

Protecting and Improving the Health of Iowans

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Health Care Provider COVID-19 Vaccine Frequently Asked Questions Updated October 2, 2020

Changes from the previous version are highlighted in yellow

COVID-19 Vaccine Administration

1. Will more than one dose of COVID-19 vaccine be needed?

It is anticipated the first available COVID-19 vaccines will require two doses separated by intervals of >21 or >28 days depending on the vaccine product. The different vaccine products will NOT be interchangeable. The series of two doses must be completed with the same vaccine product. Second dose reminders for patients will be necessary.

2. How will the COVID-19 vaccines be administered?

At this time, the initial doses of COVID-19 vaccines are expected to be administered by intramuscular (IM) injection. Depending on the brand of vaccine, reconstitution of the vaccine may be required. More information will be shared as it becomes available.

3. Is the COVID-19 vaccine a live vaccine?

There are currently multiple vaccine candidates in various stages of clinical trials. The first two COVID-19 vaccines anticipated to be available are not live vaccines. More information will be shared as it becomes available.

4. Who will be eligible to receive the first available COVID-19 vaccines?

Limited COVID-19 vaccines will be available initially. The vaccine supply is expected to increase substantially in 2021. Groups prioritized for initial COVID-19 vaccination have not yet been confirmed but are expected to be critical infrastructure, health care workers and high risk individuals.

5. What is the recommendation for receiving influenza vaccine this fall/winter with the current COVID-19 pandemic?

It is likely flu viruses and the virus causing COVID-19 will both be circulating. The CDC recommends everyone > 6 months receive a yearly flu vaccine. During the COVID-19 pandemic, reducing the overall burden of respiratory illnesses is especially important to protect vulnerable populations at risk for severe illness, the health care system, and other critical infrastructure. Health care providers should use every opportunity to administer influenza vaccines to all eligible persons.

6. Can other vaccines, including influenza vaccines, be administered at the same time as the COVID-19 vaccines?

The <u>General Best Practice Guidelines for Immunizations</u> from the Advisory Committee on Immunization Practices state, with a few exceptions, any inactivated vaccine may be administered either simultaneously or at any time before or after a different inactivated vaccine or live vaccine. Two or more injectable or nasally administered live vaccines not administered on the same day should be separated by at least 4 weeks. More information regarding the administration of COVID-19 vaccine with other routinely recommended vaccines will be forthcoming.

7. Should influenza vaccines be given to someone in an outpatient setting with suspected or confirmed COVID-19?

No. Vaccination should be deferred (postponed) for people in an outpatient setting with suspected or confirmed COVID-19, regardless of whether they have symptoms, until they have met the <u>criteria</u> to discontinue their isolation. While mild illness is not a contraindication to receive flu vaccination, vaccination visits for these people should be postponed to avoid exposing health care personnel and other patients to the virus causing COVID-19. When scheduling or confirming appointments for vaccination, patients should be instructed to notify the provider's office or clinic in advance if they currently have or develop any symptoms of COVID-19.

Additionally, a prior infection with suspected or confirmed COVID-19 or flu does not protect someone from future flu infections. The best way to prevent seasonal flu is to get vaccinated every year.

8. Should influenza vaccines be administered to someone with COVID-19 who is currently hospitalized or in another inpatient healthcare facility?

Excerpt from <u>Prevention and Control of Seasonal Influenza with Vaccines:</u> <u>Recommendations of the Advisory Committee on Immunization Practices-United States.</u> <u>2020-21 Influenza Season</u>:

Influenza Vaccination of Persons with SARS-CoV-2 Infection (COVID-19)

"Because SARS-CoV-2 is a novel coronavirus, clinical experience with influenza vaccination of persons with COVID-19 is limited. For those who have acute illness with suspected or laboratory-confirmed COVID-19, clinicians can consider delaying influenza vaccination until the patients are no longer acutely ill. If influenza vaccination is delayed, patients should be reminded to return for influenza vaccination once they have recovered from their acute illness."

Additionally, <u>General Best Practice Guidelines for Immunization</u>: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) states:

"The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines. The decision to administer or delay vaccination because of a current or recent acute illness depends on the severity of symptoms and etiology of the condition. The safety and efficacy of vaccinating persons who have mild illnesses have been documented. Vaccination should be deferred for persons with a moderate or severe acute illness. This precaution avoids causing diagnostic confusion between manifestations of the underlying illness and possible adverse effects of vaccination or superimposing adverse effects of the vaccine on the underlying illness. After they are screened for contraindications, persons with moderate or severe acute as soon as the acute illness has improved."

Vaccination may be deferred if a precaution is present, although a vaccination might be indicated in the presence of a precaution if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. In deciding whether to vaccinate a patient with moderate or severe illness, the clinician needs to determine if deferring vaccination will increase the patient's risk of vaccine-preventable diseases, as is the case if the patient is unlikely to return for vaccination or to seek vaccination elsewhere.

9. Is there guidance for safely administering vaccines during the COVID-19 pandemic?

CDC has released <u>Interim Guidance for Immunization Services During the COVID-19</u> <u>Pandemic</u>. This guidance is intended to help immunization providers in a variety of clinical and alternative settings with the safe administration of vaccines during the COVID-19 pandemic. This guidance will be continually reassessed and updated based on the evolving epidemiology of COVID-19 in the United States.

Interim guidance: Immunization services during the COVID-19 pandemic: Vaccination and COVID-19Vaccination Guidance During a Pandemic Protective Measures for Vaccinating During Pandemic

10. Are there specific infection control procedures to follow when administering vaccines during a pandemic?

It is important to apply infection prevention strategies to all patient encounters including physical distancing, respiratory and hand hygiene, surface decontamination, and source control. The CDC has developed <u>General Practices for Safe Delivery of Vaccination</u> <u>Services</u> and the Immunization Action Coalition has developed <u>Protective Measures for Vaccinating During Pandemic</u>.

11. Is there guidance for administering vaccines in a setting other than a doctor's office (e.g., pharmacies; temporary, off-site, or satellite clinics; and large-scale influenza clinics)?

Yes. Guidance has been developed for giving vaccines at <u>pharmacies</u>, <u>temporary</u>, <u>off-site</u>, <u>or satellite clinics</u>, and <u>large-scale influenza clinics</u>. Other approaches to vaccination during the COVID-19 pandemic may include drive-through immunization services at fixed sites, curbside clinics, mobile outreach units, and home visits. Please collaborate these plans with Local Public Health.

The general principles outlined for <u>health care facilities</u> should also be applied to alternative vaccination sites, with additional precautions for physical distancing that are particularly relevant for large-scale clinics, such as:

- Providing specific appointment times or other strategies to manage patient flow and avoid crowding.
- Ensuring sufficient staff and resources to help move patients through the clinic as quickly as possible.
- Limiting the overall number of patients at any given time, particularly for populations at higher risk for <u>severe illness from COVID-19</u>.
- Setting up a one-way flow through the site and using signs, ropes, or other measures to direct patient traffic and ensure physical distancing between patients.
- Arranging a separate vaccination area or separate hours for persons at increased risk for severe illness from COVID-19, such as older adults and persons with underlying medical conditions, when feasible.
- Selecting a space large enough to ensure a minimum distance of 6 feet between
 patients in line or in waiting areas for vaccination, between vaccination stations, and
 in post vaccination monitoring areas (the Advisory Committee on Immunization
 Practices recommends that providers consider observing patients for 15 minutes
 after vaccination to decrease the risk for injury should they faint).
 Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site
 Locations Considerations for Planning Curbside/Drive Through Vaccination Clinics

12. Will ancillary supplies be included with COVID-19 vaccine?

Yes. COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to Iowa health care providers who have completed a COVID-19 Vaccine Provider Agreement. Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders.

Each kit will contain supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (various sizes for the population served)
- Syringes, 105 per kit
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients,100 per kit

Bandages, gloves, and sharps containers will not be included. Mixing kits to reconstitute a vaccine product include needles, syringes, and alcohol prep pads for use with vaccines requiring an adjuvant or diluent mixed at the administration site.

13. Will COVID-19 vaccine be reported in IRIS?

Health care providers who receive and administer COVID-19 vaccines will be required to enter doses of vaccine administered in IRIS within 24 hours after administration.

14. Will providers wanting to provide COVID-19 vaccines need to sign an agreement to receive the vaccine?

Yes. Health care providers must enroll in IRIS and agree to terms in the federal COVID-19 Vaccination Provider Agreement. Signing a COVID-19 Vaccination Provider Agreement does not ensure the clinic will receive COVID-19 vaccine and ancillary supplies. The CDC COVID-19 VaccinationProvider Agreement will be included as part of a REDCap survey.

15. Do providers already enrolled in IRIS still need to complete the COVID-19 Vaccination Provider Agreement?

Yes. All providers planning to receive and administer COVID-19 vaccines must complete a COVID-19 Vaccination Provider Agreement.

16. Can health care providers already enrolled in IRIS add additional users for the organization?

Yes. An admin user in each organization can add additional users. Contact the IRIS help desk for additional assistance.

17. Does the provider agreement provide any liability protection for the provider?

The CDC COVID-19 Vaccine Provider Agreement specifies the requirements to receive, store and administer COVID-19 vaccines.

The administration of COVID-19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICP), not the National Vaccine Injury Compensation Program. The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the covered countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of covered countermeasures identified in a PREP Act declaration. The <u>PREP Act declaration for medical countermeasures against</u> <u>COVID-19</u> states that the covered countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP and filing a claim are available at the toll-free number 1–855–266–2427 or <u>http://www.hrsa.gov/cicp/</u>.

18. Will there be a required observation period after vaccination?

ACIP currently recommends providers should consider observing patients for 15 minutes after receipt of a vaccine.

19. We have already heard concerns from clients and patients about the safety of a new vaccine. How do we address this?

This is a very important point. The CDC and IDPH will be addressing vaccine confidence throughout the COVID-19 vaccination campaign. CDC is in the process of developing materials to address concerns about COVID-19 vaccines. Additional information will be shared when materials are available.

20. Can vaccine information be provided in multiple languages so we can help build trust for the vaccine among the diverse populations in our communities? CDC and other public health partners are working on a communication campaign which will include multiple languages and formats. Information will be shared as it becomes available.

21. When will the first doses of COVID-19 vaccine be available?

It is anticipated very small amounts of vaccine will be made available late fall 2020 with supplies increasing in early 2021.

22. Are there any contraindications with providing COVID-19 vaccine while someone is being treated with antivirals for influenza?

IDPH does not have any information on contraindications at this time. Information will be shared as COVID-19 vaccines complete clinical trials and are either approved by the FDA or are distributed under an Emergency Use Authorization (EUA).

23. Will the vaccine be mandatory for essential healthcare workers?

There will be no state mandate to receive COVID-19 vaccine. Similar to influenza requirements, health systems and clinics may choose to set policies requiring COVID-19 vaccine for organization staff.

COVID-19 Allocation and Distribution

- A medical provider has an office in one county, but the main office is either out of county or out of state. Who does the clinic work with to receive COVID-19 vaccine? LPHAs/counties in Iowa will allocate doses of vaccine to providers only within their respective counties. Each provider location will be required to sign a COVID-19 Vaccination Provider Agreement and must work with the corresponding county to receive the vaccine.
- 2. Can vaccine be redistributed among providers within the same health system? As much as possible, vaccine will be shipped to the health care provider location where it will be administered to limit the possibility of storage and handling issues. However, due to minimum order quantities, transferring the vaccine will be an acceptable practice. IDPH will be providing guidance about the process to transfer COVID-19 vaccine, approval process and the need to transfer vaccine doses in IRIS.
- 3. Can a provider choose to order/stock certain COVID-19 vaccines? No. Allocations will be based upon available COVID-19 vaccines. LPHAs will work with health care providers for the allocation and distribution of COVID-19 vaccines.

COVID-19 Storage and Handling

 What are the storage and handling requirements for the COVID-19 vaccines? The anticipated first available COVID-19 vaccines have varying storage and handling requirements, ranging from refrigerated (2-8° C) to frozen (-20° C) to ultra-frozen (-60° to -80° C). The manufacturers are conducting ongoing vaccine stability testing. Additional guidance will be provided as it is received.

An addendum to the CDC <u>Vaccine Storage and Handling Toolkit</u> specifically addressing COVID-19 vaccines is currently being developed in addition to other training materials.

2. Is it known how long it will take to thaw ultra-frozen stored COVID-19 vaccines from frozen to refrigerated?

This information has not been released from the vaccine manufacturer. Information will be shared as soon as it becomes available.

3. The Planning Assumptions refer to the ultra-frozen vaccine shipping container needing to be "recharged". Please clarify what this means.

The ultra-frozen vaccine will arrive in a shipping container able to maintain the -70°C \pm 10°C storage requirement for 5 days. The shipping container will need to be replenished (recharged) with dry ice within 24 hours of receiving the shipment and again every 5 days if agencies plan to continue to store the ultra-frozen vaccine beyond the specified timeframe.

COVID-19 Reimbursement

 Will health care providers be able to charge for the COVID-19 vaccine? No. Providers cannot charge for COVID-19 vaccines provided by the federal government. It is unknown at this time if an administration fee will be able to be charged. IDPH will share more information about reimbursement claims for administration fees as it becomes available from insurers and federal and state partners.

Influenza and COVID-19 Vaccines

1. What is the difference between influenza (Flu) and COVID-19?

Influenza (Flu) and COVID-19 are both contagious respiratory illnesses, but are caused by different viruses. COVID-19 is caused by infection with a new coronavirus (called SARS-CoV-2) and flu is caused by infection with <u>influenza viruses</u>. Some of the symptoms of flu and COVID-19 are similar and it may be hard to tell the difference based on symptoms alone. Testing may be needed to help confirm a diagnosis. Flu and COVID-19 share many characteristics, but there are some key differences between the two. <u>This table</u> compares COVID-19 and flu, given the best available information to date.

2. Will there be flu along with COVID-19 in the fall and winter?

CDC believes it is likely flu viruses and the virus causing COVID-19 will both be circulating this fall and winter. Getting a flu vaccine will be more important than ever. The CDC recommends all people 6 months and older receive the flu vaccine each year.

3. Will receiving a flu vaccine protect against COVID-19?

Getting a flu vaccine will not protect against COVID-19, however flu vaccination has many other important <u>benefits</u>. Flu vaccines have been shown to reduce the risk of flu illness, hospitalization and death. Getting a flu vaccine this fall will be more important than ever, not only to reduce the risk from flu but also to help conserve potentially scarce health care resources.

Pharmacy

 Will pharmacies be allowed to administer COVID-19 vaccine? Yes. Pharmacies will be allowed to receive and administer COVID-19 vaccine. Local Public Health Agencies may allocate doses of COVID-19 vaccine to health care providers in the county who have signed a COVID-19 Vaccination Provider Agreement.