



# COVID-19 VACCINE ALLOCATION PLAN

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Indiana Department of Health

October 2020

This is a preliminary plan. Implementation is subject to change based on vaccine availability.

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## EXECUTIVE SUMMARY

Providing a safe and effective COVID-19 vaccine to all Hoosiers is a critical component of the State of Indiana's strategy to reduce the spread of COVID-19 and related illnesses, hospitalizations, and deaths through appropriate allocation and administration of COVID-19 vaccine to all Hoosiers in a safe, timely and effective manner. The following document serves as an interim draft plan for the Indiana Department of Health (IDOH), local public health programs, and public health partners on how to plan and operationalize a vaccination response to COVID-19 within Indiana.

Indiana has established multi-agency cross-disciplinary advisory groups to enhance the development of plans, activity reach, and risk/crisis response messaging and delivery:

**Vaccine Allocation Plan Development Advisory Group:** Provided final recommendations on the ethical and equitable allocation of a limited COVID-19 vaccine. This group remains available to assemble as adjustments to the plan are needed based on the final allocation total and the safety and efficacy of the vaccine(s).

**Ethical Considerations Advisory Group:** Reviewed existing documents and assisted in writing and reviewing ethical approaches to vaccine allocation. This group founded their recommendations with the goals to decrease overall mortality, mitigate spread, steward scarce resources responsibly, ensure feasibility of implementation, reinforce and support health care infrastructure necessary to treatment of disease, protect vulnerable populations, and promote fairness.

**Vaccine Review Advisory Group:** This group will investigate available information on each COVID-19 vaccine and will specifically review the safety profile and efficacy of each population of interest (those at clinical risk and demographic factors).

**Equitable Distribution and Communication Advisory Group:** Worked to ensure that all Hoosiers were considered and represented as a component of the vaccine allocation plan. Advised on key components of communication.

**Data Advisory Group:** Explored creative data resources and compiled Indiana-specific data for critical populations.

**Vaccination Program Implementation Committee:** External committee facilitated by the Indiana Department of Health's (IDOH) State Health Commissioner with representation from state and local government organizations, private sectors, tribes, healthcare, education, and critical infrastructure.

For Phase 1, Indiana will reinforce and support the healthcare workforce and those who are at the most risk of morbidity and mortality. In the scenario that Indiana does not receive sufficient vaccine to vaccinate all included in the population of focus, the IDOH has developed a per-county percentage-based metric to ensure equitable and equal distribution across Indiana.

**Phase 1-A:** Guiding objective: Reinforce and support healthcare infrastructure & treatment of disease.

- This group includes all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious material.
- Healthcare settings include, but are not limited to: hospitals, long-term care facilities, outpatient facilities, home health care settings, pharmacies, dialysis centers, emergency medical services, frontline public health interventions, and COVID-19 diagnostic and immunization teams.

**Phase 1-B:** Guiding objective: Protect the vulnerable.

- Individuals who are at particular risk of morbidity and mortality associated with COVID-19 disease based on the latest evidence-based criteria.

**Phase 2:** Guiding objective: Mitigate spread.

- Individuals who are at elevated risk of transmission of the disease because of working or living circumstances. This includes persons living in correctional facilities, group homes or shelters, and individuals whose in-person work is essential, required, and places them in settings where social distancing is not possible and transmission risk is high.

**Phase 3:** Guiding objective: General public vaccination.

Phase 1-A will utilize hospitals that are prepared to administer vaccine to all healthcare personnel. Indiana hospitals were surveyed regarding their readiness to provide vaccine to healthcare personnel, including those not associated with their facility. Phases 1-B and 2 will expand to utilize local health departments (LHDs) and partnerships with commercial pharmacies. IDOH has provided a COVID-19 Vaccine Planning Template to the 94 LHDs and will review each of the plans prior to vaccine delivery to ensure adequate and appropriate vaccination efforts are addressed locally. The continuous quality improvement at the local level ensures state and local readiness of dispensing of mass prophylaxis, including vaccines, to Hoosiers across the state.

IDOH will further augment the local response by deployment of vaccination strike teams embedded in our 10 district mobile response units throughout the State to administer vaccine to those who are not covered by traditional vaccine providers and/or local public health efforts. Indiana is also piloting a vaccination partnership with our EMS and paramedicine providers and plans to incorporate them in COVID-19 vaccination in communities statewide. The Indiana National Guard, an important part of our testing program, will also be engaged with our phase 2 and 3 mass immunization plan.

To facilitate early vaccination efforts and to ensure proper provider coverage statewide, the IDOH has developed a web-based/on-line COVID-19 Provider Enrollment form capturing all required datasets as included in the "CDC COVID-19 Vaccination Program Provider Agreement". This web-based system will be used to collect required data that will be transmitted electronically to federal systems, therefore enrolling Indiana providers as COVID-19 Vaccine Providers. The IDOH will use Tiberius as a visualization tool for allocations, vaccine administration data monitoring, and transparency.

Currently, 743 providers enrolled in the Indiana Vaccines for Children (VFC) Program are actively vaccinating and recording vaccination administration data in the Children and Hoosier Immunization Registry Program (CHIRP), Indiana's immunization information system. There are 1,923 other facilities that have established a bi-directional interface with CHIRP. IDOH is working with a third-party registration vendor to identify a registration platform that will link to CHIRP. Registered COVID-19 vaccination providers will order COVID-19 vaccine through CHIRP. IDOH will utilize existing procedures routinely used for ordering publicly funded vaccines.

A robust and nimble communication plan will be the foundation of successful COVID-19 vaccine administration and uptake. The focus must be on ensuring consumer trust by providing information that is timely, accurate and appropriate. Messages will be crafted specifically to each audience and distributed through the most effective channels to achieve the maximum response.

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## RECORD OF CHANGES

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## I. COVID-19 VACCINATION PREPAREDNESS PLANNING

Pandemic vaccination response planning requires collaboration among a wide range of public- and private-sector partners, including immunization and public health emergency preparedness programs, emergency management agencies, healthcare organizations, industry groups that include critical infrastructure sectors, policy makers, and community vaccination providers (e.g., pharmacies, occupational health settings, doctors' offices). Many of these partners are engaged regularly in seasonal influenza and other outbreak vaccination campaigns, and many have served in past vaccination response campaigns.

### A. State Improvement Planning

Improvement planning is the identification of strengths, areas of improvements, and corrective actions that result from workshops, exercises, or real-world events. The Indiana Department of Health (IDOH) has identified strengths and gaps in program planning during exercises and real-world events. Below are lessons learned from two real-world events that have affected the state of Indiana, the 2009 H1N1 Pandemic and 2018 hepatitis A outbreak.

#### 1. 2009 H1N1 Pandemic

Following the statewide response to the 2009 H1N1 Pandemic within Indiana, specific strengths and areas of improvement were documented in Indiana's After-Action Review (AAR). A comprehensive overview of Indiana's actions, strengths, and areas of improvements can be found in the full H1N1 AAR document. Below are highlights from the AAR regarding vaccine administration, documentation, and messaging. These quality improvement actions have been incorporated into routine vaccinations and current COVID-19 vaccine implementation efforts.

##### Strengths Identified:

- Collaboration with corporations and universities to offer vaccines
- Weekly conference call communications between local health departments (LHDs) and IDOH
- Development of targeted priority groups
- Provider agreement and CHIRP forms
- IDOH training sessions on vaccines, injections, and administration for volunteers
- Higher uptake among special populations when vaccine was directly provided within the community

##### Areas of Improvement Identified:

- Timeliness and initial amount of vaccine was much lower than expected and subsequent issues getting vaccine early. If there is a delay or change, inform early, often, and why
- Provide a standardized interpretation and messaging of priority populations within all counties
- Development of centralized communications and identification of vaccine subject matter expert (SME)/spokesperson within Indiana

- Ensure all providers receive the vaccine information statement (VIS) on time
- Communicate accurate and timely information to counteract vaccine hesitancy. Low interest in vaccine from general public, providers, and healthcare workers initially
- Vaccine hesitancy due to myths and false statements on the internet.
- Provide training on proper use of ancillary supplies (i.e., syringes, needles)

## 2. 2018 Hepatitis A Outbreak

The IDOH responded to statewide hepatitis A outbreak starting in 2017 associated with a national outbreak by activating an Incident Command System (ICS). This response identified a great number of modifications that needed to be made to effectively deploy vaccination strike teams, including:

- Always have a state employee as part of the team so that state-rented vehicles can be utilized
- Establish a standard operating procedure for offsite vaccination clinics
- Establish a standard operating procedure for using the mass vaccination module in the state immunization information system
- Establish a pool of vaccinators who are willing to go into jails, homeless shelters, and high-risk areas

These modifications enabled IDOH to deploy strike teams for COVID-19 testing in long term care facilities within 24 hours.

## B. Local Improvement Planning

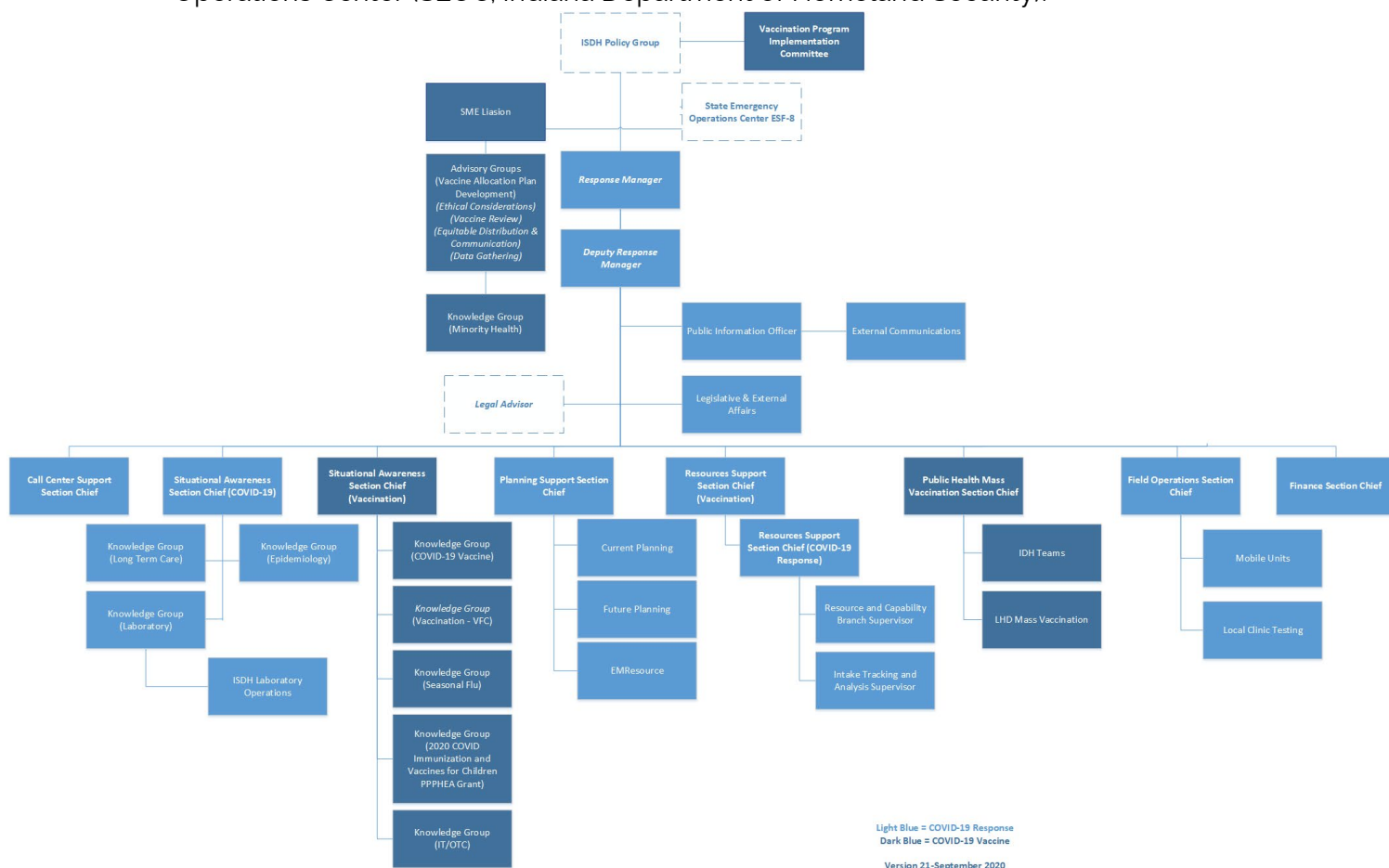
Local health departments (LHDs) frequently engage local partners in exercising Points of Dispensing (POD) operations and planning scenarios. This continuous quality improvement at the local level ensures state and local readiness of dispensing of mass prophylaxis, including vaccines, to Hoosiers across the state. This periodic review and revision of local plans is integral to the improvement process. Continuous quality improvement is ongoing as LHDs move through the various phases of workshops, tabletops, functional exercises, and real-world activities. Local improvement planning is further bolstered by the annual Public Health Emergency Preparedness (PHEP) program cooperative agreement. The PHEP cooperative agreement provides funding assistance while setting annual requirements that help health departments build and strengthen their abilities to effectively respond to a range of public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear, and radiological events. Preparedness activities funded by the PHEP cooperative agreement specifically target the development of emergency-ready public health response plans that are flexible and adaptable.

## II. COVID-19 ORGANIZATIONAL STRUCTURE AND PARTNER INVOLVEMENT

### A. IDOH Department Operations Center (DOC) Incident Support Model (ISM) Organizational Structure

The ISM is a variation of a traditional Incident Command System (ICS) structure that separates the information management/situational awareness function from the ICS Planning Section and combines the functions of the ICS Operations and Logistics Sections from the ICS Administration/Finance Section. The DOC ISM structure typically focuses exclusively on support functions rather than operations. With the hands-on nature of some COVID-19 response operations, the current IDOH ISM incorporates both situational awareness/support functions and operational elements.

As with the ICS, the director of a DOC ISM is supported by personnel designated to key functions, subject matter experts, and technical specialists. Staff supporting the Response Manager include a Public Information Officer and legal advisor. The General Staff sections consist of Situational Awareness, Planning Support, Resources Support, and DOC Center Support. The following model represents the overall DOC ISM structure, specific for COVID-19 vaccine allocation as an extension to the Indiana ESF-8, State of Indiana Emergency Operations Center (SEOC; Indiana Department of Homeland Security).



## B. Vaccine Internal Planning Group and Working Group (Internal)

The IDOH has established an internal vaccine planning group and working group. The purpose of the working group is to develop the state's COVID-19 vaccine plan and operationalize functions referenced within the plan. This group is comprised of multiple representatives from various divisions within the agency. These representatives are noted in the agency's ICS organization chart above. The internal vaccine planning group is comprised of working group members in addition to policy level executives. High level strategies, policies, tasking, and planning assumptions originate within the internal vaccine planning group. These strategies are then operationalized and developed within the working group.

Indiana Internal COVID-19 Vaccine Planning Group Representation	
Policy (State Health Commissioner, Deputy State Health Commissioner, Chief of Staff, Chief Medical Officer, Chief Data Officer, Legislative & External Affairs)	COVID-19 Response Manager
Public Information Officer & Communications	Emergency Preparedness Planning
Logistics & Resource Support	Office of Technology and Compliance (OTC) & Information Technology (IT)
Local Public Health Mass Vaccination	Immunizations
Legal	Finance

## C. Vaccination Program Implementation Committee (External)

Reaching intended vaccine recipients is essential to achieving desired levels of COVID-19 vaccination coverage. To ensure equitable access to vaccinations, information about populations within a jurisdiction and the logistical requirements for providing them access to COVID-19 vaccination services requires collaboration with external entities and community partners who are familiar with how they obtain healthcare and other essential services.

Indiana has established an external vaccination program implementation committee facilitated by the State Health Commissioner. The purpose of this external implementation committee is to enhance the development of plans, reach of activities, and messaging and delivery related to the COVID-19 vaccine. This goal of this external committee is to provide coordination and communication between state and local governments, private sectors, tribes, healthcare, education, and critical infrastructure.

Indiana External COVID-19 Vaccine Implementation Committee	
Sector within the Community	Organization(s) Represented
Corrections	Indiana Department of Corrections (IDOC)
Critical Access Hospitals / Rural Health	Margaret Mary Health
Emergency Management Agencies	Indiana Department of Homeland Security
Faith-based	Purpose of Life Ministries
Federally Qualified Health Center / Community-based Healthcare	HealthLinc
Healthcare	Indiana Health Care Association (IHCA), Indiana Hospital Association (IHA)
Higher Education	Ball State University, University of Notre Dame, Purdue University, Indiana University, Independent Colleges of Indiana
Homeless	Indiana Housing and Community Development Authority (IHCDA)
Immunization Coalition	Indiana Immunization Coalition
Jails	Indiana Sheriff's Association
Law Enforcement	Indiana State Police
Local Public Health Departments	Allen County, Ripley County, Vanderburgh County, Porter County, Marion County
Minority Health	Indiana Minority Health Coalition (IMHC), Indiana Latino Institute, Indiana Latino Expo
Occupational Health Associations	OurHealth
Organizations serving people with disabilities	Indiana Family & Social Services Administration (FSSA) – Division of Aging, Division of Disability and Rehabilitative Services, Division of Mental Health
Pharmacies	Indiana Pharmacy Alliance, Kroger
Tribal	Native American Indian Commission – Health Committee, Native American Indian Commission, Potawatomi Native Americans – St. Joseph County

#### D. Vaccine Advisory Groups (External)

The following five external advisory groups are facilitated by the IDOH Chief Medical Officer. The advisory groups convene multiple cross disciplinary subject matter experts (SMEs) to develop recommendations for equitable allocation, distribution, and accounting for COVID-19 vaccine.

##### 1. Vaccine Allocation Plan Development Advisory Group

The Vaccine Allocation Plan Development Advisory Group collaborates with the Ethical Considerations Advisory Group to review available and prior vaccine allocation recommendations to develop a plan for Indiana.

The Vaccine Allocation Plan Development Advisory Group has representation from the Indiana Hospital Association (IHA), IDOH Immunizations Division, Indiana University Richard M. Fairbanks School of Public Health, Indiana University School of Law, Butler University, Indiana Primary Healthcare Coalition, HealthLinc (federally qualified health center), Proactive Clinical Partners (medical group), and multiple health systems (Ascension St. Vincent, Community Health Network, Methodist Hospitals, and Indiana University Health).

## **2. Ethical Considerations Advisory Group**

The Ethical Considerations Advisory Group reviews existing literature and guidance regarding ethical considerations related to the vaccine. This group develops the strategy to ensure that COVID-19 vaccine is ethically allocated across the state.

The Ethical Considerations Advisory Group has representation from the Indiana Hospital Association (IHA), Indiana University School of Medicine, Indiana University School of Law, Indiana University Richard M. Fairbanks School of Public Health, Cardon & Associates, Inc. (long-term care), and multiple health systems (Decatur County Memorial Hospital, Indiana University Health, Ascension St. Vincent, Kosciusko Community Hospital, and Community Health Network).

## **3. Vaccine Review Advisory Group**

The Vaccine Review Advisory Group investigates available information on COVID-19 vaccine candidates. Based on CDC, FDA, and ACIP guidance, this advisory group will develop safety profiles per population, evaluate the efficacy of the vaccine, and develop an understanding of exclusion criteria.

The Vaccine Review Advisory Group has representation from the Indiana Hospital Association (IHA), Indiana Health Care Association (IHCA), IDOH Office of Minority Health, Indiana University School of Medicine, two local health departments (Marion County and Allen County), and multiple health systems (Eskenazi Health, Logansport Memorial Hospital, Parkview Health, Methodist Hospitals, Ascension St. Vincent, and Community Health Network).

## **4. Equitable Distribution and Communication Advisory Group**

The Equitable Distribution and Communication Advisory Group reviews and advises on equitable inclusion of populations eligible to receive the vaccine. This advisory group will develop considerations for inclusion and identify communication gaps.

The Equitable Distribution and Communication Advisory Group has representation from the Indiana Hospital Association (IHA), IDOH Office of Minority Health, Indiana Community Health Workers Association, Indiana University Richard M. Fairbanks School of Public Health, and multiple health systems (Hancock Regional, Indiana University Health, Community Health Network, and Eskenazi Health).

## 5. Data Advisory Group

The Data Advisory Group researches, collects data, and develops a process for estimating the number of individuals in each potential category for receipt of the COVID-19 vaccine.

The Data Advisory Group has representation from the Indiana State Medical Association (ISMA), Indiana Hospital Association (IHA), Indiana Professional Licensing Agency (PLA), Regenstrief Institute, Indiana Management Performance Hub (MPH), and two health systems (Indiana University Health and Ascension St. Vincent).

## E. Partnership

To implement an effective, equitable, and representative COVID-19 vaccine strategy, IDOH has leveraged existing partnerships within the agency, state and local governments, healthcare, minority groups, private industry, and higher education. These partners are represented within the internal and external implementation committees and advisory groups listed above.

## F. Multi-Agency Coordination

The evolution of the size and complexity of hazards and threats has demonstrated the need for effective planning and coordinated emergency response. These events also show disasters have no geographical, economic, or social boundaries and involve multiple jurisdictions, agencies, and organizations. To effectively manage efforts of a multi-agency coordination system, the State of Indiana has adapted its planning and response capability based upon the following operational constructs:

### 1. State Emergency Operations Center (SEOC)

The Indiana State Emergency Operations Center (SEOC) is the Indiana Department of Homeland Security-managed physical location where multi-agency coordination occurs. The purpose of the SEOC is to provide a central coordination hub for the support of local, district, and state needs. The SEOC can be configured to expand or contract as necessary to respond to different levels of incidents requiring state assistance.

The SEOC is staffed and organized with the Emergency Support Function (ESF) concept incorporated into an Incident Command System (ICS) structure. Agencies that represent ESF positions are activated in the SEOC during an incident to execute the response phase of emergency management. The designated primary and support agencies for the ESF positions in the SEOC can be arranged and tasked as needed by the IDHS Response Division Director of Operations. The elevated activation level is determined by the pandemic and the need for coordination and resource support. The ESF primary agencies remain responsible for the coordination of all phases of emergency management as outlined in their respective ESF annexes, regardless of their SEOC staffing assignments.



## 2. Executive Policy Group

Emergencies and disasters can produce issues requiring prompt decisions to serve short and long-term emergency management needs. The Executive Policy Group is a function of Indiana Department of Homeland Security (IDHS) that is established to address issues concerning the safety and welfare of Indiana residents, property, and the environment.

The Executive Policy Group has been activated to advise the Governor, local officials and the public and recommend protective actions to be taken during an emergency/event. The Executive Policy Group has assembled in the SEOC to assist in coordination and decision making.

The Executive Policy Group consists of stakeholders with the authority to make policy-related decisions or make suggestions to support the state's response and technical evaluation during an incident but varies depending upon the type, size and complexity of the incident. The IDHS Executive Director or designee serves as chairperson of the Executive Policy Group. The Executive Policy group consists of lead agency representatives from relevant ESFs as well as subject matter experts as necessary.

## 3. Indiana Districts

The State of Indiana, in conjunction with multiple agencies, has created Homeland Security and Public Health Preparedness Districts. The district organization and planning concept is comprised of multiple jurisdictions, disciplines, and agencies. Together they focus on common strategic goals and objectives to satisfy and meet national, state, and local homeland security and public safety needs. By coming together, many counties, local governments, and the State benefit from sharing resources, eliminating redundancy in critical response activities and coordinating emergency planning, training, and exercise activities. While each District varies in infrastructure, organization, hazards, and other facets, several commonalities of Districts include: District Planning Councils, Healthcare Coalitions, Indiana District Response Task Forces, and other elements.

### G. Tribal Engagement

The Pokagon Band of Potawatomi Native Americans is located in southwestern Michigan and northeastern Indiana. To engage the Pokagon Band within the State of Indiana, the IDOH is coordinating with the State of Michigan, tribal representatives, and the St. Joseph County Health Department. The Centers for

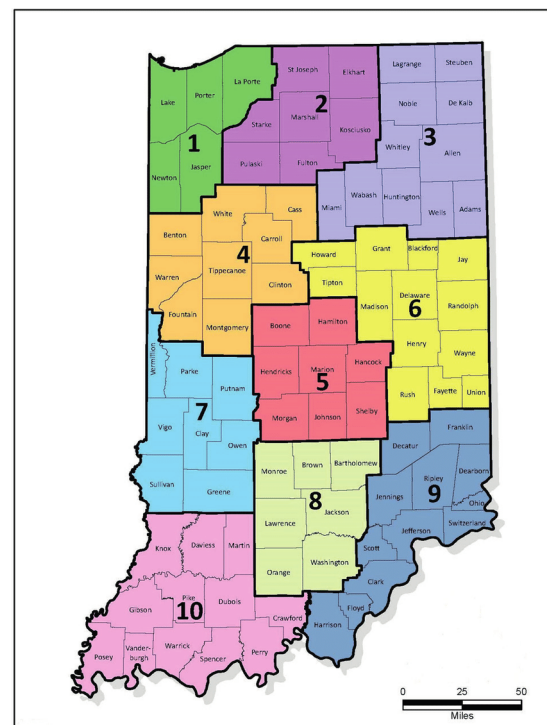


Figure 1: Indiana Health Preparedness Districts



Disease Control and Prevention (CDC) is working directly with the Indian Health Service (IHS) to provide vaccination services to the populations they serve.

IDOH coordination with the State of Michigan is crucial since most community members within the Pokagon Band seek health services through IHS locations in Michigan. The IDOH and Michigan Department of Health and Human Services (MDHHS) have a unified and coordinated approach to providing access to the COVID-19 vaccine to the Pokagon Band. Through joint coordination with MDHHS, it has been determined that 10% of the overall vaccine allocated to the Pokagon Band will be allocated to the State of Indiana to support tribal vaccination efforts. Another key partner engaged in the coordination is the St. Joseph County Health Department, which has strong existing ties and communication with the Pokagon Band.

Finally, representatives from the Pokagon Band are represented on the IDOH State Health Commissioner's External COVID-19 Vaccine Implementation Committee. Representatives include the Native American Indian Commission – Health Committee, the Native American Indian Commission, and Pokagon Band of Potawatomi Native Americans – St. Joseph County.

## H. Critical Population Partners

The IDOH has engaged multiple key partners for critical populations through its five advisory groups and external vaccine implementation committee. These groups represent the critical populations within communities across Indiana. These partners understand that populations they serve and represent and are essential in messaging and communicating about the COVID-19 vaccine. In the early phases of vaccine planning these partners are important in data gathering of critical population estimates and developing strategies for engagement and outreach.

Critical Population Partners	
Critical Population within the Community	Organization(s) Represented
Corrections	Indiana Department of Corrections (IDOC)
Critical Access Hospitals / Rural Health	Margaret Mary Health
Emergency Management Agencies	Indiana Department of Homeland Security
Faith-based	Purpose of Life Ministries
Federally Qualified Health Center / Community-based Healthcare	HealthLinc
Healthcare	Indiana Health Care Association (IHCA), Indiana Hospital Association (IHA)
Higher Education	Ball State University, University of Notre Dame, Purdue University, Indiana University, Independent Colleges of Indiana

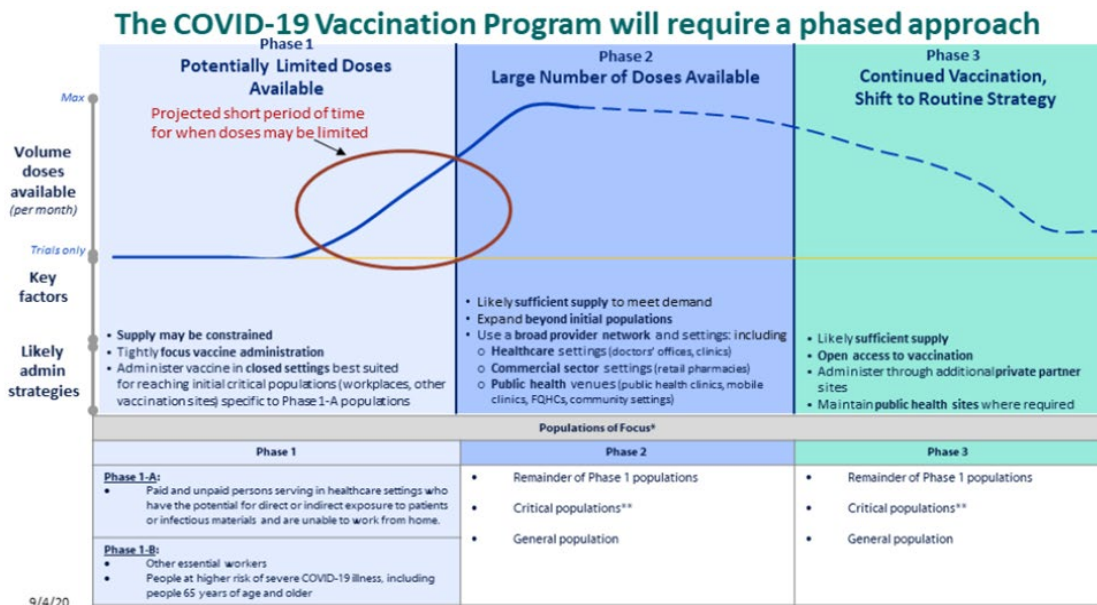
Homeless	Indiana Housing and Community Development Authority (IHCDA)
Immunization Coalition	Indiana Immunization Coalition
Jails	Indiana Sheriff's Association
Law Enforcement	Indiana State Police
Local Public Health Departments	Allen County, Ripley County, Vanderburgh County, Porter County, Marion County
Minority Health	Indiana Minority Health Coalition (IMHC), Indiana Latino Institute, Indiana Latino Expo
Occupational Health Associations	OurHealth
Organizations serving people with disabilities	Indiana Family & Social Services Administration (FSSA) – Division of Aging, Division of Disability and Rehabilitative Services, Division of Mental Health
Pharmacies	Indiana Pharmacy Alliance, Kroger
Tribal	Native American Indian Commission – Health Committee, Native American Indian Commission, Potawatomi Native Americans – St. Joseph County

### III. PHASED APPROACH TO COVID-19 VACCINATION

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. A key point to consider is that vaccine supply will be limited at the beginning of the program, so the allocation of doses must focus on vaccination providers and settings for vaccination of limited critical populations as well as outreach to these populations. The vaccine supply is projected to increase quickly over the proceeding months, allowing vaccination efforts to be expanded to additional critical populations and the general public. It is important to note that recommendations on the various population groups to receive initial doses of vaccine could change after vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors.

The goal was to make the plan simple, direct, clear, and actionable so that it is easy to interpret and implement. Keeping it simple, makes it more feasible that more people can be vaccinated quickly and in an orderly fashion. Various workgroups reviewed national and other guidance while considering any special considerations or circumstances specific to the Hoosier State. A phased approach, based on an ethical and equitable distribution schema, is necessary since not enough vaccine will be released initially to vaccinate everyone and also provides guidance as more vaccine becomes available.

A large, multidisciplinary group of statewide experts was assembled to help create, give input, and feedback, and finalize the plan. In an effort to build trust and lend credibility, IDOH had the foresight to engage this large, diverse group of local experts to assure Hoosiers that precious vaccine resources will be utilized in an efficient and equitable manner.



\*Planning should consider that there may be initial age restrictions for vaccine products.

\*\*See Section 4: Critical Populations for information on Phase 1 subset and other critical population groups.

Figure 2: COVID-19 vaccination program phases.

## A. Phase 1: Potentially Limited Supply of COVID-19 Vaccine Doses Available

In the initial phase, Phase 1, initial doses of vaccine will likely be distributed in a limited manner with the goal of maximizing vaccine acceptance and public health protection while minimizing waste and inefficiency.

### Key characteristics of Phase 1:

- COVID-19 vaccine supply may be limited
- COVID-19 vaccine administration efforts must concentrate on the initial populations of focus to achieve vaccination coverage in those groups
- Inventory, distribution, and any repositioning of vaccine will be closely monitored through reporting to ensure end-to-end visibility of vaccine doses

Indiana is concentrating early COVID-19 vaccine administration efforts on the initial critical populations identified in **Section IV: Critical Populations**. The administration of these COVID-19 vaccination services will be in point-of-dispensing (POD) settings. This allows for the maximum number of people to be vaccinated while maintaining social distancing and other infection control procedures.

Indiana is prioritizing enrollment activities for vaccination providers and settings who will administer COVID-19 vaccine to the Phase 1 populations of focus. IDOH is developing operational procedures to establish mobile clinics to provide vaccine to individuals who live in remote, rural areas, and areas with vaccination services deficiencies. While performing Phase 1 activities, IDOH will continue preparing for Phase 2. This includes recruiting additional vaccinators to staff PODs, contract needs for vaccination services, and review of state practice acts to allow for expanded professional practice, if needed.

## B. Phase 2: Large Number of Vaccine Doses Available

As the supply of available vaccine increases, distribution will expand, increasing access to vaccination services for a larger population. As these larger quantities become available, IDOH will continue to ensure these two objectives are achieved: providing equitable access to COVID-19 vaccination for all critical populations to achieve high COVID-19 vaccination coverage and ensuring high uptake in specific populations, particularly in groups that are at a higher risk for severe outcomes from COVID-19.

### Key characteristics of Phase 2:

- COVID-19 vaccine supply will likely be sufficient to meet demand for critical populations as well as the general public.
- Additional COVID-19 vaccine doses available will permit an increase in vaccination providers and locations.
- A surge in COVID-19 vaccine demand is possible, so a broad vaccine administration network for surge capacity will be necessary.
- Low COVID-19 vaccine is also a possibility, so Indiana will monitor supply and adjust our strategy to minimize vaccine wastage.

In anticipation of an increase in COVID-19 vaccine supply levels during Phase 2, IDOH will adapt strategies for administration location, vaccine providers, and access to account for this increased availability. Vaccination efforts will expand beyond the initial population group outlined in Phase 1. IDOH will ensure equitable access for all populations. The COVID-19 vaccine will be administered through additional types of vaccination sites, including, commercial and private sector partners (pharmacies, doctors' offices, clinics), and public health sites (mobile clinics, Federally Qualified Health Centers [FQHCs], rural health clinics, public health clinics, and temporary off-site clinics).

### **C. Phase 3: Sufficient Supply of Vaccine Doses for Entire Population (Surplus of Doses)**

Ultimately, COVID-19 vaccine will be widely available and integrated into routine vaccination programs, operated by both public and private partners.

#### Key characteristics of Phase 3:

- Likely sufficient COVID-19 vaccine supply where supply might exceed demand
- Broad vaccine administration network for increased access
- Increased emphasis on redistribution of existing vaccine

During Phase 3, IDOH will continue to focus on equitable vaccination access to vaccination services. COVID-19 vaccine uptake and coverage in critical populations will continually be monitored. IDOH will intervene and develop enhanced strategies to reach populations with low vaccination uptake or coverage, if observed. The development of partnerships with commercial and private entities will be utilized to ensure COVID-19 vaccine and vaccination services are widely available to Hoosiers. Vaccine wastage will continually be minimized through the monitoring of vaccine supplies and the repositioning of refrigerated vaccine products.

## IV. CRITICAL POPULATIONS

The IDOH is working with external partners within the five COVID-19 Vaccine Advisory Groups to determine populations of focus for COVID-19 vaccination and ensure equity in access to COVID-19 vaccination across the state of Indiana. A key goal is to determine critical populations for COVID-19 vaccination, including those groups identified to receive the first available doses of COVID-19 vaccine when supply is expected to be limited.

After a short period of potentially limited vaccine supply, supply will increase quickly, allowing vaccination efforts to be expanded to include additional critical populations as well as the general public. Indiana is developing strategies to ensure equitable access to vaccination for each of the critical populations identified below.

### A. Identifying and Estimating Critical Populations

IDOH is working with external partners within the External Vaccination Program Implementation Committee and the five COVID-19 Vaccine Advisory Groups to identify, collect, and compile critical population estimates. Indiana Professional Licensing Agency (PLA), U.S. Census, and industry data was used to determine the population estimates per critical population. In the future, another available option to collect this information is creating a uniform electronic template utilizing REDCap to collect critical population census data from partners and stakeholders engaged in the Vaccination Implementation Committee (External) and various Advisory Committees (External).

### B. Estimates of Critical Populations and Critical Infrastructure Workforce

The IDOH COVID-19 Vaccine Allocation Committee prioritized the healthcare workforce and those people who are at greater risk of morbidity and mortality for Phase 1 of COVID-19 vaccine distribution. Therefore, the Data Gathering Work Group focused on those populations.

Estimates of the identified critical populations and critical infrastructure workforce are based on accurate information from population representative organizations, industry leaders, and public open-source data. IDOH will also leverage the federal HHS data management system, Tiberius. These accurate estimates are leveraged to minimize potential waste of vaccine, constituent products, and ancillary supplies. Critical populations, data sources, and population estimates are shown below.

Critical Population	Data Source	Population Estimates
Critical Infrastructure Workforce		
Healthcare Personnel	PLA, Bowen Center	292,838 (licensed + trainees)
Vaccinators	PLA, Bowen Center	94,595 (RN, MD/DO, NP, PA, pharm, EMS)
Pharmacy Staff	PLA, Bowen Center	21,099 (pharm + pharm techs)
Ancillary Staff	Quarterly Census of Employment and Wages	14,579 (IU Health estimate)

School Nurses	IDOH	1,200 (estimate)
EMS Personnel	Indiana DHS, Professional Firefighters Union, Volunteer Firefighters Association	47,314 (EMS + fire)
<b>Other Essential Workers (CISA)</b>		
Communications	OES, QCEW, SOC	23,556 (telecom, internet publishing, broadcasting, print publishing, Motion picture)
Chemical	OES, QCEW, SOC	32,042 (chemical manufacturing)
Critical Manufacturing	OES, QCEW, SOC	534,258 (all)
Commercial Facilities	OES, QCEW, SOC	139,426 (construction)
Dams	OES, QCEW, SOC	6,057 (water workforce)
Defense Industrial Base	OES, QCEW, SOC	11,651 (national security)
Emergency Services	OES, QCEW, SOC	49,072 (EMS + Fire + Police)
Energy	OES, QCEW, SOC	5,527 (oil + gas)
Financial	OES, QCEW, SOC	99,112 (finance + insurance)
Government Facilities	OES, QCEW, SOC	128,492 (includes all public admin)
Food & Agriculture	OES, QCEW, SOC	161, 995 (agriculture, forestry, fishing, hunting + food/beverage manufacturing)
Nuclear Reactors, Materials, & Waste	OES, QCEW, SOC	10,201 (waste management)
Information Technology	OES, QCEW, SOC	4,790 (internet providers, web search portals, data processing servers)
Water	OES, QCEW, SOC	3,430 (waste and wastewater treatment plant)
Transportation Systems	OES, QCEW, SOC	158,775 (air, rail, water, truck, support)
Healthcare & Public Health	OES, QCEW, SOC	446,097 (healthcare and social services)
<b>People at Increased Risk for Severe COVID-19 Illness</b>		
LTCF Residents	Probari, IDOH, FSSA	34,386
People with underlying medical conditions	IHIE	1,814,769
People 65 years of age and older	Census	1,085,743
<b>People at Increased Risk of Acquiring or Transmitting COVID-19</b>		
People from racial and ethnic minority groups	Census	1,511,980
People from tribal communities	Indian Health Service	Pending data from Michigan (will allot 10% to our



		population here per CDC recommendation)
People who are incarcerated/detained in correctional facilities	Indiana Criminal Justice Institute	42,786
People experiencing homelessness/living in shelters	Indiana Housing and Community Development Authority, Indiana Coalition for Homelessness Intervention and Prevention	5,471
People attending colleges/universities	CHE	321,517
People who work in educational settings	Indiana Education Employment Relations Board	258,309
People living and working in other congregate settings	Indiana Coalition Against Domestic Violence, FSSA Division of Mental Health and Addiction, Indiana Affiliation of Recovery Residences, Indiana Division of Disability and Rehabilitative Services	5,822
<b>People with limited access to routine vaccination services</b>		
People living in rural communities	Indiana Rural Health Association	1,466,328
People with disabilities	ARC of Indiana	899,701
People who are under- or uninsured	CDC SVI	596,543

### C. Prioritization of Critical Populations

#### 1. Phase 1: Reinforce and Support Healthcare Infrastructure and Protect the Vulnerable

This group includes all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and individuals who are at particular risk of mortality and morbidity associated with COVID-19 disease.

**Group 1-A:** All paid and unpaid healthcare personnel with the potential for direct or indirect exposure to patients or infectious materials. Healthcare settings include, but are not limited to: hospitals, long-term care facilities such as assisted living or skilled nursing facilities, outpatient facilities, home health care settings, pharmacies, dialysis centers, emergency medical services, frontline public health interventions, and COVID-19 diagnostic and immunization teams. This group includes all persons meeting the definition without regard to job title. See **Attachment A: PHASE 1: INDIANA HEALTHCARE PERSONNEL** for a detailed breakdown of county/profession estimates.

This population includes, but is not limited to:

Licensed and non-licensed healthcare workers:



- Nurses, physicians, RT, PT/OT, speech therapists, pharmacy, imaging, laboratory, social services, case management, non-traditional providers (doulas, midwives), chaplain services, dental providers, emergency medical services
- EVS, dietary, maintenance, security, other patient facing ancillary staff

**Group 1-B:** Protect the vulnerable. Includes individuals who are at particular risk of mortality and morbidity associated with COVID-19 disease based on the latest, evidence-based criteria. This includes people 65 years and older, people with co-morbid conditions that place them at higher risk for morbidity or mortality from COVID-19 (see below), and residents of long-term care facilities. As more information becomes known regarding the disease and its response to vaccination, some of these individuals may not be appropriate for vaccination because it is anticipated they will have inadequate immune response to the vaccination and/or they are at increased risk of complication secondary to the vaccination itself.

CDC List of Increased Risk Medical Conditions:

- |   |                            |
|---|----------------------------|
| • Cancer  | • Obesity                  |
| • Chronic kidney disease                              | • Serious heart conditions |
| • COPD  | • Sickle cell disease      |
| • Immunocompromised state from solid organ transplant | • Type 2 diabetes          |

CDC List of Likely to Increase Risk Medical Conditions:

- |   |   |
|---|---|
| • Asthma (moderate-to-severe)   | immune weakening medications.             |
| • Cerebrovascular disease   |   |
| • Cystic fibrosis   | • Neurologic conditions, such as dementia |
| • Hypertension  | • Liver disease                           |
| • Immunocompromised state from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other | • Pregnancy                               |
|   | • Pulmonary fibrosis                      |
|   | • Smoking                                 |
|   | • Thalassemia                             |
|   | • Type 1 diabetes mellitus                |

Furthermore, some groups may be excluded because of the parameters for both emergency use authorization (EUA) and their exclusion from clinical trials, and therefore use has not been approved for them. Public health officials in consultation with COVID-19 clinical and scientific experts should arrive at the final list of eligible inclusion criteria. Prioritizing those who are most vulnerable promotes utility and stewardship, and it is a critical tool for serving the goals of equity and fairness, particularly as existing data continue to show a disproportionate burden of the pandemic on some populations.

The CDC Social Vulnerability Index will be reviewed during the allocation process and applied if there is a limited vaccine during this phase. A document that identifies the SVI and estimated counts for comorbid conditions per county will assist in targeted allocation, distribution, and communication during this phase. Counties with higher SVIs may receive an increased allocation per population.

See **Attachment B: INDIANA SOCIAL VULNERABILITY INDEX** for a detailed social vulnerability index and comorbid conditions for each county.

## 2. Phase 2: Mitigate Spread

Those at elevated risk of transmission of the disease because of working or living circumstances:

- Persons living or working in prisons, jails, detention centers, and similar facilities
- Persons living or working in group homes or shelters, including but not limited to homeless shelters, domestic violence shelters, or group homes for persons with physical or mental disabilities or in recovery
- Individuals whose in-person work is essential, required, and places them in settings where social distancing is not possible and transmission risk is high:
  - Fire and Police
  - Food service
  - Retail
  - Public transportation
  - Utilities
  - Public health
  - Manufacturing/ construction (indoors)
  - School teachers
  - Warehouse

## 3. Phase 3: General Public Vaccination

### D. Sub-Prioritization of Critical Populations

In the scenario that Indiana does not receive sufficient vaccine to vaccinate all included in the initial populations of focus, Indiana has identified the following subset groups (Phase 1-A and 1-B). These two phases will determine who will receive the first available doses of COVID-19 vaccine. Additionally, this is a general framework and guidance. Hospitals, care delivery sites, and jurisdictions have autonomy to implement these guidelines in the way that make the most sense to their specific populations and community. If the state vaccine allocation is limited so that there is insufficient supply to vaccinate healthcare personnel who are willing to receive the vaccine in phase 1a, additional parameters could be applied. This includes but is not limited to allocating the vaccine to healthcare personnel at higher risk to exposure to the vaccine or higher risk of morbidity or mortality.

The process for determining subsets of critical populations for vaccination is based on the classification of risk (low to very high based on position within an organization) for exposure to SARS-CoV-2. The U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) identifies and classifies risk of worker exposure to SARS-CoV-2. Below are examples of occupational risk classification. Additional information can be found here <https://www.osha.gov/SLTC/covid-19/hazardrecognition.html>

## **Occupational SARS-CoV-2 Hazard Recognition Categorization**

### Lower Exposure Risk (Caution)

Jobs that do not require contact with people known to be, or suspected of being, infected with SARS-CoV-2. Workers in this category have minimal occupational contact with the public and other coworkers. Examples include:

- Remote workers (i.e., those working from home during the pandemic).
- Office workers who do not have frequent close contact with coworkers, customers, or the public.
- Manufacturing and industrial facility workers who do not have frequent close contact with coworkers, customers, or the public.
- Healthcare workers providing only telemedicine services.
- Long-distance truck drivers.



*Figure 3: Occupational hazard recognition categories*

### Medium Exposure Risk

Jobs that require frequent/close contact with people who may be infected, but who are not known to have or suspected of having COVID-19. Workers in this category include:

- Those who may have frequent contact with travelers who return from international locations with widespread COVID-19 transmission.
- Those who may have contact with the general public (e.g., in schools, high population density work environments, and some high-volume retail settings).

### High Exposure Risk

Jobs with a high potential for exposure to known or suspected sources of SARS-CoV-2. Workers in this category include:

- Healthcare delivery and support staff (hospital staff who must enter patients' rooms) exposed to known or suspected COVID-19 patients.
- Medical transport workers (ambulance vehicle operators) moving known or suspected COVID-19 patients in enclosed vehicles.
- Mortuary workers involved in preparing bodies for burial or cremation of people known to have, or suspected of having, COVID-19 at the time of death.

### Very High Exposure Risk

Jobs with a very high potential for exposure to known or suspected sources of SARS-CoV-2 during specific medical, postmortem, or laboratory procedures. Workers in this category include:

- Healthcare workers (e.g., doctors, nurses, dentists, paramedics, emergency medical technicians) performing aerosol-generating procedures (e.g., intubation, cough induction procedures, bronchoscopies, some dental procedures and exams, or invasive specimen collection) on known or suspected COVID-19 patients.
- Healthcare or laboratory personnel collecting or handling specimens from known or suspected COVID-19 patients (e.g., manipulating cultures from known or suspected COVID-19 patients).
- Morgue workers performing autopsies, which generally involve aerosol-generating procedures, on the bodies of people who are known to have, or are suspected of having, COVID-19 at the time of their death.

### E. Triggers to Move Between Phases

In the case there is limited uptake of the vaccine, IDOH is prepared expand within a phase or to other phases as needed. This may occur at the state or local level as determined by the feasibility of redistribution. The success is predicated on the willingness of local communities to do work in advance: communicate their plan, identify individuals from each phase that will receive the vaccine so that communities and organizations are ready when the vaccine is released. Potential triggers that have been discussed to broaden the allocated group include:

1. Identifying what percent of a target population being vaccinated would indicate saturation of that target group,
2. Prioritizing efficiency and minimizing waste (stewardship) by expanding in situations where the vaccine administration is limited by expiration times.
3. Utilizing a system of preregistration to identify that the targeted group has received the vaccine and then opening up the vaccine to further groups or subsets.
4. Pivot to new group based on safety/efficacy data on particular groups as information becomes available.

### F. Describing, Locating, and Communicating with Critical Populations

To improve vaccination among critical population groups, Indiana must ensure these groups have access to vaccination services. To inform COVID-19 vaccination outreach efforts, Indiana has created a visual map of these populations, including places of employment for the critical infrastructure workforce category, to assist in COVID-19 vaccination clinic planning, especially for satellite, temporary or off-site clinics. Indiana is also utilizing the HHS data management and mapping tool, Tiberius, to estimate populations and to map providers and populations.

The next step is developing and sending key messages regarding vaccination logistics for these critical populations and critical infrastructure groups. This outreach will include both promotional and educational information so the critical populations know where they can get vaccinated and why they should get vaccinated.

IDOH is establishing points of contact (POCs) for each organization, employer, or community (as appropriate) within the critical population groups. Additionally, critical populations identified in Phase 1A have completed a REDCap survey to ensure readiness of vaccine allocation. Partnerships with trusted community organizations can facilitate early agreement on communication channels and methods for rapidly disseminating information and ultimately ensuring these groups have access to vaccination. These organizations include the faith-based, community regional health workers and healthcare clinics and coalitions, racial and ethnic organizations, and others across the state as informed by the data and map. Many of these groups and partner organizations are outlined in Section 2G of this plan.

## V. COVID-19 PROVIDER RECRUITMENT AND ENROLLMENT

An adequate network of trained, technically competent COVID-19 vaccination providers in accessible settings is critical to Indiana's COVID-19 vaccination program success. For this reason, the IDOH is conducting provider recruitment and enrollment in advance of COVID-19 vaccine availability. Early planning efforts are focused on engaging those vaccination providers and services that can rapidly vaccinate initial populations of focus (see Section 4: Critical Populations) as soon as a COVID-19 vaccine is available (Phase 1). Subsequent planning includes recruiting and enrolling providers to vaccinate additional critical populations and eventually the general population when sufficient vaccine supply is available (Phases 2 and 3).

### A. Provider Enrollment Efforts

The IDOH has developed a web-based COVID-19 Provider Enrollment form capturing all information defined in the "CDC COVID-19 Vaccination Program Provider Agreement" form. This web-based system will be used to enroll Indiana providers. Figures 3 and Figure 4 depict screenshots of the IDOH COVID-19 Vaccine Provider Enrollment Portal.

- The web-based app will allow for providers to submit, retrieve, and download their submitted information in PDF format.
- The application will have fields that will collect info from providers pertinent to various phases of vaccine availability to patients
- The application will verify provider license numbers with the Indiana Professional Licensing Agency (PLA) database and will allow only valid and active licensed providers to be entered.

The IDOH will work with professional organizations such as the Indiana Hospital Association and the Indiana Pharmacy Alliance to recruit members of their organizations as vaccination partners. Many of these healthcare providers are already enrolled in either the Indiana Immunization Information System or the Indiana Vaccines for Children (VFC) Program.

The information collected within the provider enrollment portal is electronically transferred to the IDOH Children and Hoosier Immunization Registry Program (CHIRP), Indiana's immunization information system (IIS) vaccine registry

Section A - Provider Requirements and Legal Agreement

Section B - Provider Profile Information

Submitter Information

Organization Identification

Responsible Officers

Agreement Requirements

Sign -Chief Medical Officer

Sign -Chief Executive Officer

Submitter Information

Submitter's Last Name:\*  
A

Submitter's Email:\*  
abc@de.com

Access Code:\*  
4123  
4 digit number that will be used retrieve your form

Organization Identification

Organization's Legal Name:\*

Figure 4: Section A (Provider Requirements and Legal Agreement) of IDOH COVID-19 Vaccine Provider Enrollment Portal.

Section A - Provider Requirements and Legal Agreement

Section B - Provider Profile Information

Organization Identification

Primary Vaccine Coordinator

Backup Vaccine Coordinator

Shipment Address

Administered Address

Days Available

Provider Type

Administer Settings

Patients Served

Vaccination Capacity

Population Served

Report Data?

Storage Capacity

Storage Details

Providers

Please complete and sign this form for your Organization location. If you are enrolling on behalf of one or more other affiliated Organization vaccination locations, complete and sign this form for each location. Each individual Organization vaccination location must adhere to the requirements listed in Section A.

Organization Identification for Individual Locations

Organization Location Name:\*

Will another Organization location order COVID-19 vaccine for this site?\*

☐ Yes; provide Organization name:

☐ No

Contact Information for Location's Primary COVID-19 Vaccine Coordinator

Figure 5: Section B (Provider Profile Information) of IDOH COVID-19 Vaccine Provider Enrollment Portal.

## B. Provider Administration

The IDOH has identified healthcare providers working in a hospital, long term care and/or pharmacy setting will be the target population for the first available COVID-19 vaccines doses. This population has been identified based on the guidance from the Centers for Disease Control and Prevention (CDC) and the Vaccine Allocation Plan Development Advisory Group hosted by the IDOH Chief Medical Officer.

The providers identified for Phase 1A will be vaccinated using a hub and spoke model. Vaccine will be sent to large hospitals in central locations and identified populations will be invited to receive vaccinations at that location (open POD model, when appropriate).

Individuals who received the vaccine as part of Phase 1A will return to the same location at the appropriate time interval to receive a second dose. An appointment for the second dose will be made prior to the healthcare professional leaving the site after receiving the first dose. Since this is a small segment of the population, individual return appointments will be easily managed. Texts and a reminder postcard will both be utilized as a method to recall individuals for their second dose for optimal protection.

### **C. Provider Enrollment Data**

COVID-19 provider enrollment data will be captured and stored in a relational database (Oracle). This will allow the IIS team to easily query the data (using SQL), transform it into CSV file format and report it electronically to CDC. The IIS Manager will be responsible for submitting the COVID-19 Vaccination Provider Agreement data to CDC twice a week: Monday and Thursday by 9:00 p.m. EST via the IZDL Partner Portal. The IIS Manager will run all necessary checks and audits to ensure that the data is complete and accurate before submitting to CDC.

### **D. Provider Credentialing**

The COVID-19 Provider Enrollment web app will verify provider license numbers with the IPLA database and will allow only valid and active licensed providers to be entered. The provider enrollment app intuitively informs the user if the license number is found inactive or does not exist in the database. The application also allows for bulk upload of provider info via Excel file to reduce the burden of data entry. The bulk upload process will verify and automatically add all providers with active license numbers. Those that could not be matched or inactive are indicated so they can be corrected.

### **E. Provider Training**

Training of COVID-19 vaccination providers is vital to ensure the success of Indiana's COVID-19 vaccine implementation. Indiana will utilize CDC-branded educational resources in addition to newly developed and pre-existing IDOH materials. These educational training materials will complement each other. IDOH specific materials will focus on IDOH specific processes, such as CHIRP reporting. Training completion is tracked within the CHIRP training module. CDC will provide provider training for federal entities and commercial partners receiving direct vaccine allocations from CDC.

Indiana will use the CHIRP learning management system, INvest. INvest is a centralized training resource already developed for enrolled VFC providers that the IDOH utilize to train enrolled COVID-19 providers. This will include slightly modified training videos and tutorials on how to use the Vaccine Order Management System (VOMS) within CHIRP for ordering, receiving, inventory management in addition to vaccine storage and handling modules, vaccine administration, vaccine wastage and temperature excursions. The IDOH also



intends to develop modules for ACIP recommendations, Vaccine Adverse Event Reporting System (VAERS), EUA fact sheets for providers and vaccine recipients, and Vaccine Information Statements (VIS). The system will also allow for a standardized training message and a tracking system for all enrolled COVID-19 providers.

The following learning objectives will be address in the training module:

- ACIP COVID-19 vaccine recommendations, when available
- COVID-19 vaccine ordering and receiving
- COVID-19 vaccine storage and handling (including transport requirements)
- Vaccine administration, such as reconstitution, use of adjuvants, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration
- Documenting and reporting vaccine administration via Indiana's IIS or other external system
- Managing vaccine inventory, including accessing and managing product expiration dates
- Reporting vaccine inventory
- Managing storage temperature
- Documenting and reporting vaccine wastage/spoilage
- Reporting moderate and severe adverse events as well as vaccine administration errors to VAERS
- Providing EUA fact sheets or VISs to vaccine recipients
- Submitting facility information for COVID-19 vaccination clinics to CDC's VaccineFinder (particularly for pharmacies or other high-volume vaccination providers/settings)

## **F. Redistribution Approval**

The IDOH will utilize the CDC's COVID-19 Vaccine Redistribution Agreement form for approval of redistribution by vaccine providers. The IDOH will develop an electronic, automated portal application for this form, similar to the COVID-19 provider enrollment form. Not all providers will qualify and receive this form.

In instances where approval is justified, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers will be allowed to redistribute vaccine. Approval is coordinated by IDOH's immunization program and cold-chain procedures are validated in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling.

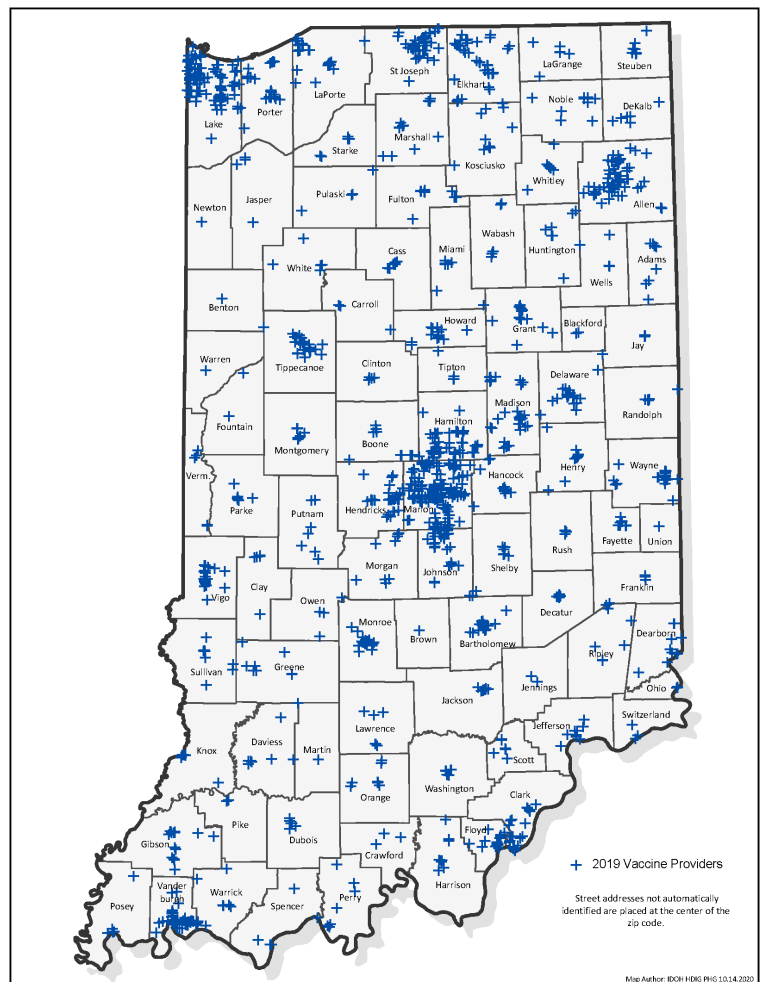
## **G. Equitable Vaccine Access**

The IDOH Chief Medical Officer chairs a Vaccine Allocation Plan Development Advisory Group to determine the need by phases in each county of the state. This data will be used to ensure an equitable distribution by phase across the state based on the percentage of healthcare workers in each county.

The IDOH is using Tiberius as a visualization tool for allocations, data monitoring and transparency. Indiana has registered individuals from the IDOH Immunizations Division, Emergency Preparedness Division, and the Office of Data & Analytics to ensure bench strength for this resource. Daily dashboards will be generated to illustrate vaccine administration, vaccine availability and utilization.

Indiana has a robust pool of vaccinators including primary care physicians, pharmacists, and local health departments. Currently, 743 providers are enrolled in the Indiana Vaccines for Children (VFC) Program who are actively vaccinating and recording vaccination administration data in CHIRP. There are 1,923 other facilities that are administering vaccine in the State of Indiana and have established a bi-directional interface with CHIRP. With this coverage, the IDOH is confident in its ability to offer vaccine to vulnerable populations no matter where they reside. *Figure 6* provides a visual representation of all vaccine provider locations in 2019. This includes private providers, local health, pharmacies, and healthcare/hospital locations.

Pharmacies are also great vaccinators in Indiana. In 2019, 5,336,699 vaccines were administered to Hoosiers in the pharmacy setting, illustrating the importance of including pharmacies in our plan for reaching vulnerable populations. Recent data from Walgreens states that 90% of Hoosiers live within 10 miles of a Walgreens store. The IDOH has had extensive conversations with Walgreens, Walmart, Meijer, and Kroger about their role in delivering COVID-19 vaccinations. The IDOH is also working with small independent pharmacies in rural areas to ensure additional vaccination touchpoints.



*Figure 6: 2019 Vaccine Provider Location Map*

The IDOH will work with providers who have a history of vaccinating a large percentage of vulnerable populations to ensure that these providers continue to provide services and build upon existing relationships. Data can be extrapolated from CHIRP on individuals who have been vaccinated over the age of 60 or at a specific provider type. This data will be

used for education on the COVID-19 vaccination efforts and outreach for enrollment in the COVID-19 vaccination effort.

#### **H. Pharmacy Enrollment**

The IDOH is working with the Indiana Pharmacists Association (IPA) to engage independent pharmacists across the state. IPA membership includes both national and regional pharmacy chains, hospital-based pharmacists, as well as smaller independent pharmacists. An IPA representative serves on the Vaccine Allocation Advisory Group and the External COVID-19 Vaccine Implementation Committee. The IPA has also connected the IDOH Immunization Division Director to Indiana's Community Pharmacy Enhanced Network, which represents 23 independent pharmacies, to understand reporting challenges and barriers.

## VI. COVID-19 VACCINE ADMINISTRATION CAPACITY

### A. Administration Capacity

"Vaccine administration capacity" is defined as the maximum achievable vaccination throughput regardless of public demand for vaccination. Public health programs should understand their jurisdiction's overall potential COVID-19 vaccine administration capacity using a variety of COVID-19 vaccination provider types and settings. The sections below describe how vaccine administration capacity has and will be determined in relation to the three phases of vaccine distribution.

#### 1. Phase 1A

Information from hospitals, healthcare systems, and long-term care (LTC) facilities that is expected to be used to determine vaccine administration capacity for Phase 1 will be obtained through the use of the Data Advisory Group and Vaccine Allocation Plan Development Advisory Group. For the Phase 1: healthcare personnel group, a REDCap survey was completed to determine several metrics, including:

- Paid and unpaid staff totals
- Ability to be a COVID-19 vaccine distribution center (internal and external HCP)
- Ability to distribute 1000 vaccine doses over 10 days
- Vaccine cold storage availability
- General concerns or issues

The responses aided in completing the required ***Ultra-Cold Distribution Template (See Attachment C)***. These partnerships allow for the continual gathering of accurate and current data on capacity for vaccine administration within the state of Indiana.

As IDOH continues to engage with the Data Advisory Group and Vaccine Allocation Plan Development Advisory Group, information on vaccine administration will continue to evolve and be added to IDOH plans to determine capacity for all hospitals statewide as well as determine their throughput rates, provider participation rates, and cold storage options..

#### 2. Phase 1B

Information from local health departments (LHDs) to be used for Phase 2 and beyond has been obtained through a REDCap survey sent out to all LHDs. This information is used to determine feasible LHD vaccine administration capacity.

LHD Vaccine Administration Capacity Information	
Average throughput per day per POD (8 Hour Shift)	1,581
Percentage of LHDs with Refrigerated Cold Storage	85%
Percentage of LHDs with Frozen (-20) Cold Chain Storage	61%

Data from this survey will also be used in Phase 3 as vaccine availability and administration capacity increase.

### **3. Phase 2**

Following the move into Phase 2, the IDOH will take a more direct role in vaccine administration through the use of strike teams and mobile units. These resources will allow IDOH to provide vaccines directly to the community, focusing specifically on populations with critical needs that have been identified in the LHD survey described above. IDOH will work with LHDs to determine places where ability to distribute vaccine would have the greatest impact and plan accordingly.

#### **Strike Teams**

The IDOH will utilize strike teams in the same manner that strike teams were utilized during COVID-19 sample collection and testing: teams will go to specific identified areas, either focusing on critical population groups or areas with abnormally high numbers of cases. These strike teams focused on long term care facilities during testing operations and will likely do the same during vaccine operations.

#### **Mobile Units**

The IDOH is obtaining ten mobile vans with cold storage to use for testing operations and vaccine distribution and administration. One mobile unit, consisting of two 4-person teams, will be based in each of the state's ten preparedness districts and will be deployed to areas with a demonstrated need of support. It is expected that these mobile units will have the same throughput capacity as a static testing site (approximately 80 – 100 tested or vaccinated per day).

### **4. Provider Recruitment Plans**

Provider recruitment plans will be dictated by the phase of vaccine administration the state of Indiana is currently experiencing. IDOH will utilize the HHS data management and mapping tool, Tiberius, to visualize areas of low provider engagement. IDOH will ensure equitable access to all Hoosiers within the state by providing targeted provider outreach in these areas.

## VII. COVID-19 VACCINE ALLOCATION, ORDERING, DISTRIBUTION, AND INVENTORY MANAGEMENT

### A. Allocation

The federal government will determine the amount of COVID-19 vaccine designated for each jurisdiction. The IDOH Immunization Division is responsible for managing and approving orders from enrolled providers based on the vaccine allotment from the federal government. The amount of vaccine allotted will change over time. Multiple factors influence allotments, such as critical population estimates, production and availability, and overall population within Indiana.

Allotments of doses to vaccination providers within Indiana will be based on the following criteria:

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

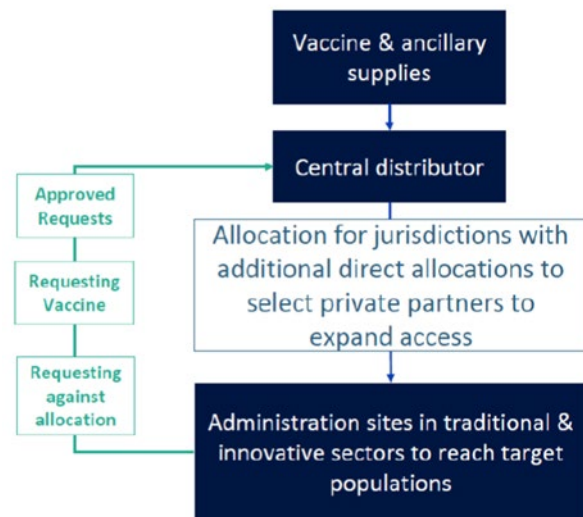


Figure 7: COVID-19 Vaccine distribution flowchart.

Indiana will develop the allocation methods for critical populations in the early distribution of vaccines and in limited supply scenarios. This will be a combination of methods using Tiberius and then utilizing CHIRP and the pre-booking module for each enrolled COVID-19 provider. This will be a percentage-based process that will allow for the IDOH to base the total number of doses allocated from the CDC, accounting for the second dose, and determining the total number of doses of the critical population reported by the provider. Once the total number of doses allocated is determined, the percentage can be entered into the pre-booking module. The system will automatically determine the number of doses per provider for the ordering cycle. For example, if 100,000 doses are allocated to Indiana in the first order cycle, the IDOH will use a percentage process to send an equitable number of doses to all Phase 1A providers based on the reported critical population totals reported. For phase 1A, the percentage of healthcare workers per county has been calculated as a proportion to the state's total healthcare worker population. If Indiana's initial allocation is insufficient to vaccinate the entire healthcare workforce, allocations will be developed based on the facility's ability to vaccinate and county proportion of healthcare workers.

Figure 8 represents the percentage of healthcare personnel who live in each county. Initial allocations for Phase 1A will utilize the percentages below to ensure equitable statewide allocation (example: if IDOH is allocated 100,000 doses initially, they will be allocated statewide based on the percentages displayed). See **Attachment A: PHASE 1: INDIANA HEALTHCARE PERSONNEL** for a detailed breakdown of county/profession estimates.

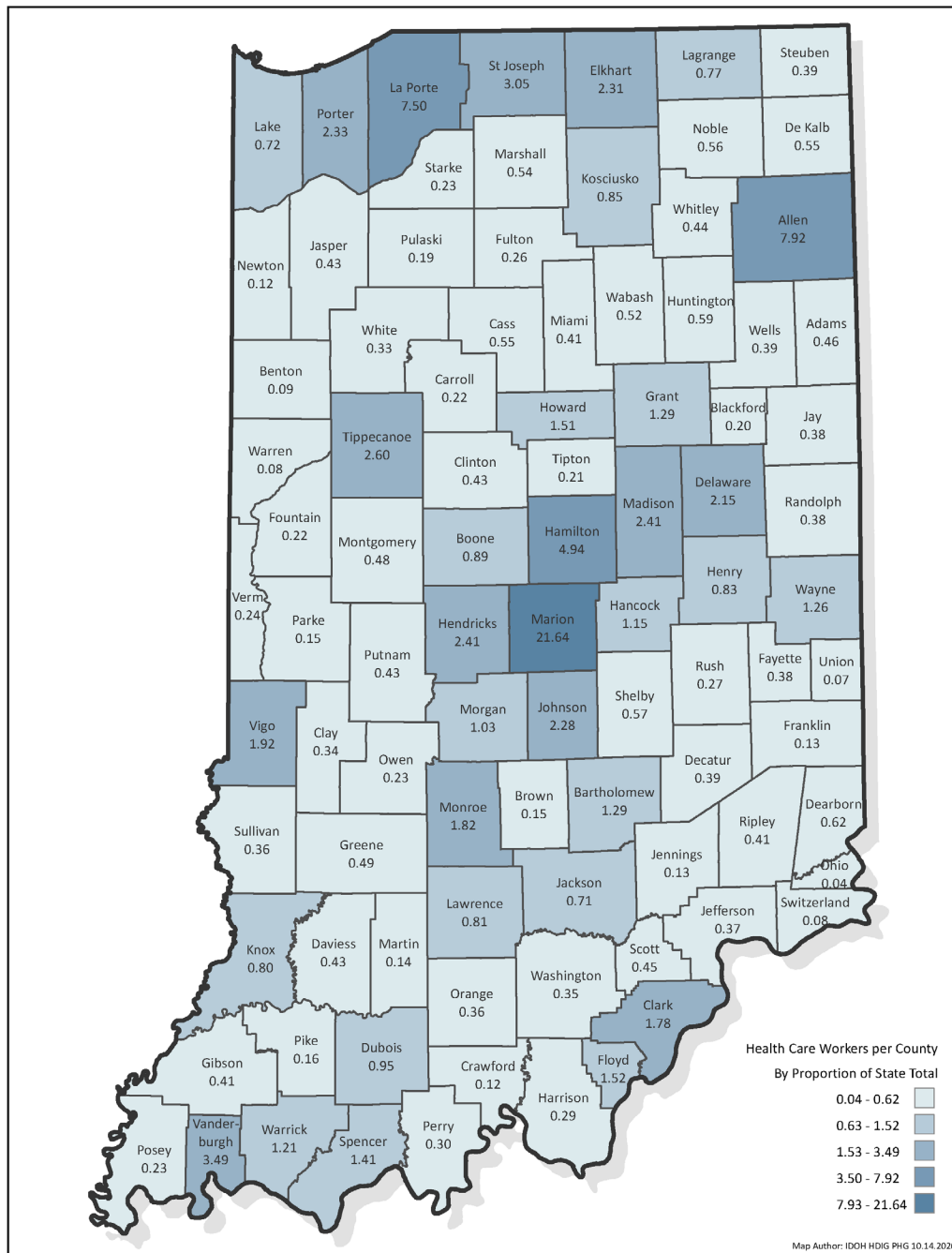


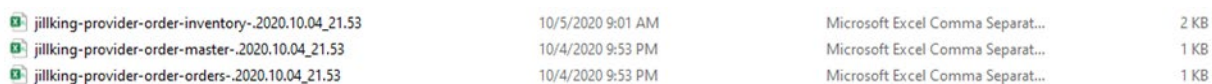
Figure 8: Healthcare Personnel Percentage by County Map



## B. Ordering

Registered COVID-19 vaccination providers enrolled in CHIRP will order COVID-19 vaccine through CHIRP. IDOH will utilize existing procedures routinely used for ordering publicly funded vaccines. This involves uploading orders received in CHIRP into CDC's VTrckS.

Indiana will initially complete the vaccine pre-booking module process for the early vaccine orders; once vaccines are more readily available, providers will be able to place orders for COVID-19 vaccines directly in CHIRP's Vaccine Order Management System (VOMS). Once vaccine orders have been reviewed and approved in VOMS, orders will be flagged to be uploaded to VTrckS. This process involves uploading three separate files in the CDC's EXiS system: Provider Order Master, Provider Order Inventory, and Provider Order Orders.



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jilking-provider-order-master-.2020.10.04_21.53	10/4/2020 9:53 PM	Microsoft Excel Comma Separat...	1 KB
jilking-provider-order-orders-.2020.10.04_21.53	10/4/2020 9:53 PM	Microsoft Excel Comma Separat...	1 KB

Figure 9: Screenshot of file upload of CHIRP ordering information into VTrckS.

All files are uploaded in a .csv format, and each contain specific information that is used to establish the new order requirements in VTrckS and must be uploaded in this order. If there are any errors in any line item of the upload process, the .csv file must be corrected before it will be accepted. All funding information must also meet the necessary funds codes and allocation limits set by the CDC. Any order that does not meet the allocation limits will be rejected and remain unapproved until allocation limits are reached.

CDC will provide the IDOH with regular updates on the available vaccine supply and vaccine product-specific allocations. During Phase 1, when supply is limited to critical populations, the IDOH will approve orders based on the likely populations served by the vaccination provider, the provider's capacity to store and handle the COVID-19 vaccine products, and existing inventory. The minimum order size and increment for centrally distributed vaccines may be 100-1000 doses per order, dependent on updated CDC guidance. Early in the response during Phase 1, some ultra-cold vaccine (if authorized for use or approved) may be shipped directly from the manufacturer in large quantities.

Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders 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 order vaccination provider)
- Syringes, 105 per kit
- Alcohol prep pads, 210 per kit
- Surgical masks (4) and face shields (2) for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit

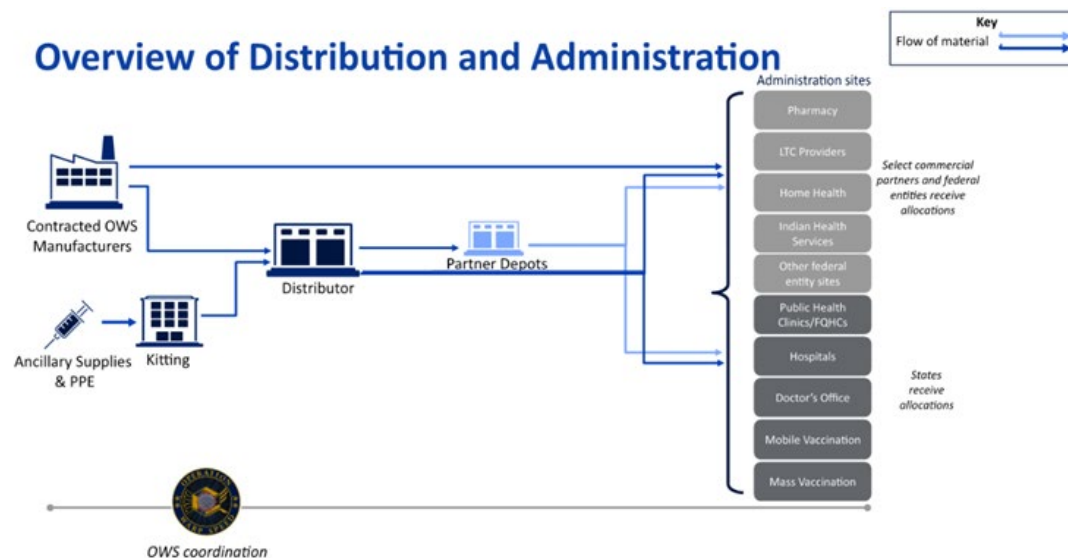


For COVID-19 vaccines that require reconstitution with diluent or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies will be included. Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.

The IDOH has existing contracts for distribution assistance. Long-standing relationships with other state agencies are also in place to expedite services for transportation and storage of supplies and goods. These same strategies will be utilized for vaccine supplies as needed.

Facilities ordering outside of Indiana's allocation (i.e., commercial and federal entities with federal MOUs in place) will order directly from CDC, and CDC will be responsible for approval of those orders.

### C. Distribution



8/26/20

Figure 10: Overview of distribution and administration of COVID-19 vaccine from federal level to end-user providers.

The federal government will procure and distribute COVID-19 vaccines and ancillary supplies at no cost to enrolled COVID-19 vaccination providers. CDC will use its centralized distribution contract to fulfill orders for most vaccine products and associated ancillary supplies. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site.

Indiana will ensure accurate and complete shipping information (e.g., shipment address, provider contact information, shipping hours) is available in VTrckS for all vaccine shipments to enrolled vaccination providers. The IDOH sent a survey to determine accurate POD

addresses for all LHDs within Indiana. In addition, the survey also identified populations with critical needs within the populations each LHD serves.

The CDC's central vaccine distributor, McKesson, has indicated some holiday "blackout" days. During these identified blackout days, vaccine will not be shipped from the distributor. The finalized blackout schedule is not available but will have fewer blackout periods compared to routine VFC vaccine holiday blackout shipments.

COVID-19 vaccine (and diluent or adjuvant, if required) will be shipped to vaccination provider sites enrolled by the IDOH Immunization Division 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.

The federally contracted vaccine distributor uses validated shipping procedures to maintain COVID-19 vaccine cold chain and minimize the likelihood of vaccine loss or damage during shipment. Once a vaccine product has been shipped to a COVID-19 vaccination provider site, the federal government will neither redistribute the product nor take financial responsibility for its redistribution.

Whenever possible, vaccine should be shipped to the location where it will be administered to minimize potential breaks in the cold chain. However, there may be circumstances where COVID-19 vaccine needs to be redistributed beyond the identified primary CDC ship-to sites (i.e., for orders smaller than the minimum order size or for large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations). In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers may be allowed, if approved by the IDOH Immunization Division, to redistribute COVID-19 vaccine if validated cold-chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling. These entities must complete and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement for the sending facility/organization and have a fully completed CDC COVID-19 Vaccination Provider Profile provider enrollment portal entry for each receiving location. The IDOH will be extremely judicious in allowing redistribution and limit any redistribution to refrigerated vaccines only. Redistribution of other vaccine temperatures is subject to change and guidance from CDC and manufactures.

IDOH may allow local transport of vaccines, when approved by IDOH, from one location to another if adherence to cold chain and tracking requirements are maintained. IDOH has surveyed local health departments (LHDs) to determine the ability of LHDs to support local healthcare providers and entities. Redistribution beyond the initial designated primary CDC ship-to location, must be conducted with the use of vaccine-specific refrigerators and/or qualified containers and pack-outs. IDOH has engaged a dry ice vendor within Indiana to provide statewide services, if needed.

## D. Shipment Modalities

The U.S. Department of Defense (DOD) will assist with the distribution and administration of the vaccine. While the U.S. Department of Health and Human Services (HHS) will remain the lead agency for the federal COVID-19 response, the Defense Logistics Agency (DLA) will provide contract, logistics, and administrative support to the distribution process.

### 1. Direct Shipment to Healthcare Providers and Pharmacies

The IDOH, in coordination with LHDs, will recruit vaccine providers and sites to be COVID-19 vaccine providers. Providers willing to administer the vaccine enroll with IDOH and agree to the requirements for receiving, storing, administering, and tracking vaccine administration. Enrolled providers will place orders for the vaccine with the IDOH Immunization Division.

The CDC provides each state a daily allocation of vaccine based on population, and the state will prioritize and fill orders by the state immunization program against the allotment. Orders are then sent to the CDC, and vaccines will be shipped directly to the provider through a centralized vaccine distributor. For some critical workforce groups, the state will coordinate separate vaccine clinics with employers, for example, hospitals or health systems to vaccinate their own workforce.

### 2. Direct Shipment to Local Health Department for Distribution

The IDOH will allocate a portion of COVID-19 vaccines to LHDs for administration and outreach within their communities.

### 3. Direct Shipment to IDOH for Local Distribution

The IDOH will administer some of the vaccine through state-run vaccination sites. To support these operations, some vaccine allocations will be directly shipped to the IDOH warehouse. The IDOH warehouse has the capability of distributing vaccine and ancillary supplies to LHDs, healthcare providers, and IDOH-operated mobile units.

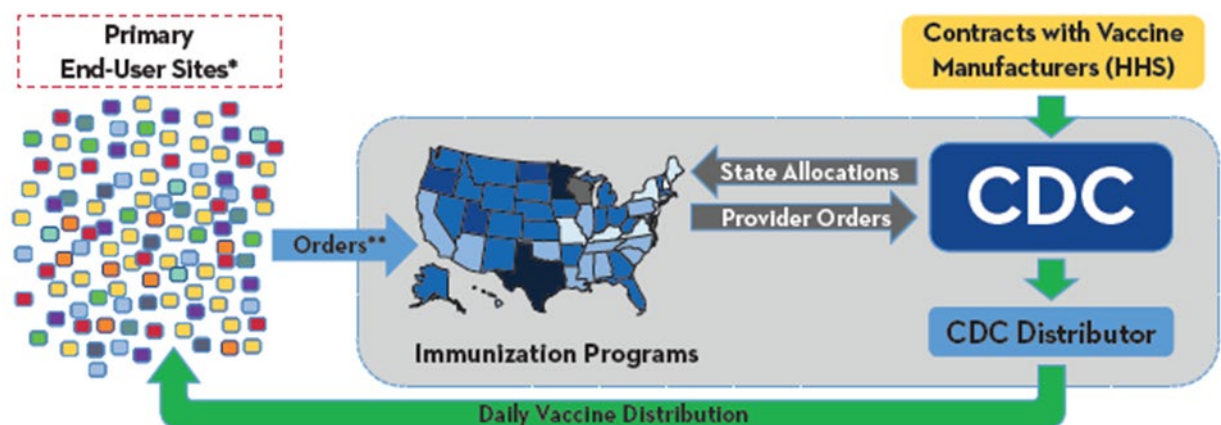


Figure 11: Graphic of vaccine allocation, ordering, and distribution process.

## E. Inventory Management

COVID-19 vaccination providers will be required to report inventory of COVID-19 vaccines. Indiana has a process in CHIRP for ensuring that vaccine inventory is submitted prior to placing a vaccine order. The IDOH currently requires that providers submit their vaccine inventory within 14 days of submitting a vaccine order, preferably the same day the order is being placed. This process, vaccine reconciliation, allows the provider to document if any doses were wasted or re-distributed (transferred) during the time period since the last vaccine order was placed. This information will be essential in maintaining accountability of all COVID-19 doses through the ordering and vaccination process.

It is anticipated that the COVID-19 vaccine will initially be authorized under an FDA EUA. Vaccines authorized under an EUA will contain slight variation from approved FDA products, including:

- Expiration Date: The vaccine vials and cartons will 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. Current expiration dates by vaccine lots for all authorized COVID-19 vaccines will be posted on the HHS website (weblink pending), accessible to all COVID-19 vaccination providers. To ensure that 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 of 12/31/9999 to be read by a scanner. The placeholder 12/31/9999 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 of 12/31/9999.
- 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 information by vaccine lot will be available on the CDC and HHS websites for public access.

## **F. COVID-19 Vaccine Recovery**

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. Indiana will work with staff at each COVID-19 vaccination provider site to ensure appropriate vaccine storage and handling procedures are established and followed.

It is expected that cold chain storage and handling requirements for COVID-19 vaccine products will vary in temperature from refrigerated (2°C to 8°C) to frozen (-15 to -25°C) to ultra-cold (-60°C to -80°C in the freezer or within the dry ice shipping container in which product was received). Ongoing stability testing may impact these requirements. For a reliable cold chain, three elements must be in place:

- Well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

The cold chain begins at the COVID-19 vaccine manufacturing plant, includes delivery to and storage at the COVID-19 vaccination provider site, and ends with administration of COVID-19 vaccine. The IDOH and 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 vaccine will be delivered from CDC's centralized distributor directly to the location where the vaccine will be stored and administered, although some vaccine may be delivered to secondary depots for redistribution. Certain COVID-19 vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site.

The IDOH will have mechanisms in place to provide pro-active support for vaccine recovery and will continually monitor vaccine usage, to determine if state-level intervention is required. The IDOH is prepared to help support dry ice replenishment through a state-contracted vendor when local resources are exhausted. Any unused products nearing expected usage deadlines will be evaluated for redistribution to other locations. The IDOH will utilize the redistribution strategy outlined above in the distribution section.

## **G. Satellite, Temporary, and Off-Site Clinic Storage and Handling**

Satellite, temporary, or off-site clinics in collaboration with community or mobile vaccinators will assist in providing equitable access for COVID-19 vaccination. However, these situations require additional oversight and enhanced storage and handling practices, including:

- 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 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 CDC's Vaccine Storage and Handling Toolkit.
- At the end of the clinic day, temperature data must be assessed prior to returning 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 fluctuations at any time, the temperature excursion should be documented and reported according to the IDOH Immunization program procedures for temperature reporting through CHIRP. The vaccines that were exposed to out-of-range temperatures must be labeled "do not use" and stored at the required temperature until further information.

## H. Local Dispensing

Two models will be utilized to distribute the vaccine – push and pull. Indiana will use a variety of methods to dispense vaccines: distribution directly to residents through state-administered vaccine sites (strike teams or mobile teams) or LHD PODs, local agencies and/or private sector partners. When selecting a strategy, the IDOH will consider operational capacity, the amount of vaccine available, available staff, and facility requirements.

### 1. Vaccine Providers

#### LHD PODs

LHDs utilize a pull model to allow the public to retrieve vaccines from PODs (e.g., drive-through clinics, clinics established at schools, and other areas). LHDs will utilize pre-existing POD plans to register, administer, and document the COVID-19 vaccine.

#### Private Partners and Major Retail Providers

Private health care providers, hospitals, and retail pharmacies enrolled will be able to administer the COVID-19 vaccine. The vaccine will be direct shipped to their facility



from the federal government's distributor. These entities will report vaccine administration to the IDOH.

#### IDOH Mobile Units

The IDOH COVID-19 mobile testing units will serve as multi-purpose mobile vaccination clinics. The mobile units will utilize a push model requiring state officials to push the vaccine out to entities who are responsible for delivering the vaccine to specific populations. The mobile units will conduct outreach to vulnerable and at-risk populations across the state. The units are pre-positioned in the ten preparedness districts and ready to respond to requests from LHDs and other state-directed initiatives.

Given the disproportionate burden of COVID-19 on communities of color, the elderly, and individuals in congregate care settings, "push models" into communities that face barriers to vaccine access will be important to support equitable distribution for those most at-risk.

## 2. Vaccine Surge Support

Indiana National Guard (INNG) medics may be available as a surge support option to provide increased manpower to administer vaccines in Indiana. To utilize INNG medics for vaccine administration, current certification by the National Registry of EMTs will need to be elevated, and an exception approved by IDOH leadership and IDHS-EMS in order to administer vaccine to civilians. INNG general laborers may also be utilized to provide registration and administrative assistance at dispensing locations. Support from the INNG can be requested through the State Emergency Operations Center (SEOC) for State Active Duty (SAD), if approved by IDHS. Indiana EMS and paramedicine providers can be utilized to provide vaccine administration and support. Coordination with the IDHS and local EMS providers will be leveraged to provide surge support locally.

State leaders will review state laws and consider the legal implications of utilizing state emergency laws to expand existing scopes of practices for vaccine administration. Below are examples of modified scopes utilized during the H1N1 pandemic and the state adopting each strategy.

Practitioner	Modified Scope
Pharmacists	<ul style="list-style-type: none"><li>• Pharmacists could administer pneumococcal and influenza vaccinations (including H1N1) to persons 18 and older with a written protocol and standing order from physician licensed in DC. (DC)</li><li>• Pharmacists could have protocol agreements with physicians permitting a pharmacist to order and dispense influenza vaccine without an individual prescription; limit of 10 orders per physician</li></ul>

	<p>within the same or adjacent county to physician's principal place of business. (GA)</p> <ul style="list-style-type: none"> <li>• Pharmacists' scope of practice modified to allow them to administer seasonal and H1N1 vaccine to people 9 years or older. (IL)</li> <li>• Age range of vaccinees expanded by type of vaccine. (IN)</li> <li>• Specified pharmacists authorized to administer influenza vaccinations via written protocol rather than individual prescription. (LA)</li> <li>• Pharmacists permitted to administer influenza and other vaccines to persons aged 9 or older with a prescription. (ME)</li> <li>• Licensed, certified pharmacists authorized to vaccinate adolescents ages 13 and older. (MD)</li> <li>• Commissioner of health authorized to permit pharmacists to administer seasonal and H1N1 vaccine. (MA)</li> <li>• Commissioner of health authorized to permit pharmacists to administer vaccinations if a local board of health requests state assistance to respond to a public health threat. (MN)</li> <li>• Pharmacists allowed to administer seasonal and H1N1 vaccinations at points of dispensing (PODs) under limited circumstances. (NY)</li> <li>• Pharmacists permitted to administer influenza vaccine to persons over age 7 without a physician-patient relationship. (TX)</li> </ul>
Pharmacy Students	<ul style="list-style-type: none"> <li>• Licensed or certified professionals authorized to administer seasonal and H1N1 vaccine as per state health agency instructions and completion of a training program. (IL)</li> </ul>
Paramedics	<ul style="list-style-type: none"> <li>• Paramedics authorized to administer vaccines under local optional scope of practice. (CA)</li> <li>• Licensed or certified professionals authorized to administer seasonal and H1N1 vaccine as per state health agency instructions and completion of a training program. (IL)</li> <li>• Paramedics allowed to administer H1N1 vaccine to public safety and healthcare personnel as well as the general public. (MD)</li> <li>• Commissioner of health authorized to permit paramedics to administer seasonal and H1N1 vaccine. (MA)</li> <li>• Paramedics permitted to administer H1N1 vaccine and H1N1-related medications under the direction of a physician and after training. (OH)</li> </ul>



EMT-Advanced	<ul style="list-style-type: none"> <li>Advanced EMTs allowed to administer seasonal and H1N1 vaccinations at PODs under limited circumstances. (NY)</li> </ul>
EMT-Intermediate	<ul style="list-style-type: none"> <li>Licensed or certified professionals authorized to administer seasonal and H1N1 vaccine as per state health agency instructions and completion of a training program. (IL)</li> <li>Intermediate EMTs permitted to administer H1N1 vaccine and H1N1-related medications under the direction of a physician and after training. (OH)</li> </ul>
Cardiac Respiratory Therapists (CRTs)	<ul style="list-style-type: none"> <li>CRTs allowed to administer H1N1 vaccine to public safety and healthcare personnel as well as the general public. (MD)</li> </ul>
EMT/EMS (General)	<ul style="list-style-type: none"> <li>Health Commissioner authorized to permit EMTs to administer vaccinations if a local board of health requests state assistance to respond to a public health threat. (MN)</li> <li>Conditions of EMS vaccination authority clarified: only if there is a local/state emergency declaration, an emergency mission number issued, and EMS providers are registered as emergency workers under state law and acting under the direction of state/local emergency management or incident commander. (WA)</li> </ul>
Dentists	<ul style="list-style-type: none"> <li>Licensed or certified professionals authorized to administer seasonal and H1N1 vaccine as per state health agency instructions and completion of a training program. (IL)</li> <li>Commissioner of health authorized to permit dentists to administer seasonal and H1N1 vaccine. (MA)</li> <li>Commissioner of health authorized to permit dentists to administer vaccinations if a local board of health requests state assistance to respond to a public health threat. (MN)</li> <li>Dentists allowed to administer seasonal and H1N1 vaccinations at PODs under limited circumstances. (NY)</li> </ul>
Dental Hygienists	<ul style="list-style-type: none"> <li>Dental hygienists allowed to administer seasonal and H1N1 vaccinations at PODs under limited circumstances. (NY)</li> </ul>
Podiatrists	<ul style="list-style-type: none"> <li>Commissioner of health authorized to permit podiatrists to administer vaccinations if a local board of health requests state assistance to respond to a public health threat. (MN)</li> <li>Podiatrists allowed to administer seasonal and H1N1 vaccinations at PODs under limited circumstances. (NY)</li> </ul>
Physician Assistants	<ul style="list-style-type: none"> <li>Physician assistants allowed to administer seasonal and H1N1 vaccinations at PODs under limited circumstances. (NY)</li> </ul>
Midwives	<ul style="list-style-type: none"> <li>Midwives allowed to administer seasonal and H1N1 vaccinations at PODs under limited circumstances. (NY)</li> </ul>

Medical Students	<ul style="list-style-type: none"> <li>• Licensed or certified professionals authorized to administer seasonal and H1N1 vaccine as per state health agency instructions and completion of a training program. (IL)</li> <li>• Commissioner of health authorized to permit medical students to administer seasonal and H1N1 vaccine. (MA)</li> </ul>
Registered Nurses	<ul style="list-style-type: none"> <li>• Registered nurses (RN) could have protocol agreements with physicians permitting a RN to order and dispense influenza vaccine without an individual prescription; limit of 10 orders per physician within the same or adjacent county to physician's principal place of business. (GA)</li> </ul>
Nursing Students	<ul style="list-style-type: none"> <li>• Licensed or certified professionals authorized to administer seasonal and H1N1 vaccine as per state health agency instructions and completion of a training program. (IL)</li> <li>• Commissioner of health authorized to permit nursing students to administer seasonal and H1N1 vaccine. (MA)</li> </ul>
Assistive Personnel and Specialist Assistants	<ul style="list-style-type: none"> <li>• Specialist assistants allowed to administer seasonal and H1N1 vaccinations at points of dispensing (PODs) under limited circumstances. (NY)</li> <li>• Licensed nurses authorized to delegate technical vaccine administration activities (not professional judgment or decision making) to unlicensed assistive personnel during a defined immunization event and consistent with agency policy and procedures. (NC)</li> </ul>
Veterinarians	<ul style="list-style-type: none"> <li>• Commissioner of health authorized to permit veterinarians to administer vaccinations if a local board of health requests state assistance to respond to a public health threat. (MN)</li> </ul>

## VIII. COVID-19 VACCINE STORAGE AND HANDLING

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. Indiana will work with staff at each COVID-19 vaccination provider site to ensure appropriate vaccine storage and handling procedures are established and followed.

It is expected that cold chain storage and handling requirements for COVID-19 vaccine products will vary in temperature from refrigerated (2°C to 8°C) to frozen (-15°C to -25°C) to ultra-cold (-60°C to -80°C in the freezer or within the dry ice shipping container in which product was received). Ongoing stability testing may impact these requirements.

For a reliable cold chain, three elements must be in place:

- Well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

The cold chain begins at the COVID-19 vaccine manufacturing plant, includes delivery to and storage at the COVID-19 vaccination provider site, and ends with administration of COVID-19 vaccine. IDOH and 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 vaccine will be delivered from CDC's centralized distributor directly to the location where the vaccine will be stored and administered, although some vaccine may be delivered to secondary depots for redistribution. Certain COVID-19 vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site. If redistributing vaccine, all cold chain requirements must be adhered to and should limit transport of frozen or ultra-cold vaccine products.

### A. Cold Chain Management

Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2°C to 8°C) to frozen (-20°C) to ultra-cold (-60°C to -80°C) temperatures, and ongoing stability testing may impact these requirements.

Some vaccine will require ultra-low cold (ULC) chain. Ultra-low cold chain can go as low as -80 °C. Vacci-coolers, freezers, coolers, and other cold storage solutions will be utilized to maintain the vaccine designated temperature. Temperatures are tracked on a continual basis and are reported and stored in CHIRP.

The IDOH has a network of 750 healthcare providers with the capacity to store and transport publicly funded vaccine. Each of the 750 healthcare providers enrolled in the program have stand-alone vaccine storage equipment with continuous temperature monitoring equipment.

Once vaccine has been ordered and received, strict storage and handling guidelines must be followed. Vaccines are temperature-sensitive and must be stored and handled correctly to ensure efficiency and maximize shelf-life.

## B. Temperature Monitoring

Indiana will be working on determining the best method for continuous monitoring of all COVID-19 vaccines, including ultra-cold vaccines. The IDOH currently use data loggers for all vaccine temperature monitoring in all permanent storage units and all vaccine transport units and will require that all providers utilize continuous monitoring systems and will provide these, as needed.

CHIRP has the capability to allow providers to enter their daily temperatures (min/max). The system also has the ability for providers to upload their daily temperature log in a specified format. IDOH vaccine ordering management staff can set up alerts when temperature excursions are recorded within CHIRP. Figure 11 depicts the temperature recording feature within CHIRP.

Storage Unit	Wednesday 10/07/2020	Thursday 10/08/2020	Friday 10/09/2020	Saturday 10/10/2020	Sunday 10/11/2020	Monday 10/12/2020	Tuesday 10/13/2020
 HELMER SCIENTIFIC #1 ID 471 °C	 9:00 am <input type="text"/> °C	 9:00 am <input type="text"/> °C	 9:00 am <input type="text"/> °C	 9:00 am <input type="text"/> °C	 9:00 am <input type="text"/> °C	 9:00 am <input type="text"/> °C	 9:00 am <input type="text"/> °C
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Figure 12: temperature monitoring interface in CHIRP.

## C. Strategy to Engage Dry Ice Vendor

The IDOH will follow the Indiana Department of Administration (IDOA) Delegation of Purchasing Authority Program (DPAP) guidelines for procurement of goods and services. No less than three vendors will be contacted for their services/products. Vendor selection will be performed as required by the DPAP guidelines, by an authorized purchasing agent, and approved by IDOA procurement approvers. The method of selection will be by competitive bid or special procurement by justification of emergency need, reviewed and approved by the IDOA procurement approvers. Once selected a requisition and purchase order will be created, approved and dispatched to the vendor. The vendor will be contacted

with delivery locations 24 hours prior to when products are needed and will invoice accordingly.

#### **D. Redistribution Transportation**

The IDOH will leverage existing private and public partners in the transportation of redistributed COVID-19 vaccine. Existing partners include, the Indiana Department of Transportation (INDOT) and private logistics company, Langham Logistics. The identified modalities have the ability to provide temperature-controlled transportation. Transportation will include transit to LHD-operated clinics, state-operated mobile sites, and other health care provider locations. Supplies transported include the vaccine and ancillary supplies. LHDs have been surveyed to determine their ability to support redistribution locally. Finally, another redistribution option available to the IDOH is its ten mobile response vehicles, prepositioned in the ten Indiana preparedness districts and available to provide testing, vaccine, and outbreak response support across the state. Each vehicle is outfitted with cold storage capabilities. As vaccine is redistributed, the IDOH will leverage the systems identified in **Section IX: Vaccine Administration Documentation and Reporting** to track the movement of the vaccine.

## IX. COVID-19 VACCINE ADMINISTRATION DOCUMENTATION AND REPORTING

### A. Collection of COVID-19 Vaccine Doses Administered Data

#### 1. CHIRP

Immunization information systems (IISs), also known as vaccine registries, are confidential, population-based computerized systems for recording information, including vaccination history and vaccine doses given by participating health care providers.

Within the state of Indiana, the Children and Hoosier Immunization Registry Program (CHIRP) is utilized. CHIRP is a secure web-based application administered by the IDOH. CHIRP is a lifespan registry designed to permanently store a person's immunization records in an electronic format. Healthcare providers can use the registry to both review vaccination records for their patients and to record all newly administered vaccinations. The State of Indiana mandates the reporting of vaccine administration by certain age groups and provider types.

Interfaces with electronic health records and data clearinghouses account for 90% of all data reported to CHIRP. This data is reported using a Health Level Seven (HL7) message. A HL7 message is an international standard for the transfer of clinical and administrative data between software applications. Indiana Code requires the information to be reported within seven days of vaccine administration.

The IDOH is working with a third-party vendor to help providers collect vaccine dose level info and report to the registry. PrepMod is currently being evaluated as an option.

- Existing IIS providers reporting electronically -- Providers who are currently reporting to the IIS will continue to report COVID-19 dose-level information as they do other vaccines. The only change in their workflow is that COVID-19 administered doses will need to be reported with 24 hours of administration.
- IIS direct data entry -- Providers have the option to directly log into the IIS and record patient and vaccine info. The IIS has several functions available for providers to monitor inventory at the dose level by vaccine, lot number, and other parameters as well as track wastage and returns.

#### 2. PrepMod

The IDOH is currently evaluating a third-party vendor, PrepMod, as an option to help providers collect and report vaccine info to the IIS. PrepMod is an end-to-end system that manages key aspects of mass vaccination efforts and pandemic responses. It connects the public, health care providers, government, and businesses for realtime recording, reporting, and monitoring of uptake, coverage, and supply inventory. It features online

consent, self-scheduling of appointments, recording and reporting encounters, and interfaces with state IISs and other electronic systems.

#### **B. Transition of Data to IZ Gateway**

The IDOH has signed a memorandum of understanding (MOU) and data use agreement (DUA) to connect and shared vaccination data via the Immunization (IZ) Gateway. We are working with the IIS vendor and American Immunization Registry Association (AIRA) to set the connections up between the IIS and the IZ Gateway. Once the connections have been set within the IIS, the system will be able to query for a patient with all states connected to the IZ Gateway to which the IIS has access. The IZ Gateway will automatically report to the IIS any Indiana patient who got a vaccine dose in any of the states connected to the IZ Gateway.

#### **C. Provider Reporting Readiness**

The IDOH ensures that each COVID-19 vaccination provider is ready and able to report COVID-19 vaccine administration and inventory information into CHIRP. The reported information includes the CDC-defined required data elements. Indiana will use the learning management system within CHIRP, called INvest. INvest is a centralized training resource already developed for enrolled VFC providers that the IDOH will utilize to train enrolled COVID-19 providers. This provider training ensures provider reporting readiness. Providers must ensure that they have trained staff, internet connection, and adequate reporting equipment to report vaccine administration data elements every 24 hours.

#### **D. Real-Time Reporting**

Satellite, temporary and off-site clinics will be able to directly enter data to the IIS via manual data. CHIRP is a web-based app and is accessible via any internet-enabled device. and has a standalone inter-op engine, PHC-Hub, that handles all electronic data reported to the system. All data that is sent to PHC-Hub is set for immediate deduplication which will enable ~90% of the data reported to CHIRP to be instantly available to the providers to be viewed or queried.

#### **E. Provider Accountability**

The Vaccine Ordering Module is a part of the IIS which gives IDOH administrative staff full access to provider inventory. The IIS also has several inbuilt reports that will help staff monitor inventory, doses administered, and reported to the system (see Figure 10). IIS staff also have access to the IIS database run ad hoc reports using database queries to monitor data for completeness, timeliness, and accuracy. Immunization and IIS staff will follow-up with providers that do not comply with the documentation and reporting requirement to ensure compliance. Further future order requests from these providers can be denied for failing to meet with the program requirements. Appropriate disciplinary actions will be determined on an as-needed basis, if on-time reporting issues occur.



Reports	
<b>Vaccinations</b>	<b>Patients</b>
Vaccination Totals	Daily Patient Immunization List
Vaccinations Breakdown	Patient Detail <span>Schedule</span>
Lot Number Summary	Patient Totals
Lot Usage and Recall Report	Recall for Inactivation
Vaccine Deferrals	Updated Patients Labels
Vaccine Lots to Expire <span>Schedule</span>	Clinical Notes
Daily Inventory Report	Contraindication Report
Reminder/Recall Success <span>Schedule</span>	Aggregate Contraindication Report
<b>Vaccines for Children</b>	<b>Site Information</b>
VFC Vaccinations Breakdown	Provider Contact
Vaccine Administered <span>Schedule</span>	Physician/Vaccinator Detail
VFC Accountability Log <span>Schedule</span>	
VFC Profile Report	
<b>Registry</b>	<b>Quality</b>
Provider Submission Detail <span>Schedule</span>	Patient Data Quality Detail
Provider Submission <span>Schedule</span>	Vaccination Data Quality <span>Schedule</span>
Registry Statistics <span>Schedule</span>	Vaccination Data Quality Detail
Coverage Rate Report <span>Schedule</span>	HL7 Certification Report
	Administrator Data Quality <span>Schedule</span>
	Pre and Post Enhancement Benchmark Report
Coverage Rate Report <span>Schedule</span>	HL7 Certification Report
	Administrator Data Quality <span>Schedule</span>
	Pre and Post Enhancement Benchmark Report
<b>Vaccine Management</b>	<b>Administrative</b>
Inventory Transaction Report	Patient Queries
Inventory Submission Report	
Monthly Inventory Reconciliation Audit Report	
Cost Report By Lot Number	Patient Changes
Cold Chain Tolerance Exception Report <span>Schedule</span>	Usage Tracking
Order History Comparison Report <span>Schedule</span>	Datamart Refresh
VOIMS Vaccine Shipment Summary	
Vaccine Return Adjustment Notification	
Aggregate Wastage Report	
Inventory Adjustment Report	
Vaccine Dispensed Report <span>Schedule</span>	

Figure 13: Examples of inbuilt reports that assist staff in monitoring inventory and doses administered and reported within CHIRP.

## F. COVID-19 Vaccine Reports

The IDOH will use CHIRP to generate reports on vaccine utilization by provider, county, and the state on at least a weekly basis. This functionality is existing and will be set up as a canned report to be automatically generated on a regular interval. This information will be submitted to the IDOH Office of Data and Analytics for inclusion in dashboards and to analyze vaccine utilization in areas of the state.

The IDOH has recently registered and been granted access to the HHS application, Tiberius, and will use Tiberius as an additional tool for assessing vaccine coverage in high risk areas and targeting areas of low vaccine utilization.

These two data utilities will enable the State of Indiana to track vaccine utilization across the state and look for pockets of need. If pockets of need are identified, the IDOH will work with community vaccination partners to increase vaccination efforts in that area. LHD efforts are



being positioned as back-up vaccinators for identified areas of need or as a vaccination touchpoint for areas of the state that do not have other vaccination resources.

Areas of low vaccination utilization will be provided to the State Health Commissioner on a weekly basis so that IDOH leadership is aware of the issue and can allocate resources to address coverage.

The IDOH will also use CHIRP to track the number of individuals who received a first dose of COVID-19 vaccine and need a second dose. Daily reports will be run to determine individuals that need a second dose and what presentation was previously received so that reminder recalls can be generated for series completion. Daily reports will also be generated on the number of individuals that are fully protected against the virus due to be fully vaccinated per ACIP recommendations.

## **X. COVID-19 VACCINATION SECOND-DOSE REMINDERS**

### **A. Notification Timing and Product Type**

For most COVID-19 vaccine products, two doses of vaccine, separated by at least 21 days, will be needed. Because different COVID-19 vaccine products will not be interchangeable, a vaccine recipient's second dose must be from the same manufacturer as the first dose. Second-dose reminders for vaccine recipients will be critical to ensure compliance with vaccine dosing intervals and achieve optimal vaccine effectiveness. COVID-19 vaccination providers should make every attempt to schedule a patient's second-dose appointment when they get their first dose.

### **B. Notification Modalities**

Redundant methods and systems will be used to remind vaccine recipients about their need for second doses. Indiana will utilize current practices for patient reminder/recall in existing healthcare provider organizations and pharmacies, such as through healthcare electronic health records (EHRs).

#### **1. Vaccination Record Cards (included in ancillary kits)**

COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. Vaccination providers should be highly encouraged to complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each patient who receives vaccine to ensure a basic vaccination record is provided. Vaccination providers should encourage vaccine recipients to keep the card in case the IIS or other system is not available when they return for their second dose. The card provides room for a written reminder for a second-dose appointment. If vaccine recipients have a smartphone, they may consider documenting their vaccine administration with a photo of their vaccination record and entering the date the next vaccine dose is due on their electronic calendar.

#### **2. CHIRP Reminder Recall**

CHIRP has a reminder recall option with ability to send emails and text messages to vaccine recipients. This option is only available if the patient information is available and accurate within the registry.

#### **3. Postcards**

The IDOH has budgeted supplemental funding for second dose reminder postcards, printing, and postage. The postcard information and distribution schedule would be determined by information collected in CHIRP.

#### **4. Scheduling of Second Dose During First Dose Administration**

During Phase 1, providers may choose to pre-schedule a second dose appointment at the same vaccination site. This option will be utilized in occupational health settings where site operations and scheduling are more predictable and anticipated. This option is currently being evaluated for utilization within Phase 2 and Phase 3.

## 5. Electronic Medical Records (EMR)

Many health systems, provider offices, and pharmacy locations within Indiana have robust electronic medical records (EMR) systems. Similar to routine vaccination reminders, providers will utilize EMR notifications to remind patients of a need for a second dose.

## XI. COVID-19 REQUIREMENTS FOR IIS OR OTHER EXTERNAL SYSTEMS

### A. High-Volume Data Management and Contingency

The IDOH has developed solutions for documenting vaccine administration in temporary and high-volume vaccination settings. Planned contingencies for network outages and other potential access issues are included.

1. In case of providers using the CDC VAMS application to record and track COVID-19 doses, CHIRP will receive these via the IZ Gateway.
2. CHIRP currently has a mass immunization module (MIM) to handle high volume data. However, the current MIM does not have the ability to collect all the COVID-19 info that CDC is requiring jurisdictions to collect. Our IIS vendor is working on updates to this MIM to able to collect more info than what is being collected now with the targeted date for completion of these updates in the month of December.
3. CHIRP's interop engine is able to handle rapid onboarding on new interfaces in case this becomes necessary
4. CHIRP is hosted on the vendor AWS cloud environment providing reliable backup, and disaster recovery capabilities to handle network outages and access issues

### B. Indiana IIS (CHIRP) Data Variables

CHIRP captures the variables below for persons who will receive COVID-19 vaccine. Currently, CHIRP can receive race and ethnicity info (both manually and electronically), and the IDOH is working with the IIS vendor to have all other fields added to the IIS database so these can be recorded if reported:

- Administration location
- Administration location: type
- Administration address: city
- Administration address: county
- Administration address: state
- Administration address: street
- Administration address: zip code
- Administration date
- CVX (product)
- Dose number
- IIS recipient ID
- IIS vaccination event ID
- Lot number: unit of use
- MVX
- Recipient address: county
- Recipient address: city
- Vaccine route of administration
- Recipient address: state
- Recipient address: street
- Recipient address: zip code
- Recipient date of birth
- Recipient name: first
- Recipient name: middle
- Recipient name: last
- Recipient race
- Recipient ethnicity
- Recipient sex
- Sending organization
- Vaccine administering provider suffix
- Vaccination series complete
- Vaccine administering site
- Vaccine expiration date

The IDOH is working with the vendor to add the optional data elements requested by CDC:

- Comorbidity status
- Recipient missed vaccination appointment
- Serology results and vaccine refusal

### C. Data Capacity

CHIRP is currently hosted on the vendor AWS cloud environment. Our Service level contract with our vendor ensures 99.9% system availability through the year.

CHIRP allows for bidirectional data exchange with electronic medical records (EMR) systems. Providers can submit demographic and vaccine related info to the IIS and query demographic, vaccine and forecast info from the IIS. Below is a summary of IDOH's current bidirectional interfaces numbers as of date.

Total of all Facilities Bidirectional, Active, Testing, to Test	2715
Total Facilities Live in Production	2330
Total Facilities Currently Testing	336
Total Facilities Pending to Test	49

The IIS vendor releases monthly patch updates that includes bug fixes, new features and enhancements related to the interop system. We plan to update the system with these latest releases within 2-3 weeks of the release.

### D. IIS Enrollment and Onboarding

The IDOH plans to rapidly enroll and onboard providers to CHIRP. The IDOH will roll out an online COVID-19 provider enrollment application to electronically collect information and store in a relational database. The IDOH is currently determining with the IIS vendor if this information can be directly uploaded to the IIS. In the meantime, the IDOH will hire 1-2 data entry contract staff to transfer the enrollment info to the IIS. In addition, the IDOH is also in the process of hiring an onboarding contact staff to help with onboarding providers who will report data to the IIS electronically.

### E. IZ Gateway Connection

The IDOH has executed a memorandum of understand (MOU) and data use agreement (DUA) to connect and share vaccination data via the IZ Gateway. the IDOH is working with the IIS vendor and AIRA to set the connections up with the IZ Gateway.

### F. Data Use Agreements

The IDOH has established DUAs with the Association of Public Health Laboratories (APHA) to participate in the IZ Gateway. A DUA has been established with CDC for national coverage analysis. Finally, an MOU has been executed to share data with other jurisdictions via the IZ Gateway share component.

## G. Contingency Planning

CHIRP is a web-based software system, so internet connectivity is required. The IDOH currently does not have a solution for offline use. Providers will need manually record details on paper and have it entered the system once they have internet connectivity. The IIS is hosted on the AWS cloud environment. IDOH's service level contract with the vendor ensures 99.9% system availability through the year.

## H. Data Quality

The IDOH is working on the following measures to ensure data completeness, accuracy, timeliness, and consistency. These include:

- Working with the IIS vendor to ensure infrastructure is in place to handle additional load on the system
- Working with the IIS vendor to ensure existing modules are updated and new modules are in place to collect relevant information
- Ensuring reporting modules are in place to check for data completeness, accuracy and timeliness
- Hiring a Business Analyst contractor to help with onboarding of providers to report to the IIS electronically and help with ongoing quality assurance activities with respect to data completeness, accuracy and timeliness
- Ensuring the IIS team has access to the IIS database to run scheduled and ad hoc queries
- Adding additional staff members to help with onboarding and monitoring ongoing data reporting from providers

## XII. COVID-19 VACCINATION PROGRAM COMMUNICATION

Starting before COVID-19 vaccines are available, clear, effective communication will be essential to implementing a successful COVID-19 vaccination program. Building vaccine confidence broadly and among groups anticipated to receive early vaccination, as well as dispelling vaccine misinformation, are critical to ensure vaccine uptake.

### A. COVID-19 Communication Objectives

- Ensure public confidence in the approval or authorization process, safety, and efficacy of COVID-19 vaccines.
- Help the public to understand key differences in FDA EUA and FDA approval (i.e., licensure).
- Engage in dialogue with internal and external partners to understand their key considerations and needs related to COVID-19 vaccine program implementation.
- Ensure active, timely, accessible, and effective public health and safety messaging along with outreach to key state/local partners and the public about COVID-19 vaccines.
- Provide guidance to local health departments, clinicians, and other hosts of COVID-19 vaccination provider locations.
- Track and monitor public receptiveness to COVID-19 vaccination messaging.

### B. Key Audiences

A robust and nimble communication plan will be the foundation of successful COVID-19 vaccine allocation and uptake. The focus must be on ensuring consumer trust by providing information that is timely, accurate and appropriate. Messages will be crafted specifically to each audience and distributed through the most effective channels to achieve the maximum response.

Key audiences identified include:

- |  |  |
|--|--|
| • Critical infrastructure workers                                  | COVID-19 or develop serious illness)   |
| • Emergency preparedness districts and health care coalitions      | • Healthcare providers and pharmacists |
| • Employers and businesses   | • Law enforcement and corrections      |
| • Federally-Qualified Health Centers (FQHCs) and community clinics | • Local health departments             |
| • Faith-based communities  | • Long-term care facilities            |
| • General public (at-risk groups those mostly likely to spread     | • Media                                |

### C. Broad Communication Planning Phases

Communication of Indiana's COVID-19 vaccination plan will be coordinated by the IDOH Office of Public Affairs (OPA). The OPA team has already begun to inform key stakeholders of the planning process already under way at the state level. The IDOH has also engaged partners as plans are developed for both the initial Phase 1-A vaccination distribution and mass vaccination clinics.

OPA is also working with agency leadership and the Vaccination Allocation Advisory Committee as each phase of the vaccine implementation plan is defined and establishing a communication plan that corresponds to the overarching operationalization of the vaccination program.

- Phase 1: Potentially Limited COVID-19 Vaccine Doses Available
  - Healthcare workers, EMS, long-term care staff and residents, local health departments, emergency preparedness districts and healthcare coalitions
- Phase 2: Large Number of Doses Available; Supply Likely to Meet Demand
  - Corrections, other critical infrastructure workers, other congregate settings
- Phase 3: Likely Sufficient Supply
  - General public with focus on developing strategies to ensure equitable access to COVID-19 vaccination services

The IDOH established a communication plan to guide the communication process throughout the vaccine program operation, with timelines and tracking mechanisms to ensure that communications are timely and proactive as much as possible, yet flexible to adjust to program changes, including supply and other available information.

#### D. Communication Activities

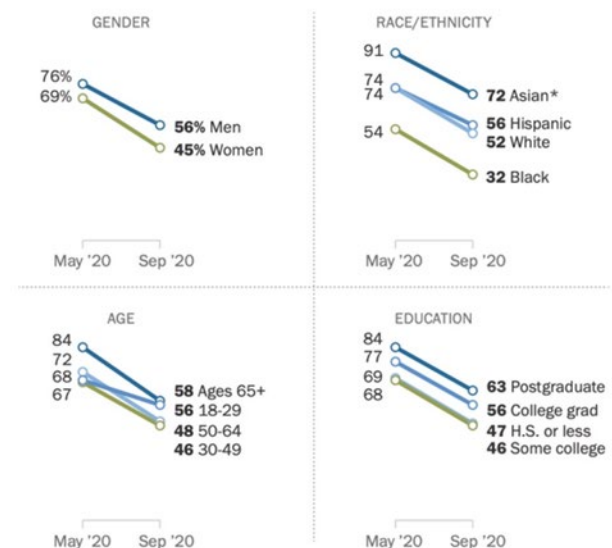
OPA reviews research and monitors social media awareness regarding the public's perception of the COVID-19 vaccine. This information will help guide messaging to ensure that communication addresses the barriers that most influence vaccine uptake.

Initial areas of focus:

- About half of U.S. adults (51%) say they would definitely or probably get a vaccine to prevent COVID-19 if it were available today.
- Individual barriers to vaccine acceptance, such as **fear of side effects, low perception of the efficacy, negative past experiences with vaccination services, lack of knowledge, are discussed as well as the broader sociocultural context.**
- African American adults are much less likely to say they would get a vaccine than other Americans.

#### Widespread declines in the shares who say they would get a COVID-19 vaccine

% of U.S. adults who say they would definitely/probably get a vaccine for COVID-19 if one were available today



\* Asian adults were interviewed in English only.

Note: Respondents who gave other responses or did not give an answer are not shown. White, Black and Asian adults include those who report being only one race and are not Hispanic. Hispanics are of any race.

Source: Survey conducted Sept. 8-13, 2020.

"U.S. Public Now Divided Over Whether To Get COVID-19 Vaccine"

PEW RESEARCH CENTER

Figure 14: Pew Research Center survey results on COVID-19 vaccine interest.



- Concerns about *side effects and uncertainty around the effectiveness of a vaccine* are widely cited as reasons by those who would not get a COVID-19 vaccine if one were available today.
- Fewer adults cite **not thinking they need the vaccine** (31%) or the **vaccine's cost** (13%) as a major reason they would not likely get vaccinated.

Other sources for communication guidance include:

- <https://www.astho.org/Programs/Immunization/Communicating-Effectively-About-Vaccines--New-Communication-Resources-for-Health-Officials/>
- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5137540/>
- <https://pubmed.ncbi.nlm.nih.gov/28215120/>
- [https://www.who.int/vaccine\\_safety/initiative/communication/en/](https://www.who.int/vaccine_safety/initiative/communication/en/)
- <https://www.cdc.gov/flu/pdf/partners/nivdp-webinar-communicating-with-patients.pdf>
- <https://jamanetwork.com/journals/jamapediatrics/fullarticle/2647983>

OPA has also planned the following initiatives:

- Prepare SmartSheet with vaccination distribution phase, communication medium, responsible party, distribution method and deadline with flexibility to adjust to fluid situations that will track and coordinate messaging efforts.
- Work in tandem with state's vaccination work group that focuses on communications in an advisory capacity to ensure throughout the rollout that the IDOH is addressing any gaps in reaching those audiences that may require additional or focused outreach.
- Coordinate with the IDOH Immunization Division and Office of Technology and Compliance to send reminder/recall messages for appropriate second dose and location, along with scheduling system through external vendor that also provides registration services.
- Establish dedicated vaccine webpage within the IDOH website that has more detailed information and possible links to registration maximizing existing audience of more than 187,000 subscribers already receiving web updates.
- Participate in vaccine planning with IDOH Vaccine Working group as plans are created to ensure advance communication is accurate and consistent based on available information. Verify that outreach is made with intent and efficiency.
- Ensure that communication meets accessibility guidelines and other requirements for those with disabilities as well as language requirements.
- Host focus groups throughout the state to identify barriers to vaccine uptake and inform communications strategy.

- Track and provide education about vaccine safety and efficacy to create materials to address vaccination barriers.
- Communicate updates to the media through weekly press briefings and as needed based on the information available.
- Provide support for local health departments, including a toolkit to help promote local vaccination clinics and regular updates through weekly webcasts.
- Use existing listservs and the Indiana Health Alert Network to provide messaging directly to healthcare providers to share with patients.
- Create media campaign aimed at increasing uptake of COVID-19 and influenza vaccinations.

## E. Messaging Considerations

All communication will be presented clearly and crafted with the specific audience in mind. This will include consultation with the IDOH Office of Minority Health and translations as needed. Placement of the messages will also incorporate a variety of delivery methods.

### Key content to be covered in communication efforts:

- |                                  |                                      |
|----------------------------------|--------------------------------------|
| • Vaccine is available           | • Addressing psychological barriers  |
| • Cost                           | • The why: for family, for community |
| • Information on safety/efficacy | • What happens after vaccination     |

All communications will pass the accessibility checker to ensure they can be available to those with disabilities. The IDOH will also utilize in-house translation services, as well as help from partners to provide translations in Spanish, Chinese, Creole and Burmese to further address any communication barriers to ensure access and understanding of COVID-19 vaccination.

Messaging will need to be layered, starting with simple messaging about vaccine availability and effectiveness and addressing any psychological barriers to vaccine uptake. Other messaging will be more detailed, such as what is available on the website where the public can find more detailed information.

Targeted outreach to rural areas and other specific communities, such as Amish or Potawatomi Indian populations, will also be necessary to provide direct outreach to those who may not have access to information or fewer healthcare resources in less populated areas of the state.

Messaging will begin with outreach to the Phase 1A key audiences, including healthcare providers and associations and the local health departments so they can begin preparations.

The IDOH has also convened an Equitable Distribution and Communication Advisory Group to help review the state's messaging strategy. This group includes a cross-section of professionals in the healthcare, as well as various communities throughout the state.

The advisory group's role is to:

- Identify critical populations to receive vaccine and identify approximate estimate of these populations.
- Identify subsets of populations based on vaccine availability.
- Advise lead Vaccine Allocation Committee to ensure vaccine is distributed equitably based on supply.
- Review communications plan for roll out of vaccine.

Key components of vaccine communication:

- Ensure it is culturally and generationally sensitive
- Create messaging that is simple and straightforward
- Be transparent
- Distribute in multiple languages and formats
- Partner with other trusted entities to educate critical populations

## **F. Communication Channels**

Traditional media channels:

- Press releases to print, radio and television
- Advertising campaign promoting influenza and COVID-19 vaccine

Digital Media:

- Indiana's COVID-19 website (187,000 subscribers)
  - Add page with vaccination information and helpful links.
  - Map of vaccination sites
- Weekly social media messaging to promote press releases, web updates, and other important education:
  - Facebook
  - Twitter
  - Instagram
- Social media advertising campaign promoting influenza and COVID-19 vaccine

Print resources:

- Multilingual infographics on vaccine education
- Toolkit for LHDs to promote vaccination clinics

Webinars/webcasts:

- Weekly LHD webcasts, with recordings available and presentation with any links sent immediately following
- Biweekly webcasts for healthcare providers within the state

- Begin regular WebEx meetings with epidemiology field staff to provide vaccine updates and information that they can share in the field

### G. Partners and Trusted Sources

OPA will work in coordination with the following state agencies and organizations to identify, develop and distribute communication throughout the vaccination implementation:

- Equitable Distribution and Communication Advisory Group
  - Refugee Health Program
  - Office of Minority Health
  - Immunization Division
- Healthcare Associations:
  - Indiana State Medical Association
  - Indiana Hospital Association
  - Pharmacists Association
  - Indiana Immunization Coalition
- Indiana Agencies
  - Family and Social Services Administration
  - Indiana Department of Insurance
  - Indiana Department of Education
- Indiana Sheriff's Association
- Indiana media organizations
- Indiana Chamber of Commerce
- Central Indiana Council on Aging
  - Indiana Minority Health Coalition, Inc.
  - Indiana Commission on Hispanic and Latino Affairs
- Indiana Department of Health Divisions
  - Rural Health Division
  - Emergency Preparedness
  - Long-term Care
  - Long-term care associations
  - Indiana Community Health Workers Association
  - Rural Health Care Association
- Indiana Housing & Community Development Authority
- Indiana Department of Corrections
- Indiana Professional Licensing Agency
- AARP
- American Red Cross
- Minority health organizations
  - Indiana Native American Indian Affairs Commission
  - Refugee Health Center
  - Rebecca and Vic Stolzhus (Amish community)

### H. Crisis and Risk Communication

In a health emergency, people make decisions differently. They tend to simplify the issues to for easier understanding with so much new and changing information. They also cling to current beliefs as a way to provide stability during a difficult period. People may refer to what they have seen or have previously experienced, which means that first messages carry more weight. Our driving principles are to be first, be right and be credible while adhering to the values, goals and initiatives of the IDOH.

In this public health crisis, it is essential that we initially communicate:

- Simply
- Timely
- Accurately
- Repeatedly
- Credibly
- Consistently

We can build trust and credibility by expressing:

- Empathy and caring
- Competence and expertise
- Honesty and openness
- Commitment and dedication

The goal of our messaging is to acknowledge uncertainty and fears and to reassure as appropriate with facts and information from credible sources. The IDOH also wants to give people action items to help reduce their anxiety about the vaccine, which will include resources for detailed and consistent talking points and resources to find additional information. The IDOH will be knowledgeable and transparent to build trust and credibility in all fact sheets, media releases, social media posts and other communication resources with the public and various stakeholders through the appropriate channels.

### XIII. REGULATORY CONSIDERATIONS FOR COVID-19 VACCINATIONS

#### A. Emergency Use Authorization Fact Sheets

The EUA authority allows the 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 to use the vaccine. 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 will be authorized for a specific time period to meet response needs (i.e., for the duration of the COVID-19 pandemic).

Product-specific EUA fact sheets for COVID-19 vaccination providers will be made available that will include information on the specific vaccine product and instructions for its use. An EUA fact sheet for vaccine recipients will also be developed, and both will be made available on the FDA website and through the CDC website. Indiana 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 vaccine.

Indiana will use INvest, the learning management system within CHIRP. INvest is a centralized training resource already developed for enrolled VFC providers that the IDOH will utilize to train enrolled COVID-19 providers. The IDOH will develop training modules for EUA fact sheets for providers and vaccine recipients, and Vaccine Information Statements (VIS). The system will instruct enrolled COVID-19 providers to provide EUA fact sheets or VIS, as applicable, to each vaccine recipient prior to vaccine administration. It will also allow for a standardized training message and a tracking system for all enrolled COVID-19 providers.

## XIV.COVID-19 VACCINE SAFETY MONITORING

An “adverse event following immunization” is a health problem or negative condition that happens after vaccination (i.e., a temporally associated event). It might be truly caused by the vaccine or it might be purely coincidental and not related to vaccination. CDC continuously monitors the safety of vaccines given to children and adults in the United States. VAERS, co-administered by CDC and FDA, is the national frontline monitoring system for vaccine safety.

### A. Vaccine Adverse Event Reporting System

Healthcare providers should report clinically important adverse events following COVID-19 vaccination to VAERS. VAERS is a national early warning system to detect possible safety problems with vaccines. Anyone—a doctor, nurse, pharmacist, or any member of the general public—can submit a report to VAERS. VAERS is not designed to detect whether a vaccine caused an adverse event, but it can identify “signals” that might indicate possible safety problems requiring additional investigation. The main goals of VAERS are to:

- Detect new, unusual, or rare adverse events that happen after vaccination
- Monitor for increases in known side effects
- Identify potential patient risk factors for particular types of health problems related to vaccines
- Assess the safety of newly licensed vaccines
- Detect unexpected or unusual patterns in adverse event reports

Per the CDC COVID-19 Vaccination Program Provider Agreement, COVID-19 vaccination providers are required to report adverse events following COVID-19 vaccination and should report clinically important adverse events even if they are not sure if the vaccination caused the event. Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention. VAERS data-sharing agreements with Department of Defense and IHS healthcare facilities are being coordinated through the federal government. Indiana will ensure that enrolled COVID-19 vaccination providers understand the procedures for reporting adverse events to VAERS. This information will be included in INvest. More information on submitting a VAERS report electronically can be found at <https://vaers.hhs.gov/reportevent.html>.

### B. Vaccine Safety Datalink

The Vaccine Safety Datalink (VSD) is a collaboration between CDC's Immunization Safety Office and nine healthcare organizations. This active surveillance system monitors electronic health data on vaccination and medical illnesses diagnosed in various healthcare settings and conducts vaccine safety studies based on questions or concerns raised from medical literature and VAERS reports.

### C. Clinical Immunization Safety Assessment Project

CDC's Clinical Immunization Safety Assessment Project is a national network of vaccine safety experts from CDC's Immunization Safety Office and seven medical research centers. This project conducts clinical research and assesses complex adverse events following

vaccination. Healthcare providers can request a consultation for a complex vaccine safety issue with an individual patient at [CISAeval@cdc.gov](mailto:CISAeval@cdc.gov)



## **XV. COVID-19 VACCINATION PROGRAM MONITORING**

Continuous monitoring for situational awareness throughout the COVID-19 vaccination program is crucial for a successful outcome. Prior to receiving COVID-19 vaccine, Indiana has established procedures for monitoring various critical program planning and implementation elements, including performance targets, resources, staffing, and activities.

### **A. COVID-19 Vaccination Program Monitoring**

Vaccine Ordering and Distribution – Reports can be pulled from both VOMS and VTrckS to track the number of doses that have been ordered and shipped to COVID-19 providers by PIN # on a daily, weekly and monthly basis to monitor progress on number of doses shipped versus number of doses administered. This will allow the program to determine if the IDOH is meeting the needs in each county or part of the state based on the critical population designated by each provider in each phase.

### **B. Resource Monitoring**

#### **1. Budget and Finance**

The IDOH is tracking the budget based on standard accounting principles set forth in the Accounting and Financial Reporting Regulation Manual by the State Board of Accounts in PeopleSoft Financial Systems (PeopleSoft). A reconciliation of the funding is done monthly based on queries pulled from PeopleSoft.

#### **2. Staffing**

Having enough adequately trained staff with current situational awareness is key to successful program implementation. Specialized expertise is required, and it is important to have backups in each specialty area to guard against interruption of activities because of illness or other personal situations. For example, if staff are supporting temporary or off-site COVID-19 vaccination clinics, the hours are likely to be long and physically taxing. Managers and supervisors need to regularly check in with and support assigned staff's wellness and overall resilience to perform the assigned tasks.

#### **3. Supplies**

Important activities during the COVID-19 vaccination program might be halted if certain supplies are depleted without replenishment. Indiana will utilize existing inventory management processes monitoring for various program components (e.g., temporary/off-site clinics, vaccination provider enrollment and training, vaccine management). Regular monitoring of such records will foster early prompts to order and replenish supplies and ensure availability as needed. The IDOH will utilize PPE burn rates from testing operations and other response activities and extrapolate this burn rate to vaccine activities. Procedures are in place for ordering and procuring additional supplies through existing vendors with IDOH.

### C. Communication Monitoring

The IDOH has created a SmartSheet to track all communication related to the COVID-19 vaccine program. The tracking sheet is shared and used within OPA, listing each communication piece, status, distribution method, responsible party, description, deadline, status notes and translation to ensure that each communication document is well organized and targeted to the intended audience. The sheet also tracks the approval process, recipients and completion date to ensure follow through and efficiency. This tool has been used as our tracking method throughout the response with favorable results.

The IDOH will monitor vaccine uptake and monitor social media to gauge the effectiveness of the messaging. We will also receive reports on reach for social media posts, media campaign and any press release and other information. Based on that information, we will adjust the focus of the communication plan. For example, if we see a lower than expected uptake of vaccine among the older population, we will target messaging to those older than 65 years through a variety of partners, including long-term care associations, primary care providers, Facebook and the Central Indiana Council on Aging and our rural health partners.

### D. Local Monitoring

The District and Local Readiness section, within the Division of Emergency Preparedness, supports local public health and healthcare preparedness throughout Indiana. This is accomplished through Northern, Central, and Southern Regional Managers. Each Regional Manager oversees the District Public Health Coordinator and District Healthcare Coordinator for each respective District. This section primarily works with local health departments, hospitals, healthcare coalitions, and other public health and healthcare partners in each District. This preparedness work includes all five mission areas of the National Preparedness Goal: Prevention, Protection, Mitigation, Response, and Recovery. Additionally, the District and Local Readiness section works closely with several other state agencies, public health and healthcare associations, and many other organizations that have local roles in public health and healthcare preparedness.

Throughout the response, monitoring and outreach efforts have occurred with LHDs to maintain a common operating picture. The following highlight action items either ongoing or that have occurred previously:

- Ongoing weekly LHD webinars with IDOH Executive Staff and SMEs
  - Webinars will continue with a heightened emphasis on vaccine planning
- LHD survey completed to ascertain LHD readiness to distribute vaccine
- LHD COVID-19 Vaccine Planning Template
  - Distributed to 94 LHDs on 10/16/2020; Anticipated completion date to return vaccination plans to IDOH for review is 12/01/2020
  - The IDOH will ensure that LHDs have sufficiently prepared for vaccine distribution through via a 2-stage review process

## E. Program Metrics

Leveraging the data from the state's IIS platform, CHIRP, we will be able to provide a variety of program metrics in both visual, e.g., interactive dashboards, and tabular formats. Some of the metrics will include: vaccination provider enrollment, doses distributed, doses administered, vaccination coverage, along with a variety of population metrics. In addition, we will map out provider enrollment sites such as pharmacies, hospitals, and LHDs similar to how we mapped out our testing sites, <https://www.coronavirus.in.gov/2524.htm>, throughout the state. These metrics and maps will be presented within the state's existing COVID-19 website, <https://www.coronavirus.in.gov/>. Lastly, we will monitor the effectiveness (TBD) of the vaccinations and presenting this on our website.