Information Systems and Data Flow for COVID-19 Vaccine Distribution and Administration

Efforts to develop and manufacture COVID-19 vaccines are well underway with expectation that the U.S. Food and Drug Administration will authorize at least one vaccine candidate before the end of 2020. Once authorized, success will hinge on the ability to quickly distribute and administer the vaccine across the country. Processes for vaccine allocation, distribution, administration, tracking, and reporting will be complex and rely on effective use of data. All states have existing data systems and processes upon which to build and will need to navigate unique dynamics for COVID-19 vaccines, which may include enhancing, augmenting, and adapting existing infrastructure to allow for effective coordination with federal and local governments as well as providers and data intermediaries such as health information exchanges (HIEs). Please see *Appendix A* for additional information on new and existing information systems that will support vaccine distribution and administration and related considerations for COVID-19 vaccine planning.

There are numerous factors contributing to the complexity of data collection and information sharing for COVID-19 vaccine distribution and administration in the United States, including:

- **New Systems and Processes**. While the United States has extensive experience with vaccine distribution and administration, new systems and processes are being implemented to meet the unique demands of COVID-19. As such, states and other public health jurisdictions may choose to use new systems to augment current capabilities to meet federal requirements. The Centers for Disease Control and Prevention (CDC) outlined a number of immediate priorities for states related to data reporting in its COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. Please see *Appendix B* for additional information on CDC's data reporting priorities for states.

- **Phased Rollout**. Once authorized, vaccine supply will initially be limited until production capacity accelerates, necessitating a phased rollout of the vaccine. Initial recipients of the vaccine will include high priority populations. Data and technology will be essential to integrating a wide range of demographic, employment, and public health information to identify and locate priority populations and support decisions for allocating vaccine doses as part of a phased approach.

- **Provider Enrollment and Onboarding**. To facilitate timely, widespread, and equitable vaccination in the United States, states are actively enrolling providers to administer vaccines and targeting settings where COVID-19 vaccination services are accessible to the critical populations. Part of this process involves onboarding providers to the state's Immunization Information System or other external system and training them on ordering, documentation, and other system functions.
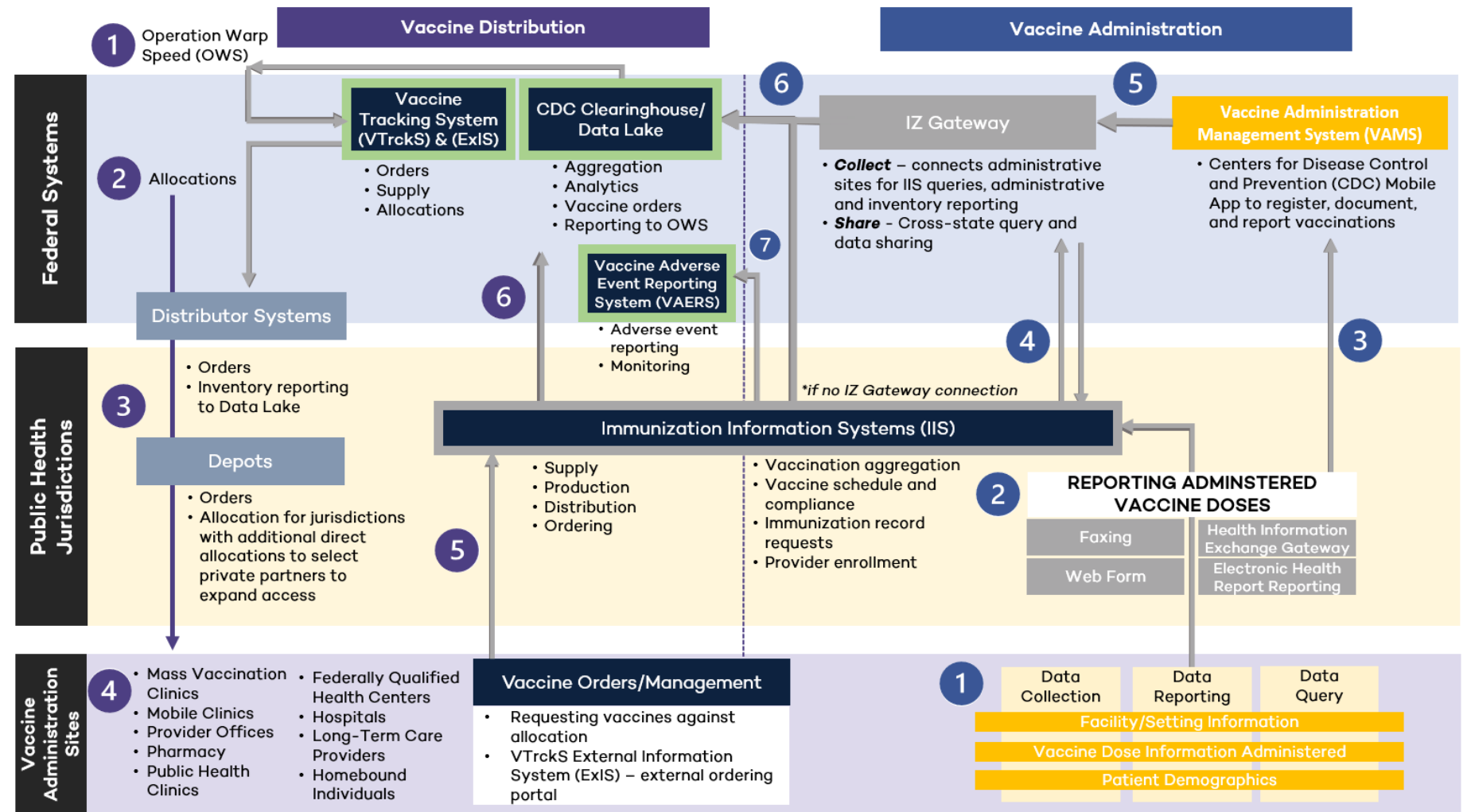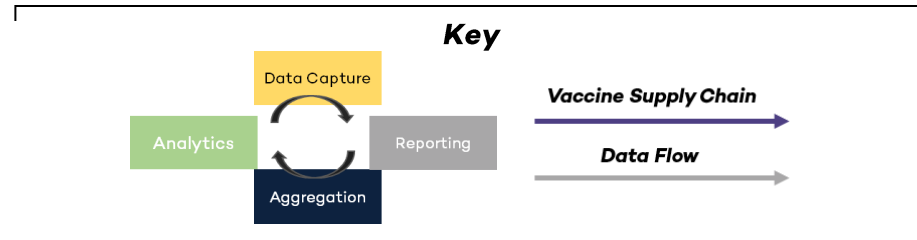
- **Ultra-Cold Storage Requirements**. Each COVID-19 vaccine candidate in development has unique storage and handling requirements. At least one vaccine candidate in late-stage development is anticipated to have strict requirements regarding ultra-cold storage and transport, which will impact distribution processes and require strict adherence to tracking and reporting protocols to avoid waste.

- **Multiple Vaccines and Doses**. It is likely that more than one vaccine will be authorized for COVID-19 and all but one of the vaccine candidates in late-stage development requires administration of two doses separated by several weeks. The vaccine candidates are not interchangeable, both doses must be the same product. Data will need to be collected and shared to ensure that individuals receive each dose of the correct vaccine at the right time.

- **Mass Vaccination Sites.** Public health jurisdictions planning for satellite, temporary, or off-site vaccination locations should consider the additional technical tools and data elements required for CDC reporting as identified in the [COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations.](#) Mass Vaccination data elements are likely to require enhancements or a Mass Vaccination module for data collection and reporting.[1]

The data flow below depicts anticipated vaccine distribution and administration processes and associated information systems. The left side– Vaccine Distribution – depicts the processes and systems used to facilitate vaccine allocation, ordering, distribution to vaccine administration sites, inventory management, and tracking. The right side – Vaccine Administration – shows the processes and systems used to facilitate vaccine administration, including scheduling and reminders, and subsequent documentation and reporting. The data flow also differentiates roles and responsibilities at the federal level (blue), state/jurisdiction level (yellow), and administration site level (purple).

Depending on the specific strategy employed by a given state or jurisdiction, some of the steps in these processes may vary. For example, not all states are connected to the federal system for cross-state immunization record query and vaccine administration sites will have differing levels of sophistication to document and report information. Additional details on these considerations are outlined in *Appendix A*.

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[1] To support the expanded functions for tracking, reporting, and administration at temporary sites, states will have to either 1) enhance the IIS platforms, 2) use CDC available options, or 3) identify 3rd party vendor solutions.

Information Systems and Data Flow for COVID-19 Vaccine Distribution and Administration

Key

- Data Capture
- Analytics
- Aggregation
- Reporting
- Vaccine Supply Chain
- Data Flow

Federal Systems

Vaccine Distribution

Vaccine Administration

1 Operation Warp Speed (OWS)

2 Allocations

Vaccine Tracking System (VTrckS) & (ExIS)
- Orders
- Supply
- Allocations

CDC Clearinghouse/ Data Lake
- Aggregation
- Analytics
- Vaccine orders
- Reporting to OWS

6

IZ Gateway
- **Collect** – connects administrative sites for IIS queries, administrative and inventory reporting
- **Share** - Cross-state query and data sharing

5 **Vaccine Administration Management System (VAMS)**
- Centers for Disease Control and Prevention (CDC) Mobile App to register, document, and report vaccinations

7 **Vaccine Adverse Event Reporting System (VAERS)**
- Adverse event reporting
- Monitoring

6

Public Health Jurisdictions

Distributor Systems

3
- Orders
- Inventory reporting to Data Lake

Depots
- Orders
- Allocation for jurisdictions with additional direct allocations to select private partners to expand access

*if no IZ Gateway connection

Immunization Information Systems (IIS)

- Supply
- Production
- Distribution
- Ordering

- Vaccination aggregation
- Vaccine schedule and compliance
- Immunization record requests
- Provider enrollment

2 **REPORTING ADMINSTERED VACCINE DOSES**

| Faxing | Health Information Exchange Gateway |
| Web Form | Electronic Health Report Reporting |

5

Vaccine Administration Sites

4
- Mass Vaccination Clinics
- Mobile Clinics
- Provider Offices
- Pharmacy
- Public Health Clinics
- Federally Qualified Health Centers
- Hospitals
- Long-Term Care Providers
- Homebound Individuals

Vaccine Orders/Management
- Requesting vaccines against allocation
- VTrckS External Information System (ExIS) – external ordering portal

1 Data Collection | Data Reporting | Data Query

- Facility/Setting Information
- Vaccine Dose Information Administered
- Patient Demographics

Appendix A

The table below depicts the systems that will play a critical role in the distribution and administration processes for the COVID-19 vaccine. It includes information about which systems existed before COVID-19 and key considerations for states.

Data Systems for COVID-19 Vaccine Distribution and Administration

System	Purpose	New or Existing	Data Considerations
Vaccine Allocation, Monitoring, Tracking, and Distribution Systems			
Vaccine Tracking System (VTrckS)	Web-based information technology system to order and manage vaccine distribution among state, local, and territorial health departments and health care providers.	Existing	Direct upload or extensible XML information set (ExIS)
External Information System (ExIS)	The VTrckS ExIS is an interface through which state, local, and territorial health departments can process vaccine requests by uploading data from their IIS to VTrckS.	Existing	
Tiberius platform	The "Tiberius" platform integrates the related manufacturing, supply chain, allocation, state and territory planning, delivery and administration of both vaccine products and ancillary kits. The 2020 technology provides visibility across all U.S. jurisdictions to provide decision support and ease the burden of public health officials throughout the nation.	New	
Immunization Information System (IIS)	IISs, also known as "vaccine registries," are confidential, population-based, computerized databases for recording information on vaccine doses. IISs are maintained by a jurisdiction's immunization program. In many jurisdictions, routine vaccination providers enroll in public vaccine programs, order vaccines, report inventory, document vaccine spoilage/wastage, and remind patients when vaccine doses are due using the IIS. IIS allows monitoring of immunization history and compliance based on immunization schedule.	Existing	Sixty-four jurisdictions currently have an IIS (51 states/district, eight territories, and five city local immunization programs) Providers must report within 24 hours IIS Data Implementation Guide Administration site data to be collected and reported includes location, type, address, and data. Vaccine data must be captured, such as vaccine lot number, vaccine manufacturer, and expiration date. Electronic health records may leverage 2D barcoding technology to improve

	The IIS is typically the source of truth for vaccines supply, ordering, tracking, and monitoring in states.		workflow and vaccine information data quality. Vaccine recipient data must be captured, such as demographics, race, ethnicity, address, date of birth, name, sex, IIS recipient ID, vaccination event ID, administering site (on the body), Consider leveraging existing electronic reporting capabilities from electronic health records or HIE gateways for timely reporting and data quality.
Vaccine Administration Tracking Systems			
CDC Vaccination Clinic Mobile Application: Vaccine Administration Management System (VAMS)	Mobile App to register, document, and report vaccinations for temporary, high-volume sites. Option for state and provider use.	New	Four VAMS modules under development for use by IIS jurisdictions, employers/organizations, clinics, and vaccine recipients. Different data elements required for standard and mass vaccination sites. Some states are using third party system, PrepMod, for the vaccine tracking work, as well as the mass vaccination registration, documentation, and reporting.
Immunization Gateway (IZ Gateway)	The IZ Gateway developed in 2019 aims to increase the availability and volume of complete and accurate immunization data stored within IIS and available to providers and consumers regardless of their jurisdictional boundaries. The IZ Gateway will support • Cross-state query and data sharing • Administrative data reporting • Inventory reporting • Mass vaccination reporting, and • Consumer access tools	Existing	Currently, 13 states are connected to the IZ Gateway with eight actively connected, four in testing, and one piloting the consumer app. Not all IIS are connected to the IZ Gateway for cross-state immunization record query. States must sign data use agreement (DUA) with IZ Gateway to connect the IIS, memorandum of understanding to receive data from other states' IIS, and DUA with CDC for the national coverage analysis.

			IZ Gateway reports to the CDC COVID-19 Clearinghouse/Data Lake
COVID-19 Clearinghouse (a secure data lake)	An analytic environment that will be used to consolidate, deduplicate, and reconcile vaccine administration information from multiple sources (e.g. jurisdictional immunization programs, pharmacies, Department of Defense, Veterans Affairs, Bureau of Prisons, Indian Health Service).	New	Any identifiable data elements will be used to facilitate deduplication of data within the Immunization Data Lake. Data Lake will not store identifiable data elements. The jurisdiction must use a system that supports dose-level accountability—from the time vaccine leaves the distributor until the vaccine is administered or unused vaccine is returned—and provides data to CDC that meet defined standards. Jurisdictions will need to have a solution (either leveraging existing or new) for extracting required data from their IIS as a contingency for network outages.
Vaccine Adverse Event Reporting Systems (VAERS)	VAERS co-administered by CDC and FDA, is the national frontline monitoring system for vaccine safety. a national early warning system to detect possible safety problems with vaccines.	Existing	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.

Appendix B

CDC Priorities for State Planning on Data Reporting

On September 16, the CDC released its [COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#) (updated on October 29) to serve as a guide for state, territorial, tribal, and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their jurisdictions. On October 16, states submitted [interim plans](#) to the CDC based on parameters outlined in the playbook.

The playbook outlines specific steps for states to ensure their IIS or other external system's infrastructure is ready to support COVID-19 vaccination efforts. In particular, the playbook identifies several immediate priorities for immunization programs related to data reporting:

- Determine and implement a solution for documenting vaccine administration in temporary or high-volume settings (e.g., VAMS or similar application, IIS or module that interfaces with the IIS, or other jurisdiction-based solution)
- Ensure system capacity for data exchange, security, storage, and reporting
- Enroll vaccination provider facilities/organizations anticipated to vaccinate essential workers
- Connect IIS to the IZ Gateway for cross-jurisdiction IIS queries, administrative, inventory reporting or through an alternative method from IIS to CDC COVID-19 Clearinghouse
- Establish required DUAs
- Assess and improve data quality. Ensure data are available, secure, complete, timely, valid, accurate, consistent, and unique