AIRA
AMERICAN IMMUNIZATION
REGISTRY ASSOCIATION

MASS VACCINATION CAPABILITIES SUMMARY

A SUMMARY OF IIS AND EXTERNAL MASS VACCINATION SOLUTIONS

JULY 2020

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EXECUTIVE SUMMARY

In September 2019, the American Immunization Registry Association (AIRA) was awarded a two-year cooperative agreement with the CDC Office of the Associate Director for Adult and Influenza Immunization to inform strategies for improving awareness and utilization of IIS among adult health care providers under both routine and mass vaccination/emergency response conditions.

AIRA was tasked with cataloguing and reviewing existing mass vaccination solutions designed for use by immunization programs and providers[1] and identifying the essential elements that should be included in a mass vaccination module.[2]

Mass vaccination refers to the tools and processes used to facilitate vaccination activities in response to a pandemic, disease outbreak, natural disaster, or other public health emergency. A mass vaccination campaign typically exhibits the following characteristics:

- Vaccinating large numbers of people in a short time frame.
- Strategically prioritizing the vaccination of select individuals when vaccine supply is limited.
- Antigen(s) or countermeasures being administered are typically campaign specific.
- Active tracking of doses distributed, doses administered, and doses on hand is critical to informing response efforts, including the movement of inventory if needed.
- Population coverage rates are used to inform and guide ongoing response efforts/decision making.

Several tools or strategies may comprise a state's/jurisdiction's[3] overall mass vaccination solution. These include the core IIS, IIS-based mass vaccination modules, emergency preparedness/countermeasure response administration (EP/CRA) tools, and other auxiliary tools/resources (e.g., local public health apps, file conversion tools, online web-survey tools, Excel spreadsheets, and paper).

[1] See section titled Mass vaccination products in the marketspace
[2] See section titled Essential elements of a mass vaccination module
[3] Throughout this document, the term jurisdiction will refer to a U.S. city, state, or territory that operates an IIS for the capture of patients and vaccinations administered within their unique jurisdictional area. CDC recognizes 64 jurisdictions as "immunization program awardees,", meaning that they receive funding under Section 317b of the Public Health Services Act. Awardees include the 50 states, 5 cities (New York City, Philadelphia, Houston, San Antonio, and Chicago), the District of Columbia, and 8 territories. AIRA also routinely includes the city of San Diego as an IIS jurisdiction. While not a CDC awardee, the city of San Diego successfully operates an IIS that is independent from the state of California.

How tools or strategies are deployed depends on the nature of the response and whether vaccine delivery will occur through routine medical service providers or through a coordinated point of dispensing, commonly referred to as a POD or closed-POD.

In April 2020, AIRA conducted a survey of the IIS community. Of the 49 jurisdictions that responded, 77% of jurisdictions plan to use their core IIS as a main component—or *the* main component—of their mass vaccination solution. Approximately half (53%) of the respondents indicated that they plan to use some sort of IIS-based mass vaccination module. Further, 53% of respondents indicated that their mass vaccination response would likely include the use of two or more tools or platforms.

Ideally, a mass vaccination or EP/CRA solution should maximize clinic throughput, prevent bottlenecks, provide real-time metrics for response administrators, and support post-event follow-up and analysis. Mass vaccination modules are commonly deployed to support PODs/closed-PODs because these tools have been strategically designed for rapid data entry of patients and vaccinations and for facilitating high-volume throughput. An interface with the IIS ensures that all data collected during a mass vaccination event is reported to the central IIS for active monitoring of the overall campaign, consolidation of patient records, and facilitation of post-event activities. In addition, a mass vaccination solution helps to avoid the use of paper and alleviates the general administrative burden of paper, delays in data reporting, and decreased data quality.

Beyond examining the core elements of a mass vaccination module, there are numerous considerations that may impact how or if mass vaccination solutions can be used to meet the collection and reporting requirements of a mass vaccination event or campaign. Some of the considerations detailed in this document include:

- Appropriateness of expanding IIS-based mass vaccination solutions beyond vaccinations to include the capture of other countermeasures, medications, testing kits/supplies, expendable supplies (e.g., syringes, band-aids, PPE), and other resources (e.g., ventilators, blankets)
- Examining opt-in and opt-out consent mandates for IIS reporting and sharing during an emergency response scenario
- Appropriateness of the capture and storage of questionnaires/screening forms, priority tier/risk group designations, sensitive contraindications and precautions, immunity indicators (labs/titers), and occupation; challenges of validating, capturing, and maintaining this type of information

- Exploring the feasibility and challenges of incorporating patient history and forecast into a mass vaccination workflow
- Challenges of capturing and associating a separate adjuvant product
- Ensuring the security of patient and vaccination data collected and stored on local devices (e.g., mobile devices, thumb drives, laptops with a local database)
- Addressing programmatic/operational concerns regarding the enrollment of new providers, increased onboarding efforts, and additional training and support needs for new users
- Challenges of building tools that are fully featured, easy to configure, intuitive to most users, and versatile enough to be used beyond emergency response events (e.g., annual influenza campaigns, school vaccination clinics, workplace vaccination, health fairs)

In December of 2019, COVID-19 emerged, becoming a pandemic shortly thereafter, and directly impacted the nature of the mass vaccination deliverables for this project. The information in this document represents a point-in-time assessment of the tools available to support mass vaccination activities in the spring of 2020. Due to the timing of this project in the midst of an active pandemic, this document may best serve as a baseline view of pre-COVID-19 mass vaccination functionality. Post-event analysis will likely inform the evolution of functionality for the next generation of mass vaccination modules.

Information for this project was collected through a Mass Vaccination Quick Survey of the IIS community, a poll of National Adult and Influenza Immunization Summit (NAIIS) participants, IIS interviews conducted by the CDC IIS Support Branch (IISSB), and review of several mass vaccination/countermeasure response modules. This document has been written for practical use and reference by the CDC Office of the Associate Director for Adult and Influenza Immunization and the CDC IIS Support Branch to guide and inform efforts currently in progress for facilitating the COVID-19 response. This document is not intended for distribution to an expanded audience.

1 INTRODUCTION

SECTION 1 INTRODUCTION

As the world finds itself in the midst of a pandemic, awaiting the development and release of a new vaccine, immunization programs in the United States are preparing their immunization information systems (IIS) to facilitate the dissemination of a COVID-19 vaccine.

IIS will likely play a significant role in the ordering and distribution of vaccine, capture and recording of dose administrations, reporting to CDC and other incident command centers, coordination of reminder/recall activities for a multi-dose series, and production of population-based coverage assessments. During the 2009 H1N1 pandemic, IIS were leveraged extensively to support mass vaccination efforts.[4] After-action reports helped to identify the strengths and weaknesses of the systems and processes that existed at the time. These lessons learned have been referenced and used to improve IIS and IIS program operations to better position IIS to support the next big event. These improvements will now be tested with the COVID-19 response.

In September 2019, just prior to the COVID-19 outbreak, the American Immunization Registry Association (AIRA) was awarded a two-year cooperative agreement with the CDC Office of the Associate Director for Adult and Influenza Immunization. The results of this project will be used to inform stakeholders and guide CDC and IIS toward improving awareness and use of IIS among adult health care providers under both routine and mass vaccination/emergency response conditions. This project has several deliverables, one of which examines the role of IIS and third-party mass vaccination modules to support a response effort. Under this deliverable, AIRA was tasked with cataloguing and reviewing existing mass vaccination solutions designed for use by immunization programs and providers[5] and identifying the essential elements that should be included in a mass vaccination module.[6] The following document will detail these findings.

[4] AIRA Discovery Session: H1N1 Lessons Learned: https://repository.immregistries.org/resource/aira-discovery-session-h1n1-lessons-learned-and-how-they-are-informing-the-response-to-covid-19/
[5] See section titled Mass vaccination products in the marketspace
[6] See section titled Essential elements of a mass vaccination module

AIRA routinely uses a community-informed approach to gather input from IIS jurisdictions,[7] IIS vendors, critical stakeholders, and other subject matter experts. This information-gathering process typically includes a survey of the IIS community and other relevant partners, interviews with selected subject matter experts, and in-person facilitated meetings to gain consensus. Due to the unique circumstances of the COVID-19 pandemic, AIRA project staff were limited in their ability to collect information and carry out some of the validation and follow-up processes that would typically be conducted as part of a similar assessment effort. Though circumstances were not ideal, AIRA was able to administer a Mass Vaccination Quick Survey to the IIS community,[8] poll the participants of the National Adult and Influenza Immunization Summit (NAIIS),[9] participate as a silent observer in 19 IIS interviews conducted by the CDC IIS Support Branch (IISSB),[10] and review several mass vaccination/countermeasure response modules. This project was determined to be non-human subject research and therefore did not require approval by an Institutional Review Board. The information collected during the interviews and product reviews was summarized and paired with findings from the quick survey and NAIIS poll to develop the narrative and advise the considerations that appear in this document. The information in this document represents a point-in-time assessment of the tools available to support mass vaccination activities in the spring of 2020.

This document has been written for practical use and reference by the CDC Office of the Associate Director for Adult and Influenza Immunization and the CDC IIS Support Branch to guide and inform efforts currently in progress for facilitating the COVID-19 response. While COVID-19 activities increased the urgency of developing this document, the broader assessment and core messages contained in this document account for a more holistic response to any emergency that may require a mass vaccination component. This document does not explore or address broader policy-based issues or concerns about the capture and reporting of mass vaccination data. This document has not been written for distribution to an expanded audience.

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[7] Throughout this document, the term jurisdiction will refer to a U.S. city, state, or territory that operates an IIS for the capture of patients and vaccinations administered within their unique jurisdictional area. CDC recognizes 64 jurisdictions as "immunization program awardees,", meaning that they receive funding under Section 317b of the Public Health Services Act. Awardees include the 50 states, 5 cities (New York City, Philadelphia, Houston, San Antonio, and Chicago), the District of Columbia, and 8 territories. AIRA also routinely includes the city of San Diego as an IIS jurisdiction. While not a CDC awardee, the city of San Diego successfully operates an IIS that is independent from the state of California.

[8] Administered April 2, 2020–April 24, 2020 to 64 CDC awardees plus the city of San Diego, California. Survey Monkey was used to collect responses.

[9] Administered May 26, 2020–June 5, 2020 to NAIIS participants. Survey Monkey was used to collect responses.

[10] IISSB conducted a series of interviews with all 64 immunization awardees. All interviews were completed over a two-and-a-half week period in April 2020 using several interview teams. The AIRA project team attempted to join as many interviews as possible within that time frame and strategically prioritized some key jurisdictions. The document titled "Awardee Pandemic Response Functionality Insights" was prepared by IISSB to summarize the results of the overall effort.

2 FINDINGS

SECTION 2 FINDINGS

Millions of doses of vaccine are distributed and administered each year through the efforts of the national immunization program.

IIS provide the critical infrastructure needed to facilitate the ordering, distribution, tracking, and reporting of these vaccinations. This document focuses on a specific subset of vaccinations that may be administered in response to a pandemic, disease outbreak, natural disaster, or other public health emergency necessitating a mass vaccination response. Mass vaccination refers to the tools and processes leveraged to facilitate response activities.

Mass vaccination campaigns typically exhibit the following characteristics:

- **Vaccinating large numbers of people in a short time frame.**
- **Strategically prioritizing the vaccination of select individuals when vaccine supply is limited.**
- **Antigen(s) or countermeasures being administered are typically campaign specific.**
- **Active tracking of doses distributed, doses administered, and doses on hand is critical to informing response efforts, including the movement of inventory if needed.**
- **Population coverage rates are used to inform and guide ongoing response efforts/decision making.**

A mass vaccination *campaign* is typically composed of a series of mass vaccination events. A campaign may be organized for a specific vaccine (like COVID-19 or influenza), outbreak response, natural disaster, or emergency response. Mass vaccination events are used to administer vaccine(s)/countermeasure(s) to the target population(s).

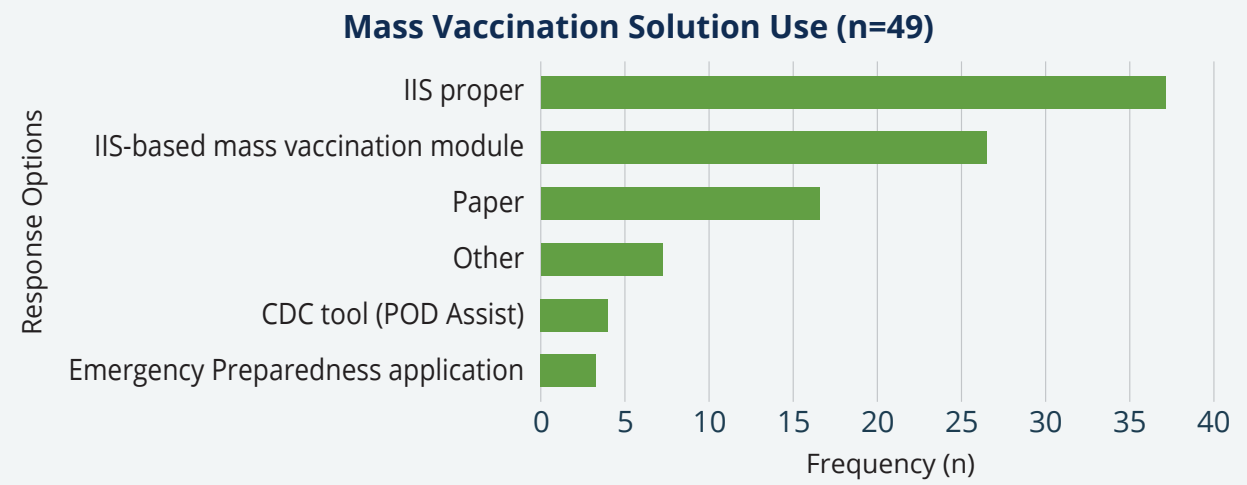
Several tools or strategies may comprise a jurisdiction's overall mass vaccination solution. How tools or strategies are deployed depends on the nature of the response and whether vaccine delivery will occur through routine medical service providers or through a coordinated point of dispensing, commonly referred to as a POD. A POD is a temporary vaccination clinic typically held at a large public facility (e.g., school gymnasium or parking lot) where members of the community can present themselves for vaccination in response to a mass vaccination campaign. On occasion, a closed-POD

model may be employed. A closed-POD is typically used to vaccinate a select group of individuals and is typically performed at a site that is specific to the target group (e.g., health care workers at a nursing home, firefighters at the firehouse, or students at school). Mass vaccination modules are most often deployed to support PODs or closed-PODs because these tools have been strategically designed for rapid data entry of patient and vaccination information and for facilitating high-volume throughput.

In order to assess which tools an immunization program/IIS would plan to employ to support a mass vaccination effort, AIRA surveyed jurisdictions to determine which tool(s) or platform(s) they would most likely use in a mass vaccination campaign.[11] Response options included core IIS, IIS-based mass vaccination module, emergency preparedness program mass vaccination/countermeasure response application, CDC countermeasure response tool (e.g., POD Assist), paper, or other. Respondents were able to select all options that applied. A comments field was provided to allow for additional elaboration.

Of the 49 jurisdictions that responded, "Core IIS" was the most common response, with 77% of respondents citing use of the IIS as either a main component or the main component of their mass vaccination solution. Approximately half (53%) of the respondents indicated that they plan to use some sort of IIS-based mass vaccination module. In addition, 53% of respondents indicated that their mass vaccination response would include the use of two or more tools or platforms. **Figures 1** and **2** provide a visual summary of the consolidated responses to this question.

Figure 1 | *Mass vaccination solution use – individual platform/tool count*



[11] Mass Vaccination Quick Survey: administered April 2, 2020–April 24, 2020 to 64 CDC awardees plus the city of San Diego, California.

Figure 2 | *Mass vaccination solution use – multiple response comparison*

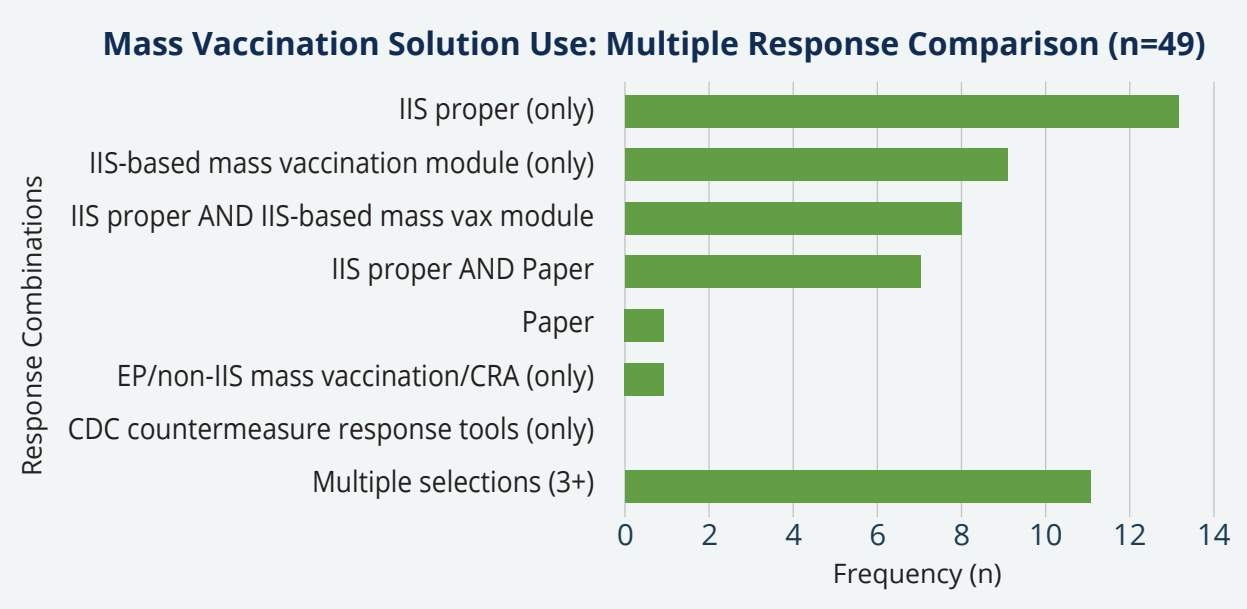


Table 1 provides a look at each jurisdiction and the various tools/components of their mass vaccination response as reported through the AIRA survey. This table elaborates on the summary views provided above and contains additional breakdown and detail collected in the open-ended response fields. The following acronyms appear in the table below and throughout the remaining document.

- Envision Technology Partners (Envision)
- STChealth (formerly Scientific Technologies Corporation) (STC)
- Wisconsin Immunization Registry (WIR)
- Awardee-developed[12] (AD)
- DXC Technology (DXC)
- HLN Consulting LLC (HLN)
- Maryland Partnership for Prevention (MPP)
- United States Centers for Disease Control and Prevention (CDC)

IIS Platforms

In the United States there are currently two commercial-off-the-shelf (COTS) IIS solutions: one is provided by Envision Technology Partners (Envision) and the other by STChealth (formerly Scientific Technologies Corporation) (STC). There is also one public domain platform, the Wisconsin Immunization Registry (WIR). The WIR system was developed for the state of Wisconsin, is licensed for use by other jurisdictions, and is typically supported by DXC Technology. In addition, there are a number of homegrown, awardee-developed applications. IIS utilization across these platforms/categories is fairly evenly distributed: Envision (27%), STC (18%), WIR (27%), and awardee-developed (27%).

[12] Non-commercial, homegrown solutions

Table 1 | *Mass vaccination solution use – individual jurisdictional responses*

STATE/ JURISDICTION	IIS PLATFORM[13]	CORE IIS	EHR INTERFACES**	IIS RAPID ENTRY SCREEN**	IIS-BASED MASS VACCINATION MODULE	EMERGENCY PREPAREDNESS TOOL	CDC RESPONSE TOOL(S)	PAPER	EXCEL/SPREADSHEETS**	OTHER
Alabama	AD				X					
Alaska	STC				X					
American Samoa	Envision	X						X		
Arizona	STC	X			X			X	X	X[14]
Arkansas	Envision				X					
California	WIR				X					X[15]
Chicago, IL*	AD-IL									
Colorado	Envision	X		X				X		
Connecticut	Envision	X								
Delaware*	Envision									
District of Columbia	AD		X					X		
Florida*	AD									
Georgia	WIR	X					X			
Guam	Envision	X						X		
Hawaii	WIR	X					X	X	X	
Houston*	WIR-TX									
Idaho*	WIR									

[13] In the United States there are currently two commercial-off-the-shelf (COTS) IIS solutions: one is provided by Envision Technology Partners (Envision) and the other by STChealth (formerly Scientific Technologies Corporation) (STC). There is also one public domain platform, the Wisconsin Immunization Registry (WIR). The WIR system was developed for the state of Wisconsin, is licensed for use by other jurisdictions, and is typically supported by DXC Technology. In addition, there are a number of homegrown, awardee-developed applications. IIS utilization across these platforms/categories is fairly evenly distributed: Envision (27%), STC (18%), WIR (27%), and awardee-developed (27%).

[14] Developed a .NET application that converts data from an Excel spreadsheet into an HL7 message and imports it into the IIS using the HL7 interface.

[15] Developed a module external to the IIS that is used for local health department mass vax flu events. The module converts data into HL7 messages and sends to the IIS in real time.

Table 1 | *Mass vaccination solution use – individual jurisdictional responses (continued)*

STATE/ JURISDICTION	IIS PLATFORM[13]	CORE IIS	EHR INTERFACES**	IIS RAPID ENTRY SCREEN**	IIS-BASED MASS VACCINATION MODULE	EMERGENCY PREPAREDNESS TOOL	CDC RESPONSE TOOL(S)	PAPER	EXCEL/SPREADSHEETS**	OTHER
Illinois	AD	X						X		
Indiana	STC				X					
Iowa	WIR	X								
Kansas	Envision			X	X			X		
Kentucky	Envision				X					
Louisiana	STC	X			X					
Maine	WIR				X					
Marshall Islands*	Envision									
Maryland	WIR					X[16]				
Massachusetts	AD	X								
Michigan*	AD									
Micronesia*	Envision									
Minnesota	WIR	X							X	
Mississippi	STC	X								
Missouri	Envision				X					
Montana	STC	X			X					
N. Mariana Islands*	Envision									
Nebraska	WIR	X								
Nevada	Envision	X						X		
New Hampshire[17]*	Envision									

[16] MPP's ReadiConsent tool, which has a bidirectional HL7 interface with the IIS
[17] New Hampshire is in the process of implementing a new IIS platform (Envision's WebIZ). The system is due to go live in 2021 but may have some limited functionality available by late 2020.

Table 1 | *Mass vaccination solution use – individual jurisdictional responses (continued)*

STATE/ JURISDICTION	IIS PLATFORM[13]	CORE IIS	EHR INTERFACES**	IIS RAPID ENTRY SCREEN**	IIS-BASED MASS VACCINATION MODULE	EMERGENCY PREPAREDNESS TOOL	CDC RESPONSE TOOL(S)	PAPER	EXCEL/SPREADSHEETS**	OTHER
New Jersey*	AD									
New Mexico	Envision	X		X						
New York City	AD/HLN	X		X				X		
New York State	WIR	X			X	X[18]				
North Carolina	WIR				X		X	X		
North Dakota	AD	X						X		
Ohio	STC	X	X		X					
Oklahoma	AD	X						X		
Oregon*	WIR									
Palau	Envision	X			X			X	X	
Pennsylvania	AD	X								
Philadelphia, PA	Envision	X								
Puerto Rico	WIR	X						X		
Rhode Island	AD/HLN	X		X			X	X		
San Antonio, TX*	WIR-TX									
San Diego, CA	AD	X								
South Carolina	AD	X								
South Dakota*	AD									
Tennessee	STC	X			X					X[19]
Texas	WIR				X					
Utah*	AD									

[18] Clinical Data Management System (CDMS); tool supports unidirectional reporting to the IIS.
[19] Uses REDCap and SAS to support mass vaccination activities

Table 1 | *Mass vaccination solution use – individual jurisdictional responses (continued)*

STATE/ JURISDICTION	IIS PLATFORM[13]	CORE IIS	EHR INTERFACES**	IIS RAPID ENTRY SCREEN**	IIS-BASED MASS VACCINATION MODULE	EMERGENCY PREPAREDNESS TOOL	CDC RESPONSE TOOL(S)	PAPER	EXCEL/SPREADSHEETS**	OTHER
Vermont	AD	X								
Virgin Islands*	WIR									
Virginia	WIR	X			X		X			X[20]
Washington	STC	X	X		X					
West Virginia	STC	X			X					
Wisconsin	WIR	X			X					
Wyoming	STC	X			X					

** Did not respond to the AIRA survey.*[21]

*** These categories were extrapolated from the open-ended comments field that accompanied this question in the survey and received multiple mentions. Other jurisdictions might have selected these options directly if they had been available as a formal response option in the survey questionnaire. EHR interfaces are essentially sub-components of the Core IIS solution, and IIS rapid entry screens—as described here—are represented as an alternative to a more traditional "mass vaccination module."*

[20] Local health departments in Virginia also use a homegrown billing system in which they enter doses administered that their staff have completed. This data is loaded into IIS daily.

[21] Response rate was 75%.

3

MASS VACCINATION SUPPORT TOOLS

SECTION 3 MASS VACCINATION SUPPORT TOOLS

The IIS and other mass vaccination tools provide functionality needed to facilitate a mass vaccination response as well as the capture of patient demographic and vaccination details.

These tools generally fall into one of four categories: (1) core IIS, (2) IIS-based mass vaccination tools, (3) emergency preparedness/countermeasure response systems, and (4) local/clinic-level solutions.[22] The following sections will provide a description of each category along with when and how each tool is used to support a mass vaccination response. This section will also identify existing tools available in the marketspace and provide an assessment of core functional attributes across the various mass vaccination tools.

CORE IIS

The purpose of the core IIS is to track patients and routine vaccination encounters. IIS serve as a centralized resource for consolidated patient immunization records and collectively contain tens of millions of patient and vaccination records. IIS have evolved over the years into sophisticated data management systems with tools and processes to support the entire immunization workflow for vaccination providers, state/local immunization program staff, and a variety of stakeholders. IIS-based tools to support mass vaccination campaigns have also evolved over time, and these tools rely heavily on the infrastructure of the core IIS.

In general, the core IIS fulfills the following roles for both routine vaccination and mass vaccination campaign support:

- Provider site management and user access
- Vaccine ordering and order fulfillment
- Inventory management and accountability

[22] Catch-all category to include EHRs, pharmacy systems, and other locally developed solutions used by medical providers, public health clinicians, and pharmacists to capture and report vaccinations administered through the health care delivery system.

- Campaign and event set-up for IIS-based mass vaccination solutions
- Capture of contraindications/precautions and adverse reactions
- Vaccine forecasting (clinical decision support) and reminder/recall for multi-dose series
- Coverage assessment
- Advanced reporting capabilities (e.g., canned reports and ad hoc queries)[23]

In addition, most vaccine providers leverage an electronic health record (EHR) system to enter and record all patient interactions. Pharmacies take a similar approach by relying on their existing pharmacy management systems. During a mass vaccination campaign using a dispersed (non-POD) vaccination model, many prospective vaccine recipients will likely visit their primary care provider, a public health immunization clinic, or a pharmacy to receive a vaccine.[24, 25] Over the past several years, IIS have prioritized and accelerated efforts to establish electronic interfaces between these provider platforms/pharmacy systems and the IIS in order to collect vaccine administrations in real time. Many IIS plan to leverage these existing interfaces, to the extent possible, for managing the collection of doses administered in traditional, non-POD settings.

IIS-BASED MASS VACCINATION TOOLS

IIS-based mass vaccination support tools can be loosely grouped into three categories: (1) rapid entry or quick-add screen, (2) integrated mass vaccination module, or (3) interfaced mass vaccination module. Mass vaccination modules were divided into "integrated" and "interfaced" modules based on wide-ranging differences identified during the attributes assessment (see also General attributes assessment). IIS-based mass vaccination tools have been used successfully to support various mass vaccination campaigns, such as the H1N1 pandemic, disease outbreak response efforts, and natural emergency displacements like Hurricane Katrina.

[23] Some IIS/immunization programs may be limited in their ability to generate their own ad hoc reports. This may present challenges, especially when trying to meet the needs of federal reporting requirements during a pandemic.

[24] The NAIIS survey revealed that 64% of respondents indicated that adults are most likely to get vaccinated with vaccines other than flu at their primary care provider, followed by pharmacies (14%) and hospitals (11%). When looking at flu vaccination, 48% of respondents indicated that adults are mostly likely to receive a flu vaccination from a pharmacy, followed by primary care provider (30%) and public health entity (8%). Additional results can be reviewed in Appendix D. NAIIS Poll Results – Adult Vaccination Practices.

[25] The NAIIS survey results for influenza vaccination echo results published in the Morbidity and Mortality Weekly Report (MMWR). The most common place for adults 18 years or older to receive flu vaccine in 2011–2012 was a doctor's office (38.2%), followed by a workplace (20.3%) or pharmacy (18.8%). https://www.cdc.gov/mmwr/preview/mmwrhtml/ss6204a1.htm

IIS RAPID ENTRY SCREEN

Rapid entry screens are an integrated component of the core IIS, and access is granted by user-based roles and permissions. These screens are simply streamlined versions of the typical patient search, demographic entry, and vaccination entry screens used in the routine IIS workflows/screenflows. These streamlined screens can be configured to require fewer data entry fields and maximize the use of user-selected default values. The primary goals of a rapid entry screen are to reduce data entry burden, decrease the amount of time required to enter a record, and increase the volume of records entered within a short time period. Rapid entry screens are ideal for entering large volumes of paper records into the IIS, with some IIS successfully leveraging the screens to support onsite, real-time data entry during mass vaccination events. Use of rapid entry screens relies on the availability of an active internet connection.

The following list includes common features of a rapid entry screen:

- Requires an IIS username/password to log in and access the rapid entry screen
- Provides immediate access to all patient records that exist in the core IIS
- Tools to expedite entry of patient demographics during patient registration/intake
  - Reduce or minimize the number of required data entry fields
  - Allow users to establish and leverage default values for fields that routinely have the same value
- Tools to expedite data entry during vaccine/countermeasure administration
  - Reduce or minimize the number of required data entry fields
  - Allow users to establish and leverage default values for fields that routinely have the same value
- Doses are immediately recorded in the IIS database
- Ability to automatically decrement inventory count as administered doses are recorded

INTEGRATED MASS VACCINATION MODULES

Integrated mass vaccination modules are integrated components of the core IIS, and access is granted by user-based roles and permissions. Like rapid entry screens, mass vaccination modules are configured to require fewer data entry fields and maximize the use of user-selected default values. Unlike rapid entry screens, integrated mass vaccination modules are configured to support specific mass vaccination campaign(s) or event(s). Mass vaccination modules are streamlined to support real-time data entry during a mass vaccination event. Use of integrated mass vaccination modules relies on the availability of an active internet connection.

The following list includes common features of an integrated mass vaccination module:

- Requires an IIS username/password to log in and access the mass vaccination module
- Provides immediate access to all patient records that exist in the core IIS
- Ability to tie patients, vaccinations, inventory, and reporting to a specific event or campaign
- Ability to leverage unique inventory items that will be used for the specific event or campaign
- Tools to expedite patient lookup during patient registration/intake
  - Use barcodes generated by the IIS and displayed on client documents (e.g., official immunization records, reminder/recall notices,[26] consumer portal printouts[27])
- Tools to expedite entry of patient demographics during patient registration/intake
  - Reduce or minimize the number of required data entry fields
  - Allow users to establish and leverage default values for fields that routinely have the same value
  - Auto populate city and state from ZIP code
- Ability for user to assign individuals to a specified priority group or tier
- Tools to expedite data entry during vaccine/countermeasure administration
  - Reduce or minimize the number of required data entry fields
  - Allow users to establish and leverage default values for fields that routinely have the same value:
    - Clinic location
    - Date of administration (date of clinic)
    - Vaccinating/administering provider
    - Vaccine Information Statement (VIS) date
    - VIS date given (date of clinic)
    - Inventory item details (if pulling from a single lot number)
  - Use inventory bar code scanning from boxes or vials to populate inventory item details[28]
  - Use inventory barcodes generated by the IIS (e.g., scan sheets[29])
    - Doses are immediately recorded in the IIS database
    - Ability to automatically decrement inventory count as administered doses are recorded
    - Ability to support multiple mass vaccination campaigns simultaneously (e.g., COVID-19, annual influenza campaign, and hepatitis A outbreak)
    - Ability to configure a single campaign to support multiple vaccines/countermeasures as part of the same event (e.g., COVID-19 vaccine and annual influenza vaccine)

[26] STC's IWeb
[27] STC's MyIR (Louisiana, Maryland, Arizona)
[28] STC's IWeb and Mass Immunizations Module, and CDC's POD Assist
[29] Envision's Mobile WebIZ, STC's IWeb and Mass Immunizations Module, and CDC's POD Assist

INTERFACED MASS VACCINATION MODULES

Interfaced mass vaccination modules have dependencies on the core IIS but operate as stand-alone tools on mobile devices (e.g., tablets, thumb drives, disconnected laptops). Like integrated mass vaccination modules, interfaced modules are configured to support specific mass vaccination campaign(s) or event(s) and are streamlined to support real-time data collection during a mass vaccination event. Interfaced mass vaccination modules are internet neutral and can operate without an active internet connection. Because these tools can operate with or without internet, they are typically configured ahead of time with details from the IIS (e.g., campaign/event information, inventory, user and vaccinator details, pre-defined patient cohorts[30]). When an active internet connection is available, the interfaced module may have the ability to search the IIS database in real time and report patients and vaccination details to the IIS upon administration. When no internet connection is available, all patients and vaccination details are reported back to the IIS post-event.

The following list includes common features of an interfaced mass vaccination module:

- Requires a username/password for logging in and accessing the platform
- Potential to provide immediate access to all patient records that exist in the core IIS with an internet connection and bidirectional interface
- Ability to tie patients, vaccinations, inventory, and reporting to a specific event or campaign
- Ability to leverage unique inventory items that will be used for the specific event or campaign
- Tools to expedite patient lookup during patient registration/intake
  - Leverage cohorts to identify participants prior to event
  - Use driver's license barcode scanning[31] to generate search criteria (e.g., first name, last name, date of birth, and address)
  - Use barcodes generated by the IIS or CRA module and displayed on client documents (e.g., official immunization records, reminder/recall notices,[32] consumer portal printouts,[33] clinic registration confirmation[34])

[30] A cohort is a group of individuals who have been identified and grouped together based on specific characteristics (e.g., age or age bracket, occupation, affiliation with a clinic or school).
[31] Envision's Mobile WebIZ
[32] STC's IWeb
[33] STC's MyIR (Louisiana, Maryland, Arizona)
[34] MPP's ReadiConsent tool and CDC's POD Assist

- Tools to expedite entry of patient demographics during patient registration/intake
  - Reduce or minimize the number of required data entry fields
  - Use driver's license barcode scanning to populate core demographic fields (e.g., first name, last name, date of birth, and address)[35]
- Ability for user to assign individuals to a specified priority group or tier
- Tools to expedite data entry during vaccine/countermeasure administration
  - Reduce or minimize the number of required data entry fields
  - Use inventory barcodes generated by the IIS or CRA module (e.g., scan sheets[36] or mobile device quick response (QR) codes[37])
- Mechanism to report patients and doses administered to the core IIS, preferably in real time when internet access is readily available
- Ability to automatically decrement inventory count as administered doses are reported to the IIS
- Ability to support multiple mass vaccination campaigns simultaneously (e.g., COVID-19, annual influenza campaign, and hepatitis A outbreak)
- Ability to configure a single campaign to support multiple vaccines/countermeasures as part of the same event (e.g., COVID-19 vaccine and annual influenza vaccine)

Interfaced mass vaccination modules may also have capabilities beyond those found in an integrated mass vaccination module. While interfaced modules are closely tied to the IIS, these tools have evolved on independent platforms and are not as constrained by the core IIS infrastructure as their integrated counterparts. Some of the unique features that may be available in an interfaced mass vaccination module include:

- **Front-end/back-end workflows –** ability to leverage technology to support a variety of clinic layouts and workflows (see also the section titled POD flow dynamics)
- **Electronic user consent –** ability to read and electronically sign a consent to treat statement
- **Full-scale patient screening –** ability to capture responses to a screening questionnaire[38] prior to vaccine/countermeasure administration
- **DMV license scans –** ability to scan the barcode on a driver's license or state issued identification card to search for a patient in the database and/or populate the basic demographic information from the scan (e.g., first name, last name, date of birth, and address)
- **Tracking of labs/lab testing –** ability to document that a sample was taken, that a test had been run, and/or the result of a test that had been run

[35] Envision's Mobile WebIZ
[36] Envision's Mobile WebIZ, STC's IWeb and Mass Immunizations Module, and CDC's POD Assist
[37] Envision's Mobile WebIZ
[38] Form examples: https://www.immunize.org/catg.d/p4060.pdf and https://www.immunize.org/catg.d/p4065.pdf

EMERGENCY PREPAREDNESS/COUNTERMEASURE RESPONSE ADMINISTRATION TOOLS

Emergency preparedness/countermeasure response administration (EP/CRA) tools[39] have evolved independent of IIS-based solutions. The scope of these tools is typically expanded beyond vaccinations to include the capture of countermeasures, medications, and laboratory testing and occasionally includes other expendable supplies (e.g., syringes, band-aids, personal protective equipment (PPE)). EP/CRA are stand-alone tools. As such, these applications have no dependencies on their respective IIS counterpart(s). System configuration, event support features, and the database used to collect patient and vaccination data are managed entirely within the EP/CRA. While EP/CRA tools typically support some high-level inventory management features (e.g., doses on hand, doses administered), these solutions do not include functionality for vaccine ordering, order fulfillment, or the end-to-end accountability available through an IIS platform.

Some additional features that are unique to EP/CRA solutions include:

- Self-registration through a website or mobile device application (completed onsite or prior to the event)[40]
- Householding features (the ability to register multiple individuals living at the same address using a single registration form)
- Appointment scheduling tools
- Ability to recommend vaccine/countermeasure based on screening questionnaire responses
- Insurance billing support

Because EP/CRA are stand-alone tools, they do not share the benefits of accessing patients, vaccination records, and clinic inventory that exist within the IIS. Further, EP/CRA tools have minimal reporting, data analytic options, and patient follow-up features. EP/CRA solutions may or may not have an established interface for reporting dose administrations to the IIS. When doses administered are not reported to the IIS, the doses are not integrated with the patient's complete/official immunization record and are more at risk of becoming lost or misplaced. EP/CRA solutions would need to establish a unidirectional or bidirectional HL7 interface with the IIS or leverage a flat file upload in order to take advantage of the more robust patient support and reporting features available through the IIS.

[39] "Emergency Preparedness Tool" and "CDC Response Tool(s)," from Table 1. Mass Vaccination Solution Use – Individual Jurisdictional Responses, were combined and categorized as EP/CRA tools because these tools/solutions display the same/similar core attributes.
[40] MPP's ReadiConsent tool and CDC's POD Assist

OTHER SOLUTIONS

There were also a few miscellaneous solutions reported by the IIS community or identified through research that do not fit into one of the primary options detailed above. These solutions include the use of paper, Excel spreadsheets, web-based survey tools, and locally developed/clinic-level solutions.

Many immunization programs and IIS plan to use paper forms as a backup option should something go wrong with their IIS-based or EP/CRA solution.[41] Some jurisdictions reported that paper may be their primary data collection strategy. Ideally paper should be avoided to the greatest extent possible. Paper reporting creates additional administrative burden on staff to print, collect, enter, and dispose of forms. Paper also introduces concern about infection control from physical handling. Additionally, handwritten responses can be difficult to read, and transcription leads to increased data entry errors. Ability to track inventory and doses administered within a meaningful time frame is also impacted due to data entry delays. Following H1N1, a number of jurisdictions discussed paper-based challenges and expressed disappointment over the number of paper records that never made it into the IIS.

Some immunization programs/IIS have explored or implemented a spreadsheet-based alternative. The benefit of a spreadsheet is that data can be converted into a format that can ultimately be uploaded or scripted into the IIS database. The state of Arizona developed a .NET application to convert data from an .xls file into HL7 messages that can be uploaded through the IIS HL7 web service. Spreadsheets are typically being populated using one of three methods: (1) data from paper forms are entered into an Excel spreadsheet during an event or after, (2) data are entered into an Excel spreadsheet in real time as an alternative "rapid entry screen," or (3) a web-based survey tool, like REDCap or SurveyMonkey, is used for data collection in real time, and an .xls file is produced from the survey tool post event. These spreadsheets can then be uploaded to the IIS. Use of spreadsheets provides a readily accessible, low-cost alternative for jurisdictions that do not already have access to a mass vaccination solution.

Finally, there are a number of locally developed solutions. These solutions have been developed to fulfill locally defined business needs or requirements for clinic-level support. These local tools are generally not scalable to fulfill the needs of a nationwide mass vaccination response.

[41] In the AIRA Mass Vaccination Quick Survey of the IIS community, 33% of respondents included "paper" as one of the tools they are most likely to use during a mass vaccination campaign.

MASS VACCINATION PRODUCTS IN THE MARKETSPACE

In conjunction with the AIRA Mass Vaccination Quick Survey question used to assess immunization program/IIS mass vaccination solutions, respondents were asked to describe the specific tools being used in their respective jurisdiction and to identify the vendor/product developer. Additional tools were identified in conjunction with the Literature Review deliverable provided to the CDC Office of the Associate Director for Adult and Influenza Immunization under separate cover. **Table 2** represents all *known* tools and resources currently (or recently) available in the marketspace to support mass vaccination efforts as of the date of this report. Due to the limited and/or restricted access to immunization program staff and other emergency response staff in conjunction with COVID-19, it is possible that this list does not represent every tool that exists across the entire immunization/emergency preparedness community.

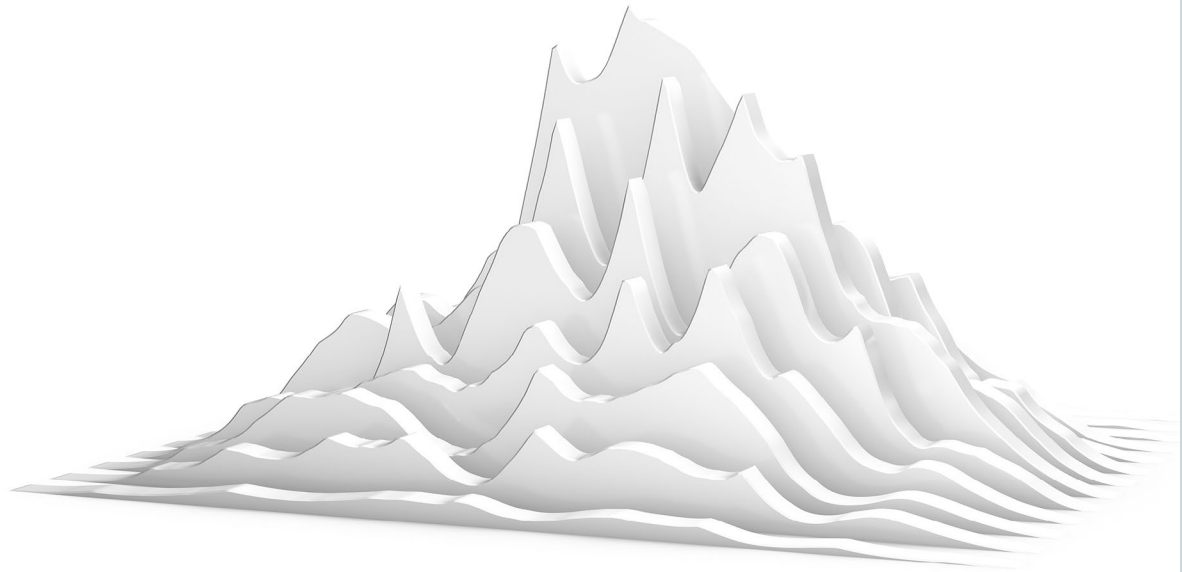


Table 2 | *Mass vaccination tools and resources*

TOOL TYPE	PRODUCTS/VENDORS
Rapid entry screen	• WebIZ IZ Quick Add Module* – Envision • Rapid Data Entry Module – Rhode Island/HLN • Quick-Add Module – New York City/HLN • Paper Data Entry Module (sunset) – STC
Mass vaccination modules (integrated and interfaced)	• Mass Immunization Module* – STC • Mass Immunization Stand-alone* – STC • First Responder Module* – STC • WebIZ Mass Events Module* – Envision • Mobile WebIZ* – Envision • Mass Vaccination Module (WIR-Maine edition) – DXC • Mass Vaccination/CRA Module (WIR-North Carolina edition) – DXC • Mass Vaccination Module (WIR-Wisconsin edition) – DXC
Emergency preparedness/ CRA modules	• POD Assist – CDC • Dispense Assist – CDC • Vaccine Administration Management System (VAMS) – CDC (scheduled release: July 2020) • ReadiConsent/ClinicWizard/PrepMod – MPP • Vaxigo – AZOVA • Clinical Data Management System (CDMS) – New York state • WebCRA (sunset) – Envision • Countermeasure and Response Administration System (sunset) – CDC
Local and clinic-level examples	• Handheld Automated Notification for Drugs and Immunizations (HANDI) – Denver Public Health • Local health department mass influenza module – California Immunization Program • Local health department billing systems – Virginia Immunization Program • VaxCare Mobile Clinic Solution – VaxCare Corporation
Excel/web survey solutions	• .NET application (converts .xls to HL7 messages) – Arizona IIS • REDCap – Tennessee IIS

** Add-on module available for an additional cost. Features may not be available to all jurisdictions using the respective IIS platform.*

GENERAL ATTRIBUTES ASSESSMENT

As part of the information gathering process, AIRA had the opportunity to observe demonstrations and/or review documentation for several of the mass vaccination and EP/CRA solutions. Systems were assessed against a simple attributes matrix of common core functionality. Due to the limited and/or restricted access to product vendors and immunization program/IIS staff in conjunction with COVID-19, AIRA was not able to assess all of the mass vaccination platforms, gather all desired information, or validate/confirm assessment findings with vendors and immunization program/IIS staff. **Table 3** provides a summary of common attributes that comprise the various mass vaccination support tools.

It should be noted that the table does not present an assessment of each individual product/vendor but, rather, a collective assessment of features and functionality based on the general tool "type" or category. The general attributes assessment reflects features that are common (or not common) across all or most solutions of this "type." As such, there may be features that exist in one platform but do not commonly exist in others. The color coding in the table can be interpreted as follows:

- Attribute is present in all or most solutions
- Attribute is present to some degree or present in some solutions
- Attribute is not common or not typically present
- Attribute relies on the core IIS*

***An item designated as having an attribute that relies on the core IIS means that the tool itself does not have this feature but directly leverages the IIS and IIS database to provide this support for the mass vaccination tool. EP/CRA tools will never have this designation because these tools are separate from the IIS and have no IIS dependencies.**

Table 3 | *General attributes assessment*

	IIS CORE	RAPID ENTRY	MASS VAX – INTEGRATED	MASS VAX – INTERFACED	EP/CRA
SYSTEM CONFIGURATION					
Provider enrollment	◎	⚙	⚙	⚙	◎
User enrollment	◎	⚙	⚙	⚙	◎

Table 3 | *General attributes assessment (continued)*

	IIS CORE	RAPID ENTRY	MASS VAX – INTEGRATED	MASS VAX – INTERFACED	EP/CRA
SYSTEM CONFIGURATION					
Online ordering/ distribution	●	⚙	⚙	⚙	◎
Inventory management	●	⚙	⚙	⚙	●
Countermeasures/ medications	◎	◎	◎	◎	●
Expendable supplies/materials	◎	◎	◎	◎	○
CAMPAIGN/EVENT SUPPORT					
Configure campaign[43]	●	⚙	⚙	⚙	●
Designate an event or campaign	○	○	●	●	●
Support multiple campaigns simultaneously	○	○	●	●	○
Support multiple vaccines/ countermeasures for a single campaign[44]	○	○	●	●	◎
Use of mobile devices	◎	◎	◎	●	●
Front-end/back-end workflows	◎	◎	◎	●	●
Ability to schedule appointments	◎	◎	◎	◎	●

● Attribute is present in all or most solutions
○ Attribute is present to some degree or present in some solutions
◎ Attribute is not common or not typically present
⚙ Attribute relies on the core IIS*

[43] Examples include: naming the campaign, forms selection and forms language, field selection and field labels/values, identifying which countermeasures will be included in the campaign, tier group designations, and loading of patient cohorts/rosters (especially if deploying to an offline clinic site).

[44] Some tools/platforms have functionality to support a campaign that offers more than one vaccine/countermeasure (e.g., COVID-19 and influenza) as part of the same campaign. Other tools are able to support only a single vaccine/countermeasure for a campaign. For those offering only a single vaccine/countermeasure, users would have to set up a campaign for COVID-19 or for influenza. For systems with functionality to support multiple campaigns that can run simultaneously, users would have to configure a separate campaign for COVID-19 and a separate campaign for influenza that would run in parallel but independently of each other.

Table 3 | *General attributes assessment (continued)*

	IIS CORE	RAPID ENTRY	MASS VAX – INTEGRATED	MASS VAX – INTERFACED	EP/CRA
CAMPAIGN/EVENT SUPPORT					
Captures electronic user consent	◉	◉	◉	◉	◉
Full patient screening	◉	◉	◉	◉	◉
Tier group assignment	◉	◉	◉	◉	◉
Recommend vaccines/ countermeasures from screening responses	◉	◉	◉	◉	◉
EXPEDITED PATIENT LOOKUP					
Patient rostering/cohorts	◉	◉	◉	◉	◉
Driver's license scanning	◉	◉	◉	◉	◉
Scanning of system generated barcodes/QR	◉	◉	◉	◉	◉
EXPEDITED DEMOGRAPHIC ENTRY					
Reduced data entry requirements	◉	◉	◉	◉	◉
User-selected default values	◉	◉	◉	◉	◉
Using driver's license scan to populate demographics	◉	◉	◉	◉	◉
Self-registration interface	◉	◉	◉	◉	◉
Householding	◉	◉	◉	◉	◉

◉ Attribute is present in all or most solutions

◉ Attribute is present to some degree or present in some solutions

◉ Attribute is not common or not typically present

⚙ Attribute relies on the core IIS*

Table 3 | *General attributes assessment (continued)*

	IIS CORE	RAPID ENTRY	MASS VAX – INTEGRATED	MASS VAX – INTERFACED	EP/CRA
EXPEDITED VACCINE/ COUNTERMEASURE ENTRY					
Reduced data entry requirements	◎	◎	◎	◎	◎
User-selected default values	◎	◎	◎	◎	◎
Barcode scanning from boxes or vials	◎	◎	◎	◎	◎
Scanning of system generated barcodes/QR	◎	◎	◎	◎	◎
OTHER					
Capture contraindications/ precautions	◎	⚙	◎	⚙	◎
Track adverse reactions	◎	⚙	⚙	⚙	◎
Capture lab order, test, and/or test result	◎	◎	◎	◎	◎
Reminder/recall	◎	⚙	⚙	⚙	◎
Insurance billing	◎	◎	◎	◎	◎
REPORTING					
Doses administered (individual patient list)	◎	⚙	⚙	⚙	◎
Doses administered (aggregate count)	◎	⚙	⚙	⚙	◎

◎ Attribute is present in all or most solutions

◎ Attribute is present to some degree or present in some solutions

◎ Attribute is not common or not typically present

⚙ Attribute relies on the core IIS*

Table 3 | *General attributes assessment (continued)*

	IIS CORE	RAPID ENTRY	MASS VAX – INTEGRATED	MASS VAX – INTERFACED	EP/CRA
REPORTING					
Doses administered by age (aggregate counts)	◎	⚙	⚙	⚙	◎
Inventory: doses ordered	◎	◎	◎	◎	◎
Inventory: doses distributed	◎	◎	◎	◎	◎
Inventory: available doses on hand	◎	⚙	⚙	⚙	◎
Ad hoc reporting capabilities	◎	⚙	⚙	⚙	◎
Coverage assessments	◎	⚙	⚙	⚙	◎
INTEROPERABILITY					
Unidirectional HL7	◎	◎	◎	◎	◎
Bidirectional HL7	◎	◎	◎	◎	◎
Flat file transmission	◎	◎	◎	◎	◎
Server syncing	◎	◎	◎	◎	◎

◎ Attribute is present in all or most solutions

◎ Attribute is present to some degree or present in some solutions

◎ Attribute is not common or not typically present

⚙ Attribute relies on the core IIS*

POD FLOW DYNAMICS

Flow dynamics and the placement of technology in the clinic workflow is an important factor when assessing the capabilities and attributes of the various mass vaccination tools. This is especially true for PODs since these are temporary vaccination clinics hosted in non-traditional settings. Some mass vaccination solutions are capable of supporting a front-end/back-end workflow, whereas others can be used only with a single-station model. The primary goal is to avoid bottlenecks and maximize clinic throughput.

In a single-station model, data entry for patient registration and vaccination occur at the same workstation. There may be multiple workstations operating in parallel, but each station is responsible for an individual patient from start to finish. Data entry may occur in real time, at the point of checkout, or post event. The downside of real-time data entry is that vaccinating clinicians may spend a lot of time performing patient searches and demographic data entry, which may not be the most efficient or effective use of these clinical staff resources.

In a front-end/back-end workflow, there is a patient registration phase and a vaccination phase. On the front end, patient demographics are collected, consent is gathered (if needed), and a screening questionnaire[45] is completed. At this point, capable systems will either queue patients to a roster (aka "rostering") or provide a QR code or barcode that the patient can present at the vaccination station. Depending on system capabilities, the registration phase may be completed independently by the individual using a home computer, tablet, or smartphone. Registration may also be performed once the individual arrives onsite. On the back end, the screening questionnaire is reviewed, and vaccinations are administered and recorded. Patients who had been queued to a roster are pulled up from the list to complete recording of the vaccination encounter. For systems using a QR code or barcode, the code is scanned at the vaccination station, and the patient's record is pulled into context in order to proceed with entry of the vaccination details.

Table 4 below provides a summary of which mass vaccination tools are best suited to the alternative workflow options described above. While all of the tools can be used to support a single-station workflow, only interfaced mass vaccination tools, EP/CRA platforms, and paper forms are well suited for a front-end/back-end clinic flow dynamic.

[45] Screening can take place at either the registration or vaccination station. Placement may be determined by the desired workflow and/or system capabilities.

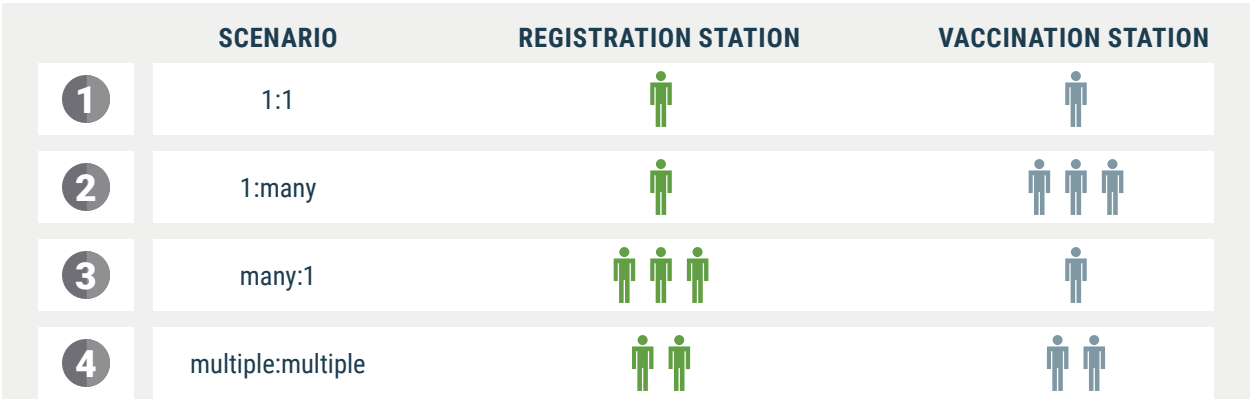
Table 4 | *Mass vaccination tools and workflows*

	SINGLE-STATION	FRONT-END/BACK-END
IIS core	■	■
Rapid entry screen	■	■
Mass vax – integrated	■	■
Mass vax – interfaced	■	■
EP/CRA	■	■
Paper	■	■
Excel spreadsheet	■	■

■ Supported
■ Partially supported
■ Not supported

For systems capable of supporting a front-end/back-end workflow, available staff and technical resources may ultimately determine how a POD is configured. Clinic flow should be configured to maximize throughput and minimize bottlenecks. If patient registration is a bottleneck, more registration stations may be needed. If patient registration is streamlined or most patients self-registered prior to the event, more vaccination stations may be needed. **Figure 3** below depicts some of the possible configuration scenarios a POD administrator may consider. POD configuration may also depend on the nature of the emergency and the nature of the response.

Figure 3 | *POD station scenarios*



4 CONSIDERATIONS

SECTION 4 CONSIDERATIONS

The following sections describe some additional considerations that may directly impact how or if an IIS-based mass vaccination or other emergency response solution can be used to meet the collection and reporting requirements of a mass vaccination event or campaign.

The following narrative also examines whether existing IIS-based solutions can be expanded to properly support efforts that may include countermeasures/medications and/or laboratory testing components. Topics covered in this section include:

- Vaccine/countermeasure support
- Inventory management
- Consent
- Identifying high-risk populations/priority tiers
- Clinical decision support
- Security
- Operational challenges
- Usability

VACCINE/COUNTERMEASURE SUPPORT

All IIS, mass vaccination modules, and EP/CRA modules are enabled to support the tracking and distribution of any vaccine currently listed on the Advisory Committee on Immunization Practices (ACIP) recommended immunization schedules for children and adults.[46] Most platforms also provide support for travel vaccines and bioterrorism threats (e.g., smallpox and anthrax). For an IIS-based solution, vaccine/countermeasure support features extend to managing inventory, recording of a vaccine administration, interoperability through electronic interfaces with provider EHR systems, clinical decision support, full reporting capabilities, reminder/recall support, and generating coverage assessments.

When a vaccine for a novel virus like influenza H1N1 or SARS-CoV-2 enters the marketspace, a new CVX code[47] and corresponding National Drug Code (NDC) number(s) must be added to the database

[45] https://www.cdc.gov/vaccines/schedules/index.html

[47] A vaccine administered (CVX) code is used to uniquely identify active and inactive vaccines available in the U.S. and for recording non-U.S. vaccine administrations. The CVX code set is used primarily for electronic data exchange. Current CVX code set: https://www2a.cdc.gov/vaccines/IIS/IISStandards/vaccines.asp?rpt=cvx.

in order to properly manage the new vaccine. The new vaccine must then be added to all relevant system operations and reports. Because the development life cycle[48] can be time consuming, the sooner these codes are identified, the sooner product vendors/developers can queue up and deploy the necessary changes.

With the ongoing development of a SARS-CoV-2 vaccine, early discussion indicates that one or more formulations could potentially require the use of a separate adjuvant. This is typically not an issue for vaccine products already on the market that contain an adjuvant added directly during the manufacturing process. The challenge for IIS and IIS-based mass vaccination modules is that there is not a good model for capturing a vaccine that is paired with a separate adjuvant product (i.e., unique products packaged separately), and the situation becomes increasingly complicated if the vaccine and adjuvant are produced by different manufacturers. In addition, if tracking of a separate adjuvant becomes necessary, especially if the vaccine/adjuvant are part of a multi-dose series, IIS will also need a mechanism to recognize the pairing for both reminder/recall and vaccine safety monitoring.

If a separate adjuvant administration should become necessary, there are two options: (1) collect the vaccine and adjuvant as separate vaccination events, or (2) collect the vaccine and adjuvant as the same vaccination event. In general, IIS, mass vaccination modules, and EP/CRA modules could be equipped to collect an adjuvant as a separate event if the adjuvant is assigned a unique CVX code and NDC number. The challenge is that the adjuvant will appear as a separate vaccine, separate inventory item, and separate vaccination event, not a component of the SARS-CoV-2 administration. If the vaccine and adjuvant are manufactured by the same pharmaceutical company and can be packaged together, the vaccine and adjuvant could feasibly be tracked as a single vaccination event using a process similar to a Pentacel (DTaP-IPV-Hib) vaccine administration. Pentacel, manufactured by Sanofi Pasteur, is packaged with a single-dose vial of liquid DTaP-IPV that is used to reconstitute the powdered Hib component. The Pentacel box and Hib component have the same lot number, and this lot number is used to record and track the administration of all three components of the combination vaccine. There is currently no precedent or prototype supported in the IIS infrastructure to track an individual vaccine (unique CVX/NDC, manufacturer, lot number) and an individual adjuvant (unique CVX/NDC, manufacturer, lot number) together as a single vaccination event. If this level of functionality is needed or desired, considerable guidance would be needed on how to successfully accomplish a pairing of this nature.

[48] A typical development life cycle includes the following stages: (1) requirements/design, (2) system coding, (3) testing/quality assurance (QA), (4) code fixes and retesting if needed, and (5) deployment to client environments. Following deployment, jurisdictions often perform their own testing in a testing or QA environment before deploying to their production environments. If there are issues during client-level testing/QA, especially critical issues, these issues are reported back to the developer, and the development life cycle begins again as a bug fix.

Some IIS and mass vaccination modules are or can be equipped to also capture countermeasures/medications. In some cases, these items must be added directly to the database by the system vendor/developer through the back end. Addition of a countermeasure/medication is driven entirely by the NDC number since these items are not assigned to the CVX code set. In general, the functionality for countermeasure/medication administration is more commonly found in EP/CRA modules where the user can readily create a campaign/event and inventory items to support the capture of countermeasures/medications. There are currently no examples of these administrations being reported back to the IIS. In some jurisdictions, the legal authority for the IIS may expressly prohibit the collection of non-vaccine administrations.[49] In other jurisdictions, while technically feasible, there are no plans to expand—or interest in expanding—the IIS to support non-vaccine administrations.

On occasion, a need may arise to monitor the distribution and use of other supplies (e.g., syringes, band-aids, PPE) or other resources (e.g., ventilators, blankets). Of the systems reviewed for this project, only the MPP ReadiConsent/ClinicWizard/PrepMod tool supported the capacity to track this type of inventory. There are no plans currently to expand IIS or mass vaccination modules to support distribution and use of supplies or other resources.

INVENTORY MANAGEMENT

Most IIS have the ability to identify providers that are participating in a special vaccination effort, such as H1N1 or COVID-19, and differentiate these providers from traditional vaccinators, such as Vaccines for Children (VFC) providers or adult vaccinators. The most common methods for differentiating providers include:

- Assignment of a modified personal identification number (PIN) for vaccine ordering (e.g., all COVID-only providers begin with the number 8)
- Creation and assignment of special order sets (e.g., pediatric order set, adult order set, COVID-only order set)
- Designation to a special category or program in the facility's IIS profile identifying the clinic as a mass vaccination participant
- Use of a special naming scheme (e.g., COVID – Primary Care Associates) or facility type (e.g., COVID provider)

[49] For example, in Arizona non-vaccines are not covered under state mandate/authorization.

This allows the IIS to offer continued support to routine VFC and Section 317 providers while also accommodating the ordering and distribution needs of the pandemic/emergency response efforts. Additional benefits of using the IIS to facilitate mass vaccine distribution include the ability to leverage the existing IIS-VTrckS-McKesson interface/infrastructure,[50] all of the vaccine accountability tools that exist in IIS platforms, and the advanced reporting tools available through IIS canned reports and ad hoc back-end queries.

One of the primary challenges for use of the IIS in a mass vaccination scenario is the ability to manage pre-booking of vaccine and/or push-based allocation of initial inventory once vaccine becomes available. Most IIS operate on a standard order>>order approval>>order fulfillment methodology; however, during a pandemic or emergency event where there is high demand, low supply, and a need to prioritize vaccine requests, alternative approaches may be needed. Pre-booking allows providers to request the amount of vaccine needed to protect their respective patient population and helps immunization programs and planners gauge overall demand. Pre-booking is typically done during the planning and preparation phase of a mass vaccination campaign. Push-based allocation allows immunization programs to prioritize where and how limited vaccine supply will be allocated to ensure that the highest-priority providers and/or highest-priority recipients receive vaccine in the initial waves. Some IIS have functionality to support pre-booking,[51] others have functionality to support allocation,[52] but very few have the ability to support both.[53]

Many immunization programs opt instead to use spreadsheets or web-based survey tools to capture vaccine pre-booking requests, and then they fill orders or determine allocations based on these requests. This process allows immunization programs to prioritize provider requests, fulfill partial orders, and distribute vaccine as the supply catches up to demand. Spreadsheets and web-based survey tools offer an easy, cost-effective method for immunization programs to manage these processes. At present, most immunization programs plan to apply the tools and processes they use for annual influenza planning and distribution to respond to the current COVID-19 pandemic.

Many immunization programs opt instead to use spreadsheets or web-based survey tools to capture vaccine pre-booking requests, and then they fill orders or determine allocations based on these

[50] This infrastructure is currently used for the ordering and fulfillment of all VFC vaccine inventory requests and was used as the primary ordering and distribution mechanism during the H1N1 response. A graphic depiction of this process is provided in Appendix E. IIS-VTrckS-McKesson Data Flow. VTrckS is CDC's ordering and inventory tracking solution for publicly funded vaccine.
[51] Delaware, Kentucky, Michigan, Pennsylvania
[52] Arizona, Louisiana, Maryland, Massachusetts, New Mexico
[53] Rhode Island, Wisconsin

requests. This process allows immunization programs to prioritize provider requests, fulfill partial orders, and distribute vaccine as the supply catches up to demand. Spreadsheets and web-based survey tools offer an easy, cost-effective method for immunization programs to manage these processes. At present, most immunization programs plan to apply the tools and processes they use for annual influenza planning and distribution to respond to the current COVID-19 pandemic.

CONSENT

The newer EP/CRA modules and the more robust mass vaccination modules are now enabled with digital consent as part of the online registration process. These consent forms typically address consent to treat, but language can also be expanded to include consent to bill insurance for services. Consent forms are stored locally in the application. Following vaccination, consent to treat or bill is typically not reported to the IIS and, if it is, is not visible through the core IIS user interface.

In jurisdictions where the IIS operates under an opt-in consent mandate, these digital consent features could possibly be expanded to address explicit consent requirements. This information would need to be transmitted and recorded in the IIS in accordance with the specific mandate and respective IIS functionality. During a mass vaccination campaign, state and local consent mandates for IIS are often suspended temporarily to accommodate federal and command center needs for real-time updates on inventory availability, community demand, and population coverage.[54] Currently, only three states have a standing opt-in requirement for children and adults (Texas, Montana, and Kansas). These states require formal written consent for inclusion in the IIS. New York state (including New York City) requires that adults opt in to the IIS, but consent can be written or verbal.[55] During the H1N1 response effort, opt-in jurisdictions were able to successfully suspend their consent requirements on a temporary basis.

[54] Suspending of consent mandates may also expand to opt-out jurisdictions during public health emergencies. For instance, if an individual receives a COVID-19 vaccine but does not want to be included in the IIS, opting out may not be an option. Management of records created under a public health emergency, regardless of opt-in or opt-out mandates, could possibly be revisited post event (e.g., short-term collection/storage with option for removal at a later date).

[55] Consent status obtained from a September 2018 study performed by the University of Colorado

IDENTIFYING HIGH-RISK POPULATIONS/PRIORITY TIERS

IIS do not include questionnaires/screening forms[56] to be completed prior to vaccination, do not capture or store screening form responses from external applications, and do not suggest/forecast the administration of a particular vaccine or countermeasure based on a screening response.[57] These features are most common in EP/CRA modules and may also be present to a lesser degree in some mass vaccination modules. When supported, the screening tools/questionnaires are used in conjunction with patient consent and registration. Responses are then stored locally for the sole purpose of establishing priority assignment and determining whether to vaccinate or administer a specific countermeasure. More commonly, mass immunization modules are configured with the ability to capture a simple priority/tier group designation at the highest level (e.g., tier 1, tier 2, tier 3). Following vaccination, screening information is rarely reported to the IIS and, if it is, is typically not visible through the core IIS user interface.

In general, most IIS support the ability to capture the common contraindications and precautions detailed in the General Best Practice Guidelines for Immunization[58] established by ACIP. When captured, many IIS will leverage this information in forecasting vaccinations and generating reminder/recall notifications; however, some IIS simply capture this information in a "comments" field that is stored informationally but not tied to other functionality. Very few support the extended Coded Observations (SNOMED) detailed in the Clinical Decision Support for Immunizations (CDSi) Supporting Data Version 4.3.[59] These extended coded observations include acute and chronic medical conditions, lifestyle indicators, laboratory results, and occupational hazards.

Most IIS have the ability to capture general evidence of immunity for specific vaccine types (e.g., "laboratory evidence of immunity"[60] or "history of disease"[61]), but some jurisdictions offer an immunity option for varicella only. Alternatively, there are a few jurisdictions that offer support for the capture of actual labs and titers.[62] Of the mass vaccination/CRA tools reviewed through this project, only the Maryland tool[63] and Envision's Mobile WebIZ (to a lesser degree) capture lab orders

[56] Form examples: https://www.immunize.org/catg.d/p4060.pdf and https://www.immunize.org/catg.d/p4065.pdf
[57] Only Pennsylvania reported the ability to support some of this functionality in its IIS.
[58] https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
[59] https://www.cdc.gov/vaccines/programs/iis/cdsi.html
[60] Typically used for hepatitis A, hepatitis B, measles, mumps, rubella, and varicella
[61] Typically used only for varicella and herpes zoster
[62] Minnesota, Pennsylvania, Michigan
[63] MPP's ReadiConsent tool

and lab results; however, these results are not reported to the IIS. When evidence of immunity is captured, many IIS will factor this information into the vaccine forecast and other clinical decision support tools. Concern was expressed by some participants in the CDC IISSB interviews that recording of immunity in the IIS may be considered unreliable based on misinterpretation of lab results and concerns over false positives/false negatives.

Of the IISSB awardee interviews that AIRA observed, fewer than half of the IIS interviewed reported that they capture patient risk factors, and only one fourth reported that they are capable of capturing and storing occupation in the IIS. When captured, this information is typically recorded in a comments field and is difficult to report out in a meaningful way. In addition, it was reported that there is very little data in these fields in general. Some reported the ability to capture this information in their mass immunization/CRA modules, but not in the IIS. When captured in the mass immunization/CRA modules, the occupations or occupational categories and other designated risk factors can be created specifically for the current event or campaign. As noted previously, this may also be captured as a generic tier designation (e.g., tier 1, tier 2, tier 3).

When assessing the capture of contraindications/precautions, immunity status, and occupation as a means to identify high-risk/high-priority individuals, there are three primary concerns: (1) most EHRs don't capture or record this information, and even fewer actually transmit this information through their HL7 interface with the IIS,[64] (2) some IIS have privacy/legal concerns about the capture of these data elements, and (3) if captured, this information is rarely maintained and can quickly become outdated making it inaccurate/unreliable.

Note on IIS Scope

A larger concern among some in the IIS community is whether the capture and storage of the information described in this section is appropriate for an IIS. In some cases, there are simple privacy concerns; in others, there is established legal authority that prohibits the IIS from collecting this information. These concerns apply to the capture of screening questionnaire results, certain contraindications/precautions such as acute and chronic medical conditions, antibody and lab titer results, and even occupation and other risk factors. While this information may be critical at the point of vaccination during a mass vaccination event, the appropriateness of the capture and long-term storage in an IIS requires further consideration and national best practice guidance.

[64] Note: "Occupation" is not supported in the HL7 2.5.1 Implementation Guide for either the PID or PD1 segments. Similar to how contraindications, immunities, adverse events, and numerous other items are captured, the OBX segment could potentially be used to capture occupation data; however, there are several challenges and considerations regarding how this could be accomplished. Messaging support for occupation requires further investigation, discussion, and development of proper implementation guidance.

CLINICAL DECISION SUPPORT

When leveraging the core IIS, either directly or through a bidirectional interface, vaccine providers have the ability to view a patient's entire vaccination history and review a vaccine forecast prior to making the clinical decision to vaccinate. Most mass vaccination tools do not provide this capability. By nature, a mass vaccination tool operates on the assumption that a patient is presenting for the sole purpose of being vaccinated as part of the current campaign/event. The tool collects a minimum amount of demographic data and details about the vaccination encounter with the primary goal of vaccinating as many people as possible, as quickly as possible.

Access to vaccination history and evaluation/forecast could potentially be beneficial in the following scenarios:

- In a multi-dose series, the vaccinating provider would need access to information about the initial dose to ensure that the proper dosing interval has been met prior to administering a subsequent dose.
- If different formulations of vaccine exist for a multi-dose series, the vaccines may have different schedules or may not be interchangeable. It may be important that the second dose is the same formulation as the first for optimal antibody response. This may also be a factor with the use of a separate adjuvant product.
- If an individual has recently received a vaccination of another type, vaccine interactions may be a concern (e.g., two live virus vaccines must be given concurrently or separated by 28 days).
- A mass vaccination campaign could feasibly be used to facilitate the administration of more than one vaccine type (e.g., COVID-19 and seasonal influenza vaccine).

Access to vaccination history and evaluation/forecast during a mass vaccination event could prevent improper vaccine spacing, over-vaccination among individuals already immunized, off-license interchangeability, vaccine interactions, and possibly missed opportunities. Some of this information may be collected from patient-reported responses to a screening questionnaire and/or review of a hand-carried immunization record, but nuanced details are unlikely to be captured at the level needed to support all possible scenarios.

In a dispersed vaccination model where most vaccinations are administered through primary care providers, public health immunization clinics, and pharmacies, direct access to the core IIS and

bidirectional interfaces between the IIS and EHR/pharmacy management systems provide access to consolidated records and forecasts. While there is global consensus across vaccinating providers that clinicians/vaccinators should have access to full vaccination records and clinical decision support tools, it is not clear how this functionality could or should be integrated into mass vaccination tools designed to support the traditional, POD-based mass vaccination dynamic without compromising throughput. More discussion and guidance may be needed on how to best address this topic.

SECURITY

Immunization information systems are expected to adhere to industry standards for system security and data safeguards. These include network and system protections, data protection and encryption, user account management, and secure encrypted messaging. These protections also include intrusion detection, audit logging, attack mitigation, and system backup and recovery. These IIS safeguards may or may not extend to mass vaccination modules and EP/CRA modules, especially if the system is not an integrated component of the IIS platform. With mass vaccination modules or EP/CRA modules that have a stand-alone or mobile device component, there are additional security considerations because data is sometimes held locally until it can be uploaded to the IIS and/or cleared from the device. Devices may include thumb drives, tablets, smartphones, or laptops.

One consideration is how to maintain a chain of custody for these devices. It is often a good practice for a central point of contact to manage the distribution and collection of any devices used at a POD or other vaccination event. Each device should be uniquely identified. A log should be maintained to document when a device is issued, who the device was given to, and when the device was checked back in. Each user should sign necessary user agreements and be properly credentialed with a username and password for accessing the device and/or application being used for data collection.

Following a POD or vaccination event, data from the device should be transferred/transmitted to the IIS if it was not occurring in real time throughout the event. There should be some pre-defined mechanism or protocol to validate that all of the records captured on the device were successfully recorded in the IIS. Once data transfer has been confirmed, all data from the individual device(s) should be cleared in its entirety.

OPERATIONAL CHALLENGES

There are several challenges that an immunization program/IIS may face operationally as it prepares for a mass vaccination response. In the AIRA mass vaccination quick survey of the IIS community, more than half (53% or more) of the respondents cited concerns about each of the following issues related to a mass vaccination response[65]:

- Expanding access to new users or clinics
- Capturing vaccination data from non-traditional providers or points of service
- Ramp-up of onboarding activities
- Decreased data quality
- Training
- Identifying high-risk/priority populations

The most commonly voiced concerns from the CDC IISSB awardee interviews included:

- System improvements, funding to make necessary changes, and timeline required to implement changes[66]
- Enrollment of new providers who will be administering COVID-19 vaccine
- Increased onboarding activities with new providers and increased interface monitoring
- Training new providers on the use of the IIS, mass vaccination module, and/or emergency preparedness/CRA module

New providers, onboarding, and training were echoed in both the survey and the CDC interviews. While assessing and addressing these challenges is beyond the scope of this document,[67] it is important to note that a number of IIS have developed tools and processes to support some of these efforts.

[65] A summary of additional challenges and concerns documented through the survey is presented in Appendix C. AIRA Mass Vaccination Quick Survey Results – IIS Challenges and Concerns.

[66] This issue is particularly difficult to overcome in the pre-response period when there are numerous unknowns (e.g., formulations, dose schedule, priority groups, vaccine distribution mechanism).

[67] These issues will be addressed to some extent through the broader strategies to improve adult capture in the IIS that will be covered in AIRA's other deliverables under the adult vaccination project.

Enrolling New Providers

To the extent possible, immunization programs/IIS should attempt to identify possible vaccinators, enroll new organizations/facilities in the IIS, and establish new user accounts as early as possible during the planning phase. For enrolling new providers, some IIS have implemented solutions worth considering for broader application across the IIS community:

- **Automating the enrollment process through an online provider enrollment module[68]**
- **Using a web-based survey tool or Excel spreadsheet to streamline the collection of organization/facility and user details for loading directly into the IIS database[69]**
- **Creating organization/facility profiles during the planning phase of a campaign so the set-up is ready to go ahead of vaccine release[70]**

Some IIS also support the ability to establish organization-level administrators who can help to create and manage facility-level users within their organizations. These downstream permissions help to offload the administrative burden from IIS staff.[71]

When examining provider reporting mechanisms for mass vaccination of the general population, IIS should carefully evaluate and prioritize which providers are good candidates for an HL7 interface versus those better suited for direct data entry into the IIS user interface. Some jurisdictions focus on prioritizing all providers that vaccinate currently and are most likely to continue routine vaccination activities outside of a mass vaccination campaign. Some jurisdictions fast-track interfaces with EHR vendors that have already established a production interface with the IIS for other providers in the jurisdiction. Another strategy is to establish at least one connection with each vendor being used in the jurisdiction to make it easier to onboard additional providers using the same product. In general, electronic HL7 reporting is preferred over direct data entry into the IIS; however, electronic reporting may not be feasible for some small and midsize providers, and/or the establishment of an electronic interface may be cost-prohibitive for some providers. The ultimate goal is to avoid paper recording to greatest extent possible.

[68] Kentucky, Louisiana, Syntopi Pandemic PREP (AMCI Health Informatics), MPP's ReadiConsent tool
[69] Maryland, Minnesota, North Carolina
[70] Michigan
[71] Minnesota

As a final consideration, current technologies provide numerous training options that were not available during previous pandemics and mass vaccination campaigns. IIS routinely leverage training videos, recorded webinars, live web-based trainings, interactive tutorials, and embedded, page-specific user guidance to help users navigate IIS and mass vaccination modules. Maximizing training tools and technologies, especially those offered as on-demand resources, can reduce the burden on immunization program and IIS staff as they prepare providers for use of the IIS and/or other tools during a mass vaccination campaign.

USABILITY

In AIRA's mass vaccination quick survey of the IIS community, over half (51%) of the jurisdictions did not have a mass vaccination or EP/CRA module, and more than one fourth (27%) of the survey respondents were concerned that their mass vaccination tool had not been properly tested, maintained, or exercised. For those without a mass vaccination or EP/CRA module, the jurisdictions are experienced with using their IIS to support emergency response efforts and plan to leverage and maximize their existing IIS features and interfaces. For those with concerns about their mass vaccination solution, this was further explained during the CDC IISSB interviews. Some jurisdictions reported that their mass vaccination tools are not intuitive, require a lot of set-up and configuration to support a campaign or event, require significant enhancement, rely on external hardware or technical support, and/or are limited in their ability to facilitate real-time data entry.

A mass vaccination or EP/CRA solution is most beneficial when it can be used to maximize clinic throughput, prevent bottlenecks, provide real-time metrics for response administrators, and support post-event follow-up and analysis. Tools are not helpful when they hinder workflow, create technical challenges, or require a significant amount of user training and support. The primary challenge remains for solution developers to deliver a tool that is both fully featured and intuitive to most users. Developing an interface capable of facilitating rapid data entry and real-time reporting while leveraging all of the data and support features of the core IIS presents a best-case scenario.

5

ESSENTIAL ELEMENTS OF A MASS VACCINATION MODULE

SECTION 5 ESSENTIAL ELEMENTS OF A MASS VACCINATION MODULE

The preceding narrative detailed the various elements, limitations, and considerations that determine the features and functionality of the tools currently available to support a mass vaccination campaign.

Many of the existing mass vaccination solutions are IIS-based. IIS-based tools provide the advantage of leveraging the entire database of existing patient and vaccination records, existing electronic interfaces with provider EHR systems and pharmacy management systems, full ordering and inventory management features, and robust reporting capabilities. These features would be extremely difficult to replicate in a stand-alone application. A primary limitation of IIS-based tools is that they are not full CRA solutions, and it may not be appropriate to evolve IIS-based mass vaccination tools into CRA tools without further discussion across the larger immunization/IIS community.

A core deliverable of this project was to identify the essential elements that should be included in a mass vaccination module. Based on the findings of this assessment of mass vaccination solutions, the following list details the core capabilities and attributes that should be included in a model mass vaccination module[72].

- Requires a username/password for logging in and accessing the system
- Provides immediate access to all patient records that exist in the core IIS
- Ability to tie patients, vaccinations, inventory, and reporting to a specific event or campaign
- Ability to leverage unique inventory items that will be used for the specific event or campaign
  - Vaccine type or specific countermeasure (CVX and NDC number)
  - Manufacturer
  - Lot number
  - Expiration date
  - Dose count/quantity
  - Funding source (if applicable)

[72] A supplemental one-sheet reflecting this information is also available in Appendix F: Essential Elements of a Mass Vaccination Module and a version without page numbers is available here.

- Tools to expedite patient lookup during patient registration/intake. Examples include:
  - Leverage cohorts or rostering features[73] to identify participants prior to event
  - Use driver's license barcode scanning[74] to generate search criteria (first name, last name, date of birth, and address)
  - Use barcodes generated by the IIS or CRA module and displayed on client documents (e.g., official immunization records, reminder/recall notices,[75] consumer portal printouts,[76] clinic registration confirmation[77])
- Tools to expedite entry of patient demographics during patient registration/intake. Examples include:
  - Reduce or minimize the number of required data entry fields*
  - Allow users to establish and leverage default values for fields that routinely have the same value
  - Auto populate city and state from ZIP code
  - Use driver's license barcode scanning to populate core demographic fields (first name, last name, date of birth, and address)[78]
  - Promote self-registration through a website, mobile device application,[79] or registration kiosk
  - Use "householding" to simultaneously register all members of the same household through a single registration form[80]
- Ability for user to assign individuals to a specified priority group or tier
- Tools to expedite data entry during vaccine/countermeasure administration. Examples include:
  - Reduce or minimize the number of required data entry fields

***Required Data Entry Fields**
At minimum, a mass vaccination tool must collect enough demographic information to uniquely identify an individual and provide a mechanism to contact them post event if needed. Typically the minimum mass vaccination demographic data set includes: First Name, Last Name, Date of Birth, Sex/Gender, and Address. In the core IIS, there are a number of additional demographic data elements that are considered core: https://www.cdc.gov/vaccines/programs/iis/core-data-elements/iis-func-stds.html.

These data elements could be added (or removed) from a mass vaccination module depending on the needs of the specific campaign/event. There has been some discussion of the need to routinely capture race and ethnicity as part of the minimum mass vaccination data set in order to assess coverage disparities; however, additional discussion is needed to further analyze whether this should become a recommended best practice.

[73] This is supported by some IIS as core functionality. This is also supported in Envision's Mobile WebIZ application and MPP's ReadiConsent tool.
[74] Envision's Mobile WebIZ
[75] STC's IWeb
[76] STC's MyIR (Louisiana, Maryland, Arizona)
[77] MPP's ReadiConsent tool and CDC's POD Assist
[78] Envision's Mobile WebIZ
[79] MPP's ReadiConsent tool and CDC's POD Assist
[80] MPP's ReadiConsent tool

    - Allow users to establish and leverage default values for fields that routinely have the same value:
        - Clinic location
        - Date of administration (date of clinic)
        - Vaccinating/administering provider
        - Site/route
        - VIS date
        - VIS date given (date of clinic)
        - Inventory item details (if pulling from a single lot number)
    - Use inventory bar code scanning from boxes or vials to populate inventory item details[81]
    - Use inventory barcodes generated by the IIS or CRA module (e.g., scan sheets[82] or mobile device QR codes[83])
- Mechanism to report patients and doses administered to the core IIS – preferably in real-time when internet access is readily available
- Ability to automatically decrement inventory count as administered doses are recorded
- Ability to represent an accurate, "on hand" available dose count for each vaccination site[84]
- Ability to calculate an accurate aggregate doses administered count for each vaccination site[85]
- Ability to support multiple mass vaccination campaigns simultaneously (e.g., COVID-19, annual influenza campaign, and hepatitis A outbreak)
- Ability to configure a single campaign to support multiple vaccines/countermeasures as part of the same event (e.g., COVID-19 vaccine and annual influenza vaccine)

In addition to the core functional attributes detailed above, there are other features that could be considered high priority for a model mass vaccination module.

- **Ability to support a front-end/back-end workflow**. Some models include an option for user self-registration using a link from their home computer, tablet, or smartphone. This registration is then used to generate a QR code or barcode that can be scanned when the individual presents to a mass vaccination clinic or POD. An alternative option is that the registration queues the individual to a roster where the individual can easily be pulled up once they present to the mass vaccination clinic or POD. See also POD flow dynamics.

[81] STC's IWeb and Mass Immunizations Module, and CDC's POD Assist
[82] Envision's Mobile WebIZ, STC's IWeb and Mass Immunizations Module, and CDC's POD Assist
[83] Envision's Mobile WebIZ
[84] This represents the minimum reporting capabilities that a mass vaccination tool should be able to perform in order to meet any immediate reporting requests. As data is reported back to the IIS, the IIS can be used to facilitate more advanced reporting needs or to assess the mass vaccination effort across the entire jurisdiction.
[85] Idem.

- **DMV license scanning**. Some models include the ability to leverage the 3D barcode on a state-issued driver's license or identification card to (1) pre-populate search criteria for locating a patient in the IIS/mass vaccination module database and/or (2) use demographic details contained in the DMV barcode to populate or update essential fields in the IIS/mass vaccination module (e.g., first name, last name, date of birth, current address).
- **Clinical decision support tools.** Access to a complete immunization history and forecast during the vaccination encounter may be necessary to properly support a multi-dose series or to navigate complex licensing nuances. Some models may include the ability to query the IIS in real time and display a vaccination history and forecast for review by the vaccinating clinician. See also Clinical decision support.
- **Ability to support operations when internet is not available.** Most IIS and IIS-based mass vaccination solutions are internet dependent. Some models include the ability to continue operations even when internet access is not available. This includes the ongoing capture of patients and vaccinations in real time with an option to sync to the IIS database once connectivity is re-established. Internet technologies have exponentially improved over the years, but contingency options are critical to good planning and execution.
- **Flexibility to address other requirements of a federally directed response effort.** CDC may issue directives for data collection and reporting required to execute a particular response effort. Some models provide the ability for system administrators to readily add fields or update field values to support required data capture. Reporting requirements and frequency tend to be campaign specific but can often be accomplished using ad hoc reporting capabilities in the core IIS.
- **Avoid all paper.** Paper creates additional administrative burden through printing, data entry, document storage, and record disposal. Paper also introduces concern about infection control from physical handling. While mass vaccination modules can address the real-time electronic capture of patient and vaccination records, other required forms are predominantly paper-based. Some models include functionality to facilitate the electronic *collection* of user consent, patient screening responses, and even billing/insurance details. The *storage* of this information in an IIS is a concern for some jurisdictions. As such, further discussion is needed to develop national best practice guidance as to whether this information should be stored (rationale/justification), how it should be stored, who should have access to this information, and whether the information can be meaningfully leveraged post event.

SECTION 6 CONCLUSION

With COVID-19 response planning actively in progress, the situation is evolving by the day as more information is learned about SARS-CoV-2 vaccine research and development, possible formulations and dosing schedules, and timelines for release of a vaccine.

Response planners must operate on assumptions based on what they know—and what they *think* they know—at any given point in time. This includes determining how the initial doses of vaccine will be allocated, how vaccine recipients will be prioritized, which tools will be used to capture patients and doses administered, and what the reporting/data needs might be for those directing response activities.

The information in this document represents a point-in-time assessment of the tools available to support mass vaccination activities in the spring of 2020. At the writing of this report, vendors have been actively enhancing and evolving their existing tools, and CDC has initiated development on a new mass vaccination tool/platform. The CDC VAMS tool is being developed to address some gaps identified in the existing IIS-based and EP/CRA-based mass vaccination solutions. At this point, jurisdictions will have a variety of tools to consider as they plan their COVID-19 response.

Due to the timing of this project in the midst of an active pandemic, this document may best serve as a baseline view of pre-COVID-19 mass vaccination functionality. Much like H1N1, after-action analysis will inform what a new "model" mass vaccination module could/should look like along with the new lessons learned about how these tools fit into the global workflow. It may be a year or more before stakeholders are able to reflect on the COVID-19 response, analyze the benefits and shortcomings of existing tools, and determine a new set of system requirements and best practices.

As a final note, the COVID-19 pandemic presents an opportunity for advancing provider participation and the capture of adult vaccinations in IIS through the use of IIS-based mass vaccination solutions. COVID-19 creates a sense of urgency across both the medical and public health communities, and concern about the disease increases the community demand for protection from the virus by way of vaccination. As observed with H1N1, provider enrollment in the IIS increased considerably in response to pandemic-related vaccination activities. This included training providers for online ordering and management of vaccine inventories, training providers for direct data entry into the IIS, and establishing electronic interfaces between IIS and EHR/pharmacy management systems. Not every provider that enrolled during H1N1 continued to actively report post event, but many did. A similar pattern of behavior is expected in relation to COVID-19 and can serve as a launching point to expand and sustain current activities for adult vaccination and IIS reporting.

APPENDICES

APPENDIX A ACRONYM TABLE

Table 5 | *Abbreviations/Acronyms*

ABBREVIATIONS/ACRONYMS	
ACIP	Advisory Committee on Immunization Practices
AD	Awardee-developed
AIRA	American Immunization Registry Association
CDC	United States Centers for Disease Control and Prevention
CDMS	Clinical data management system
CDSi	Clinical decision support for immunizations
COTS	Commercial-off-the-shelf
CRA	Countermeasure response administration
CVX	Vaccine administered (code)
DMV	Department of Motor Vehicles
DXC	DXC Technology
EP	Emergency preparedness
FQHC	Federally Qualified Health Center
HANDI	Handheld Automated Notification for Drugs and Immunizations
HL7	Health Level Seven International (messaging standard)
HLN	HLN Consulting LLC
IIS	Immunization information system
IISSB	CDC IIS Support Branch
LOINC	Logical observation identifiers names and codes (clinical naming/identification standard)
MPP	Maryland Partnership for Prevention
NAIIS	National Adult and Influenza Immunization Summit
NDC	National Drug Code (Number)
POD	Point of dispensing
PPE	Personal protective equipment
QA	Quality assurance
QR	Quick response (code)
SAS	Statistical Analysis System/SAS (analytics software and solutions)
SNOMED	SNOMED International (common language for clinical terminology)
STC	STChealth (formerly Scientific Technologies Corporation)
VAMS	Vaccine Administration Management System
VFC	Vaccines for Children Program
VIS	Vaccine Information Statement
WIR	Wisconsin Immunization Registry
W/S/E	Wasted, spoiled, expired

APPENDIX B REFERENCE LIST

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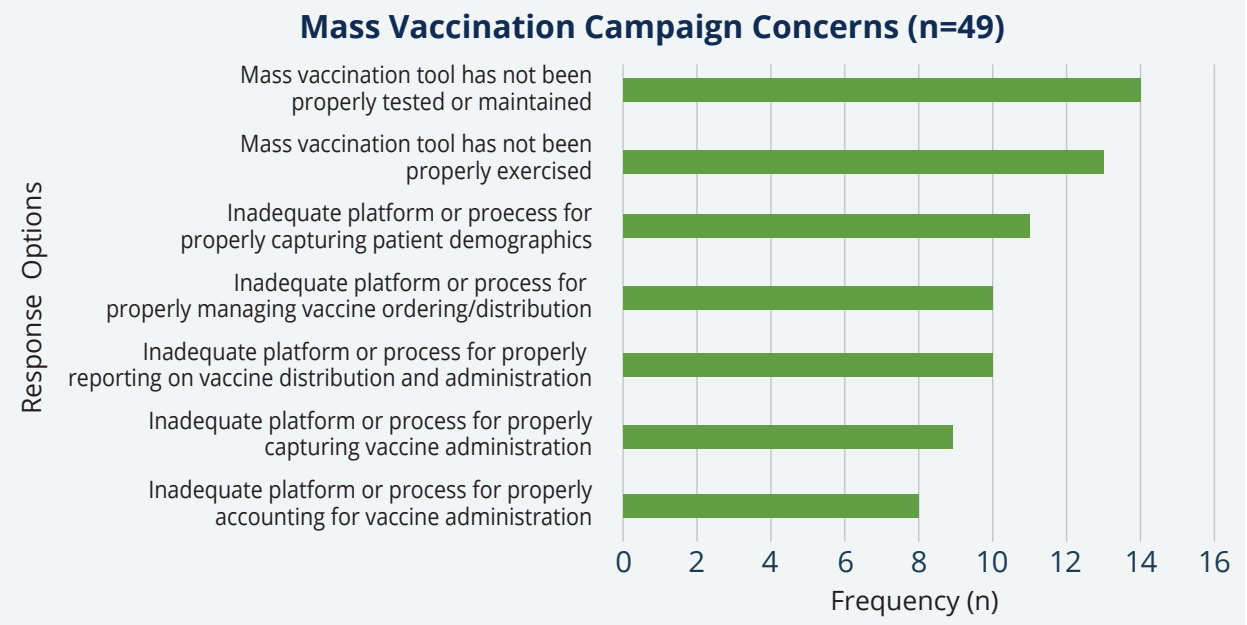
APPENDIX C AIRA MASS VACCINATION QUICK SURVEY RESULTS – IIS CHALLENGES AND CONCERNS

Survey was administered by AIRA to the 64 CDC awardees plus the city of San Diego, California. Survey was open from April 2, 2020, through April 24, 2020. Responses were received from 49 jurisdictions, with a response rate of 75%.

Q: Please indicate if any of the following might be concerns in your jurisdiction during a mass vaccination campaign (check all that apply).

- **a.** Inadequate platform or process for properly managing vaccine ordering/distribution
- **b.** Inadequate platform or process for properly capturing patient demographics
- **c.** Inadequate platform or process for properly capturing vaccine administration
- **d.** Inadequate platform or process for properly accounting for vaccine administration (e.g., dose received, doses admin, doses W/S/E)
- **e.** Inadequate platform or process for properly reporting on vaccine distribution and administration within your jurisdiction
- **f.** Mass vaccination tool has not been properly tested or maintained
- **g.** Mass vaccination tool has not been properly exercised

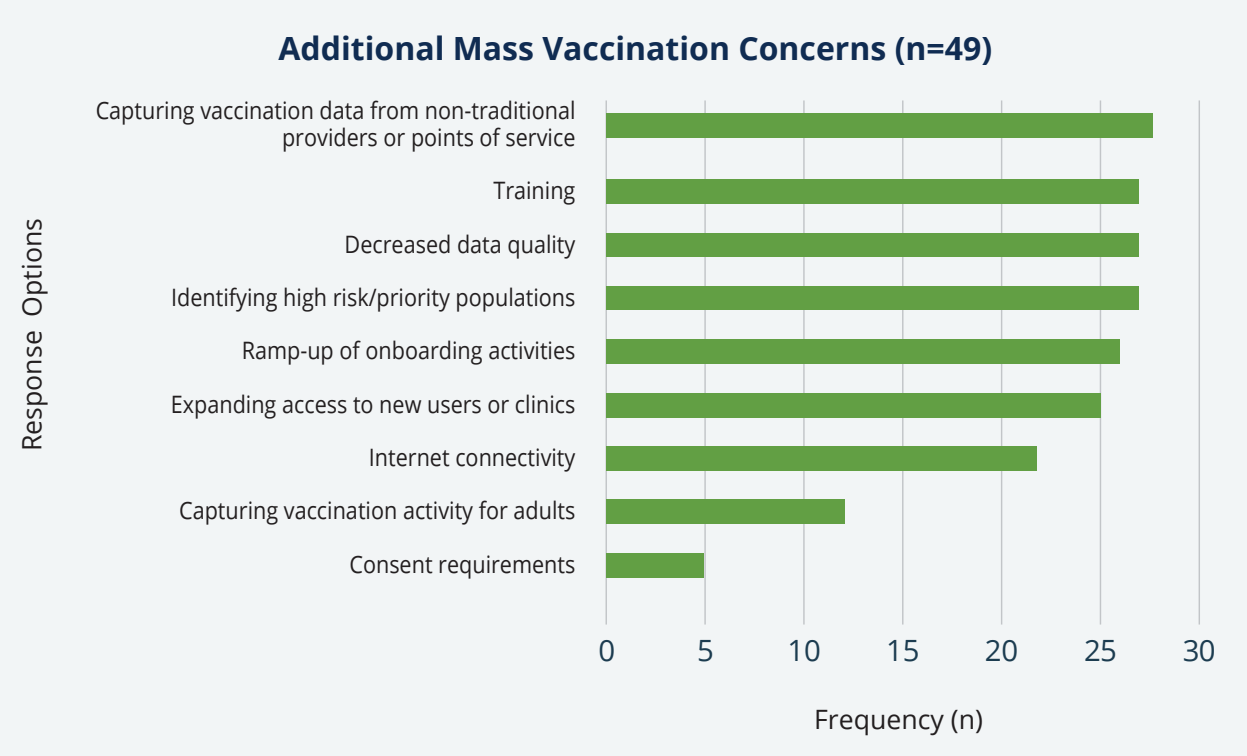
Figure 4 | *Mass vaccination campaign concerns (results)*



Q: Please indicate if any of the following might be additional challenges/concerns in your jurisdiction during a mass vaccination campaign (check all that apply).

- **a.** Consent requirements
- **b.** Identifying high-risk/priority populations
- **c.** Capturing vaccination activity for adults
- **d.** Capturing vaccination data from non-traditional providers of points of service
- **e.** Ramp-up of onboarding activities
- **f.** Expanding access to new users or clinics
- **g.** Training
- **h.** Decreased data quality
- **i.** Internet connectivity

Figure 5 | *Additional mass vaccination concerns (results)*



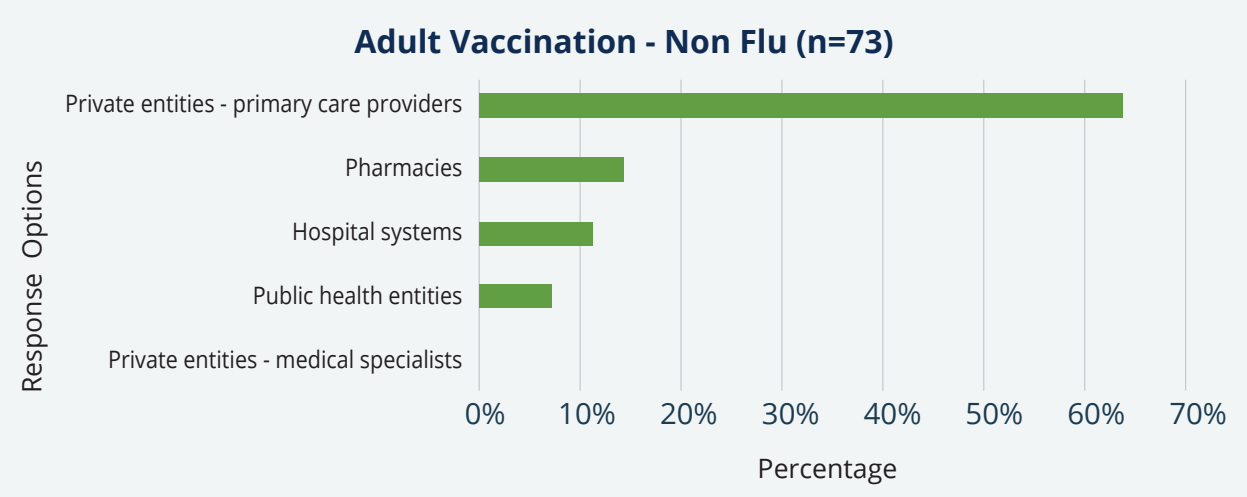
APPENDIX D NAIIS POLL RESULTS – ADULT VACCINATION PRACTICES

Poll was administered by NAIIS and AIRA to the participants of the 2020 National Adult and Influenza Immunization Summit. Poll was open from May 21, 2020, through June 5, 2020. A total of 73 responses were received.

Q: Where do you think adults most frequently get vaccinated with vaccines other than flu (select one)?

- **a.** Hospital systems (public or private)
- **b.** Public health entities (i.e. local health departments, federally qualified health centers (FQHCs), tribal health)
- **c.** Private entities – primary care providers
- **d.** Private entities – medical specialists
- **e.** Pharmacies
- **f.** Unknown
- **g.** Other

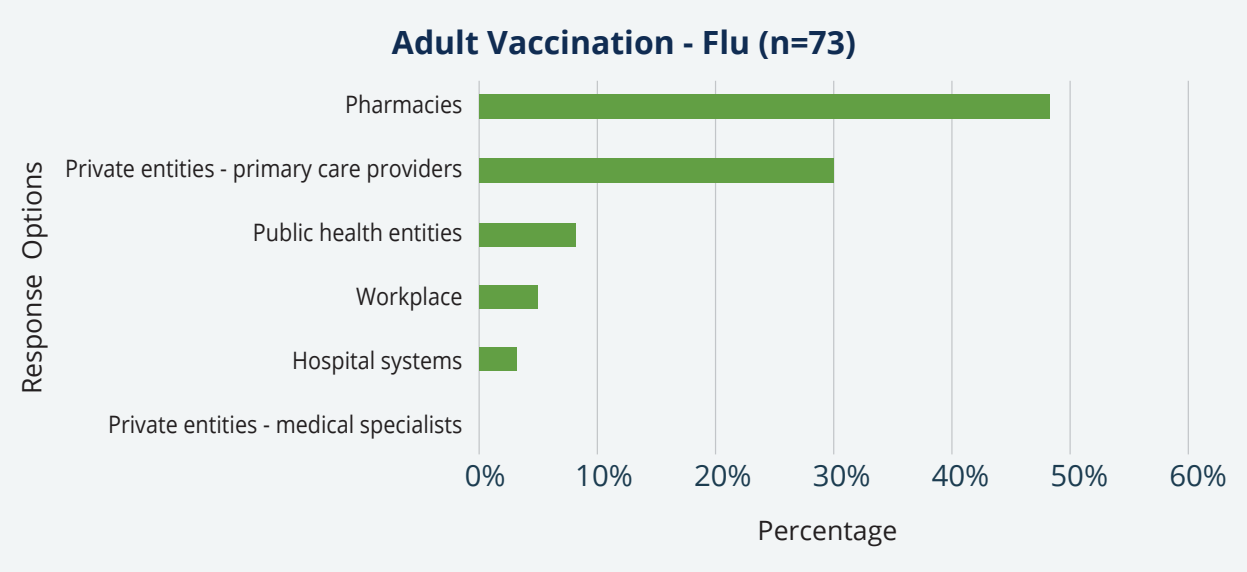
Figure 6 | *Adult vaccination – non flu (results)*



Q: Where do you think adults most frequently get vaccinated with flu vaccine (select one)?

- **a.** Hospital systems (public or private)
- **b.** Public health entities (e.g., local health departments, FQHCs, tribal health)
- **c.** Private entities – primary care providers
- **d.** Private entities – medical specialists
- **e.** Pharmacies
- **f.** Workplace
- **g.** Unknown
- **h.** Other

Figure 7 | *Adult vaccination – flu (results)*



APPENDIX E IIS-VTRCKS-MCKESSON DATA FLOW

Figure 8 | *IIS-VTrckS-McKesson*

For more information about the VTrckS ExIS interface see:
https://www.cdc.gov/vaccines/programs/vtrcks/topics/index.html

ESSENTIAL ELEMENTS OF A MASS VACCINATION MODULE

A core deliverable of this project was to identify the essential elements that should be included in a mass vaccination module.

Based on the findings of this assessment of mass vaccination solutions, the following list details the core capabilities and attributes that should be included in a model mass vaccination module.

- Requires a username/password for logging in and accessing the system
- Provides immediate access to all patient records that exist in the core IIS
- Ability to tie patients, vaccinations, inventory, and reporting to a specific event or campaign
- Ability to leverage unique inventory items that will be used for the specific event or campaign
  - Vaccine type or specific countermeasure (CVX and NDC number)
  - Manufacturer
  - Lot number
  - Expiration date
  - Dose count/quantity
  - Funding source (if applicable)
- Tools to expedite patient lookup during patient registration/intake. Examples include:
  - Leverage cohorts or rostering features[72] to identify participants prior to event
  - Use driver's license barcode scanning[73] to generate search criteria (first name, last name, date of birth, and address)
  - Use barcodes generated by the IIS or CRA module and displayed on client documents (e.g., official immunization records, reminder/recall notices,[74] consumer portal printouts,[75] clinic registration confirmation[76])
- Tools to expedite entry of patient demographics during patient registration/intake. Examples include:
  - Reduce or minimize the number of required data entry fields*
  - Allow users to establish and leverage default values for fields that routinely have the same value
  - Auto populate city and state from ZIP code
  - Use driver's license barcode scanning to populate core demographic fields (first name, last name, date of birth, and address)[77]
  - Promote self-registration through a website, mobile device application,[78] or registration kiosk
  - Use "householding" to simultaneously register all members of the same household through a single registration form[79]
- Ability for user to assign individuals to a specified priority group or tier
- Tools to expedite data entry during vaccine/countermeasure administration. Examples include:
  - Reduce or minimize the number of required data entry fields
  - Allow users to establish and leverage default values for fields that routinely have the same value:
    - Clinic location
    - Date of administration (date of clinic)

        - Vaccinating/administering provider
        - Site/route
        - VIS date
        - VIS date given (date of clinic)
        - Inventory item details (if pulling from a single lot number)
    - Use inventory bar code scanning from boxes or vials to populate inventory item details[80]
    - Use inventory barcodes generated by the IIS or CRA module (e.g., scan sheets[81] or mobile device QR codes[82])
        - Mechanism to report patients and doses administered to the core IIS – preferably in real-time when internet access is readily available
        - Ability to automatically decrement inventory count as administered doses are recorded
        - Ability to represent an accurate, "on hand" available dose count for each vaccination site[83]
- Ability to calculate an accurate aggregate doses administered count for each vaccination site[84]
- Ability to support multiple mass vaccination campaigns simultaneously (e.g., COVID-19, annual influenza campaign, and hepatitis A outbreak)
- Ability to configure a single campaign to support multiple vaccines/countermeasures as part of the same event (e.g., COVID-19 vaccine and annual influenza vaccine)

***Required Data Entry Fields**

At minimum, a mass vaccination tool must collect enough demographic information to uniquely identify an individual and provide a mechanism to contact them post event if needed. Typically the minimum mass vaccination demographic data set includes: First Name, Last Name, Date of Birth, Sex/Gender, and Address. In the core IIS, there are a number of additional demographic data elements that are considered core: https://www.cdc.gov/vaccines/programs/iis/core-data-elements/iis-func-stds.html.

These data elements could be added (or removed) from a mass vaccination module depending on the needs of the specific campaign/event. There has been some discussion of the need to routinely capture race and ethnicity as part of the minimum mass vaccination data set in order to assess coverage disparities; however, additional discussion is needed to further analyze whether this should become a recommended best practice.

[72] This is supported by some IIS as core functionality. This is also supported in Envision's Mobile WebIZ application and MPP's ReadiConsent tool.
[73] Envision's Mobile WebIZ
[74] STC's IWeb
[75] STC's MyIR (Louisiana, Maryland, Arizona)
[76] MPP's ReadiConsent tool and CDC's POD Assist
[77] Envision's Mobile WebIZ
[78] MPP's ReadiConsent tool and CDC's POD Assist
[79] MPP's ReadiConsent tool
[80] STC's IWeb and Mass Immunizations Module, and CDC's POD Assist
[81] Envision's Mobile WebIZ, STC's IWeb and Mass Immunizations Module, and CDC's POD Assist
[82] Envision's Mobile WebIZ
[83] This represents the minimum reporting capabilities that a mass vaccination tool should be able to perform in order to meet any immediate reporting requests. As data is reported back to the IIS, the IIS can be used to facilitate more advanced reporting needs or to assess the mass vaccination effort across the entire jurisdiction.
[84] Idem.

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- Rhode Island
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- *President* • **Aaron Bieringer,** Minnesota Department of Health
- *President-Elect* • **David McCormick,** Indiana State Department of Health
- *Secretary* • **Dannette Dronenburg,** Washington State Department of Health
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