Questions and Answers Regarding COVID-19 Vaccine in Long-term Care Facilities

Process Questions

1) **How will new staff and residents be vaccinated once the three on-site clinics through the pharmacy partnership are complete?**
   Facilities can request on-site vaccination for new residents, staff and regular visitors of the facility by completing the following Google form: https://forms.gle/12fqgKaJScA348WH7. Staff can also be vaccinated by Local Health Departments (LHD) and pharmacies. Facilities may request residents get vaccinated prior to admission or work with local hospitals to ensure residents have received their first dose before being discharged. The Moderna or Pfizer vaccine should only be offered if there is a plan for the resident to receive their second dose from the same manufacturer. The Janssen (Johnson & Johnson) is a single dose vaccine and requires no follow-up.[1]

2) **How will we know the vaccination rates of the long-term care facilities? Will we have long-term care specific information at the facility level on the vaccine surveillance dashboard in real-time?**
   We are still collecting data and we encourage facilities to continue to collect vaccination rates through the method below. We will need your help to make this work. Facilities need to fill out the Long-Term Care Facility Vaccination Session Form that will be emailed to you following each vaccination clinic. Include how many staff and residents (including those returning for a second dose) are in your facility as well as how many were vaccinated with each dose that specific day. Once facilities have completed the vaccination clinics, please reach out to the HAI team for vaccine reporting instructions.

3) **Should vaccinations be provided to those currently infected with COVID-19? How long after a staff member or resident tests positive can we vaccinate? Should vaccinations be provided to COVID-19-exposed staff and residents on quarantine?**
   Vaccination should be deferred for anyone with an active COVID-19 infection until discontinuation of isolation precautions. For persons with a potential exposure, the vaccine should be given if COVID-19 is not suspected, including if testing is pending.

4) **When should those treated with monoclonal antibodies or convalescent plasma get the vaccine?**

Vaccination should be deferred for at least 90 days after administration of monoclonal antibodies or convalescent plasma.

5) **Can immunocompromised people be vaccinated? Who should we exclude from vaccinations?**

It is recommended for those who are immunocompromised to receive the vaccine as they are often the ones who can have severe outcomes if they become infected with COVID-19. Those with severe allergies (i.e., those who carry an EpiPen due to their allergies) should not receive the vaccine due to the possibility of anaphylactic reaction. Vaccinations are also not recommended for those with active cases of COVID-19. The vaccine should only be given after discontinuation of Transmission-based precautions in accordance with Centers of Disease Control and Prevention (CDC) recommendations.

6) **Can a staff/residents receive the COVID-19 vaccine if they have recently been tested for TB (tuberculosis)? Can TB testing be performed after the COVID-19 vaccine has been administered?**

There is no reason to believe either the Tuberculin Skin Test (TST) or blood draw for interferon gamma release assay (IGRA) would affect the safety or effectiveness of COVID-19 vaccines. For healthcare personnel or patients who require baseline TB testing (at onboarding or entry into facilities) at the same time they are to receive COVID-19 vaccine, consider the following:

- Perform TB symptom screening on all healthcare personnel or patients.
- If utilizing the IGRA, draw blood for interferon gamma release assay prior to COVID-19 vaccination.
- If utilizing the TST, place prior to COVID-19 vaccination.
- If vaccination has been given and testing needs to be performed, defer TST or IGRA until 4 weeks after COVID-19 vaccine series completion.
- All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.

For healthcare personnel who require testing for other reasons:

- Perform TB symptom screening on all healthcare personnel. Test for infection should be done before or at the same time as the administration of COVID-19 vaccination. If this is not possible, prioritization of test for TB infection needs to be weighed with the importance of receiving COVID-19 vaccination based on potential COVID-19 exposures and TB risk factors. Healthcare personnel with

high-risk conditions for TB progression should be fully evaluated as soon as possible.

- Healthcare personnel without high-risk conditions for TB progression should proceed with contact tracing (i.e., symptom screening, chest radiograph or other imaging, specimen for microbiologic evaluation), but delay test for TB infection (TST or IGRA) if prioritized for receiving COVID-19 vaccination. All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.[6]

7) **Will there be any vaccine mandates? Is the Centers for Medicare and Medicaid Services (CMS) mandating residents to be vaccinated with COVID-19 vaccine?**
   Federal and state governments cannot mandate a vaccine with an Emergency Use Authorization (EUA). Mandates can be a condition of employment in the private sector. CMS is not mandating residents be vaccinated. Please refer to CMS directly for requirements regarding COVID-19 vaccine in LTCFs.[1]

8) **Is it guaranteed that people who get the first dose of Moderna or Pfizer vaccine, will have access to the second dose?**
   We anticipate adequate supply to provide second doses to anyone who has received Moderna or Pfizer for their initial dose. The Janssen (Johnson & Johnson) vaccine does not require a second dose.

9) **How soon can the second Moderna or Pfizer vaccine dose be administered?**
   The minimum recommended interval between vaccine doses is 3 weeks for Pfizer and 1 month (28 days) for Moderna. Persons should not be scheduled to receive the second dose earlier than recommended. It is preferable to wait until the full time period has lapsed. However, administration within the grace period may be appropriate in special circumstances, such as a resident who will be discharging and may not follow up for their second dose. The second dose of Pfizer and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose. Currently, only limited data are available on efficacy of mRNA COVID-19 vaccines administered beyond this window.[6]

10) **Who will pay for vaccine administration? Will residents and staff be charged for the vaccine?**
    People who receive the vaccine will not be charged for the vaccine regardless of insurance. The federal government will provide the vaccine, and the healthcare providers who administer the vaccine will be reimbursed by the patient's insurance or, in the case of uninsured patients, the Health Resources and Services Administration

(HRSA) program for uninsured patients, for the administration of the vaccine. CMS and Utah Medicaid established reimbursement rates for administration of the vaccine for patients covered by Medicare and Medicaid as well as those covered by the program for the uninsured.

11) How do I report if I have a problem or bad reaction after getting a COVID-19 vaccine?

Vaccine Adverse Events Reporting (VAERs) instructions can be found at https://vaers.hhs.gov/. This national system collects data to look for adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns of occurrence. Healthcare providers will be required to report certain adverse events following vaccination to VAERS. Healthcare providers must also adhere to any revised safety reporting requirements according to FDA's conditions of authorized use throughout the duration of any EUA; these requirements would be posted on FDA's website.[5] Anaphylaxis and administration errors should be reported to COVIDVaxProvider@utah.gov so public health can follow up with our CDC partners.

CDC is also implementing a new smartphone-based tool called V-Safe to check-in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a V-Safe information sheet telling you how to enroll in V-Safe. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.[1] Additional information can be found at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

12) Can we stop screening testing?

We still do not know if the vaccine prevents asymptomatic COVID-19 cases. Ongoing screening testing is an important step to help us understand if this is an issue. We anticipate the need for screening testing to diminish over time. CMS has made no changes to screening and outbreak testing rules.

13) Does vaccination change quarantine requirements?

Staff are no longer required to quarantine in the community following a higher risk exposure to COVID-19, provided it occurred at least two weeks after completing their COVID-19 vaccine series. They may also continue to work if needed to address staff shortages.[10] Symptomatic individuals should still isolate and get tested, regardless of vaccination status. Fully vaccinated residents are still advised to quarantine during an outbreak or after COVID-19 exposure, but no longer need quarantine upon admission or following leave of absences.[10]

14) Can we open up to more visitation?

Safe visitation depends on developing herd immunity in our communities as well as in facilities. As we are able to get more of the public vaccinated and decrease community transmission, visitation can be gradually increased. Refer to the Utah Department of Health visitation guidelines on the Long-term care facilities webpage.

Education Questions

1) Why should I get vaccinated?

Getting vaccinated is a necessary first step in combating COVID-19. The vaccine has been shown to prevent severe illness, decrease rates of hospitalization, and death. Getting vaccinated may help to protect you, your family, and residents. It may help stop spread in the community and sets the example for others, including residents, families, co-workers, and the community-at-large.

2) Can you get COVID-19 from the vaccine?

No, COVID-19 vaccines do not contain COVID-19 virus and you cannot get the virus from the vaccine. After receiving the vaccine, you may experience short-term side effects such as fatigue, headache, muscle pain, chills, fever and pain at injection site. This means your body is doing its job and making antibodies to fight the COVID-19 virus. It does not mean that you got COVID-19 from the vaccine.

3) What are some of the common side effects of the COVID-19 vaccine?

Most post-vaccination side effects are mild to moderate in severity, occur within the first three days of vaccination, resolve within 1-2 days of onset, and are more frequent and severe following the second dose and among younger persons compared to those who are older (<55 years). Common side effects may include pain at the injection site, fever, fatigue, headache, chills, or body aches.

4) Should residents and staff be tested if they experience side effects after vaccination?

The following symptoms are not consistent with post-vaccination side effects and may indicate COVID-19 or another infection: cough, shortness of breath, runny nose/nasal congestion, sore throat, or loss of taste or smell.[2] Residents and staff experiencing these symptoms should be tested for COVID-19. If symptoms start 48 hours after vaccination or persist longer than 48 hours after vaccination, testing for COVID-19 should occur.

5) How effective are the COVID-19 vaccines?

All three approved vaccines (Pfizer, Moderna, and Janssen (Johnson & Johnson)) are extremely effective in preventing severe illness and death. They all offer substantial protection from contracting COVID-19 as well, though no vaccine offers perfect

protection. All vaccines were effective across all race, ethnicity and age groups that were tested. We currently don't have data on the frail older adult population, but anticipate effectiveness to be lower in this population due to declining immune function.

6) **Can mRNA change my DNA? How does the mRNA vaccine work?**
No, the mRNA vaccine cannot change your DNA. mRNA technology instructs our cells to make a harmless piece that looks like the "spike protein." The spike protein is found on the surface of the COVID-19 virus. Our bodies recognize that this protein should not be there, so they build antibodies that will remember how to fight the virus that causes COVID-19.

7) **Is a Vaccine Information Sheet (VIS) available yet?**
The COVID-19 vaccine has a fact sheet that is similar in purpose and content to the vaccine information statements (VIS) for licensed vaccines, but differs in that the EUA fact sheet is specific to each authorized COVID-19 vaccine, is developed by the manufacturer of the vaccine, and is authorized by the FDA.[4] For more information visit: https://www.cdc.gov/vaccines/covid-19/eua/index.html.

8) **Do I need two doses of the vaccine? Do I have to get the same vaccine type for the second dose?**
If you receive the Pfizer or Moderna vaccine, you need the second dose of the vaccine to be adequately protected. The vaccine you received for your first dose (Pfizer/Moderna) should be the same type you receive for your second dose. The Janssen (Johnson & Johnson) requires only a single dose.

9) **Are COVID-19 vaccines safe even though they were produced so quickly?**
Safety is the most important priority in vaccine approval. To assess safety, the FDA typically advises that a minimum of 3,000 participants are included in the trial. The current COVID-19 vaccine trials include 30,000 to 50,000 participants. No steps were "skipped." The FDA used the same strict standards that it has for decades. Monitoring for safety will continue as the vaccine is distributed to the public.

10) **What is an Emergency Use Authorization (EUA)?**
Emergency Use Authorization (EUA) for a vaccine is based on the need to use a vaccine to save lives during a public health emergency. An EUA does not imply that the authorization was done too quickly, is experimental or that the vaccine is not safe.

11) How was the vaccine developed so quickly?

For most vaccines, clinical trials are performed first and then production starts after the trials prove the vaccine to be effective. Because the government and other entities were able to provide funding, resources, technology and manpower, production was performed at the same time as the clinical trials cutting the amount of time to make a vaccine.

12) When and how long will I be protected by the COVID-19 vaccine?

The vaccines are not fully effective until at least two weeks after completing the series (2 doses for Pfizer and Moderna, 1 dose for Janssen (Johnson & Johnson). We will not know how long these vaccines will be protective until more time passes in the current research. The COVID-19 vaccines may need to be administered on a regular basis, like the flu vaccine.

13) Will I still need to wear a mask and other personal protective equipment (PPE)?

Yes, similar to other vaccines, a large number of people in the community need to get vaccinated before transmission drops enough to stop the use of PPE. Because testing was performed only when vaccine trial recipients experienced symptoms, it is possible someone who has been vaccinated can develop an asymptomatic case of COVID-19 and unknowingly transmit it to others. As widespread vaccination occurs this question will be resolved, but for the time being universal masking remains the strongest recommendation for preventing the spread of COVID-19.

14) Which vaccine products will be used?

To date, the Pfizer, Moderna, and Janssen (Johnson & Johnson) vaccines have all received Emergency Use Authorization (EUA). The Pfizer and Moderna vaccines are both 2-dose mRNA vaccines. The (Janssen) Johnson & Johnson is a single dose, adenovirus-based vaccine.

References

1. Pharmacy Partnership for Long-Term Care Program for COVID-19 Vaccination https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships-faqs.html.
2. Post Vaccine Considerations for Healthcare Personnel https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html.
3. Frequently Asked Questions about COVID-19 Vaccination https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html.
4. Frequently Asked Questions about COVID-19 Vaccination https://www.cdc.gov/vaccines/hcp/vis/index.html.
5. COVID-19 Vaccines - FDA https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.
6. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
7. About Variants of the Virus that Causes COVID-19 https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant.html.
8. Information About Johnson & Johnson's Janssen COVID-19 Vaccine https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html#:~:text=Information%20on%20how%20well%20the,2%20weeks%20after%20getting%20vaccinated.
9. Strategies to Mitigate Healthcare Personnel Staffing Shortages https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html.