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 limite your normal daily activities
Severe = symptoms make normal daily activities difficult or impossible

(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 symptoms or health conditions you reported today cause you to (Select all that apply):

☐ Be unable to work?

☐ Be unable to do your 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 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 pregnant at the time of your COVID-19 vaccination?
(*This is only asked for the only initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*

☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch for your next check-in.

14 days (2 weeks) survey following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder(text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

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

☐ Yes ☐ No

(if Yes) Please describe:

_____

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

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you 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 last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

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

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

Alternate onscreen completion message FOR PFIZER and NOVOVAX RECIPIENTS:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
You'll need to get your 2nd COVID-19 vaccine next week. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

21 days (3 weeks) following COVID-19 vaccination- DOSE 1:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
For Pfizer/Novovax recipients:

Hi <name>.
Let's start today's health check-in.

Did you get your 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 received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Moderna/AZ/Johnson & Johnson recipients & Pfizer/Novovax who did not get dose 2:

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check in, have you 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 to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you 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 last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?
☐ Yes ☐ No

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

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Moderna/AZ/:
Thanks for completing today's check-in.
Depending on your answers, someone from CDC may call you to check on you.
You'll need to get your 2nd COVID-19 vaccine next week. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.
For Pfizer/Novovax recipients who did not receive dose 2:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

28 days (4 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above

For all Moderna, AZ and those Pfizer/Novovax who did not previously report Dose 2:

Hi <name>.

Did you get your 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 received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

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

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you 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 to (check all that apply):

- ☐ Be unable to work?
- ☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you 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 last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

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

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Johnson & Johnson recipients:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.
For Pfizer/Novovax/Moderna/AZ recipients who did not receive dose 2:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

35 days (5 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder (text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
For all Moderna, AZ/ Pfizer/Novovax who did not previously report receipt of Dose 2:

Hi <name>.

Did you get your 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 received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Johnson & Johnson and all 2 dose recipients who report 'No' above
Hi <name>.
Let's start today's health check-in .

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you 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 to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you 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 last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

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

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if yes then no more pregnancy questions asked for Dose 1)*
☐ Yes ☐ No ☐ Don't know

Onscreen completion thank you message:

For Johnson & Johnson recipients:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.
For Pfizer/Novovax/Moderna/AZ recipients who did not receive dose 2:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
It is time to get your 2nd COVID-19 vaccine. Please remember to make an appointment if you have not done so already!
After you receive your 2nd COVID-19 vaccination, please sign into your v-safe account and update your vaccination information.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).

42 days (6 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your 6 week v-safe check-in. (*link to personalized survey)*
Reminder (sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above
For all Moderna, AZ/ Pfizer/Novovax who did not previously report receipt of Dose 2:

Hi <name>.

Did you get your 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 received your 2nd COVID-19 vaccine.
Please click the View My Account button below to view your account and register your 2nd COVID-19 vaccine.

For Johnson & Johnson and all 2 dose recipients who report 'No' above
Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you 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 to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you 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 last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐ No

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

How would you describe your current state of health?

☐ Excellent
☐ Good
☐ Fair
☐ Poor

How is your health now compared to your heath before your last COVID-19 vaccination?

☐ Better
☐ About the same
☐ Worse

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

☐ Yes
☐ No

Were you pregnant at the time of your COVID-19 vaccination?
(*This is asked only for the initial survey taken for Dose 1; if this is the first survey then question below is not asked)*
☐ Yes ☐ No ☐ Don't know

Since your last COVID-19 vaccination, have you had a home or laboratory pregnancy test that was positive?
(*This is only asked if participant answered above pregnancy question in a previous survey)*

- ☐ Yes
- ☐ No

Onscreen completion thank you message:
For all vaccine recipients at Day 42:
Thanks for completing today's check-in. Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Depending on your answers, CDC may call you to get more information about your symptoms. If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe. We'll be in touch

V-safe Dose 2 surveys through Day 42:

Dose 2

Day 0 post vaccination

Text Message after + 2nd vaccine info completed

Hi <NAME>. It's time to check-in with v-safe for your 2nd vaccine dose. (*link to personalized v-safe survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Since your second COVID-19 vaccination, have you had a fever or felt feverish?
☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

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

Since your second COVID-19 vaccination, have you had any of these symptoms at or near the injection site?

Select all that apply: ☐ Pain ☐ Redness ☐ Swelling ☐ Itching

(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 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_____

Medical 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"

(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 symptoms or health conditions you reported TODAY cause you to (Select all that apply):

☐ Be unable to work?
☐ Be unable to do your 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 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 pregnant at the time of your second COVID-19 vaccination? (*This is 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

Onscreen completion thank you message:
Thanks for completing today's check-in.
Depending on your answers, someone from CDC may call to check on you.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch tomorrow.

Days 1-7 post vaccination

Text message & reminder:

Invitation text: Hi <name>. It's time for your daily v-safe check-in. (*link to personalized survey)*

Reminder text (only sent for Day 7 survey, 3 days after original text sent): Hi <name>. Please remember to do your daily v-safe check-in. ((*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Fever check
Have you had a fever or felt feverish TODAY?
☐ No ☐ Yes

(If Yes) Do you know your highest temperature reading from today?
☐ Yes- in degrees Fahrenheit
☐ Yes- in degrees Celsius
☐ No- I don't remember the reading
☐ No- I didn't take my temperature

Enter your highest temperature reading from today (degrees Fahrenheit)
Enter your 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 had any of these symptoms at or near the injection site today?

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

(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 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_____

Medical 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"

(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 symptoms or health conditions you reported today cause you to (Select all that apply):

☐ Be unable to work?

☐ Be unable to do your 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 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 pregnant at the time of your second COVID-19 vaccination? (*This is 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

Onscreen completion thank you message:
Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following your COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch for your next check-in.

Weekly surveys: Days 14, 21, 28, 35– Dose 2

Text message and reminder:
Invitation: Hi <name>. It's time for your weekly v-safe check-in. (*link to personalized survey)*
Reminder(text sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you 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 to (check all that apply):"

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) "What type of healthcare visit did you 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 last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

□ Yes □No

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

Were you pregnant at the time of your second COVID-19 vaccination? (*This is 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

Onscreen completion thank you message:

Thanks for completing today's check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
We'll be in touch next week.

42 days (6 weeks) following COVID-19 vaccination:

Text message
Invitation: Hi <name>. It's time for your 6 week v-safe check-in. (*link to personalized survey)*
Reminder (sent 3 days later): Hi <name>. Please remember to do your weekly v-safe check-in. (*link to personalized survey)*

Online survey from link in text message above

Hi <name>.
Let's start today's health check-in.

How are you feeling today? ☺
☐ Good ☐ Fair ☐ Poor

Since your last check-in, have you 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 to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you 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 last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

□ Yes □No

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

How would you describe your current state of health?

☐ Excellent
☐ Good
☐ Fair
☐ Poor

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

☐ Better
☐ About the same
☐ Worse

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

☐ Yes
☐ No

Were you pregnant at the time of your COVID-19 vaccination?
(*This is only asked for the initial survey taken for Dose 2; if this is the first survey then question below is not asked)*
☐ Yes ☐ No ☐ Don't know

Since your last COVID-19 vaccination, have you had a home or laboratory pregnancy test that was positive?
(*This is only asked if participant answered above pregnancy question in a previous survey)*

☐ Yes
☐ No

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 answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
Take care and stay safe. We'll be in touch in a few months.

V-safe 3, 6 and 12 month surveys:

Monthly survey

Hi <name>.

Since we last contacted you, have you 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 to (check all that apply):

☐ Be unable to work?

☐ Be unable to do your normal daily activities?

☐ Get care from a doctor or other healthcare professional for your symptoms or health conditions?

☐ None of the above

(If Yes to got care [above]) What type of healthcare visit did you 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 last check-in, did you have a positive COVID-19 test or were you told by a health care provider that you had COVID-19?

☐ Yes ☐No

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

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

☐ Yes
☐ No

How would you describe your current state of health?

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

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

- ☐ Better
- ☐ About the same
- ☐ Worse

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

- ☐ Yes
- ☐ No

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

12 Month:
Congratulations! You have completed your final v-safe check-in.
Depending on your answers, CDC may call you to get more information about your symptoms.
If you had symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. You can also report your experience to the Vaccine Adverse Event Reporting System (VAERS).
Thank you for participating in v-safe! Your contributions are helping CDC monitor the safety of COVID-19 vaccines.
Take care and stay safe.

Attachment 2: Adverse Events of Special Interest

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

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