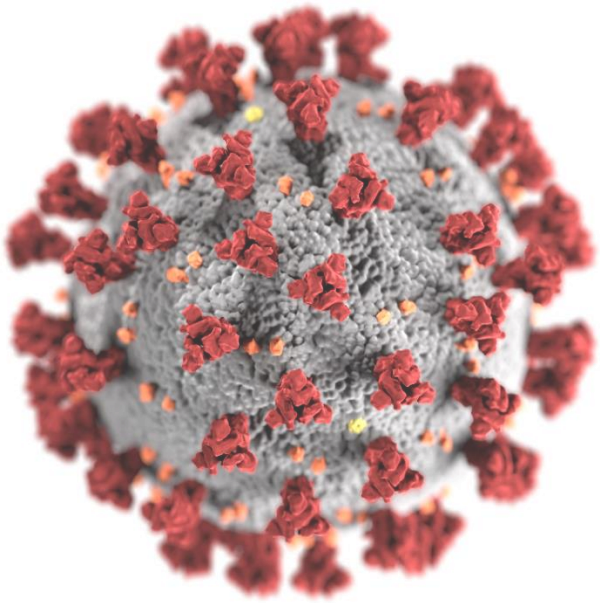


COVID-19 Vaccination Strategy - Draft

IOWA

Iowa Department of Public Health
DECEMBER 4, 2020 VERSION 2.0

IOWA COVID-19 VACCINATION STRATEGY

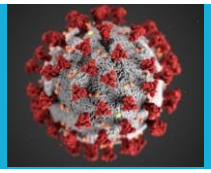
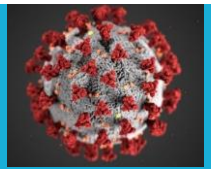


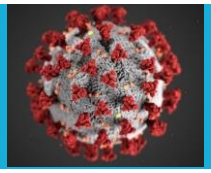
Table of Contents



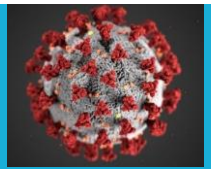
Record of Changes

Date of original version: October 11, 2020 Version 1.2

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author
	Version 2.0	11.25.20	Corrected Name: Iowa Veterans Home, throughout the document.	Rebecca Curtiss
	Version 2.0	11.25.20	Review of Technical Assistance Comments completed.	Rebecca Curtiss
	Version 2.0	11.25.20	Provide clarification on the anticipated frequency for updates to the strategy document.	Rebecca Curtiss
	Version 2.0	11.25.20	Reference to Sac and Fox of the Mississippi in Iowa (locally known as the Meskwaki Nation) in the Introduction. Updates to Introduction.	Rebecca Curtiss
	Version 2.0	11.25.20	Update to the Infectious Disease Advisory Committee (IDAC). Section 2.	
	Version 2.0	11.25.20	Added information that the Meskwaki Nation will receive vaccine directly from IHS. Updates to Section 2.	Rebecca Curtiss
	Version 2.0	11.25.20	Aligned language regarding early populations of focus with ACIP workgroup discussions on priority populations. Link to additional information regarding Advisory Council Updates to Sections 2 and 3	Rebecca Curtiss
	Version 2.0	11.25.20	Updated lists and information regarding the maps available to local partners related to the identification of priority populations for vaccine planning. Updates to Section 4.	Rebecca Curtiss
	Version 2.0	11.25.20	Vaccine Provide Agreement Status. Updates to Section 5.	Rebecca Curtiss
	Version 2.0	11.25.20	Added information on the federal pharmacy partnership for COVID-19 vaccination in LTCFs. Section 5	Rebecca Curtiss



	Version 2.0	11.25.20	Added information on federal direct allocations to pharmacy partners (Phase 2). Section 5.	Rebecca Curtiss
	Version 2.0	11.25.20	Added information on direct federal allocations to federal entities. Section 5.	Rebecca Curtiss
	Version 2.0	11.25.20	Added details of ancillary kit contents. Section 7.	Rebecca Curtiss
	Version 2.0	11.25.20	Added information that IDPH will report vaccine inventory to VaccineFinder. Section 7.	Rebecca Curtiss
	Version 2.0	11.25.20	Updated product labeling information. Section 7.	Rebecca Curtiss
	Version 2.0	11.25.20	Added information about vaccine A pre-positioning. Section 7.	Rebecca Curtiss
	Version 2.0	11.25.20	Updated information for vaccine allocation, ordering, direct shipment, receipt, storage and handling of vaccine. Section 7.	Rebecca Curtiss
	Version 2.0	11.25.20	Added information on vaccine storage temperature monitoring and use of digital data loggers. Section 8.	Rebecca Curtiss
	Version 2.0	11.25.20	Additional information added and updated regarding the Emergency Use Authorization (EUA). Section 13.	Rebecca Curtiss
	Version 2.0	11.25.20	Added information on smartphone app V-Safe. Section 14.	Rebecca Curtiss
	Version 2.0	11.25.20	Updated information on CDC dashboards and use of Tiberius. Section 15.	Rebecca Curtiss
	Version 2.0	12.3.20	Updated information on ACIP recommendations throughout the strategy	Rebecca Curtiss



Preface

The Iowa Department of Public Health (IDPH) developed this COVID-19 Vaccination Strategy in response to requests from the Center for Disease Control and Prevention (CDC) and other federal partners. Immunization with a safe and effective COVID-19 vaccine is a critical component Iowa's approach to reduce COVID-19-related illnesses, hospitalizations, and deaths and to help restore societal functioning. This strategy is designed to assist local, state and federal partners in understanding how Iowa will operationalize vaccine distribution.

Introduction

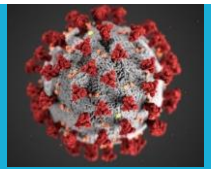
Early in the COVID-19 Vaccination Campaign, there may be a limited supply of COVID-19 vaccine. Vaccination efforts will focus on those critical to the response; including those who, provide direct care, and maintain critical infrastructure, as well as those at highest risk for developing severe illness from COVID-19.

As CDC has requested this information is in 15 main sections, which cover specific areas of COVID-19 vaccination program implementation and provide key components to operationalize this strategy. Each section has subsections that detail very specific descriptions for how the Iowa Department of Public Health (IDPH) intends to implement vaccine distribution and reporting in Iowa.

IDPH developed this strategy in coordination with a wide range of public and private sector partners, including immunization and public health emergency preparedness programs, Sac and Fox of the Mississippi in Iowa (locally known as the Meskwaki Nation), emergency management agencies, healthcare organizations, industry groups that include critical infrastructure sectors, policy makers, and community vaccination providers (e.g., pharmacies, occupational health settings, and doctors' offices). The collaboration and preparation of these partners to receive and administer COVID-19 vaccine is a key component in the distribution and administration of COVID-19 vaccine to all Iowans in a safe and equitable manner.

Purpose

The purpose of the Iowa COVID-19 Vaccine Strategy is to assist partners in a shared understanding of pandemic response which includes planning and strategy assumptions, roles and responsibilities, ordering and reporting, and mass vaccination tools to reduce morbidity and mortality from COVID-19. This strategy is being used to describe operational components and strategies for the distribution and administration of medical countermeasures such as vaccine distribution currently in place as documented in the Iowa Department of Public Health (IDPH) Emergency Response Plan.



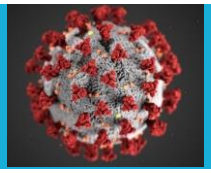
The Public Health Emergency Response Plan is confidential under Iowa Code section 22.7(50). This section provides in relevant part that the following documents are confidential: information and records concerning physical infrastructure, cyber security, critical infrastructure, security procedures, or emergency preparedness developed, maintained, or held by a governmental body of life or property, if disclosure could reasonably be expected to jeopardize such life or property. Such information and records include, but are not limited to information directly related to vulnerability assessments; information contained in records relating to security measures such as security and response plans; security or response procedures; emergency response protocols; and information contained in records that if disclosed would significantly increase the vulnerability of critical physical systems or infrastructures to attack.

This strategy outlines the Iowa concepts for the allocation, distribution, redistribution, transportation, dispensing, and administration of state allocated COVID-19 vaccines. The strategy is based upon the availability of COVID-19 vaccines, and distribution occurring through existing infrastructure using the state immunization program as is currently used for routinely recommended publicly funded vaccines. For discussion and definition 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.

Given COVID-19 vaccine supply will increase incrementally as vaccines are produced during the pandemic, targeted decisions must be made in the initial allocations provided to this state. Such decisions will be based on vaccine supply, pandemic severity and impact in different parts of the state, potential for disruption of community critical infrastructure, and operational considerations, such as storage capabilities. Prioritization of populations to be reached early in the vaccination response when vaccine supply is limited is being considered by the Advisory Committee on Immunization Practices and the National Academy of Medicine. Iowa will use this information and work with the Iowa Infectious Disease Advisory Committee (IDAC) and the IDPH Medical Director to support targeted COVID-19 vaccination guidance and orders. See page 13 of this document for additional information regarding IDAC.

Background

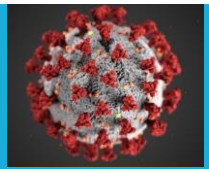
The SARS-CoV-2 virus, which causes COVID-19 disease, continues to threaten the health of Americans. The U.S. Department of Health and Human Services (HHS) is working with partners, including vaccine manufacturers, to develop vaccines against SARS-CoV-2 infection. COVID-19 vaccination response operational guidance is developing, providing instructions to public health programs for implementation of state and local COVID-19 vaccination response. Iowa will utilize the following COVID-19 vaccination approaches and recommended initial action steps included in this strategy.



Guidance on determining and providing vaccines to priority groups will be based on the principles included in the CDC "Updated Planning Guidance on Allocating and Targeting Pandemic Influenza Vaccine during an Influenza Pandemic" and the "COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations."

Development and Maintenance

This document was developed by IDPH internal and external partners in accordance with CDC and other Federal partners. This strategy will be implemented and updated at least monthly through July 2021, and based on additional information provided by CDC and other partners (such as ACIP, National Institutes of Health, National Academy of Science, National Academy of Engineering and Sciences, among others) over the implementation period of the COVID-19 Vaccine campaign. IDPH fully expects to receive near daily updates from internal, external and federal partners over the next weeks and months. The Bureau of Emergency and Trauma Services is responsible for the review and maintenance of this document in coordination with the Bureau of Immunization and Tb.



Section 1: COVID-9 Vaccination Preparedness Planning

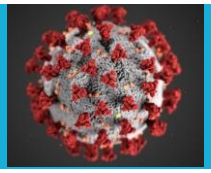
A. ***Describe your early COVID-19 vaccination program planning activities, including lessons learned and improvements made from the 2009 H1N1 vaccination campaign, seasonal influenza campaigns, and other responses to identify gaps in preparedness.***

EXCERPT FROM 2009 H1N1 AFTER ACTION IMPROVEMENT PLAN*: The response in Iowa to 2009 H1N1 was widely regarded as well coordinated based on survey results. Prevention, communication, and mitigation comprised the primary portions of the response. There were AARs created for both the Spring and Fall Events. The fall response provided an opportunity to implement improvements suggested from the spring response, and to provide prevention and mitigation information and response assistance to Iowa's communities. IDPH coordinated planning processes and information sharing between IDPH, local public health agencies, and partners. These relationships have improved public health preparedness and response capabilities across the state. The groundwork for these relationships has been laid through years of multi-disciplinary planning on local, regional, and state levels and between private and public agencies. The importance placed on these partnerships is evident in the fact that 100 percent of local public health agencies who responded to the H1N1 survey reported sharing information with their local partners. Effective communication with partners is a key component of effective responses.*

As in 2009, IDPH has a robust internal planning team. The team meets daily and updates vaccine distribution and communication guidelines and documents. IDPH has implemented information sharing with local health departments and healthcare providers through weekly webinars as information from CDC becomes available. CDC and Iowa specific documents are also updated daily and posted to the Iowa Health Alert Network (HAN) Document library for partner reference.

EXCERPT FROM 2009 H1N1 AFTER ACTION IMPROVEMENT PLAN: *IDPH established their ability to maintain timely and effective communication with response partners through use of the Health Alert Network and conference calls.*

As in 2009, the Iowa Health Alert Network remains IDPH's primary communication and information sharing tool with local partners. COVID-19 folders on the document library have been established and updated documents are shared daily. In 2009, IDPH hosted many conference calls to share information and to answer outstanding questions. IDPH currently hosts ZOOM meetings with local public health agencies weekly to provide updated vaccine information and answer questions. A process has been implemented for posting a Frequently Asked Questions (FAQ) document for local public health agencies following every ZOOM Meeting.



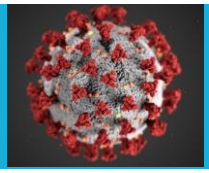
EXCERPT FROM 2009 H1N1 AFTER ACTION IMPROVEMENT PLAN: *During the fall response to 2009 H1N1, vaccine was available to prevent illness. IDPH handled the ordering and allocation of 2009 H1N1 vaccine. Ninety-eight percent of local public health agencies (81 of 83) reported receiving sufficient information on the overall process utilized for allocation of 2009 H1N1 vaccine. Using data collected from November 2009 through February 2010, it was determined that Iowa had a higher vaccination rate than the national average. In Iowa, 28 percent of adults and 40 percent of children were vaccinated for 2009 H1N1. In the United States as a whole, 15 percent of adults and 32 percent of children were vaccinated for 2009 H1N1.*

EXCERPT FROM 2009 H1N1 AFTER ACTION IMPROVEMENT PLAN: *The overall response to 2009 H1N1 was highly successful. With every response, however, comes the opportunity to learn and identify areas for improvement.*

The IDPH internal planning team has established processes for the ordering and allocation of COVID-19 vaccines very similar to the processes successful in 2009.

- The IDPH internal planning group began officially meeting the week of August 17, 2020.
- Prior to that date the Bureau of Immunization had been working very closely with CDC and other partners regarding the federal expectations of states to plan for the allocation and distribution of federally provided COVID-19 vaccine.
- Once this group convened, the team immediately initiated an action plan; including establishing goals, objectives and timelines.
- The group established five phase 1 vaccine planning goals with specific objectives, each objective has associated tasks with timelines delegated to individual team members. Tasks are updated daily.
    - IDPH will prepare for the allocation and distribution of COVID-19 vaccine and ancillary supplies.
    - IDPH will develop a communication strategy to ensure Immunization stakeholders and the public receive timely COVID-19 vaccination information.
    - IDPH will encourage and promote the importance of continuing routine immunization programs.
    - IDPH is technologically prepared to allocate, distribute, and administer COVID-19 vaccine.
    - IDPH will use data for decision making.

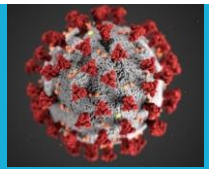
Internal tracking documents have been established to monitor specific goals and expectations, and allow for the weekly review for after action items and continuous quality improvement. Daily reminder prompts were added to the internal tracking documents.



B. ***Include the number/dates of and qualitative information on planned workshops or tabletop, functional, or full-scale exercises that will be held prior to COVID-19 vaccine availability. Explain how continuous quality improvement occurs/will occur during the exercises and implementation of the COVID-19 Vaccination Program.***

IDPH is working to assess priority groups, vaccine distribution, vaccine tracking and monitoring, documenting doses administered and reporting on vaccine status. In order for IDPH to be prepared to distribute COVID-19 vaccines for administration and record administered COVID-19 vaccine doses as soon as the vaccine is available, an assessment of current systems and processes was conducted by the IDPH internal planning team. Testing and exercises of internal processes will be ongoing throughout the coming weeks and months. Continuous quality improvement will be ongoing for each process of planning for COVID vaccine administration in the State of Iowa.

See Section 15 for additional information regarding methods and procedures for monitoring internal and external progress in the COVID Vaccination program implementation.



Section 2: COVID-19 Organizational Structure and Partner Involvement

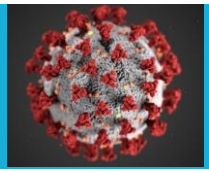
A. *Describe your organizational structure.*

The Iowa Department of Public Health (IDPH) is the lead state department in developing the strategy for COVID-19 vaccination distribution. IDPH is composed of the Director's Office plus five divisions, four boards, and the Office of the State Medical Examiner. Each unit of IDPH has specific areas of responsibilities during day-to-day operations. The Director's Office, divisions, and bureaus work together to support the Department's mission and objectives. During a response to a potential or actual public health emergency or disaster the Department's Director, Deputy Director, Duty Officer, and the Division of Acute Disease Prevention and Emergency Response and Environmental Health (ADPER & EH) assumes or assigns leadership roles and initiates the response. The ADPER & EH Division works closely with the IDPH Medical Director and the Center for Acute Disease Epidemiology (CADE) which includes the Deputy State Epidemiologist.

Meetings are held three times a week to review COVID-19 vaccine distribution goals and expectations. The Division of Acute Disease Prevention, Emergency Response and Environmental Health (ADPER & EH) is the division that organizationally contains the Bureau of Immunization and Tuberculosis as well as the Bureau of Emergency and Trauma Services (PHEP and HPP Preparedness and Response). Throughout the COVID-19 response this division has been functionally involved in nearly every aspect of COVID-19 response. The Bureau of Immunization and Tuberculosis has been participating in meeting with federal partners for several months preparing for the release of the COVID-19 vaccine.

B. *Describe how your jurisdiction will plan for, develop, and assemble an internal COVID-19 Vaccination Program planning and coordination team that includes persons with a wide array of expertise as well as backup representatives to ensure coverage.*

IDPH has convened an internal COVID-19 Vaccine Planning team with representation from the state immunization bureau, the hospital and public health preparedness and response bureau that includes the IDPH Strategic National Stockpile (SNS) Officer, risk communication officer, planning and performance officers, the IDPH Medical Director and State Epidemiologist, Deputy State Epidemiologist, Governor's office staff, and fiscal specialists, and other members of the department's incident management roster that includes staff from the Bureau of Environmental Service and Radiological Health. This internal group meets daily to review a mission task list and required reporting updates.



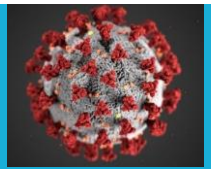
C. ***Describe how your jurisdiction will plan for, develop, and assemble a broader committee of key internal leaders and external partners to assist with implementing the program, reaching critical populations, and developing crisis and risk communication messaging.***

D. ***Identify and list members and relevant expertise of the internal team and the internal/external committee.***

In mid-September, 2020 the internal planning group reached out to the following partners to inform and gather feedback.

This broad group of key external partners met and will continue to meet to assist with implementing the program and strategies discussed in this document, reaching critical populations and assuring the crisis and risk communication messages are shared broadly. The following list will be expanded as needed and sub groups may be developed for additional focused vaccine distribution strategies as needed:

- Iowa Hospital Association
- Iowa Health Care Association
- Iowa Board of Pharmacy
- Iowa Public Health Association
- Iowa Chapter American Academy of Pediatrics (AAP)
- Mercy Hospital-Des Moines
- UnityPoint Health System
- Polk County Public Health
- Marion County Public Health
- Iowa Governor's Office
- HHS
- Iowa Department of Human Rights
- Iowa Osteopathic Medical Association
- Iowa Medical Society
- Leading Age Iowa
- Iowa Pharmacy Association
- Iowa Academy of Family Physicians (IAFP)
- Iowa Immunization Coalition
- University of Iowa Hospital & Clinics
- Johnson County Public Health
- Linn County Public Health
- Harrison County Public Health
- Shelby County Public Health
- CDC Project Officer-Immunization
- Iowa Department of Human Services
- Department of Corrections
- Iowa Veterans Home



IDPH has implemented the following general readiness activities in an effort to communicate updates with Local Public Health Agencies (LPHAs), providers, and other partners (IA AAP, IAFP, Medical Society, LTC Association).

- Conducting weekly webinars with LPHAs
- Vaccine Info Brief sent weekly to LPHAs and healthcare partners
- Frequently Asked Questions (FAQ) documents for HealthCare Provider, Public, and LPHAs
- Vaccine specific email (COVID19Vaccine@idph.iowa.gov) for healthcare provider's COVID-19 vaccine questions
- COVID-19 vaccine call center established for vaccine questions from healthcare providers
- Public-facing documents are posted to the IDPH website

Additionally, the IDPH Medical Director and State Epidemiologist will convene a group of infectious disease specialists, the Infectious Disease Advisory Committee (IDAC), to review the priority groups for COVID-19 vaccine and make recommendations to IDPH regarding these groups. While the ACIP has provided clarity on these first priority populations, we will convene a team of external and internal subject matter experts, known collectively as the Infectious Disease Advisory Council (IDAC), to provide additional clinical guidance.

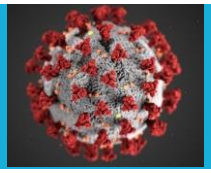
This council will assist the State in developing COVID-19 vaccine prioritization of populations for early stages in the vaccination response when supply is limited.

This group will bring together ethical and clinical expertise from across the state to represent multiple perspectives including:

- Rural/urban populations
- Hospital administration
- Infectious disease specialists
- Vulnerable populations in congregate settings
- Advocates for aging populations
- Individuals with intellectual and developmental disabilities
- Refugees

The reason for this is to minimize health inequities based on geography, poverty and other social determinants. This group will also provide input as additional vaccines become available, as well as therapeutics.

Additional information regarding IDAC can be found at this link:
https://idph.iowa.gov/Portals/1/userfiles/61/covid19/vaccine/IDAC_Framework_Dec2020.pdf



During this public health emergency, the IDPH bureau of Immunization and Tuberculosis (ITB), and BETS in coordination with the Governor's office, will coordinate and deliver risk communication and public health information through a variety of channels, including but not limited to the following stakeholders.

- The media
- The IDPH web site
- Social media
- Partners/stakeholders
- A Joint Information Center (JIC) if activated

Additionally, communication efforts will be conducted in close coordination with Iowa Homeland Security and Emergency Management, other appropriate state agency public information officers, and local public health departments. The COVID-19 Communications Plan is attached to this plan as Appendix A.

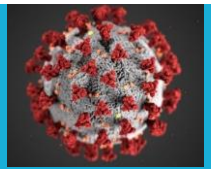
The communication plan objectives include the following.

- Educate the public about COVID-19 vaccine development, authorization prioritization, distribution, and implementation.
- Ensure public confidence in the process, safety, and efficacy of COVID-19 vaccines.
- Ensure active, timely, effective public health and safety messaging along with outreach to key state and local partners, populations of focus, and the public.
- Provide communication messaging, products, guidance to support health departments and others administering vaccine.
- Share timely ongoing COVID-19 vaccine tracking and administration data with public and partners.

E. *Describe how your jurisdiction will coordinate efforts between state, local, and territorial authorities.*

Collaboration and coordination are the keys to success for implementing vaccine response efforts. IDPH coordinates activities with CDC, Assistant Secretary for Preparedness and Response (ASPR), the Regional Emergency Coordinators (RECs) and other federal partners during preparedness and response activities. These relationships provide access to national resources when local and State resources have been depleted. IDPH has a strong working relationship with federal project officers and the RECs, both in the course of day-to-day activities and during this COVID-19 response.

Coordination and communication with Iowa's 99 local public health agencies is essential to the vaccine response.



Weekly webinars and meetings are scheduled ongoing for the communication, information sharing and provision of guidance documents to local public health. IDPH holds high expectations of local public health for continued information sharing at the local level. Local public health agencies are most in tune with local providers and priority populations.

Communication will also be provided through the preparedness healthcare coalitions (HCC). The HCCs core members include: local public health, hospitals, emergency management, and EMS. Iowa's HCCs all have multiple representatives from each of the disciplines. Additional members represented in the HCCs include volunteer organizations and church groups, private businesses, mental health partners, clinics, and others. These secondary groups are included based on the needs identified within each coalition.

Additional communications and relationships exist between IDPH and Iowa's Homeland Security and Emergency Management Department (HSEMD), the Iowa Department of Education (DE), the Iowa Department of Human Services (DHS), Iowa Department of Aging, Iowa Department of Public Safety (DPS), the State Hygienic Laboratory and the State Fusion Center.

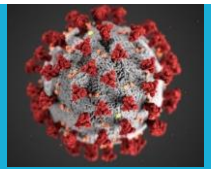
Engagement of non-governmental partners such as pharmacies and healthcare entities and clinics is also essential to ensuring success. Many resources needed for this vaccine response are owned and operated by the private sector.

IDPH continues to work closely with internal and external teams to develop small group meetings as needed to address ongoing concerns and to provide specific guidance.

F. *Describe how your jurisdiction will engage and coordinate efforts with leadership from tribal communities, tribal health organizations, and urban Indian organizations.*

The Iowa Department of Public Health's work with the Sac and Fox of the Mississippi in Iowa (locally known as the Meskwaki Nation) was reviewed as part of meeting Public Health Accreditation Board (PHAB) standards and measures. IDPH staff provide technical assistance internally related to communications and requests of the Tribe. The Medical Director and State Epidemiologist serves as a central point of contact for the leader of the Tribal Health Center. The IDPH Medical Director and State Epidemiologist is continuing efforts to communicate directly with the tribal clinic director.

This team is available to assist in engaging with the Tribe about vaccine preparedness and planning. Team members also participate in regional efforts related to work with the various Tribes in the Midwest, such as an Opioid Surveillance Taskforce through the Great Plains Tribal Epidemiology Center. In addition, the tribal health clinic is a Vaccines for Children (VFC) program provider. The Meskwaki Nation will receive direct vaccine distribution from Indian Health Services.



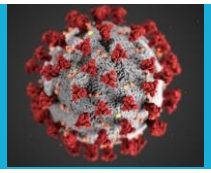
Staff from the Bureau of Immunization and Tuberculosis are in frequent contact with clinic staff and will continue to reach out to tribal partners. Regular communication between the Immunization Bureau and the VFC coordinator at the tribal health clinic has been established and is ongoing.

G. ***List key partners for critical populations that you plan to engage and briefly describe how you plan to engage them, including but not limited to:***

- ***Pharmacies***
- ***Correctional facilities/vendors***
- ***Homeless shelters***
- ***Community-based organizations***

Key partners for critical populations and the engagement of local partners is a focus for state and local public health agencies. IDPH has engaged the Iowa Board of Pharmacy in internal conversations and have included the association in the external planning workgroup. Local partners have developed relationships that have enhanced the ability to serve at-risk and individuals with health disparities during this COVID response such as homeless shelters, correctional facilities and vendors.

Local public health engagement during this COVID-19 response with community-based organizations such as social services and faith-based organizations have assisted with identifying and communicating with at-risk individuals. IDPH and local public health will continue to work with VFC Program providers and other child health-focused organizations to consider the unique challenges associated with children in the COVID-19 vaccine efforts. IDPH will continue to work with schools to complete educational outreach to children with the intent of reducing children's vulnerability to illness and understanding age-appropriate actions to reduce the spread of disease with vaccines when it is available for this population.



Section 3: Phased Approach to COVID-19 Vaccination

A. ***Describe how your jurisdiction will structure the COVID-19 Vaccination Program around the three phases of vaccine administration:***

Iowa has developed a detailed strategy regarding distribution to vulnerable populations first, allowing for additional ramp-up as additional supply becomes available in the initial launch phase, and the State anticipates vaccine supply will be limited. As such, the beginning of the campaign will focus on vaccination providers and settings for vaccination of limited critical populations as well as outreach to these populations. Iowa expects the vaccine supply to increase quickly over the subsequent months, allowing vaccination efforts to be expanded to additional critical populations and the general public.

IDPH anticipates ongoing federal guidance regarding priority population groups to receive initial doses of vaccine. However, priority designations could change after the vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors. Due to changing vaccine supply levels at various points during the COVID-19 Vaccination Program, planning needs to be flexible but as specific as possible to accommodate a variety of scenarios. Decisions making is ongoing about use of initially available supplies of COVID-19 vaccines. These decisions are partially informed by the proven efficacy of the vaccines coming out of Phase 3 trials.

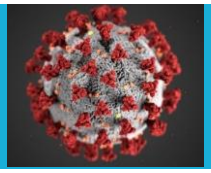
On December 2, 2020, ACIP issued The Advisory Committee on Immunization Practices (ACIP) announced their recommendations for the initial phase of the COVID-19 vaccination program (Phase 1a) vaccination should be offered to both:

- Health care personnel (HCP) and,
- Residents of long-term care facilities (LTCs)

Phase 1: Potentially Limited Doses Available

IDPH will use the Immunization Registry Information System (IRIS) for the ordering, distribution and documentation of COVID-19 vaccine doses administered. Local public health agencies will be responsible for the allocation of COVID-19 vaccine to local healthcare providers and other organizations such as pharmacies. Healthcare provider sites interested in offering pandemic vaccines must also enroll in IRIS.

The success of the COVID-19 vaccination campaign will depend upon the collaboration of the IDPH, Iowa local public health agencies and Iowa healthcare providers to administer pandemic vaccines. All healthcare providers and organizations sites interested in receiving and administering COVID-19 vaccines in Iowa are required to complete the CDC COVID-19 Vaccination Program Provider Agreement (Appendix C). IDPH will utilize a REDCap survey to document provider acceptance of the terms to serve as a COVID-19 vaccine provider.



The survey includes a PDF of the CDC COVID-19 Vaccination Program Provider Agreement in its entirety.

In addition to completing the CDC COVID-19 Vaccination Program Provider Agreement, healthcare providers will also need to provide basic information regarding the organization, including clinic hours/days of operation, provider type and setting, patient population served, demographic logistical information for receiving COVID-19 vaccine shipments, number of patients the clinic is able to vaccinate weekly and vaccine storage capacity (refrigerated/frozen/ultra-cold temperature).

IDPH has widely distributed the CDC COVID-19 Vaccination Scenarios for Jurisdictional Planning for Phase I.

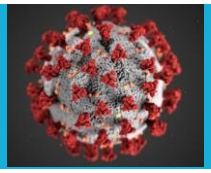
The Iowa planning team will use the following assumption In Phase 1:

Target Populations**:**
CDC guidance and tools will assist the Iowa internal and external planning teams to create estimates of the number of residents in each target/priority group to be determined. Priority group assumptions are currently being used to develop baseline estimates for prioritization.

Prioritization of COVID-19 Vaccines:
Vaccination activities will include populations considered high-risk for complications and comorbidities, disparate populations, and the providers working with these populations.

In addition, The Centers for Disease Control and Prevention (CDC) have created tiers for vaccine prioritization for use in routine influenza season that may initially be used.

- Recommendations on priority groups for COVID-19 vaccine will likely change throughout the response, depending on vaccine supply and disease epidemiology.
- 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 critical infrastructure.
- CDC's Advisory Committee on Immunization Practices (ACIP), the National Institutes of Health, and the National Academies of Sciences, Engineering, and Medicine (NASEM) will continue to determine populations of focus for COVID-19 vaccination and ensure equity in access to COVID-19 vaccination availability across the United States.



- IDPH intends 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 and the IDPH planning team for targeted COVID-19 vaccination guidance. IDPH may issue a Vaccine Shortage Order or other guidance during Phase 1 to ensure that vaccines are administered solely to those in a priority designation and in accordance with the COVID-19 vaccination guidance.

Efforts are ongoing to estimate state and county level population size for the following groups. These estimates are being shared with local partners for planning purposes and additional priority groups are added as established and data becomes available:

- Critical workforce who provide healthcare and have direct or indirect exposure to patients in such settings as hospitals and long term care facilities (LTC)
- Non-healthcare worker critical workforce such as agriculture and food processing as well as other key critical infrastructure
- People at high risk for COVID-19 illness-LTC residents and staff

IDPH has shared with local partners, CDC's Roadmap to Implementing Pandemic Influenza Vaccination of Critical Workforce. This CDC planning guide provides additional information and tools for state and local planners on how to operationalize and implement specific plans for targeting critical workforce groups during an influenza pandemic response. The identification of critical populations in Iowa is ongoing based on several federally prepared and shared documents to define, identify and provide planning numbers and scenarios for additional essential workers.

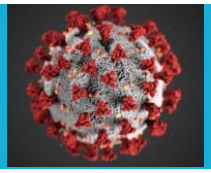
Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand

Planning with local partners for open and closed points of distribution (POD) of medication and vaccines has been in place for many years through the preparedness programs. IDPH has provided planning workbooks, guidance and toolkits for local public health to establish these high throughput vaccine venues. The local public health agencies and City Readiness Initiative (CRI) counties have been planning and exercising these PODS for many years.

In Phase 2, IDPH and local partners will focus on ensuring access to vaccines for members of Phase 1 critical populations not yet vaccinated as well as for the general population.

Additionally, each county LPHA is updating a workbook that identifies planned POD locations, if the planned location is an open or closed POD, a drive through, or walk in clinic, number of dispensing stations, and total expected throughput.

Mass vaccination planning at the local level requires that sufficient numbers of PODs are identified so all people in the county, regardless of demographics or location, have access to these vaccines.



LPHA must identify a strategy to identify, assign and incorporate PODs into operations. Population density, geographical location, proximity to public transportation, and community and business demographics play key roles in strategies used to identify sufficient numbers of PODS to ensure 100 percent of the identified populations can vaccine. Zip code, geography and population density are several common strategies for identification. Other strategies identified include characteristics of the facility, proximity to target populations, and reach or catchment for vulnerable populations.

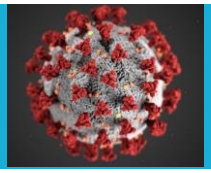
As COVID-19 vaccine supply will likely be sufficient to meet demand for critical populations as well as the general public in Phase 2, IDPH and LPHA will continue to encourage and increase vaccination providers and locations. Additionally, low COVID-19 vaccine demand is also a possibility, so IDPH will closely monitor supply and adjust strategies to minimize vaccine wastage.

Local public health agencies are preparing for the following types of vaccination clinics in Phase 2:

- Appointment clinics,
- Direct collaboration with pharmacies
- Community clinics
    - Homeless shelters,
    - non-profit agencies,
    - free clinics,
    - assisted living facilities,
    - nursing homes,
    - residential care facilities,
    - group homes, and
    - community centers
    - schools
- Corrections (jails, prisons or other transitional correctional facilities)
- Drive through settings as used annually for influenza vaccine
- Home visits
- Mass clinics
- Private/Closed clinics by employers

Phase 3: Likely Sufficient Supply, Slowing Demand

IDPH will continue to focus on equitable vaccination access to vaccination services. COVID-19 vaccine uptake and coverage will be monitored in critical populations and enhanced strategies to reach populations with low vaccination uptake or coverage will be implemented.
IDPH will partner with commercial and private entities to ensure COVID-19 vaccine and vaccination services are widely available. IDPH will constantly monitor supply and reposition vaccine products to minimize vaccine wastage.



Section 4: Critical Populations

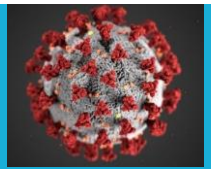
A. ***Describe how your jurisdiction plans to: 1) identify, 2) estimate numbers of, and 3) locate (e.g., via mapping) critical populations. Critical population groups may include:***

- ***Healthcare personnel***
- ***Other essential workers***
- ***Long-term care facility residents (e.g., nursing home and assisted living facility residents)***
- ***People with underlying medical conditions that are risk factors for severe COVID-19 illness***
- ***People 65 years of age and older***
- ***People from racial and ethnic minority groups***
- ***People from tribal communities***
- ***People who are incarcerated/detained in correctional facilities***
- ***People experiencing homelessness/living in shelters***
- ***People attending colleges/universities***
- ***People living and working in other congregate settings***
- ***People living in rural communities***
- ***People with disabilities***
- ***People who are under- or uninsured***

In the event that the vaccine allocation during Phase 1 is insufficient to vaccinate all those included in the initial populations of focus, it is important to identify and estimate the subset groups (i.e., Phase 1-A, Phase 1-B) within these initial populations of focus to determine who will receive the first available doses of COVID-19 vaccine. IDPH has reviewed current ACIP guidance to identify, prioritize, and estimate Phase 1 sub-population groups.

Considerations for Phase 1 subset groups include:

Phase 1-A: Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials. Long Term Care Facility (LTCF) residents and staff.



Phase 1-B: Iowans living in residential care facility, assisted living program, elder group home, and independent living facility residents and people 65 years of age or older. People who play a key role in keeping essential functions of society running and cannot socially distance in the workplace (e.g., emergency and law enforcement personnel not included in Phase 1-A, food packaging and distribution workers, teachers/school staff, childcare providers), and adults with high-risk medical conditions who possess risk factors for severe COVID-19 illness such as:

- Cancer
- Chronic kidney disease
- COPD (chronic obstructive pulmonary disease)
- Immunocompromised state from solid organ transplant
- Obesity (Body Mass Index of 30 or higher)
- Serious heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
- Sickle cell disease
- Type 2 diabetes mellitus

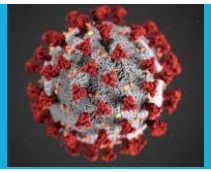
To inform COVID-19 vaccination provider outreach efforts, IDPH has created lists and maps so local plans can be developed to assist in determining where these groups are located.

IDPH is currently working with internal and external planning groups to establish categories and total populations for other types of essential workers. The Iowa Governor's office and the Iowa Department of Homeland Security and Emergency Management are working to locate, map and estimate the total number of legislative staff to ensure continuity of government, total number of law enforcement personnel, workers in food and meat processing plants to name a few, that will likely be identified as essential across the State of Iowa.

As previously mentioned, IDPH has several mechanisms of communication with the tribal community in Iowa and will work directly with those contacts to ensure inclusion in the vaccination strategy.

Organizationally, the majority of all the healthcare professional licensing boards in the State of Iowa are located within the IDPH structure. IDPH has provided local public health with a numerical list and a by county map of every licensed nurse, EMS provider, physician, physician assistant, respiratory therapist and pharmacist by county in the state. These lists are being updated to include; optometry, dietetics, dentistry, podiatry, massage therapy, chiropractic, physical and occupational therapy, psychology, behavioral science, and social work.

Also, included is a listing and map of long-term care facilities in the state of Iowa and associated resident and staff numbers. This information has been gathered during the COVID-19 response by the State of Iowa Regional Medical Coordination Centers (RMCC).



Six RMCCs across the state support multi-agency coordination of medical resources and critical information sharing.

Lists and maps have been provided to include several demographic databases to determine the number of people 65 years or older, people from racial and ethnic minority groups, people with disabilities and people living in rural communities.

IDPH has worked with the Iowa Department of Corrections to calculate the total number of individuals incarcerated, along with locations/mapping of the correctional institutions.

IDPH has identified and mapped all college and university staff and student populations.

IDPH has worked with the Iowa Department of Human Services to identify the numbers of state licensed and private daycare providers.

Additionally, IDPH has provided information and maps of Iowans who are under or uninsured, those receiving Medicaid benefits and those residing in state facilities.

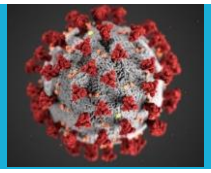
IDPH has identified and mapped populations with underlying conditions (as listed above), and those living in homeless shelters or other congregate settings.

IDPH has provided lists of the number of students and staff in each educational district in Iowa.

IDPH has worked closely with Iowa Workforce Development to identify the sectors and subsectors of essential function populations.

The local public health agencies and healthcare entities will begin using the provided lists and maps with priority critical populations to create the priority subgroup numbers in each county for the identified priority groups once ACIP, CDC and the Iowa Infectious Disease Advisory Committee provide guidance. IDPH will provide technical assistance in creating priority sub groups as needed.

Local public health agencies have established communication methods in place to contact and communicate with their most vulnerable populations that are difficult to quantify at the state level such as homeless populations and those in shelters. Technical assistance will be provided by IDPH as necessary.



B. ***Describe how your jurisdiction will define and estimate numbers of persons in the critical infrastructure workforce, which will vary by jurisdiction.***

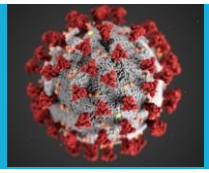
Please refer to section 4-A above.

C. ***Describe how your jurisdiction will determine additional subset groups of critical populations if there is insufficient vaccine supply.***

Please refer to section 4-A above. Additional critical populations will be determined by the IDAC referenced in previous sections and the external workgroup.

D. ***Describe how your jurisdiction will establish points of contact (POCs) and communication methods for organizations, employers, or communities (as appropriate) within the critical population groups.***

Please refer to the communication plan (Appendix A). IDPH will work closely with local public health partners and other community organizations to assure POCs are defined and added to the communications plan as needed.



Section 5: COVID-19 Provider Recruitment and Enrollment

A. ***Describe how your jurisdiction is currently recruiting or will recruit and enroll COVID-19 vaccination providers and the types of settings to be utilized in the COVID-19 Vaccination Program for each of the previously described phases of vaccine availability, including the process to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.***

B. ***Describe how your jurisdiction will determine the provider types and settings that will administer the first available COVID-19 vaccine doses to the critical population groups listed in Section 4.***

IDPH will collaborate with each county for the allocation of COVID-19 vaccine to healthcare providers who complete a COVID-19 Vaccination Program Provider Agreement.

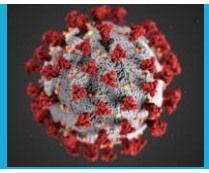
IDPH will utilize the Immunization Registry Information System (IRIS) for the allocation, distribution, and documentation of COVID-19 vaccine. As part of this process, IDPH has identified a single public health entity in the county for the allocation of vaccines to respective healthcare providers. This public health entity must be enrolled in IRIS as part of the allocation and distribution process.

The county local boards of health have been provided a list of entities identified in each county which function as the public health/immunization provider. The local boards of health are verifying the entity that will function as the COVID-19 vaccines provider within the respective county. Once information is verified, IDPH will work to set up the entity in IRIS and provide training on the allocation process.

Additionally, IDPH has sent information and an invitation to all potential providers of vaccines, including pharmacists, physician offices, clinics, long term care centers and more to begin enrolling in IRIS. This enrollment process is ongoing. Every entity that is enrolled in IRIS, is shared with local public health agencies, this information is updated and shared daily.

IDPH has created an internal vaccine process for the receipt and allocation of COVID-19 vaccines using established priority groups. This process will include IDPH approval of allocated doses, VTrckS documentation and approval processes. A communication process has been established to notify local public health agencies doses have been allocated and how to determine Phase 1 allocations to priority populations.

All healthcare providers and organizations interested in receiving and administering COVID-19 vaccines in Iowa are required to complete the CDC COVID-19 Vaccination Program Provider Agreement.



IDPH will utilize a REDCap survey to document provider acceptance of the terms to serve as a COVID-19 vaccine provider. The Iowa REDCap COVID-19 Vaccination Program Provider Agreement will require each vaccination provider to be credentialed/licensed in Iowa.

As REDCap surveys are completed, the IDPH has established a process to ensure the provider has completed the form correctly and is enrolled as an IRIS user. The process verifies providers listed are licensed to practice in Iowa and are in good standing with their respective licensing board.

The IDPH has partnered with the licensing boards to receive lists of all MD, DO, PA, ARNPs and RPh licensed in Iowa. The process outlines if the Chief Medical Officer license is not in good standing, the COVID-19 Vaccination Program Provider Agreement will not be approved. An email will be sent to the primary and secondary contacts to remediate the situation. If a prescribing provider is not in good standing, the organization will be notified the provider will be removed, but the organization is still able to enroll as a COVID-19 vaccine provider.

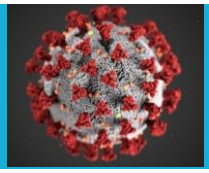
As of November 25, 2020 over 1,100 Vaccine Provider Agreement have been received and approved by IDPH. The list of providers is updated daily and posted to the HAN.

IDPH will use the Immunization Registry Information System (IRIS) for the ordering, distribution and documentation of COVID-19 vaccine doses administered. Local Public Health Agencies will be responsible for the allocation of COVID-19 vaccine to local healthcare providers and other organizations. Healthcare provider sites interested in offering pandemic vaccines must also enroll in IRIS. Sites not currently enrolled in IRIS, are being encouraged to do so.

Healthcare providers and organizations who enroll in IRIS and complete the COVID-19 Vaccination Provider Agreement are not obligated to provide COVID-19 vaccines. In addition, enrollment in IRIS and completing the COVID-19 Vaccination Provider Agreement does not guarantee the receipt of COVID-19 vaccines.

C. ***Describe how provider enrollment data will be collected and compiled to be reported electronically to CDC twice weekly, using a CDC-provided Comma Separated Values (CSV) or JavaScript (JSON) template via a SAMS-authenticated mechanism.***

As mentioned previously, all healthcare providers and organizations interested in receiving and administering COVID-19 vaccines in Iowa are required to complete the CDC COVID-19 Vaccination Program Provider Agreement.



The CDC COVID-19 Vaccination Program Provider Agreement includes basic information regarding the organization, including clinic hours/days of operation, provider type and setting, patient population served, demographic logistical information for receiving COVID-19 vaccine shipments, number of patient's the clinic is able to vaccinate weekly and vaccine storage capacity (refrigerated/frozen/ultra-cold temperature).

IDPH has established a process to review and approve all COVID-19 Vaccination Program Provider Agreements. REDCap survey data for approved COVID-19 vaccination providers can be exported in CSV format. Staff are able to export data elements using a CDC-provided Comma Separated Values (CSV) via the SAMS-authenticated mechanism. In the IDPH process for COVID-19 Vaccination Provider approval, staff have been identified with access to the SAMS system for reporting as required.

Staff are in place and additional staff are being trained to complete reports for review and validation prior to submission. Staff have access to the SAMS system for reporting as required. IDPH will follow all guidance provided by CDC regarding mandatory tracking processes and procedures.

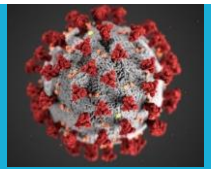
D. ***Describe the process your jurisdiction will use to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.***

The COVID-19 Vaccination Program Provider Agreement was released to Iowa healthcare partners on September 30, 2020. Iowa healthcare providers who intend to provide COVID-19 vaccines are required to complete the COVID-19 Pandemic Vaccination Provider Agreement via a REDCap survey. IDPH has introduced local healthcare providers to the provider agreement through webinars, HAN alerts and mass email blasts. IDPH has provided an agreement explanation letter which provides a link to the REDCap survey and information regarding IRIS enrollment. Additionally, IDPH has created, posted and emailed a Frequently Asked Questions (FAQ) document for assistance in completing the COVID-19 Vaccination Program Provider Agreement. IDPH has instructed all local public health agencies and healthcare providers to distribute these resources to partners.

IDPH has partnered with the licensing boards to receive lists of all MD, DO, PA, ARNP and RPh licensed in Iowa. The process outlines if the Chief Medical Officer license is not in good standing, the COVID-19 Vaccination Program Provider Agreement will not be approved. An email will be sent to the primary and secondary contacts to remediate the situation.

If a prescribing provider is not in good standing, the organization will be notified the provider will be removed, but the organization is still able to enroll as a COVID-19 vaccine provider.

Each COVID-19 Vaccination Program Provider Agreement received through the REDCap Survey will be individually reviewed and validated by IDPH staff.



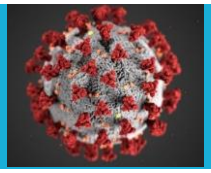
Each medical prescriber license will be validated as active and in good standing using data provided by the Iowa Boards of Medicine, Iowa Board of Nursing and the Iowa Bureau of Professional Licensure.

Each approved COVID-19 Vaccination Program Provider Agreement will be added daily to a spreadsheet daily and shared with local partners.

E. ***Describe how your jurisdiction will provide and track training for enrolled providers and list training topics.***

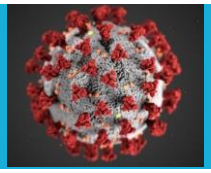
IDPH, Bureau of Immunization staff has distributed IRIS instructions for all users regarding the functionality of the Pandemic Vaccine module. Training sessions will be hosted per webinar, all users will be invited, and the sessions will be recorded and posted to websites for later viewing.

All training sessions will have an attached agenda and presentation slides. Participants will be required to register for the webinar sessions. IDPH will require local public health participation and attendance will be recorded. Additionally, IDPH has established the IRIS Help Desk phone 1-800-374-3958 and additional healthcare help desk lines and emails for questions regarding the COVID-19 Vaccine Provider Agreement at 1-800-831-6293 or COVID19Vaccine@idph.iowa.gov. IDPH will use a list serve of all COVID-19 vaccine providers to send communications.



CDC has committed to completing and providing the following training sessions. All CDC Training documents will be shared with local partners, IDPH will review and share the information once received by CDC:

PRODUCT	NEW/UPDATE	ADDITIONAL INFORMATION
Storage and Handling Toolkit	Update	General COVID-19 vaccine storage, handling and transport
COVID-19 training module	New	Under development is a web-based module. Topics will include storage/handling, vaccine indications, contraindications/precautions, administration and documentation
Vaccine product summary sheets	New	Fact sheets with storage, handling, preparation, indications, contraindications/precautions and administration will be developed for each vaccine
Comprehensive table of vaccine products	New	A table of COVID-19 vaccine products with key information will be updated as vaccines are approved.
Beyond use dates and expiration date tracking tools	New	A resource will be provided to track BUD and expiration dates, for use early in the vaccine distribution process.
Advisory Committee on Immunization Practices recommendation summary information	New	Conduct webinar, slide deck for use by awardees and other partners
You Call the Shots Web-based Training	Update	Updates to the You Call the Shots Vaccine Administration and Storage and Handling modules to refer users to appropriate COVID-19 vaccine websites..
HCP FAQs	New	Web-based FAQ document
Providing vaccinations Safely during a pandemic	Update	CDC has developed this website to provide guidance about safely providing vaccines during COVID 19. The website will be updated as appropriate.



F. ***Describe how your jurisdiction will approve planned redistribution of COVID-19 vaccine (e.g., health systems or commercial partners with depots, smaller vaccination providers needing less than the minimum order requirement).***

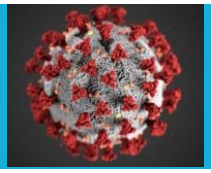
To limit storage and handling issues, IDPH has instructed LPHA to allocate doses in IRIS directly to healthcare providers so the shipment of COVID-19 vaccine will be shipped directly from the manufacturer to the healthcare provider location where the vaccine will be administered. Transferring COVID-19 vaccine should be the exception and providers should monitor vaccine inventory and vaccine usage patterns closely. However, due to minimum order quantities and unique storage and handling requirements, there may be circumstances where COVID-19 vaccines need to be redistributed beyond the identified primary ship-to location. In these instances, IDPH will allow the transferring of COVID-19 vaccine. IDPH has developed a COVID-19 Vaccine Transfer Authorization Process to ensure accountability of all doses of COVID-19 vaccine. This process has been included in Appendix D.

The IDPH Iowa Immunization Program requires that organizations (COVID-19 vaccination providers) are compliant with program requirements. All doses of vaccine distributed to COVID-19 vaccination providers must be accounted for and inventoried. COVID-19 vaccines will only be allowed to be transferred to providers with an approved COVID-19 Vaccination Program Provider Agreement. Additionally, vaccine transfers of COVID-19 vaccine will only occur after receiving approval from the Iowa Immunization Program. A COVID-19 Vaccine Redistribution Form must be completed and submitted to IDPH. IDPH will review and approve each vaccine transfer request within 24 hours and notify providers if the transfer request has been approved. IDPH will track transfers in IRIS to ensure the vaccine has been properly transferred between providers and accepted into the receiving provider's vaccine inventory. Any inventory adjustments or transfer of vaccine not approved by IDPH may result in the loss of COVID-19 vaccine provider status and capability. The COVID-19 Vaccine Redistribution Form has been included as Appendix E.

G. ***Describe how your jurisdiction will ensure there is equitable access to COVID-19 vaccination services throughout all areas within your jurisdiction.***

IDPH will closely follow the recommendations by health authorities, including the Advisory Committee on Immunization Practices (ACIP), as they create and implement national and/or local guidelines for COVID vaccine allocation. Additionally, as previously stated, the IDPH Medical Director, State Epidemiologist will convene a team of external and internal subject matter experts, known collectively as the Infectious Disease Advisory Council (IDAC), to provide additional clinical guidance.

This council will assist the State in developing COVID-19 vaccine prioritization of populations for early stages in the vaccination response when supply is limited.



- Criteria that should be used in setting priorities for equitable allocation of vaccines.
- How the criteria should be applied in the State of Iowa for determining the first tier of vaccine recipients and as more vaccines become available, what populations should be added successively to the priority list of recipients.
- The groups will determine how the following factors are accounted for:
    - Health disparities and other health access issues
    - Individuals at higher risk (e.g., elderly, underlying health conditions)
    - Occupations at higher risk (e.g., healthcare workers, essential industries, meat packing plants, military and other law enforcement, child welfare)
    - Populations at higher risk (e.g., racial and ethnic groups, incarcerated individuals, residents of nursing homes, individuals who are homeless)
    - Geographic distribution of active virus spread
    - Countries/populations involved in clinical trials
    - Communication strategies about vaccine allocation to minimize perceptions of lack of equity
    - Steps that will be taken to mitigate vaccine hesitancy, especially among high-priority populations

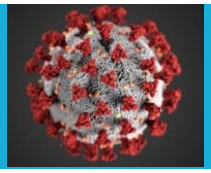
H. *Describe how your jurisdiction plans to recruit and enroll pharmacies not served directly by CDC and their role in your COVID-19 Vaccination Program plans.*

See Section 5, Sub Sections A and B above. Pharmacies are currently being enrolled for Phase 1 and will continue throughout the vaccine campaign. IDPH is working with the Iowa Board of Pharmacy as well as the Iowa Pharmacy Association to provide clear communication regarding eligibility of pharmacies to enroll in IRIS and complete the Provider Agreement and provide COVID-19 vaccines. As vaccination phases progress, IDPH will continually update and communicate any expanded roles of pharmacies with the internal and external workgroups.

Iowa Administrative Code rule 657-39.11 (155A) allows an authorized pharmacist to order and administer vaccines and immunizations pursuant to a statewide protocol, including vaccines administered in response to a public health emergency. This code also stipulates prior to the ordering and administration of an immunization pursuant to the statewide protocol, the authorized pharmacist shall consult and review IRIS.

I. *Federal Pharmacy Partnership for COVID-19 Vaccination in Long-Term Care Facilities*

CDC will collaborate with CVS, Walgreens and Community Pharmacy to provide on-site vaccination clinics for LTCF residents. CDC is working closely with LTCFs, Centers for Medicare and Medicaid Services (CMS), professional trade organizations that serve nursing homes and assisted living facilities, and pharmacy partners to inform facilities of their options to receive COVID-19 vaccine.



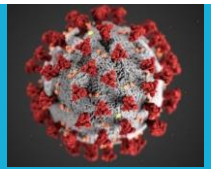
The links for LTC and ALF to register with the federally operated program was broadly shared by IDPH. The list of accepted facilities is received weekly from CDC, shared with partners and posted to the HAN.

J. *Federal Direct Allocation to Pharmacy Partners (Phase 2)*

To vaccinate a broader population group in Phase 2, vaccine will be allocated and distributed directly from the federal government to select pharmacy partners. Direct allocation opportunities will be provided to retail chain pharmacies and networks of independent and community pharmacies (those with a minimum of 200 stores). All partners must sign a pharmacy provider agreement with the federal government. As part of such agreement, before receiving COVID-19 vaccine, the partner must propose, in writing, its minimum capacity for vaccine administration, including a) the number and location of facilities that will administer COVID-19 vaccine, b) the estimated number of COVID-19 vaccine doses that each facility will be able to administer within defined periods, and c) estimated cold chain storage capacity.

On a daily basis, pharmacy partners must report to CDC via designated methods the number of doses of COVID-19 vaccine a) ordered by store location; and b) on hand in each store reported through VaccineFinder. Pharmacy providers will also be required to report CDC-defined data elements related to vaccine administration to the state jurisdiction IIS. CDC will provide information on these data elements and reporting methods if stores are not able to directly provide data to state jurisdiction IISs.

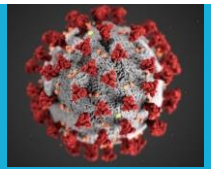
Partnerships with pharmacies will need to be synchronized with local jurisdictions to improve vaccination coverage and ensure transparency across the COVID-19 Vaccination Program. IDPH will have visibility on vaccine supply and uptake data by store within the state.



K. *Federal Direct Allocation to Federal Entities*

Outlined below are the federal entities (and their respective populations) that will receive a direct allocation of COVID-19 vaccine.

Federal Entity	Population Served
Bureau of Prisons (BoP)	• All BoP-managed facilities: facility staff and inmates • Private contracted facilities and contracted residential reentry centers (RRCs) not included
Department of Defense (DoD)	• Active duty personnel and their dependents • Retirees (does not include their dependents) • U.S. Coast Guard (does not include their dependents) • DoD civilian and contractor employees (those who regularly receive care through DoD as well as those who don't) • To be determined: Reserves and National Guard (including those not activated)
Department of State (DoS)	• All personnel under Chief of Mission eligible to receive care through DoS • Stateside civil service employees
Indian Health Service (IHS)	• Tribal nations selecting IHS for vaccine allocation (see page 12: Tribal Nations and Tribal Communities) • Potentially includes IHS/Tribal/Urban facility staff and individuals served
Veterans Health Administration (VHA)	• VA staff (including volunteers and trainees) and veterans regularly receiving care at VHA facilities (State Veterans Homes not included)



Section 6: COVID-19 Vaccine Administration Capacity

A. ***Describe how your jurisdiction has or will estimate vaccine administration capacity based on hypothetical planning scenarios provided previously.***

Given projected limited COVID-19 vaccine availability for late 2020, initial COVID-19 vaccination efforts will target those at highest risk of developing complications from COVID-19 and those in critical workforce/infrastructure industries. Although subject to change, and in addition to the ACIP prioritized groups of Health care personnel (HCP) and Residents of long-term care facilities (LTCs, planning for these initial doses of COVID-19 vaccine will likely target the following:

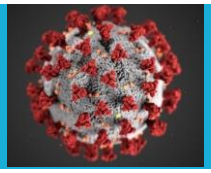
- Critical, frontline healthcare personnel evaluating and caring for COVID-19 patients,
- Other essential workers including public safety, education, staff in congregate living facilities, and
- Persons at highest risk developing complications from COVID-19, including staff and residents of nursing homes, long-term care facilities, assisted care facilities, and clients of senior daycare facilities or similar.

Based on the current vaccine distribution assumptions for Phase I, Iowa local public health agencies and healthcare partners have the capacity to administer vaccines to the above priority target populations. IDPH will use the Immunization Registry Information System (IRIS) for the ordering, distribution and documentation of COVID-19 vaccine doses administered. Local Public Health Agencies will be responsible for the allocation of COVID-19 vaccine to local healthcare providers and other organizations. Those administering the vaccine during Phase 1 will be required to do so in accordance with the priority designation tiers outlined in IDPH's Vaccine Shortage Order.

For Phase 2, once vaccine supply increases, leveraging a wide variety of potential community COVID-19 vaccination providers and settings is essential to providing equitable access to COVID-19 vaccination for all people in all communities. Planning with local partners for open and closed points of distribution (POD) of medication and vaccines has been in place for many years. IDPH has provided planning workbooks, guidance and toolkits for local public health to establish high throughput vaccine venues.

These efforts will expand upon the focused distribution strategies from Phase 1. IDPH and local partners will focus on ensuring access to vaccines for members of Phase 1 critical populations who were not yet vaccinated as well as for the general population.

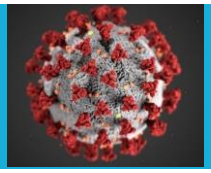
Mass vaccination planning at the local level requires that sufficient numbers of administration locations are identified so that all people in the county, regardless of demographics or location, have access to these vaccines.



B. ***Describe how your jurisdiction will use this information to inform provider recruitment plans.***

IDPH and local partners continue to recruit local healthcare and pharmacy partners to enroll in IRIS and as COVID-19 vaccine providers. Additionally, as of September 30, 2020, the COVID-19 Vaccination Program Provider Agreement has been widely disseminated to public health and healthcare providers in the state. All healthcare providers and organizations interested in receiving and administering COVID-19 vaccines in Iowa are required to complete the CDC COVID-19 Vaccination Program Provider Agreement. IDPH will utilize a REDCap survey to document provider acceptance of the terms to serve as a COVID-19 vaccine provider. The survey will allow IDPH to assess and strategize capacities related to:

- COVID-19 vaccine storage capacity at all locations (e.g., quantity of COVID-19 vaccine that can be stored, storage equipment and temperature monitoring devices that meet CDC requirements)
- Existing vaccine administration capacity during seasonal influenza or other high vaccination periods
- Current staffing levels
- Routine immunization programs being conducted simultaneously that may affect throughput for COVID-19 vaccination in certain vaccination provider settings
- Infection control measures (i.e., scheduling, distancing, donning and doffing personal protective equipment, cleaning/sanitation procedures) that may slow the vaccination process
- Timing and duration of COVID-19 vaccination provider participation due to changes in staffing or other resources throughout the response and ongoing needs assessments
- Clinic closure due to environmental or other factors (e.g., seasonal weather, holidays etc.)



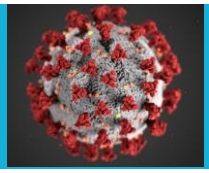
Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

A. ***Describe your jurisdiction's plans for allocating/assigning allotments of vaccine throughout the jurisdiction using information from Sections 4, 5, and 6. Include allocation methods for populations of focus in early and limited supply scenarios as well as the variables used to determine allocation.***

The federal government will determine the amount of COVID-19 vaccine designated for each state. Iowa's planning efforts including multiple scenarios – population-based or percentage of critical populations – and will adjust as the allotments of state allocation increases. IDPH will determine allotments of vaccines to counties/Local Public Health Agencies based on the following factors:

- ACIP recommendations
- Estimated number of doses allocated to the state and timing of availability
- Populations served by vaccination providers and geographic location to ensure distribution throughout the state
- Vaccination provider site vaccine storage and handling capacity
- Minimizing the potential for wastage of vaccine, constituent products, and ancillary supplies

CDC will provide IDPH with regular updates on the available vaccine supply and vaccine product-specific allocations. During Phase 1 of the vaccination campaign, when there is limited vaccine supply for critical populations, IDPH will allocate and approve vaccine doses based on the likely populations served by the LPHA and the healthcare providers in those counties. IDPH may issue a Vaccine Shortage Order to healthcare providers to expressly outline priority designation tiers approved for vaccination. Healthcare providers include clinics, hospitals, pharmacies and other healthcare providers (will be referred to as "healthcare providers" in the remainder of this section) and capability to store and handle various COVID-19 vaccine products, and existing inventory. The minimum order size and increment for CDC contract distributor will be 100 doses per order; though early in the response, some ultra-cold (-60°C to -80°C) vaccine (if authorized for use or approved) may be shipped directly from the manufacturer in larger quantities (1,000 doses).



Local public health agencies have been notified ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders the Iowa Immunization Program places in VTrckS. Each kit will contain supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider) o 25-gauge, 1" (if vaccination indicated for pediatric population)
- 22–25-gauge, 1-1.5" (adult)
- Syringes, 105 per kit (ranging from 1–3 mL)
- 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
- Vaccine needle guide detailing the appropriate length/gauge for injections based on route, age (for children), gender, and weight (for adults)

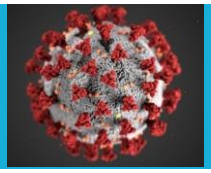
Local public health agencies have been notified ancillary supplies for COVID-19 vaccines requiring reconstitution with diluent or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies will be included.

Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) will also be needed depending on vaccination provider site resources. IDPH is currently working with LPHAs and the Iowa Department of Homeland Security and Emergency Management (HSEMD) to assure guidance and availability of additional PPE and supplies upon request through local emergency management coordinators. IDPH is working with LPHAs and local healthcare providers to ensure local availability of an adequate supply of sharps containers and sharps disposal contracts are in place.

IDPH plans to implement the following LPHA COVID-19 Vaccine Allocation Process for vaccine allocation, ordering, distribution, and inventory management.

It is anticipated that COVID-19 vaccines will initially be authorized under an EUA. Vial and carton labels for vaccines *authorized* under an EUA will contain slight variations from labels typical of *approved* Food and Drug Administration (FDA) products, including:

Expiration Date: The vaccine vials and cartons may not contain a printed expiration date. Expiration dates may be updated based on vaccine stability studies occurring simultaneously with COVID-19 vaccine distribution and administration. Additional information will be provided about how to access expiry information for individual vaccines. To ensure information systems continue to work as expected, CDC has worked with FDA and the manufacturers to include a two-dimensional (2D) barcode on the vaccine vial (if possible) and carton (required) labels that includes a National Drug Code (NDC), lot number, and a placeholder expiration date.



The placeholder expiration date is not visible on the vaccine packaging nor found anywhere else; it is only to facilitate information system compatibility. CDC is developing "beyond use date" (BUD) tracker labels to assist clinicians with tracking expiration dates at the point of vaccine administration. The label templates will be available on the CDC website.

Manufactured Date: A manufactured date will be on the packaging and should not be used as the expiration date when documenting vaccine administration. This date is provided to help with managing stock rotations; however, expiration dates should also be considered (see above) as using manufactured date alone could have some limitations.

2D Barcode: The 2D barcode available on the vaccine carton (also on the vials for some vaccines) will include NDC, lot number, and a placeholder expiration date.

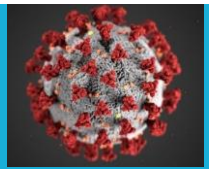
QR Code: Each vaccine manufacturer will include a Quick Response (QR) code on the vaccine carton for accessing FDA-authorized, vaccine product-specific EUA fact sheets for COVID-19 vaccination providers and COVID-19 vaccine recipients.

A list of authorized COVID-19 vaccine products with corresponding EUA fact sheets for healthcare providers and vaccine recipients, and up-to-date expiration information by vaccine lot will be available on an HHS website.

IDPH and CDC are working together to pre-position vaccine to ensure that supply is closer to the administration sites where vaccine is needed once FDA issues an EUA and ACIP recommendations are made. This pre-positioning is a onetime effort intended to shorten the timeline between EUA release and the initiation of vaccine administration (e.g., if initial prioritization focuses on administration of vaccine to healthcare providers). IDPH has worked with 6 healthcare entities to plan for the pre-positioned vaccine focusing on Vaccine A given the unique storage and handling considerations.

COVID-19 vaccine will be allocated to Iowa according to the following principles:

- Allocations will be calculated pro-rata based on the size of the jurisdiction's population and the quantity of ready-to-ship doses from manufacturer(s).
- Allocation amounts will be communicated to jurisdictions weekly. These allocations will be immediately available for ordering.
- If a jurisdiction does not order the full allocation, the remainder will roll over for future ordering. Unused allocations will not be reallocated to other jurisdictions.



For the two initial vaccine candidates, two doses will be required, and the same product must be used for both doses. Two-dose vaccine allocations will be managed in the following way:

- In coordination with vaccine manufacturers, CDC will reserve and store inventory of second-dose product to include in future allocations for ordering at the appropriate time (e.g., 2 weeks after first doses are ordered for a product requiring the second dose on Day 21).
- CDC does not expect jurisdictions or federal and commercial partners to maintain physical inventory of second-dose product (i.e., jurisdictions will not be expected to store product for 21–28 days to prepare for second-dose administration).

Iowa Specific Allocation:

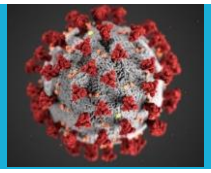
- LPHA will receive allocation of COVID-19 vaccine from IDPH in IRIS and will receive a HAN notification that the allocation has been added to IRIS
- LPHA is the only entity in each county able to allocate COVID-19 vaccine to other healthcare providers. LPHA may allocate COVID-19 vaccine at their discretion consistent with the established priority groups, to healthcare providers that are approved COVID-19 vaccine providers
- Healthcare providers will not order COVID-19 vaccines directly from IDPH Healthcare providers will only receive an allocation from LPHA.
- The allocation of vaccines to a healthcare provider by LPHA will create a vaccine order in IRIS. COVID-19 vaccine orders will be distributed directly to the healthcare provider from a CDC contract distributor
- LPHA has the ability in IRIS to view all healthcare providers in their county who have completed a COVID-19 Vaccine Provider Agreement. IRIS functionality includes the ability to assign vaccines to a specific provider.
- Providers who indicate they cannot store frozen vaccines will not be listed under the NDC for this vaccine
- Allocations of vaccine may be made to healthcare providers in the county and to the county LPHA. Allocation of vaccine is at the discretion of the county LPHA.
- LPHA may choose not to allocate all doses of COVID-19 vaccine. Doses of vaccine not allocated by LPHA will be added back into IRIS for reallocation to other LPH

Ordering:

IDPH will order COVID-19 Vaccine utilizing the VTrcks System

IDPH will receive allocations (order caps) weekly in VTrckS.

IDPH will submit orders for vaccination provider sites as directed by local jurisdictions. These orders will be processed against the allocation (order cap). Federal and commercial partners may pull order files from the Vaccine Provider Ordering Portal (VPoP) to upload into VTrckS.



Orders will be scheduled for delivery Monday through Friday.

Direct-Ship Vaccine (Vaccine A):
IDPH has identified locations to receive early (pre-positioned) shipments of this vaccine once the Food and Drug Administration (FDA) issues an Emergency Use Authorization (EUA). This will ensure that product is available at the jurisdictional level and jurisdictions are ready to support vaccine administration.

The minimum order volume for Vaccine A is 975 doses.

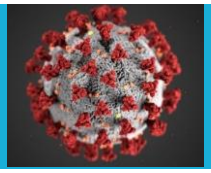
IDPH has identified delivery sites to receive initial shipments of product. Once vaccine is available IDPH will decide what quantity to order for each initial site (in 975-dose increments), based on what is feasible to administer.

Along with vaccine, each site will receive ancillary kits and an initial dry ice resupply to facilitate storage in coordination with each vaccine shipment. IDPH will have the option to allow sites to opt out of the
Initial dry ice resupply if desired. Sites will receive this initial dry ice resupply in coordination with receipt of the product, as they will need to replenish the dry ice upon product receipt. Further details about shipping and receipt of dry ice will be forthcoming.

- IDPH will review every vaccine order submitted in IRIS by LPHA and any healthcare provider that will receive vaccines to assure a valid vaccine provider agreement is in place
- IDPH will approve vaccine orders for submission or may modify orders as necessary
- IDPH will import vaccine orders into the CDC Vaccine Tracking System (VTrckS)

Distribution:

- CDC will receive and approve vaccine orders to assure consistency with Iowa's vaccine allocations
- CDC will distribute vaccine orders directly to healthcare provider sites using a CDC contracted distributor
- Vaccine (and diluent, if required) will be shipped to the healthcare provider within 48 hours of order approval. Because of cold chain requirements, ancillary supply kits (and diluent, if applicable) will ship separately from vaccine but should arrive before or on the same day as vaccine.
- CDC will provide vaccine order distribution data back to IDPH to be uploaded in IRIS to populate healthcare provider vaccine inventory



Tracking:

- CDC is anticipating the need for accurate, rapid data on COVID-19 vaccine administration
- IDPH will download daily inventory reports to VaccineFinder as required.
- Data in IRIS will be consistent, near real time, de-identified, and record level
- IRIS includes functionality to allocate COVID-19 vaccine, track individual healthcare provider inventory and vaccine doses administered
- IRIS also includes functionality for healthcare providers to send reminders (letters, postcards) when patients are due for additional doses of vaccine or recall patients to schedule immunization appointments

B. ***Describe your jurisdiction's plan for assessing the cold chain capability of individual providers and how you will incorporate the results of these assessments into your plans for allocating/assigning allotments of COVID-19 vaccine and approving orders.***

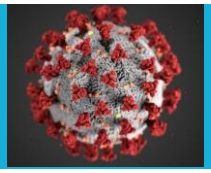
IDPH will utilize a REDCap survey to document provider acceptance of the terms to serve as a COVID-19 vaccine provider. The survey will allow IDPH to assess and plan for true capacities related to COVID-19 vaccine storage capacity at all locations (e.g., quantity of COVID-19 vaccine that can be stored, storage equipment and temperature monitoring devices that meet CDC requirements). See section 7-A above for allocation and allotment assignments. Only COVID-19 Providers that have indicated capabilities for certain vaccine type will be allocated those doses.

C. ***Describe your jurisdiction's procedures for ordering COVID-19 vaccine, including entering/updating provider information in VTrckS and any other jurisdictional systems (e.g., IIS) used for provider ordering. Describe how you will incorporate the allocation process described in step A in provider order approval.***

See Section 7-A above.

D. ***Describe how your jurisdiction will coordinate any unplanned repositioning (i.e., transfer) of vaccine.***

To limit storage and handling issues, IDPH will encourage the shipment of COVID-19 vaccine directly to the healthcare provider location where the vaccine will be administered. COVID-19 vaccine will be shipped directly to COVID-19 vaccine providers using a CDC contracted distributor. Transferring COVID-19 vaccine should be the exception and providers should monitor vaccine inventory and vaccine usage patterns closely. However, due to minimum order quantities and unique storage and handling requirements, there may be circumstances where COVID-19 vaccines need to be redistributed beyond the identified primary ship-to location.



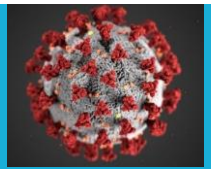
In these instances, IDPH will allow the transferring of COVID-19 vaccine. The IDPH has developed a COVID-19 Vaccine Transfer Authorization Process to ensure accountability of all doses of COVID-19 vaccine. This process has been included in Appendix D.

The IDPH Iowa Immunization Program requires organization (COVID-19 vaccination providers) compliance of program requirements. All doses of vaccine distributed to COVID-19 vaccination providers must be accounted for and inventoried. COVID-19 vaccines will only be allowed to be transferred to providers with an approved COVID-19 Vaccination Program Provider Agreement. Additionally, vaccine transfers of COVID-19 vaccine will only occur after receiving approval from the Iowa Immunization Program. A COVID-19 Vaccine Transfer Form must be completed and submitted to IDPH. IDPH will review and approve each vaccine transfer request within 24 hours and notify providers if the transfer request has been approved. IDPH will track transfers in IRIS to ensure the vaccine has been properly transferred between providers and accepted into the receiving provider's vaccine inventory.

Any inventory adjustments or transfer of vaccine not approved by IDPH may result in the loss of COVID-19 vaccine provider status and capability. The COVID-19 Vaccine Transfer Form has been included as Appendix E.

E. ***Describe jurisdictional plans for monitoring COVID-19 vaccine wastage and inventory levels.***

See Section 7-A above.



Section 8: COVID-19 Vaccine Storage and Handling

A. ***Describe how your jurisdiction plans to ensure adherence to COVID-19 vaccine storage and handling requirements, including cold and ultra-cold chain requirements, at all levels:***

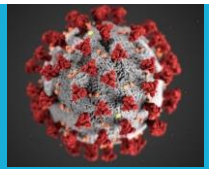
- ***Individual provider locations***
- ***Satellite, temporary, or off-site settings***
- ***Planned redistribution from depots to individual locations and from larger to smaller locations***
- ***Unplanned repositioning among provider locations***

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness. IDPH will work with each LPHA and each COVID-19 vaccination provider to ensure appropriate vaccine storage and handling procedures are established and followed.

The cold chain begins at the COVID-19 vaccine manufacturer, which includes delivery to and storage at the COVID-19 vaccination provider site, and ends with administration of COVID-19 vaccine to a person. The LPHA and the vaccination providers are responsible for maintaining vaccine quality from the time a shipment arrives at a vaccination provider site until the dose is administered. To minimize opportunities for breaks in the cold chain, most COVID-19 vaccines will be delivered from CDC's contracted distributor directly to the location where the vaccine will be stored and administered, although some vaccines may be redistributed to other COVID-19 vaccine providers. Certain COVID-19 vaccine products, such as those with ultra-frozen temperature requirements, will only be shipped directly from the manufacturer to the vaccination provider site. If redistributing vaccines, LPHAs and healthcare entities must adhere to all cold-chain requirements and limit transport of frozen or ultra-frozen vaccine products.

Every vaccine storage unit/container must have a temperature monitoring device. CDC recommends digital data loggers (DDLs). One vaccine product is stored at ultra-cold temperatures and will require a DDL that can register these temperatures. IDPH has access to DDLs and will distribute as necessary for use with ultra-cold vaccines, in addition to the DDLs needed for storage of refrigerated and frozen (-20°C) vaccines. DDLs using a buffered temperature probe provide the most accurate measurement of vaccine temperatures. However, many manufacturers use pure propylene glycol (freezing point -59°C) or a glycol mixture with a warmer freezing point in their probes. For accurate temperature monitoring of ultra-cold vaccines, it is essential that an air-probe or a probe designed specifically for ultra-cold temperatures is used with the DDL.

Training to local partners will include information regarding the use of satellite, temporary, or off-site clinics in collaboration with community or mobile vaccinators.

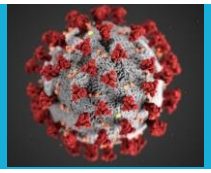


However, these situations require additional oversight and enhanced storage and handling practices, including the following:

- The quantity of COVID-19 vaccine transported to a satellite, temporary, or off-site COVID-19 vaccination clinic should be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and transport the vaccine appropriately. This is essential to minimizing the potential for vaccine wastage and spoilage.
- COVID-19 vaccines may be transported-not shipped-to a satellite, temporary, or off-site COVID-19 vaccination clinic setting using vaccine transportation procedures outlined in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit. The procedures will include transporting vaccines to and from the provider site at appropriate temperatures, using appropriate equipment, as well as monitoring and documenting temperatures.
- Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.
- Temperature data must be reviewed and documented according to guidance in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit.
- At the end of the clinic day, temperature data must be assessed prior to returning the vaccine to fixed storage units to prevent administration of vaccines that may have been compromised.
- As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions at any time, the temperature excursion should be documented and reported to the Iowa Immunization Program at 1-800-831-6293 ext. 1.
- Vaccines exposed to out-of-range temperatures must be labeled "do not use" and stored at the required temperature until further information on usability can be gathered or further instruction on disposition or recovery is received.

IDPH will post links to the CDC's revised Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations as well as Vaccination Guidance During a Pandemic. These resources will be utilized in training to LPHA and other partners to provide information on additional considerations that are necessary during the COVID-19 pandemic, including social distancing, PPE use, and enhanced sanitation efforts.

IDPH will review each non-VFC healthcare provider's response to the COVID-19 Vaccination Program Provider Agreement via the REDCap survey. IDPH staff will contact each healthcare provider to discuss responses regarding the ability to store each of the temperature ranges (refrigerated, frozen and ultra-frozen), vaccine storage units and temperature monitoring devices. Based on information received from this follow up, IDPH staff will either approve the provider to store vaccines based on each temperature range or provide recommendations/corrective actions for the storage types.



Healthcare providers will not be able to receive vaccines maintained at temperature ranges the organization has not been approved to receive.

B. ***Describe how your jurisdiction will assess provider/redistribution depot COVID-19 vaccine storage and temperature monitoring capabilities.***

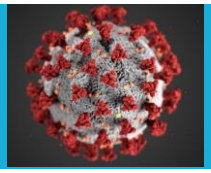
By signing the agreement, healthcare providers are agreeing to the terms and conditions, including the requirement to properly store COVID-19 vaccines. Specifically, organizations must comply with CDC requirements for COVID-19 Vaccine management. Those requirements include the following.

- Organization must store and handle COVID-19 Vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit, which will be updated to include specific information related to COVID-19 Vaccine.
- Organization must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Vaccine Storage and Handling Toolkit.
- Organization must comply with the immunization program guidance for dealing with temperature excursions.

In addition, on the CDC COVID-19 Vaccination Program Provider Profile Information section of the provider agreement, the medical/pharmacy director or vaccine coordinator is attesting that each vaccine storage unit complies with CDC's Vaccine Storage and Handling requirements and will maintain the appropriate temperature ranges.

The Iowa Immunization Program has purchased a supply of digital data loggers to provide to COVID-19 vaccine program providers. IDPH will work with health care providers to distribute the data loggers.

IDPH will ensure the CDC's "You Call the Shots" web-based training, Vaccine Product Summary and the Vaccine Storage and Handling Toolkit are available and communicated directly to all COVID-19 enrolled provider sites. This will be accomplished by utilizing methods outlined in the COVID-19 Vaccine Communication Plan and specifically a COVID-19 Provider list serve which includes each clinic's primary point of contact and primary and secondary storage and handling contacts. It is anticipated a large portion of Iowa's 600 VFC program providers will become COVID-19 vaccination providers. These providers as part of their participation in the VFC Program have extensive training and experience surrounding vaccine storage and handling. In addition, these providers are familiar with proper vaccine storage and handling requirements and have the necessary equipment to store and monitor vaccines (data loggers, vaccine storage units).



In addition, IDPH will assure healthcare providers do not receive vaccines with storage and handling requirements they indicated they are unable to meet. IRIS functionality includes the ability to assign vaccines able to be ordered to a specific provider.

For example, providers who indicate they cannot store frozen vaccines, will not be listed under the NDC for this vaccine.

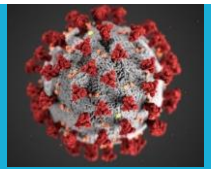
Receipt, Storage, and Handling:
CDC has updated its *Vaccine Storage and Handling Toolkit*, to include a COVID-19 Vaccine Addendum, which will provide guidance on each vaccine product. CDC will also provide additional product-specific materials, including storage, handling and administration job aids. CDC will provide these resources as soon as possible.

The Vaccine Storage and Handling Toolkit can be found at: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html. General Additional web pages with clinical guidance will be added as COVID-19 vaccine products become available.

Vaccine A:
Thermal shipping containers with Vaccine A will arrive with a GPS-enabled temperature monitoring device that will monitor temperature excursions in transit as well as at the vaccination provider site, if used.

Local vaccine providers that plan to store product in an ultra-low temperature (ULT) freezer, must remove vaccine trays from the thermal shipping container before moving them to the freezer, then monitor the temperature inside the ULT freezer using standard protocol to ensure temperature excursions are identified quickly. Once the vaccine is removed from the thermal shipping container and put in the ULT freezer, the temperature monitoring device accompanying the vaccine can no longer be used; a digital data logger (DDL), or other appropriate monitoring method, will be needed.

The local vaccine provider may also use the thermal shipping container for temporary storage of the vaccine. Instructions will be provided for monitoring vaccine temperatures in the thermal shipping container using the device that is available on the shipper (details will be forthcoming). In addition, storage and handling instructions for vaccine stored in the thermal shipper will be made available by the manufacturer and in CDC's storage and handling tool kit. Please also see Vaccine A information in version 2.0 of the CDC Playbook.



Section 9: COVID-19 Vaccine Administration Documentation and Reporting

A. ***Describe the system your jurisdiction will use to collect COVID-19 vaccine doses administered data from providers.***

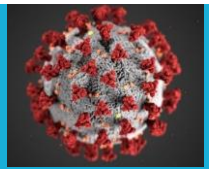
IDPH has received the required data elements to document COVID-19 vaccine doses administered from CDC. After reviewing these data elements, IDPH has determined IRIS is currently capable of collecting this information. As a result of receiving this information, IRIS will be the tool used for the distribution and documentation of all doses of COVID-19 vaccine doses administered.

When COVID-19 vaccine becomes available, IRIS will be used for allocation and distribution of vaccine and ancillary supplies.

- COVID-19 vaccine will be allocated proportionally to counties based on population size, target populations and disease epidemiology
- The LPHA will receive allocations of COVID-19 vaccine through IRIS
- COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to Iowa healthcare providers who have completed a COVID-19 Pandemic Vaccine Provider Agreement. Ancillary supply kits include needles, syringes, alcohol preps, surgical masks, and face shields. Allocation of ancillary supplies will be managed by CDC and distributed directly to healthcare providers
- Healthcare providers who receive and administer COVID-19 vaccine will be required to enter doses of vaccine administered into IRIS to support state mass vaccination efforts
- COVID-19 vaccine providers must enroll in IRIS and agree to terms in the federal COVID-19 Vaccination Program Provider Agreement

B. ***Describe how your jurisdiction will submit COVID-19 vaccine administration data via the Immunization (IZ) Gateway.***

IDPH will facilitate and monitor reporting by enrolled vaccination providers in IRIS. Each vaccination location will have trained staff, necessary equipment, and internet access (if needed) to report vaccine administration data into IRIS at the time of vaccination. If data will be entered off site, vaccination providers must ensure the required data are reported within 24 hours. Reporting data will be transmitted as directed by CDC via the IZ Gateway "Connect" component. IDPH is awaiting additional information on the reporting process and specifications from CDC. IDPH will not be responsible for reporting data from federal agencies or commercial partners who receive vaccine allocations directly from CDC.



C. ***Describe how your jurisdiction will ensure each COVID-19 vaccination provider is ready and able (e.g., staff is trained, internet connection and equipment are adequate) to report the required COVID-19 vaccine administration data elements to the IIS or other external system every 24 hours.***

IDPH will utilize the Immunization Registry Information System (IRIS) for the allocation, distribution, and documentation of COVID-19 vaccine. As part of this process, IDPH has identified a single public health entity in the county for the allocation of vaccines to respective healthcare providers. This public health entity must be enrolled in IRIS as part of the allocation and distribution process and submit a complete and validated COVID-19 Vaccination Provider Agreement (Appendix C). IRIS trainings will be provided by IDPH to assure all IRIS enrollees and those that have completed the COVID-19 Vaccination Program Provider Agreement will have access to live webinar training and recorded training to ensure staff is trained. IRIS webinar trainings will be held twice a month and are scheduled to begin in early October.

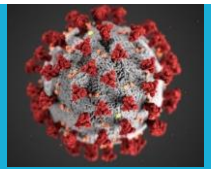
D. ***Describe the steps your jurisdiction will take to ensure real-time documentation and reporting of COVID-19 vaccine administration data from satellite, temporary, or off-site clinic settings.***

E. ***Describe how your jurisdiction will monitor provider-level data to ensure each dose of COVID-19 vaccine administered is fully documented and reported every 24 hours as well as steps to be taken when providers do not comply with documentation and reporting requirements.***

All Iowa healthcare providers who will receive and administer COVID-19 vaccines must sign the COVID-19 Vaccination Program Provider Agreement. By signing the agreement, healthcare providers are agreeing to the terms and conditions, including the requirement to report COVID-19 vaccines to the IIS within 24 hours after administration. IRIS is a web-based application which can be used at satellite, temporary and off-site clinics by using a laptop and Wi-Fi connection.

IDPH will utilize data from IRIS to monitor the timeliness of receipt of immunization data in IRIS, as measured by the difference between the date of administration and date of record submission. In addition, the Iowa Immunization Program will monitor the number of vaccine doses distributed to healthcare providers compared to vaccine doses administered data and vaccine inventory. If individual healthcare providers are delinquent in reporting vaccine doses administered data within 24 hours after vaccine administration, they will be contacted by Iowa Immunization Program staff to assess the situation which may include additional training and remediation. If healthcare providers are noncompliant, they may be removed as a COVID-19 vaccination provider. In Iowa, approximately 90 percent of the data reported to IRIS is through electronic data exchange. The majority of healthcare partners conducting electronic data exchange are submitting data real time.

IDPH has signed the IZ Gateway Data Use Agreement and has established a connection to the IZ Gateway to allow the sharing of information as required by CDC.



IRIS is a web based application which can be used at satellite, temporary and off site clinics by using a laptop and Wi-Fi connection.

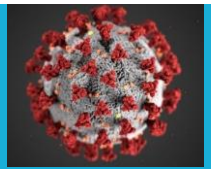
F. ***Describe how your jurisdiction will generate and use COVID-19 vaccination coverage reports.***

IDPH will use data from IRIS for the distribution and documentation of COVID-19 vaccine doses administered. The Immunization Program will extract data from the IRIS application to calculate COVID-19 vaccine county and state coverage reports. The Immunization Program has established data elements to be included in the data extract. The data extract will be imported into a data visualization tool and posted to one of the State's COVID-19 vaccine web page. A list of data elements and calculations is included as follows.

COVID-19 Vaccine Administration - Visualizations
Purpose: Daily query from IRIS to provide up-to-date COVID-19 vaccine administration data for public facing visualizations (using DOMO or other data visualization software)
Data source: IDPH Immunization Program - Immunization Registry Information System (IRIS)
File format: CSV file (most likely)
Frequency of data query: Daily, time of day TBD
Submission process: TBD, designated point of contact
Query development: In development, under discussion
Example Visualizations included

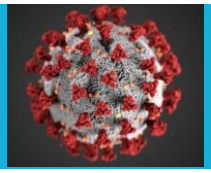
Data notes/assumptions:

- "Patient" is the IRIS term used to represent the federal term of "Recipient"
- The COVID-19 Vaccine Provider Agreement specifies vaccine providers have 24 hours after administration to report to IRIS (state's immunization information system). However, delay in reporting may occur.



Data Elements:

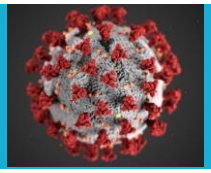
Variable	Use/ Reason
Patient's ID in IRIS	Identify unique individuals in IRIS; allow for matching of dose 1 and 2 in visualization software
Vaccine National Drug Code (NDC)	Identify required number of doses for series, validate spacing of doses, track administration of vaccine products etc.
MVX	The manufacturer of the vaccine administered
CVX	The product used in a vaccination. CDC maintains CVX codes here.
Dose Number	Report dosage/dose number being administered, if the vaccine requires more than one (e.g., dose #1, dose #2)
Date of administration for dose 1	Calculate total number of doses administered
Date of administration for dose 2	Calculates total number of doses administered and number of completed series (if valid dose and if series requires 2 doses)
Patient's date of Birth	Use to calculate age, calculated with date of administration of dose 1
Provider Type	Type of healthcare provider administering (pharmacy, private practice, hospital, local public health etc.)
County of administration	Use to track vaccine administration at county level
Patient county of residence	Use to identify vaccine coverage rate at county level
Patient Gender	Gender as captured in IRIS (male, female, unknown); not a required variable in IRIS
Patient Race	Race as captured in IRIS (American Indian or Alaska Native; Asian; Native Hawaiian or Pacific Islander; Black or African American; White; Other Race; Unknown Race); not a required variable in IRIS
Patient Ethnicity	Ethnicity as captured in IRIS (Hispanic or Latino; Not Hispanic or Latino; Unknown); not a required variable in IRIS



Vaccine Administration Visualization: Visualization below includes examples from current vaccine visualization prepared by the IDPH Immunization Program.

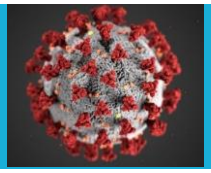
- COVID-19 Vaccine administration for state and by county
  - Select a county to see county level information and compare to state level information
  - Select "COVID-19 Series Initiated- Not Complete" or "Complete COVID-19 Vaccine Series" which are distinct and non-overlapping categories
  - Include information in hover-over/quick click feature to compare counties
- Total Doses Administered by Month
  - Start with first month products available (approximately Nov. 2020)
  - Total number of doses administered statewide, regardless of dose number (series initiation or completion)
  - Present as total number of doses administered by month
- Doses Administered by Gender:
  - Select a county to see county level information and compare to state level information
  - Select "COVID-19 Series Initiated- Not Complete" or "Complete COVID-19 Vaccine Series" which are distinct and non-overlapping categories
- Doses Administered by Age Group:
  - Select a county to see county level information and compare to state level information
  - Select "COVID-19 Series Initiated- Not Complete" or "Complete COVID-19 Vaccine Series" which are distinct and non-overlapping categories
  - May not be applicable with the first products available due to limitations in approved age groups or populations
- Data Table by County of Residence:
  - "COVID-19 Series Initiated- Not Complete" and "Complete COVID-19 Vaccine Series" which are distinct and non-overlapping categories
- Data Table by County of Administration:
  - Total number of doses, regardless of series initiation or completion

County of Administration	Number of Doses Administered
Adair	
Adams	
State	Total Number of Doses Administered



- Data Table of Doses Administered by Provider Type:
  - Total number of doses, regardless of series initiation or completion
  - Provider Type categories as identified in IRIS

County of Administration	Number of Doses Administered
Private Provider	
Local Public Health Agency	
Hospital	
Long Term Care/Nursing Home	
Pharmacy	
College/University	



Section 10: COVID-19 Vaccination Second-Dose Reminders

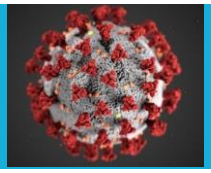
A. ***Describe all methods your jurisdiction will use to remind COVID-19 vaccine recipients of the need for a second dose, including planned redundancy of reminder methods.***

Client reminder and recall interventions will be used by LPHA, healthcare providers and pharmacies to remind members of a target population that vaccinations are due (reminders) or late (recall). IRIS includes the ability for healthcare providers to send reminders (letters, postcards) when patients are due for additional doses of vaccine or recall patients to schedule immunization appointments.

Reminders and recalls may also differ in content and are delivered by various methods- telephone, letter, postcard, text messages, or other avenues dependent upon additional methods deployed by LPHA or healthcare providers. IDPH offers Reminder/Recall postcards free of charge to Iowa healthcare providers. The Immunization Program has printed additional copies of the postcards in preparation for COVID-19 vaccines. Most reminder and recall notices are tailored for individual clients, and many are accompanied by educational messages about the importance of vaccination. 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.

IDPH will remind local partners during training sessions that reminder and recall initiatives will be expected and IRIS can be used to accomplish this. The Iowa Immunization Program has developed IRIS - Reminder/Recall instructions which can be used by all IRIS organizations to generate patient reminder and recall communications.

Individual healthcare providers can conduct reminder and recall activities for their patients and for any vaccines administered by the healthcare provider. Each LPHA has additional IRIS functionality which allow the organization to conduct reminder and recall activities for all residents in the county. This will allow for both the LPHA and individual healthcare provider to conduct reminder and recall activities.



Section 11: COVID-19 Requirements for IISs or Other External Systems

Instructions:

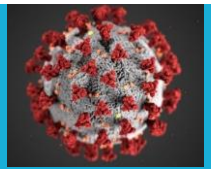
A. ***Describe your jurisdiction's solution for documenting vaccine administration in temporary or high-volume vaccination settings (e.g., CDC mobile app, IIS or module that interfaces with the IIS, or other jurisdiction-based solution). Include planned contingencies for network outages or other access issues.***

The IDPH Immunization Program has been working with Iowa healthcare providers who may choose to use other applications for the scheduling and documentation of COVID-19 vaccine doses administered (PREPMOD, Salamander). The Immunization Program will work with these healthcare providers and vendors to onboard these applications to conduct data exchange. This will allow for applications which include functionality to accommodate high-volume vaccination elements (e.g., appointment scheduling, scanner technology) to be the primary source to document COVID-19 vaccine administration and in turn submit data to IRIS via data exchange. In Iowa, approximately 90 percent of the data reported to IRIS is through electronic data exchange. The majority of healthcare partners conducting electronic data exchange are submitting data real time.

IDPH contracts for the hosting and maintenance of IRIS. The contract for IRIS specifies the application will have "System Availability" of 99.5 percent for each calendar month. System Availability is calculated as (maximum uptime minus all downtime) divided by ("maximum uptime" minus "scheduled maintenance") times 100 where:

- Maximum uptime is the maximum number of minutes available in a month outside scheduled maintenance (see below).
- Downtime is any unscheduled time the application is completely inaccessible to all authorized users through the user interface; or data exchange is completely inaccessible to all authorized provider organizations.

The IRIS application includes Mass Vaccination functionality for healthcare providers to document the administration of a single vaccine to a list of multiple vaccine recipients. Healthcare providers can document vaccine administration using alternate methods (paper forms) at remote or high volume clinics and can later be entered in IRIS using Mass Vaccination functionality. This functionality allows healthcare providers to build a roster of patients seen at a clinic or site and also allows the roster to be named and saved for future use.



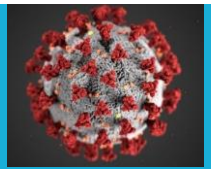
B. ***List the variables your jurisdiction's IIS or other system will be able to capture for persons who will receive COVID-19 vaccine, including but not limited to age, race/ethnicity, chronic medical conditions, occupation, membership in other critical population groups.***

IRIS will capture the following data elements and report information from these data elements through a connection to the Immunization (IZ) Gateway.

- Administered at location: facility name/ID
- Administered at location: type
- Administration address (including county)
- Administration date
- CVX (Product)
- Dose number
- IIS Recipient ID
- IIS vaccination event ID
- Lot Number: Unit of Use and/or Unit of Sale
- Manufacturer
- Recipient Address
- Recipient Date of Birth
- Recipient Name
- Recipient Sex
- Recipient Race - optional
- Recipient Ethnicity - optional
- Sending Organization
- Vaccine Administering Provider Suffix
- Vaccine Administration Site
- Vaccine Expiration date
- Vaccine Route of administration
- Vaccination series complete
- Vaccination Refusal - Optional

C. ***Describe your jurisdiction's current capacity for data exchange, storage, and reporting as well as any planned improvements (including timelines) to accommodate the COVID-19 Vaccination Program.***

Iowa has supported data exchange, or interoperability, between IRIS and electronic health records systems since 2013. As of October 5, 2020, the Immunization Program supported 1,386 organizations exchanging electronic immunization data with IRIS. Of these, 1,113 are bidirectional, meaning these organizations query for patients' immunization histories as well as submit patients' immunization records to IRIS.



The Iowa Immunization Program will be working with its IIS vendor to ensure COVID-19 vaccine doses administered data submitted to IRIS via data exchange will deduct from all healthcare providers' vaccine inventory. This will ensure the program can accurately track healthcare provider's vaccine distribution and COVID-19 vaccine doses administered. Functionality will be implemented prior to November 1, 2020.

D. ***Describe plans to rapidly enroll and onboard to the IIS those vaccination provider facilities and settings expected to serve healthcare personnel (e.g., paid and unpaid personnel working in healthcare settings, including vaccinators, pharmacy staff, and ancillary staff) and other essential workers.***

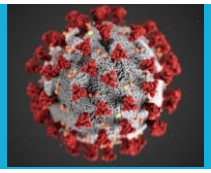
See Section 5 Subsection A-B: The Iowa Department of Public Health IDPH will collaborate with each county for the allocation of COVID-19 vaccine to healthcare providers who complete a COVID-19 Vaccination Program Provider Agreement.

IDPH will utilize the Immunization Registry Information System (IRIS) for the allocation, distribution, and documentation of COVID-19 vaccine. As part of this process, IDPH has identified a single public health entity in the county for the allocation of vaccines to respective healthcare providers. This public health entity must be enrolled in IRIS as part of the allocation and distribution process.

The county local boards of health have been provided a list of entities identified in each county which have been functioning as the public health/immunization provider. The local boards of health are verifying each entity is willing to function as a provider of COVID-19 vaccines within the respective county. Once this information is verified, the Department will begin working with entities to provide training on the allocation process.

E. ***Describe your jurisdiction's current status and plans to onboard to the IZ Gateway Connect and Share components.***

As of September 29, 2020, IDPH has signed the IZ Gateway, Data Use Agreement with the Association of Public Health Laboratories (APHL), Inc. IDPH sent the signed agreement to APHL for signature on September 30, 2020. As part of the agreement, IDPH indicated on the Task Order to the DUA the intent to participate in the following IZ Gateway Project components: Share, Provider-initiated Multi-jurisdictional Data Exchange, Access and Access: Consumer-initiated Multi-jurisdictional Data Exchange. The Network for Public Health Law confirmed receipt of the signed DUA from Iowa and indicated a fully ratified agreement will be coming soon. Additionally, Iowa's IIS vendor has convened periodic calls among the states utilizing the Wisconsin Immunization Registry (WIR) platform regarding the IZ Gateway and have dedicated an internal team to the IZ Gateway projects. IDPH is in the process of working with Audacious Inquiry and Digicert to connect to the IZ Gateway.



F. ***Describe the status of establishing:***

1. ***Data use agreement with the Association of Public Health Laboratories to participate in the IZ Gateway***
2. ***Data use agreement with CDC for national coverage analyses***
3. ***Memorandum of Understanding to share data with other jurisdictions via the IZ Gateway Share component***

As of September 29, 2020, IDPH has signed the IZ Gateway, Data Use Agreement with the Association of Public Health Laboratories (APHL), Inc. IDPH sent the signed agreement to APHL for signature on September 30, 2020.

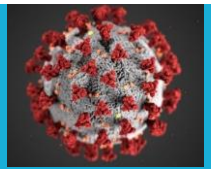
The data use agreement for national coverage analysis with the CDC has not been made available to the Iowa Department of Public Health. Upon receipt, the data sharing agreement will be coordinated through the IDPH Data Management and Health Equity Program. The Data Management and Health Equity Program will ensure the protection of data is outlined adequately in the agreement.

IDPH has provided Minnesota and Wisconsin with draft data sharing agreements. Both states use a similar IIS as Iowa and have mutual interest in sharing IIS data across jurisdictions. However, based on immunization staff responding to COVID, completion of the data sharing agreement has not occurred. IIS staff in Minnesota and Wisconsin have discussed tentative data sharing practices within each jurisdiction.

G. ***Describe planned backup solutions for offline use if internet connectivity is lost or not possible.***

In Iowa, approximately 90 percent of the data reported to IRIS is through electronic data exchange. In instances when IRIS is offline or a provider's internet connectivity is lost or a connection is not available, healthcare providers can maintain immunization data in the electronic health records (EHR). When connectivity is available or re-established the EHR can send or resend immunization data.

In addition, the IDPH Immunization Program has been working with Iowa healthcare providers who may choose to use other applications for the scheduling and documentation of COVID-19 vaccine doses administered (PREPMOD, Salamander). This will allow for applications which include functionality to accommodate high-volume vaccination elements (e.g., appointment scheduling, scanner technology) to be the primary source to document COVID-19 vaccine administration. These applications can be used when a provider's internet connectivity is lost or a connection is not available. When connectivity is available or re-established the EHR can send or resend immunization data to IRIS via data exchange.



IDPH contracts for the hosting and maintenance of IRIS. The contract for IRIS specifies the application will have "System Availability" of 99.5 percent for each calendar month. System Availability is calculated as (maximum uptime minus all downtime) divided by ("maximum uptime" minus "scheduled maintenance") times 100 where:

- maximum uptime is the maximum number of minutes available in a month outside scheduled maintenance (see below); and
- downtime is any unscheduled time the application is completely inaccessible to all authorized users through the user interface; or data exchange is completely inaccessible to all authorized provider organizations.

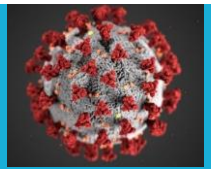
The IRIS application includes Mass Vaccination functionality for healthcare providers to document the administration of a single vaccine to a list of multiple vaccine recipients. Healthcare providers can document vaccine administration using alternate methods at remote or high volume clinics and can later be entered in IRIS using Mass Vaccination functionality. This functionality allows healthcare providers to build a roster of patients seen at a clinic or site and also allows the roster to be named and saved for future use.

H. *Describe how your jurisdiction will monitor data quality and the steps to be taken to ensure data are available, complete, timely, valid, accurate, consistent, and unique.*

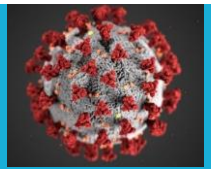
Continued monitoring of incoming data quality is essential to maintain the integrity of data within IRIS. The Iowa Immunization Program will build program-specific reports to monitor healthcare provider activity surrounding the receipt and administration of COVID-19 vaccine.

IDPH will use data from IRIS for the distribution and documentation of COVID-19 vaccine doses administered. The data will be used to monitor the timeliness of receipt of immunization data in IRIS, as measured by the difference between the date of administration and date of record submission. In addition, the Iowa Immunization Program will monitor the number of vaccine doses distributed to healthcare providers compared to vaccine doses administered data and vaccine inventory. If individual healthcare providers are delinquent in reporting vaccine doses administered data within 24 hours after vaccine administration, they will be contacted by Iowa Immunization Program staff to assess the situation which may include additional training and remediation. If healthcare providers are noncompliant, they may be removed as a COVID-19 vaccination provider. In Iowa, approximately 90 percent of the data reported to IRIS is through electronic data exchange. The majority of healthcare partners conducting electronic data exchange are submitting data real time.

The Immunization Program will extract data from the IRIS application to monitor COVID-19 vaccine administration by healthcare provider. IRIS includes Run/Match functionality which prevents the duplications of patient records and doses administered. This functionality allows IRIS staff to identify potential matches for patients and vaccines.



IRIS staff will monitor data elements throughout the COVID-19 vaccination campaign to ensure data elements are valid, accurate, consistent and unique.



Section 12: COVID-19 Vaccination Program Communication

A. ***Describe your jurisdiction's COVID-19 vaccination communication plan, including key audiences, communication channels, and partner activation for each of the three phases of the COVID-19 Vaccination Program.***

Clear and effective communication will be essential to a successful vaccination campaign. Building vaccine confidence broadly and among groups anticipated to receive early vaccination, as well as dispelling vaccine misinformation, are critical to ensure vaccine uptake. Additionally, routine immunization programs need to continue during the administration of COVID-19 vaccine. The Department has created a COVID-19 Vaccination Communication Plan creating a framework for communicating with internal and external partners during the COVID-19 vaccination campaign in Iowa. The plan is divided into different areas based on the audience and the specific communication needs of the audience. The IDPH COVID-19 Vaccination Campaign Communications Plan is attached in Appendix A.

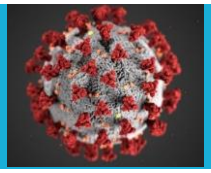
B. ***Describe your jurisdiction's expedited procedures for risk/crisis/emergency communication, including timely message development as well as delivery methods as new information becomes available.***

Appropriate, effective, and timely risk communication messages will be developed and delivered through the methods detailed in the IDPH COVID-19 Vaccination Communication Plan. Messages will be designed to explain the importance of COVID-19 vaccine along with vaccinating with confidence messaging.

Local Public Health Agencies and the IDPH have developed working relationships with local newspaper and television news staff. Press releases will be developed by the IDPH's Public Information Officer (PIO) and will be sent to LPHA via the HAN or email. Having local public health adapt these press release templates ensures news releases are consistent across the state.

Each local agency will then adapt the news release to their agency and release the information to their local newspapers, television networks, and social media platforms. The news releases may be directed toward social distancing, COVID-19 vaccine, dispelling vaccine myths, staying home when you are ill, when and how to contact your healthcare provider, and additional information on vaccine clinics.

Immunization resources will be developed to provide technical assistance and guidance for local public health agencies, hospitals, clinics, community health centers, and healthcare providers. The Department will likely utilize the COVID-19 and Vaccinating with Confidence campaigns developed by the CDC. This will allow resources to be quickly distributed and ensures a consistent message is being used.



Section 13: Regulatory Considerations for COVID-19 Vaccination

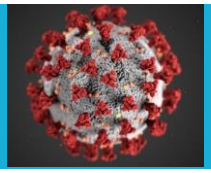
A. ***Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers are aware of, know where to locate, and understand the information in any Emergency Use Authorization (EUA) fact sheets for providers and vaccine recipients or vaccine information statements (VISs), as applicable.***

The EUA authority allows FDA to authorize either (a) the use of an unapproved medical product (e.g., drug, vaccine, or diagnostic device) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. The EUA will outline how the COVID-19 vaccine should be used and any conditions that must be met as requirements of authorized vaccine use. FDA will coordinate with CDC to confirm these "conditions of authorization." Vaccine conditions of authorization are expected to include distribution requirements, reporting requirements, and safety and monitoring requirements. The EUA would be terminated when either the HHS Secretary determines that circumstances justifying authorization of emergency use of the COVID-19 vaccine have ceased or there is a change in the approval status of the vaccine such that an EUA is no longer necessary. Additional information on EUAs, including guidance and frequently asked questions, is located on the FDA website.

Product-specific EUA fact sheets for COVID-19 vaccination providers will be made available on the COVID-19 Vaccine webpage which will include information on the specific vaccine product and instructions for use. An EUA fact sheet for vaccine recipients will also be developed by federal partners and will be placed on the COVID-19 Vaccine webpage as well. In addition, the IDPH Assistant Attorney General is creating an FAQ document regarding the Public Health PREP ACT for COVID-19 Vaccination and EUA for COVID-19 Vaccination which will be completed prior to vaccine distribution and administration in the state.

B. ***Describe how your jurisdiction will instruct enrolled COVID-19 vaccination providers to provide Emergency Use Authorization (EUA) fact sheets or vaccine information statements (VISs), as applicable, to each vaccine recipient prior to vaccine administration.***

Using communication channels outlined in the Communication Plan (Appendix A), IDPH will ensure providers know where to find both the provider and recipient fact sheets, have read and understand them, and are clear on the requirement to provide the recipient fact sheet to each client/patient prior to administering COVID-19 vaccine.



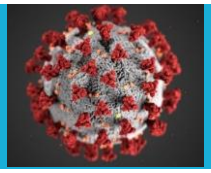
Section 14: COVID-19 Vaccine Safety Monitoring

A. ***Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers understand the requirement and process for reporting adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).***

VAERS is a passive reporting system, it relies on individuals to send in reports of personal experiences to CDC and FDA. VAERS is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. VAERS provides the CDC and FDA with valuable information that additional work and evaluation is necessary to further assess a possible safety concern.

The COVID-19 Vaccination Program Provider Agreement specifies moderate and severe adverse events following COVID-19 vaccination should be reported to the VAERS system. All providers and organizations in Iowa completing a COVID-19 Vaccination Provider Agreement will be required to report adverse COVID-19 vaccine events to VAERS. Additionally, IDPH will utilize communication methods outlined in the IDPH COVID-19 Vaccination Communication Plan (Appendix A), (LPHA webinar, Vaccine Info Brief, FAQ) to inform partners on reporting an event to VAERS. The link to the VAERS website will be posted to the IDPH COVID-19 vaccine page. COVID-19 Vaccination Program Monitoring VAERS reports should be submitted regardless of whether or not the reporter believes the adverse event was vaccine-related.

CDC will implement **v-safe**, a new smartphone-based tool that uses text messaging and web surveys to check in with vaccinated individuals for adverse events after a COVID-19 vaccination. **v-safe** will also provide second-dose reminders (if needed) and live telephone follow up by CDC if vaccinated individuals report a medically significant event during a **v-safe** check-in. **v-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. Medically significant events will be identified if the vaccinated individual reports that they missed work, were unable to complete normal daily activities, or had to seek care from a health provider or healthcare professional. The information will be used to analyze common side effects (soreness in the arm, muscle aches, etc.) and to detect unexpected, serious health problems if they occur. CDC is requesting that healthcare providers give patients a **v-safe** information sheet at the time of vaccination and encourage them to enroll and fill out the surveys when prompted to do so. The information sheet explains **v-safe** and provides step-by-step instructions on how to sign up to participate. Vaccine recipients can use the QR code or URL on this information sheet to sign up at their convenience.



Section 15: COVID-19 Vaccination Program Monitoring

A. ***Describe your jurisdiction's methods and procedures for monitoring progress in COVID-19 Vaccination Program implementation, including:***

Internal tracking documents have been established to monitor specific goals and expectations, and allow for the weekly review for after action items and continuous quality improvement. Daily reminder prompts were added to the internal tracking documents.

- ***Provider enrollment***

IDPH will utilize a REDCap survey to document provider acceptance of the terms to serve as a COVID-19 vaccine provider. The Iowa REDCap COVID-19 Vaccination Program Provider Agreement will require each vaccination provider to be credentialed/licensed in Iowa.

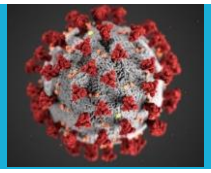
As REDCap surveys are completed, IDPH has established a process to ensure the provider has completed the form correctly and is enrolled as an IRIS user. The process verifies providers listed are licensed to practice in Iowa and are in good standing with their respective licensing board. The IDPH has built a REDCap report to extract the number of healthcare providers which have started the survey, submitted surveys, surveys requiring additional information and the number of agreements processed and approved by IDPH. Provider enrollment data will be reported daily and a list of approved COVID-19 vaccine providers will be posted on the HAN for review by LPHAs.

- ***Access to COVID-19 vaccination services by population in all phases of implementation***

IDPH and local partners are actively recruiting local healthcare and pharmacy partners to enroll in IRIS and as COVID-19 vaccine providers. Additionally, as of September 30, 2020, the COVID-19 Vaccination Program Provider Agreement has been widely disseminated to public health and healthcare providers in the state. All healthcare providers and organizations interested in receiving and administering COVID-19 vaccines in Iowa are required to complete the CDC COVID-19 Vaccination Program Provider Agreement. IDPH will utilize a REDCap survey to document provider acceptance of the terms to serve as a COVID-19 vaccine provider. IDPH will use COVID-19 vaccine provider enrollment data compared to priority group populations to evaluate healthcare providers enrolled to serve populations. The Department will use data visualization software to represent both of these groups.

- ***IIS or other designated system performance***

IDPH contracts for the hosting and maintenance of IRIS. The contract for IRIS specifies the application will have "System Availability" of 99.5 percent for each calendar month. System Availability is calculated as (maximum uptime minus all downtime) divided by ("maximum uptime" minus "scheduled maintenance") times 100 where:



- Maximum uptime is the maximum number of minutes available in a month outside scheduled maintenance (see below).
- Downtime is any unscheduled time the application is completely inaccessible to all authorized users through the user interface; or data exchange is completely inaccessible to all authorized provider organizations.

- ***Data reporting to CDC***

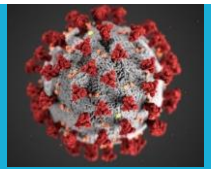
IDPH will facilitate and monitor reporting by enrolled vaccination providers in IRIS. Each vaccination location will have trained staff, necessary equipment, and internet access (if needed) to report vaccine administration data into IRIS at the time of vaccination. If data will be entered off site, vaccination providers must ensure the required data are reported within 24 hours. Reporting data will be transmitted as directed by CDC via the IZ Gateway "Connect" component. IDPH is awaiting additional information on the reporting process and specifications from CDC. IDPH will not be responsible for reporting data from federal agencies or commercial partners who receive vaccine allocations directly from CDC.

- ***Provider-level data reporting***

The IDPH Immunization Program will monitor the number of vaccine doses distributed to healthcare providers compared to vaccine doses administered data and vaccine inventory. If individual healthcare providers are delinquent in reporting vaccine doses administered data within 24 hours after vaccine administration, they will be contacted by Iowa Immunization Program staff to assess the situation which may include additional training and remediation. If healthcare providers are noncompliant, they may be removed as a COVID-19 vaccination provider. In Iowa, approximately 90 percent of the data reported to IRIS is through electronic data exchange. The majority of healthcare partners conducting electronic data exchange are submitting data real time.

- ***Vaccine ordering and distribution***

LPHAs will receive allocation of COVID-19 vaccine from IDPH in IRIS and with HAN notification. The HAN Alert will indicate the time frame LPHA have to allocate doses. IDPH will utilize IRIS functionality to run a report showing LPHA who have not placed vaccine orders. IDPH staff will follow up with the agencies to ensure the doses are allocated.



- ***1- and 2-dose COVID-19 vaccination coverage***

IDPH will use data from IRIS for the distribution and documentation of COVID-19 vaccine doses administered. The Immunization Program will extract data from the IRIS application to calculate COVID-19 vaccine county and state coverage reports. The data extract will be imported into a data visualization tool and posted to the IDPH web page. Reports detailing, "COVID-19 Series Initiated- Not Complete" or "Complete COVID-19 Vaccine Series" which are distinct and non-overlapping categories will be available for state, by county, gender and age.

B. ***Describe your jurisdiction's methods and procedures for monitoring resources, including:***

- ***Budget***

The IDPH Immunization Program and Preparedness Program have budgets by organization code and program codes which allows for the tracing of funding sources specific to each funding source. The IDPH internal planning group includes fiscal representation who has a standing agenda item during the daily briefings.

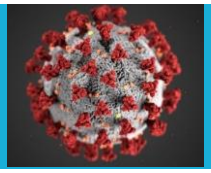
- ***Staffing***

The Division of Acute Disease Prevention, Emergency Response and Environmental Health (ADPER & EH) is the division that organizationally contains the Bureau of Immunization and Tuberculosis as well as the Bureau of Emergency and Trauma Services (PHEP and HPP Preparedness and Response). Throughout the COVID-19 response this division has been functionally involved in nearly every aspect of planning and implementation. The Bureau of Immunization and Tuberculosis has been planning and working with federal partners for several months preparing for the release of the COVID-19 vaccine.

IDPH has convened an internal COVID-19 Vaccine Planning team with representation from the state immunization bureau, the hospital and public health preparedness and response bureau that includes the IDPH Strategic National Stockpile (SNS) Officer, risk communication officer, planning and performance officers, the IDPH Medical Director and State Epidemiologist, Deputy State Epidemiologist, Governor's office staff, and fiscal specialists, and other members of the department's incident management roster that includes staff from the Bureau of Environmental Service and Radiological Health. This internal group meets daily to review a mission task list and required planning updates.

- ***Supplies***

IDPH is working with the Iowa Homeland Security and Emergency Management on the coordination of additional ancillary supplies (gloves, needles, sharps containers, etc.). Additionally, the Department is verifying the ability to obtain a vendor to supply dry ice to re-charge ultra-cold shipping containers.



The Immunization Program has purchased digital data loggers and will distribute the temperature monitoring devices to enrolled COVID-19 vaccine providers as necessary.

C. ***Describe your jurisdiction's methods and procedures for monitoring communication, including:***

- ***Message delivery***

IDPH has created a COVID-19 Vaccination Communication Plan creating a framework for communicating with internal and external partners during the COVID-19 vaccination campaign in Iowa. The plan is divided into different areas based on the audience and the specific communication needs of the audience. The IDPH COVID-19 Vaccination Campaign Communications Plan is attached in Appendix A. In addition, the Department has created a list serve specifically for COVID-19 vaccination providers. The GovDelivery list serves includes functionality to view vaccine recipients who have opened the list serve messages to view the message contents.

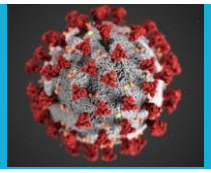
- ***Reception of communication messages and materials among target audiences throughout jurisdiction***

One of the major pieces to the awareness campaign is ensuring all Iowans are able to receive and understand messages, regardless of an individual's ability to read, speak, or write English. This outreach can be accomplished through engagement of organizations representing these populations. IDPH will leverage existing connections with different programs within the department, as well as with other state agencies and other external partners to ensure messages are received and understood.

D. ***Describe your jurisdiction's methods and procedures for monitoring local-level situational awareness (i.e., strategies, activities, progress, etc.).***

Each county is currently updating a POD Standards workbook that identifies each planned POD location, if the planned location is an open or closed POD, a drive through or walk in clinic, number of dispensing stations, and total expected throughput. Mass vaccination planning at the local level requires sufficient numbers of PODs are identified so all people in the county, regardless of demographics or location, have access to these vaccines. LPHA must identify in this workbook a strategy to identify, assign and incorporate PODs into operations. Population density, geographical location, proximity to public transportation, and community and business demographics play key roles in strategies used to identify sufficient numbers of PODS to ensure 100 percent of the identified populations can vaccine.

In addition, weekly webinars are conducted with LPHAs which allow for questions to be submitted to IDPH staff. Questions received are used to guide each week's webinar. The weekly webinars allow IDPH to determine areas of additional support or education LPHAs require.



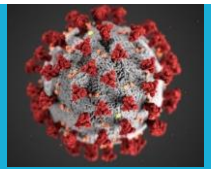
E. ***Describe the COVID-19 Vaccination Program metrics (e.g., vaccination provider enrollment, doses distributed, doses administered, vaccination coverage), if any, that will be posted on your jurisdiction's public-facing website, including the exact web location of placement.***

Final determination has not been made on the exact web location of Iowa's COVID-19 Vaccination Program metrics. It is anticipated the metrics will be displayed on the COVID-19 in Iowa web page. The Iowa Department of Public Health will use data from IRIS for the distribution and documentation of COVID-19 vaccine doses administered. The Immunization Program will extract data from the IRIS application to calculate COVID-19 vaccine county and state coverage reports. The Immunization Program has established data elements to be included in the data extract. The data extract will be imported into a data visualization tool and posted to the IDPH web page. A list of data elements and calculations is included as follows.

COVID-19 Vaccine Administration - Visualizations
Purpose: Daily query from IRIS to provide up-to-date COVID-19 vaccine administration data for public facing visualizations (using DOMO or other data visualization software)
Data source: IDPH Immunization Program - Immunization Registry Information System (IRIS)
File format: CSV file (most likely)
Frequency of data query: Daily, time of day TBD
Submission process: TBD, designated point of contact
Query development: In development, under discussion
Example Visualizations included

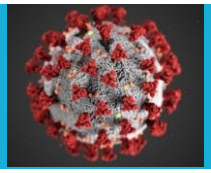
Data notes/assumptions:

- "Patient" is the IRIS term used to represent the federal term of "Recipient"
- The COVID-19 Vaccine Provider Agreement specifies vaccine providers have 24 hours after administration to report to IRIS (state's immunization information system). However, delay in reporting may occur.



Data Elements:

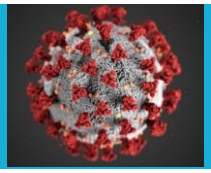
Variable	Use/ Reason
Patient's ID in IRIS	Identify unique individuals in IRIS; allow for matching of dose 1 and 2 in visualization software
Vaccine National Drug Code (NDC)	Identify required number of doses for series, validate spacing of doses, track administration of vaccine products etc.
MVX	The manufacturer of the vaccine administered
CVX	The product used in a vaccination. CDC maintains CVX codes here.
Dose Number	Report dosage/dose number being administered, if the vaccine requires more than one (e.g., dose #1, dose #2)
Date of administration for dose 1	Calculate total number of doses administered
Date of administration for dose 2	Calculates total number of doses administered and number of completed series (if valid dose and if series requires 2 doses)
Patient's date of Birth	Use to calculate age, calculated with date of administration of dose 1
Provider Type	Type of healthcare provider administering (pharmacy, private practice, hospital, local public health etc.)
County of administration	Use to track vaccine administration at county level
Patient county of residence	Use to identify vaccine coverage rate at county level
Patient Gender	Gender as captured in IRIS (male, female, unknown); not a required variable in IRIS
Patient Race	Race as captured in IRIS (American Indian or Alaska Native; Asian; Native Hawaiian or Pacific Islander; Black or African American; White; Other Race; Unknown Race); not a required variable in IRIS
Patient Ethnicity	Ethnicity as captured in IRIS (Hispanic or Latino; Not Hispanic or Latino; Unknown); not a required variable in IRIS



Vaccine Administration Visualization**:** Visualization below includes examples from current vaccine visualization prepared by the IDPH Immunization Program.

- COVID-19 Vaccine administration for state and by county
  - Select a county to see county level information and compare to state level information
  - Select "COVID-19 Series Initiated- Not Complete" or "Complete COVID-19 Vaccine Series" which are distinct and non-overlapping categories
  - Include information in hover-over/quick click feature to compare counties
- Total Doses Administered by Month
  - Start with first month products available (approximately Nov. 2020)
  - Total number of doses administered statewide, regardless of dose number (series initiation or completion)
  - Present as total number of doses administered by month
- Doses Administered by Gender:
  - Select a county to see county level information and compare to state level information
  - Select "COVID-19 Series Initiated- Not Complete" or "Complete COVID-19 Vaccine Series" which are distinct and non-overlapping categories
- Doses Administered By Age Group:
  - Select a county to see county level information and compare to state level information
  - Select "COVID-19 Series Initiated- Not Complete" or "Complete COVID-19 Vaccine Series" which are distinct and non-overlapping categories
  - May not be applicable with the first products available due to limitations in approved age groups or populations
- Data Table by County of Residence:
  - "COVID-19 Series Initiated- Not Complete" and "Complete COVID-19 Vaccine Series" which are distinct and non-overlapping categories
- Data Table by County of Administration:
  - Total number of doses, regardless of series initiation or completion

County of Administration	Number of Doses Administered
Adair	
Adams	
State	Total Number of Doses Administered



- Data Table of Doses Administered by Provider Type:
  - Total number of doses, regardless of series initiation or completion
  - Provider Type categories as identified in IRIS

County of Administration	Number of Doses Administered
Private Provider	
Local Public Health Agency	
Hospital	
Long Term Care/Nursing Home	
Pharmacy	
College/University	

Additionally, IDPH will frequently seek situational awareness throughout the COVID-19 Vaccination response on two CDC Dashboards, including:

CDC's **Weekly Flu Vaccination Dashboard** that will include weekly estimates of influenza vaccination for adults, children, and pregnant women using existing (National Immunization Survey [NIS]-Flu) data sources. Data and estimates from additional sources will be added, as available.

An additional dashboard, the Operation Warp Speed (OWS) Tiberius platform, is a COVID-19 vaccine distribution planning, tracking, modeling, and analysis application that provides flexible, real-time, data-backed processes so IDPH can make data-driven decisions. Tiberius will integrate data sources from federal agencies, state and local partners, private-sector partners, and other data providers to create a comprehensive common operating picture for the COVID-19 vaccine planning, distribution, and administration effort that awardees can use to support the COVID-19 vaccine response.

Appendix

Appendix A: Communication Plan

Appendix B: Vaccine Information Brief

Appendix C: CDC COVID-19 Vaccination Program Provider Agreement

Appendix D: COVID-19 Vaccine Transfer Authorization Process

Appendix E: COVID-19 Vaccine Redistribution Form