-- with pre-existing medical conditions are going to get this vaccine, and that's why it's important to continue to monitor the safety of vaccines once they're out there being used in the population outside of the controlled clinical trial environment. Next slide.

So, I'm going to describe one of our main systems. The Vaccine Adverse Event Reporting System, which is the nation's early warning system for vaccine safety. And VAERS is co-managed by the CDC and the FDA.

It's a spontaneous reporting or pass-through surveillance system, meaning we depend on individuals to send reports to us. So, healthcare providers, patients, parents, caregivers, manufacturers send reports into VAERS where CDC and FDA then analyze those reports. Next slide.

VAERS covers the entire US population, including all 320 million US residents. So, anyone's who's eligible to receive a vaccine would be covered under VAERS monitoring. This includes all ages, races, occupations, states and jurisdictions, healthy people, those with chronic conditions, those in long-term care facilities, and older adults living in the community. Next slide.

As a spontaneous reporting system, VAERS accepts all reports from everyone, regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event. We encourage reporting of all clinically important or medically significant adverse events following vaccination, even if it's not clear if the vaccination caused the adverse event. We will accept all these reports without judgment about causality or without judging the clinical seriousness.

The key strengths of VAERS are that it can rapidly detect potential safety problems and can detect rare adverse events. It has a large population that is being monitored. Therefore, it can detect these rare adverse events and rare safety signals. Key limitation is inconsistent quality and completeness of information, and a limitation of spontaneous reporting and passive surveillance, in general, is that we generally cannot determine cause and effect from VAERS data alone. Next slide.

So, reporting to VAERS is a fairly straightforward process. You can go to the VAERS website at VAERS.hhs.gov. It'll take you to this landing page, and up in the left-hand corner, you'll see a link for Report an Adverse Event.

You simply click on that link, and it takes you to the online reporting portal, where you can submit a report directly, or you can complete a fillable PDF and then upload that to the VAERS system. And for help, there's a 1-800 number, an email info@VAERS. org, and if you wish to watch an instructional video that was created by CDC and FDA, you can go to the link there on YouTube and watch that video. For COVID-19, FDA will issue VAERS reporting requirements under emergency use authorization, and in addition, CDC encourages reporting of any clinically important adverse event following immunization. Next slide.

The next system I'm going to describe is the v-safe system. Next slide.

So, v-safe is a new active safety monitoring system that CDC has stood up for COVID-19. It's a smart phone-based monitoring program that uses text messaging and web surveys to checks in with vaccine recipients after vaccination. Patients can report side effects and health impact events after COVID-19 vaccination.

It includes active telephone follow-up by CDC for reports of a significant health impact event. It also captures information on pregnancy status and enables follow-up on pregnant women. Next slide. So, v-safe conducts electronic health check ins with vaccine recipients daily for the first week post vaccination then weekly thereafter until six weeks post vaccination, and then additional health checks at three, six, and 12 months post vaccination. So, an individual, at the time of vaccination, at the point of service, at the clinic, self-registers, and I'll describe that process in the next slide.

Self-registers and then begins to get these messages, these text messages from CDC. Again, it's daily during the first week, weekly thereafter till six weeks, and then, at three, six, and 12 months. When an individual gets their second vaccine dose, this timeline basically resets. So, the intervals for the, at least for the vaccines that are currently under consideration are three weeks or four weeks, and you can see that that's shorter than the shorter follow-up time. So, what we're doing is when an individual gets the second dose, we ask them to identify that they got the second dose, and then this follow-up period just basically resets to the day of vaccination for the second dose and goes out for 12 months. Next slide.

So, CDC asks that healthcare providers help us get as many people to use v-safe as possible. What you see on the right-hand side there is a partial screenshot of the v-safe information sheet. What's cut off from this is the section that has the URL and the QR code. So, this is a one-page information sheet with some basic information in v-safe and instructions on enrollment.

Currently, this is a manual enrollment process, and patients have to self-enroll. What they do is they, after receiving the one-page information sheet at the healthcare provider office or clinic or place of vaccination, they can type in the URL or scan the code. It takes you to a registration page. The patient is asked to input a limited number of data elements then goes through a confirmation step and then identifies the vaccination they received and completes the registration process. Once the individual is registered, there's not a need to log into the system anymore.

Basically, there are web links embedded in the text messages that are sent out to the patient all the patient has to do is click on that link. The system recognizes that the phone is the legitimate phone of the person that registered, and it'll take you right to the survey, and the individual can complete the survey. We're asking in addition to giving the one-page information sheet to the patients, we ask that healthcare providers briefly counsel the patients on the importance of enrolling in v-safe. Now we understand that healthcare providers are going to be quite busy at vaccination clinics, and we understand that this is an extra step in the overall vaccination process, and we want to make this as least burdensome as possible on the healthcare providers. We want to allow for this to be incorporated into the normal workflow of the clinic.

We want to make this as least disruptive as possible, and again, we are asking the healthcare provider to give the individual an information sheet. If that's not possible, we would ask that the information sheet be posted somewhere in the clinic so the URL and the QR code are available for the patients to conduct a registration at that point, and to briefly encourage the patient on enrolling in v-safe and to explain the importance of vaccine safety monitoring. So, we've created an electronic version of the v-safe information sheet for a toolkit for distribution to the public health and healthcare partners. We've asked them to push this down to clinics, to healthcare providers, to the individuals who are going to be vaccinated. Next slide.

So, this is a fairly high-level schematic of the process. On the left-hand side there, you see the CDC. And on the right-hand side there you see the vaccine recipient. Again, it's a self-registration process that

uses the information on the v-safe information sheet. Once the patient is registered, we start sending them the text messages.

Again, daily for the first week. Weekly for six weeks, and then three, six, and 12 months. During these daily check-ins, we ask about local and systemic reactogenicity. So, things like arms, redness, swelling, fever, myalgia, arthralgia, and then, at the end of the check in, and we only ask these reactogenicity questions for the first week. After that, we do what's called a health impact assessment.

But at the end of every check-in, whether it's a daily, a weekly, or these monthly, we ask three simple questions. Did you miss work? Were you unable to do normal daily activities, or did you receive medical care? If the patient checks yes to any one of those, we consider that a clinically important health impact event, and at that point, we reach out to the patient through a call center and take an adverse event report. Next slide.

So, these are the resources for v-safe, the links to the CDC website. The actual v-safe information sheet was in a toolkit that was sent out to planners. However, if individuals have not received that v-safe information sheet, we can provide that to you directly. Next slide.

So, I want to briefly discuss a couple of our monitoring systems. Next slide. The CDC is also going to do monitoring in its large-linked database system, and this is really a group of large health insurers that use a common electronic health record in an administrative database system.

Unlike the Vaccine Adverse Event Reporting System and v-safe where patients and providers largely know that they're participating in the safety monitoring process. In this example, the participants are largely passive, and the information is being collected through normal, routine clinical care and hospital care. Next slide.

And finally, I'll mention our Clinical Immunization Safety Assessment Project. That's a collaboration between CDC and seven participating medical research centers.

CISA conducts clinical consult services and clinical research. It's available to provide consultations to US healthcare providers for complex adverse events, and those can be requested through CDC-Info. Next slide.

So, I want to reassure you that we have the systems in place to collect safety data. We have validated methods to rapidly analyze and interpret the data.

We have processes in place to respond to potential safety concerns when we detect them, and we have trusted partners that we will depend on as we implement the vaccination process. And I specifically want to ask our healthcare providers to help us over the coming weeks and months, as we implement the national COVID-19 vaccination program. Specifically, we ask that you participate in v-safe yourself when you get vaccinated. Healthcare providers are patients too, and will be some of the first patients that get vaccinated, and we encourage you to participate in v-safe and let us know about your post-vaccination experience. We ask that you encourage patients to participate in v-safe, and we ask that you report adverse events to VAERS.

And finally, we ask that you communicate with your patients on vaccine safety and communicate on the importance of getting vaccinated for COVID-19. Next slide.

Finally, I just want to close with the initial top-three takeaways, just to remind you that the US vaccine safety system is strong and robust. New safety systems are being added for COVID-19 vaccines, and you can play an important role in helping CDC monitor the safety of COVID-19 vaccines. Next slide.

So, here's a reference slide with some of the resources I mentioned before. Next slide.

And now I'd like to turn it over to my colleague, Dr. David Kuhar.

Thank you. So, this is Dr. David Kuhar. I'll be presenting on two guidance documents that were posted on the CDC website yesterday. The first is about the considerations for healthcare personnel with systemic signs and symptoms following COVID-19 vaccination, and the second, consideration for long-term care residents. Next slide please.

So, a couple of key points that help frame what I'm about to present is the guidances. First, we don't yet fully know the effect of receipt of vaccine on disease transmission, and until we have further information, infection control practices, including the use of facemasks for source control are unchanged, and vaccinated persons still need to adhere to recommended infection control practices in healthcare settings. Next, positive nucleic acid and antigen testing for SARS-CoV-2 should not be attributed to the COVID-19 vaccine, as the vaccine does not influence the results of these tests, and this is important, because we can still test vaccinated persons for acute disease when indicated. So, next slide please.

Alright, this slide briefly covers the systemic signs and symptoms people might experience after COVID-19 vaccination. Now those systemic signs and symptoms following COVID-19 vaccination can include fever, fatigue, headache, chills, myalgia, and arthralgia. And now, most are mild-to-moderate in severity, occur within the first three days of vaccination, and resolve within one to two days of onset. Now systemic adverse reactions have been more commonly reported after the second dose, rather than after the first, and generally, more frequent and severe in persons aged 18 to 55 than those older than 55 years. Now cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are not consistent with postvaccination symptoms and would be attributable to something else.

And it's important to note that these guidances do not address local symptoms such as pain at the injection site, you know, beyond indicating it could be managed according to usual protocols. Next slide, please.

So, let's start with the infection prevention and control considerations for healthcare personnel with systemic signs and symptoms following a COVID-19 vaccination. Next slide, please.

So, the concern is that healthcare personnel with postvaccination signs and symptoms could be mistakenly considered infectious and restricted from work unnecessarily.

Hence, the strategies and the guidance on evaluating and managing the postvaccination systemic signs and symptoms in personnel are needed to avoid unnecessarily excluding personnel with only postvaccination signs and symptoms from work, as well as avoid inadvertently allowing contagious personnel to work. The strategies are intended for use by occupational health programs, as well as public health officials, and they apply to all healthcare personnel working in healthcare settings. Next slide, please.

Now this slide and the next cover considerations to minimize the impact of postvaccination systemic signs and symptoms on healthcare staffing, with the first two below here aimed at logistics and vaccine delivery, and the next slide, considerations for occupational health services delivery. Now these are all considerations aimed at the broad array of US healthcare settings.

All healthcare facilities will not be able to do all of these. And they can be challenging to implement, depending on local circumstances. The guidances are intended to be adapted to local circumstances. With that said, considerations include vaccinating healthcare personnel proceeding one to two days off, during which they are not required to be in the facility, and also, staggering delivery of vaccine to personnel in the facility so that not all personnel in a single department, service, or unit, are vaccinated at the same time. Next slide, please.

Considerations related to occupational health services delivery will include -- well, the guidance emphasizes the importance of informing personnel about potential for short-term systemic signs and symptoms postvaccination and potential options for mitigating them. So, in other words, let them know what to expect and what to do as symptoms develop. Also, developing a strategy to provide timely assessment of healthcare personnel who present with symptoms, including providing or identifying options for SARS-CoV-2 viral testing, so it's readily available if indicated. Now this doesn't mean to indiscriminately test everyone with systemic symptoms, but rather, taking action to have the option for testing available when it could be needed. And lastly, offering nonpunitive sick leave options to personnel with systemic signs and symptoms postvaccination to remove barriers to reporting these symptoms in the first place. Next slide, please.

So now, onto the suggested approaches to evaluating and managing new-onset systemic postvaccination signs and symptoms in healthcare personnel. So, the following approaches are going to apply to those who have received COVID-19 vaccination in the prior three days, and that includes the day of vaccination, which is considered day one, and are not known to have an unprotected exposure to SARS-CoV-2 in the previous 14 days, which may have them quarantined at an increased risk for disease. Ultimately, clinical judgment in each individual case is needed to determine the likelihood that a provider's symptoms represent infection versus postvaccination symptoms versus something else. Next slide, please.

So, for healthcare personnel who present with signs and symptoms unlikely to be from COVID-19 vaccination, and I want to say by unlikely, we mean the presence of any systemic signs and symptoms consistent with SARS-CoV-2 infection such as cough, shortness of breath, rhinorrhea, sore throat, loss of taste or smell, or another infectious etiology that are not typical for vaccination signs and symptoms. And for those providers, the suggested approach is to exclude from work pending evaluation for possible etiologies, including SARS-CoV-2 infection as appropriate. The criteria for them to return to work in the end depends upon the suspected or confirmed diagnosis. Next slide, please.

Now onto the providers who present with signs and symptoms that may be from either COVID-19 vaccination, SARS- CoV-2 infection, or another infection.

And by these symptoms, we mean the presence of any systemic symptoms, fever, fatigue, headache, chills, myalgia, and arthralgia that are consistent with the postvaccination symptoms, SARS-CoV-2 infection, or another infectious etiology. In other words, this might be vaccine related or it might be related to something else. For these persons, the suggested approach is that personnel who meet the following criteria may be considered for return to work without viral testing for SARS-CoV-2, and the criteria include they should feel well enough and be willing to work. That they are afebrile and have

systemic signs and symptoms limited only to those observed following vaccination. Now note, if feasible, viral testing could be considered for symptomatic persons to increase confidence in the cause of their symptoms. Next slide, please.

Now to elaborate a little beyond these criteria, if symptomatic personnel return to work and symptoms are not improving or persist for more than two days, which is more than you'd expect from postvaccination signs and symptoms, then pending evaluation, they should be excluded from work and considered for viral testing. Personnel with fever should ideally be excluded from work, pending evaluation, including consideration for SARS-CoV-2 testing. If an infectious etiology is not suspected or confirmed as the source of their favor, they can return to work when they feel well enough. When critical staffing shortage are anticipated or occurring, personnel with fever and systemic signs and symptoms limited only to those observed following vaccination could be considered for return to work if they feel well enough.

Regardless, they should be reevaluated and viral testing for SARS-CoV-2 considered, especially if fever does not resolve within two days. Next slide, please.

So, moving on to long-term care residents, who will also be prioritized to receive the vaccine and may have systemic signs and symptoms after. Next slide, please.

So, strategies to appropriately evaluate and manage postvaccination signs and symptoms in long-term care residents are needed to balance the risk of unnecessary testing and implementation of transmission-based precautions for residents only with postvaccination signs and symptoms with that of inadvertently allowing residents with a contagious disease to expose others in the facility.

It's really important to remember that because information is lacking on vaccine effectiveness in the general population, resultant reduction of disease, severity, or transmission, even the duration of protection, residents and healthcare personnel should continue to follow all current infection prevention and control recommendations to protect themselves and others from SARS-CoV-2 infection regardless of their vaccination status. So, next slide, please.

So now onto the suggested approaches to evaluating and managing systemic, new-onset postvaccination signs and symptoms for residents in long-term care facilities. So, the approaches to residents who have received COVID-19 -- or sorry. The approaches apply to residents who received vaccination in the prior three days, including the day of vaccination considered day one, and the approaches should be tailored to fit the characteristics of each case. Again, clinical judgment in each case is important. Next slide, please.

So, for long-term care residents with signs and symptoms unlikely to be from COVID-19 vaccination, and by unlikely, again, similar to what I said for healthcare personnel, we mean residents with the presence of any signs and symptoms consistent with SARS-CoV-2 infection like cough, shortness of breath, rhinorrhea, sore throat, loss of taste or smell, or another infectious etiology that are not typical for postvaccination signs and symptoms, and for these residents, we suggest evaluating for possible infectious etiologies, including testing for SARS-CoV-2 or other pathogens, as appropriate. Pending evaluation, these residents should be placed in single-person rooms, if available, and cared for by personnel wearing appropriate personal protective equipment recommended for residents with suspected or confirmed SARS-CoV-2 infection. However, they should not be co-hoarded with residents with confirmed SARS-CoV-2 infection unless they have also been confirmed to have SARS-CoV-2 infection through testing.

This is important. Criteria for when transmission-based precautions may be discontinued depend on the results of the evaluation and what the cause of their symptoms is determined to be. Next slide, please. Now for residents with signs and symptoms that may be from either COVID-19 vaccination, SARS-CoV-2 infection, or another infection, and again, same as for healthcare personnel, by symptoms that may be from either, we mean systemic signs and symptoms like fever, fatigue, headache, chills, myalgia, and arthralgia that are consistent with postvaccination signs and symptoms but also other infectious etiologies. The suggested approach to these residents is to evaluate the resident.

The resident should be restricted to their current room except for medically necessary procedures and monitored until fever, if present, resolves, and symptoms improved. Next slide, please.

To elaborate a little beyond these criteria, healthcare personnel caring for these residents need to where all recommended PPE for residents with suspected or confirmed SARS-CoV-2 infection while evaluating the cause of the symptoms. If the resident's symptoms resolve within two days, precautions can be discontinued. Fever, if present, should have resolved for at least 24 hours before discontinuing precautions.

Viral testing for SARS-CoV-2 should be considered for residents if their symptoms are not improving or persist for longer than two days, and residents residing in facilities with active transmission or who have had prolonged close contact with someone with SARS-CoV-2 infection in the prior 14 days should be tested for SARS-CoV-2 infection, as would normally be done. Next slide, please.

And so, this is all that I have for today. The slide has additional resources, including links to both guidances I presented, as well as a recently published MMWR with ACIP interim recommendations on the use of the vaccine. And now I'll hang things back to our moderator.

Thank you.

Thank you very much. Presenters, thank you so much for providing our audience with such critical information. We will now go into our Q&A session. Please remember you may submit questions through Zoom by clicking the Q&A button on the bottom of your screen and then typing your question.

Our first question asks, "**Can people enroll in v-safe if they have limited data capability on their phone?**".

Hi, this is Tom Shimabukuro. The answer to that is v-safe is designed to work on any phone that has text and web browser capability. So, enrollees could complete the health check ins, which are online surveys using data on their phones or through using a Wi-Fi connection.

Thank you very much. Our next question asks, "**Our facility is not able to stagger delivery of vaccine to all of our providers. Are there other options to adhere to CDC guidance?**".

This is David Kuhar speaking. So, I can answer this. So, remember what I had said. That staggering delivery of vaccine is a consideration to minimize the impact of post-vaccine systemic signs and symptoms on staffing, but not all healthcare settings will be able to effectively implement all strategies in the guidances, and it's about adapting the guidance to local circumstances of what can be feasibly achieved. Things like even by spacing the vaccine by a few days or only for some of your personnel could still make a difference in impact to the workforce.

You know, it's about considering how you can adapt that guidance to your facility and local circumstances. Thank you for the question.

Thank you very much. Next question asks, "**Can you please clarify the role that providers have with the v-safe system, and how can providers help CDC encourage vaccine recipients to enroll?**".

I'll take that question. The main thing we're asking healthcare providers to do is to provide the v-safe information sheet to the patient, either an individual copy of the v-safe sheet to an individual patient or at least posting that in a public place in the clinic, so people have access to the URL and the QR code, and they can scan and register. We're also asking providers to briefly counsel the patients, and we have the messaging in the v-safe information sheet on what v-safe is. It's a vaccine safety monitoring system and a health check-in system, which is designed to help CDC assess the safety of the vaccination and just emphasize the importance of their participation in helping both for them to get these health check ins, but also to help CDC assess the safety profile of these vaccines. Thanks.

Thank you very much. Next question asks, "**Can you please review what adverse events providers are required to report to the vaccine adverse event reporting system?**".

This is Tom. I can take that one. The FDA has issued and will issue some very specific guidance on adverse event reporting to VAERS, and right now, that guidance is going to include mandatory reporting for a vaccine administration errors, whether or not there is an associated adverse event, serious adverse events irrespective of attribution to vaccination, and they'll give you the definition for serious, cases of multi-system inflammatory syndrome in adults and children, and cases of COVID-19 that result in hospitalization or death. So, those are the reporting requirements. In addition, CDC encourages reporting to VAERS of any clinically significant adverse event that occurs after administration of any vaccine licensed in the United States or authorized in the United States, including COVID vaccines, even if it's not clear if the vaccine caused the adverse event.

I do want to emphasize that for some adverse events, depending on whether they're classified as serious or nonserious or whether we have identified, in advance, that it is a adverse event of special interest, the VAERS program may reach out to you and request assistance with providing medical records to help CDC and FDA further assess the adverse event, and I just want to reassure healthcare providers that under HIPAA, CDC and FDA are public health authorities collecting the data and acting in a public health capacity, and you do not need individual authorization from the patient to release information. Again, this is a public health function, and you're not in violation of any federal or state regulations if you release medical records to VAERS upon request by the VAERS staff.

Again, for certain of the events, we will reach out and ask for additional information, mainly records, and this is a very important thing for us, because it allows us to further assess serious adverse events or adverse events of special interest that we've preidentified and under HIPAA, this is allowed, because this is a public health function, and CDC and FDA are conducting public health surveillance. Thanks.

Thank you for that. Our next inquirer asks, "**My facility is having PPE shortages. Is CDC going to change the personal protective equipment recommendations for healthcare providers who have been vaccinated?**".

Hi, this is David Kuhar. I can take this one. Until we know more about the effect of vaccine on preventing transmission, CDC is not changing recommendations on the use of personal protective equipment or other recommended infection control measures in healthcare settings. The expectation is

that vaccinated healthcare personnel will continue to practice source control and all other recommended infection prevention and control practices, just as unvaccinated providers will. So, thank you.

Thank you very much. Our next question is, "**Will I get an alert from CDC if my patient reports an adverse event after vaccination?**".

So, patient reporting -- this is Tom. Patient reporting to v-safe and to VAERS is confidential. So, you won't be informed of that report. However, if a healthcare provider submits an adverse event report to VAERS on one of his or her patients, you'll get confirmation of VAERS report submission and a VAERS report number.

Thank you very much. Next question asks, "**How do you identify a safety problem to the VAERS system?**".

We use different kinds of analyses when looking at VAERS data. We do what's called automated analysis. So, this is looking at large volumes of VAERS data and looking at things like counts, percents, reporting rates, and reporting trends over time and comparisons to other vaccines that might be given to individuals of the same age. We also review individual reports and do deep reviews of both reports and accompanying medical records, and another thing we do is statistical data mining to detect unusual or unexpected patterns or associations that might indicate a potential safety problem. I mentioned that one of the limitations of VAERS is we generally cannot determine cause and effect from VAERS data alone.

So, when we do detect a potential safety problem, we often go to more robust data systems, such as those that use electronic health records or administrative databases to further assess these safety signals.

Thank you very much. Our next clinician asks, "**Does my hospital have to opt in to v-safe**?".

The answer is no. It's not required for hospitals or health systems or providers to opt into v-safe. CDC is asking that healthcare providers give patients the one-page v-safe information sheet or make that information available at the clinic, and that has the enrollment instructions, and we also ask that you encourage patient participation in v-safe. But patient enrollment is completely voluntary, and patients have to self-enroll in the program.

Thank you very much. The next question asks, "**May healthcare workers who only have symptoms consistent with postvaccination signs and symptoms returned to work if they're afebrile and on analgesics, or must they be off analgesics for 24 hours before doing so?**".

Hey, this David Kuhar. I can take this one. Good question. So, the concern here is whether analgesics might mask a fever or worsening symptoms, and that is conceivable and possible. The guidance is not specific on this issue, and it's not forbidden of having people who are taking analgesics from returning to work.

I mean, ultimately, clinical judgment for each individual case is really the key. If one suspects that systemic systems are from vaccine alone, and on top of the likelihood of infection being lowered due to close proximity to receiving the vaccine, it could be very reasonable to have healthcare personnel return to work when having taken analgesics. If symptoms are getting worse on the analgesics, the situation should clearly be reassessed Anyway, thank you for the question.

Thank you very much. Our next clinician asks, "**I work in a nursing home that provides recommended testing of healthcare workers and residents. Will the vaccine affect those test results?**".

I can take this question, as well. This is David Kuhar. So, viral testing being nucleic acid or antigen testing is what's recommended to diagnose acute disease. And so, the answer is no. Receipt of the vaccine does not affect the results from nucleic acid and antigen SARS-CoV-2 testing.

Hence, a positive test among these should not be attributed to the vaccine and important to remember. Thank you.

Thank you very much. One of our clinicians is asking a counseling type question. They want to know, "**What do I tell my patient if they're concerned about sharing their personal medical information?**".

Sure, this is Tom. So, CDC will not make any surveillance data publicly available, that includes personal identifiers, that might allow trace back to an individual patient. We place a very high priority on confidentiality and patient privacy, and all the records that are received by VAERS are kept confidential, as required by law, and further, all CDC public health surveillance systems comply with CDC, HHS, and federal IT security requirements, and under no circumstances would CDC release personal identifying information or protected health information to employers or other unauthorized recipients.

Thank you very much. Our next question asks, "**If a healthcare worker lives with someone who has COVID-19, and the worker receives a vaccine and develops symptoms, would they be able to continue to work?**".

Hi, this is David. I can take this. So, no. The worker in this situation would have had a higher-risk exposure presumptively, and hence, would be quarantined for 14 days after their last exposure. So, no, they would not be able to continue working.

Thank you. We have a question about v-safe, and the clinician is asking, "**If a patient participates in v-safe, are providers still required to report to VAERS?**".

Hi, this is Tom. I'll take that. Healthcare providers are required to report adverse events to VAERS in accordance with the EUA Provider Fact Sheet, and that's the guidance specified by FDA on adverse event reporting to VAERS. And in addition, as I mentioned, CDC encourages reporting to VAERS of any clinically significant adverse health event, even if it's not clear if the vaccine caused the adverse event. Patient participation in v-safe does not preclude healthcare provider reporting to VAERS on his or her patients.

If we do get a report from both the patient themselves and the healthcare provider, we have ways of identifying those and consolidating those into single reports. So, we would encourage healthcare providers to report appropriately to VAERS.

Thank you very much. Our next question asks, "**How often and where will CDC report out data that v-safe collects?**".

Sure, this is Tom. So, CDC will regularly report out safety data at meetings of the Advisory Committee on Immunization Practices. These are public meetings that you can attend through live steam capability,

and, I mean, at these meetings, we will report out summaries of safety findings and we'll also report summaries of safety findings on the CDC websites and through publication in the MMWR.

Thank you very much. Our next question is also about v-safe. The inquirer is asking, "**Is v-safe an app that vaccine recipients have to download?**".

The answer to that is no. V-safe is a smart phone-based tool that uses text messaging and online surveys to check in on patients during this post-vaccination observation period, and the online -- the links to the online surveys are embedded in the text messages. It's not an app-based process and does not require downloading anything on a phone. It does require patients to self-register to enroll, so they can begin to receive the text messages with the embedded survey links, and these links take the participant directly to the personalized health check in, and they can be opened using data on the phone or from phones with Wi-Fi connections.

Thank you very much. Our next question asks, "**What's different about how CDC's monitoring vaccine safety for COVID vaccines?**".

Hi, this is Tom. I'll take that one, too. So, CDC is using existing systems to conduct enhanced safety monitoring, which really means focusing on a larger number of safety outcomes conducting more intense reviews of prespecified adverse events of special interest, and accelerating reporting processing time. So, we look at more outcomes. We look at these reports more intensively for outcomes that we identify in advance, which are of special interest, and we also have told the folks who are processing these claims to shorten the time so they get into the database.

So, CDC and FDA can analyze them quicker. We're also conducting extensive education and outreach to healthcare providers and other partners on VAERS awareness and VAERS reporting procedures, and we are using new systems just for COVID, such as v-safe, which I've talked about extensively, and we have some other EHR-based systems in long-term care facilities and some other processes to get more data and faster data from long-term care facilities. So, safety data on long-term care facility residents, because these individuals are in the 1a, or the highest priority for vaccination, and we want to make sure that we adequately assess the vaccine safety in these patients, as soon as possible.

Thank you very much. Our next question asks, "**What resource can providers use to get more information that they can share with their patients?**".

Hi, this is Tom again. I think the best source of information is what is posted on the CDC's website, and there's a COVID vaccine webpage that has information for patients, as well as healthcare providers, and on this website, there's a special section talking about talking to patients about COVID vaccine and answering patients' questions on safety and efficacy and other aspects of COVID-19 vaccination.

Thank you very much. We have time for one more question. "**Are healthcare workers able to continue to work if they have either redness or swelling at their injection site?**".

Hey, this is David Kuhar. I can take this. So, a good point. The guidances presented here, addresses systemic symptoms after vaccine. Local symptoms, like pain and redness at the injection site can be managed according to the usual kind of, you know, protocols.

So, assuming that the injection site, you know, signs and symptoms are just thought to be related to the vaccine, then yes, they can continue to work if they feel able. But again, that issue is not addressed in the vaccine beyond a single statement that makes that point.

Thank you very much, and again, I want to thank our presenters for sharing such critical information with us today. This concludes our Q&A session. If our audience had any difficulty accessing this webinar due to the high level of interest, please note that this webinar will be available on demand a few hours after this live call. The recording will be available on this COCA call's webpage at emergency.cdc.gov/coca. Again, that's emergency.cdc.gov/coca.

Please join us for our next COCA call, where the topic will be Practical Decision Making for Crisis Standards of Care at the Bedside during the COVID-19 Pandemic, and this call will be held this Thursday, December 17, as 2 p.m. Eastern time. Please continue to visit emergency.cdc.gov/coca to get more details about this COCA call and others, as we intend to host COCA calls to keep you informed of the latest guidance and updates on COVID-19.

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To stay connected to the latest news from COCA, be sure to like and follow us on Facebook at Facebook. com/cdc/ClinicianOutreachandCommunicationActivity. Again, thank you for joining us for today's call. Have a great day.