

2019 Novel Coronavirus Pandemic Vaccination Planning Assumptions August 18, 2020

Background

The SARS-CoV-2 virus, which causes COVID-19 disease, continues to threaten the health of Americans. The U.S. Department of Health and Human Services (HHS) is working with partners, including vaccine manufacturers, to develop vaccines against SARS-CoV-2 infection. Effective distribution and administration of COVID-19 vaccines will be critical to prevent morbidity and mortality and reduce the impact of COVID-19.

The purpose of this document is to address and provide the most recent information received by the Iowa Department of Public Health (IDPH) regarding the allocation, distribution and administration of COVID-19 vaccines. For planning purposes, *allocation* refers to the amount of COVID-19 vaccine made available to an entity. *Distribution* refers to the act of shipping COVID-19 vaccine to an entity.

Prioritization of COVID-19 Vaccines

1. Recommendations on priority groups for COVID-19 vaccine will likely change throughout the response, depending on vaccine supply and disease epidemiology.
2. Public demand for COVID-19 vaccination will likely be high, especially when supply is limited and if there is severe disease in the community. Decisions will be based on vaccine supply, pandemic severity and impact, and the potential for disruption of community critical infrastructure.
3. Prioritization of populations are being considered by the Advisory Committee on Immunization Practices (ACIP) and the National Academy of Medicine.
4. IDPH plans to follow federal guidance for vaccine prioritization unless needs in Iowa are substantially different. The IDPH Medical Director will work with the Infectious Disease Advisory Committee (IDAC) for targeted COVID-19 vaccination guidance.
5. Initial populations recommended for COVID-19 vaccination will likely include critical workforce who provide health care and maintain essential functions of society and residents in long term care facilities; all dependent on vaccine supply.

Vaccine Planning Assumptions

1. Routine immunization programs will continue during the administration of COVID-19 vaccine.
2. Seasonal influenza vaccination will be particularly important for all persons ≥ 6 months of age, especially front-line health care providers (HCPs), to limit influenza as another respiratory illness as well as a competing factor for health care resources.
3. Many different COVID-19 vaccines are in development, and it is unknown which vaccine(s) will be available. Clinical trials are being conducted with large-scale manufacturing occurring simultaneously.
4. Limited COVID-19 vaccine doses may be available as early as fall, 2020.

5. Two doses of COVID-19 vaccine, separated by ≥ 21 or > 28 days, will be necessary for immunity.
6. Interchangeability among vaccine brands/manufacturers will not be an acceptable practice, requiring completion of the vaccine series with the same vaccine manufacturer. This will require additional action to track vaccines administered and patient reminders.
7. When vaccine is in limited vaccine supply, a second dose may not be available and vaccines should not be held back to ensure persons receive their second dose.
8. Some vaccines may require ultra low cold (ULC) chain storage and handling. This may result in special considerations for local storage, distribution and administration.
9. Iowa's Immunization Registry Information System (IRIS), and possibly other federal systems will be used to distribute, report doses administered and assess and track vaccination coverage of COVID-19 vaccine.
10. Initial doses of COVID-19 vaccine may be authorized for use under an Emergency Use Authorization (EUA) issued by the Food and Drug Administration (FDA), based upon available safety and efficacy data.

National Vaccine Distribution Assumptions

1. COVID-19 vaccine will be allocated to Iowa based on population size and target populations.
2. CDC may distribute COVID-19 vaccine directly to select commercial (e.g., chain drug stores) and federal partners (e.g., veterans administration).
3. COVID-19 vaccine distribution and tracking will be conducted using principles exercised in influenza pandemic planning.
4. Iowa health care providers who intend to provide COVID-19 vaccine will need to complete a COVID-19 Pandemic Vaccine Provider Agreement. A federal provider agreement is forthcoming and will be made available as soon as received.
5. All health care providers must enroll in IRIS to be eligible to receive COVID-19 vaccine.
6. Vaccine will be sent directly to Iowa health care providers (e.g. Local Public Health Agencies, physician's office) from a central distributor contracted by the federal government.
7. IDPH will be required to report timely vaccination data to CDC to provide tracking of vaccine administration and inform safety monitoring and assessment of vaccine effectiveness. This may be accomplished using IRIS and/or other federally developed systems.

Iowa Assumptions

1. COVID-19 vaccine will be allocated proportionally to counties based on population size, target populations and disease epidemiology.
2. Counties (Local Public Health Agencies - LPHAs) will receive allocations of COVID-19 vaccine through IRIS.
3. 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 Pandemic Vaccine Provider Agreement. Ancillary supplies will include but is not limited to needles, syringes and sharps containers.
4. Allocation of ancillary supplies will be managed through IRIS and distributed directly to health care providers.
5. Health care providers who receive and administer COVID-19 vaccine will be required to enter doses of vaccine administered into IRIS and/or a federally developed system.

Draft Plan/Procedures

IDPH COVID-19 Vaccine Allocation Process

1. IDPH will receive ongoing allocations of COVID-19 vaccines from CDC.
2. IDPH will allocate doses of vaccine to LPHAs based upon population size, target populations, disease epidemiology and availability of vaccines.
3. IDPH will import county vaccine allocation amounts into IRIS.
4. IDPH will notify counties (LPHAs) when a vaccine allocation is available in IRIS and the timeframe for completion of distribution requests.

Local Public Health COVID-19 Vaccine Allocation Process

1. Counties (LPHAs) receive allocation of COVID-19 vaccine from IDPH.
2. LPHAs are the only entities in each county able to allocate COVID-19 vaccine for health care providers. LPHAs may allocate COVID-19 vaccine at their discretion consistent with the county's pandemic vaccine plan.
3. Health care providers will not order COVID-19 vaccines directly from the state or county. Health care providers will receive an allocation from the LPHA based on the county's pandemic vaccine plan.
4. Counties (LPHAs) have the ability in IRIS to view all health care providers in their county who have completed a COVID-19 Vaccine Provider Agreement.
5. Allocations of vaccine may be made to health care providers in the county or all doses of vaccine may be allocated to the county LPHA.
6. Counties (LPHAs) may choose not to allocate all doses of COVID-19 vaccine. Doses of vaccine not allocated by a LPHA will be reallocated back to IDPH for redistribution to other counties.
7. The allocation of vaccines to a health care provider by the LPHA will create a vaccine order in IRIS. COVID-19 vaccine orders will be distributed directly to the health care provider from a central distributor.

IDPH COVID-19 Vaccine Order Approval

1. IDPH will review all vaccine orders submitted by counties (LPHAs).
2. IDPH will approve vaccine orders for submission or may modify orders as necessary.
3. IDPH will import vaccine orders into the CDC Vaccine Tracking System (VTrckS).

Vaccine Distribution

1. CDC will receive and approve vaccine orders to assure consistency with Iowa's vaccine allocations.
2. CDC will distribute vaccine orders directly to health care provider sites using a central distributor.

CDC Vaccine Clinic Considerations

1. CDC has issued revised Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations ([Guidance for Planning Vaccination Clinics.](#)) The purpose of this guidance is to assist with planning and implementation of satellite, temporary, or off-site vaccination clinics by public and private vaccination organizations.
2. The Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations also provides information on additional considerations required during the COVID-19 pandemic, including physical distancing, personal protective equipment (PPE), and enhanced sanitation efforts. Additionally, curbside and drive-through clinics may provide the best option for staff and patient safety during the COVID-19 pandemic.