



October 15, 2020

Robert Redfield, MD
Director
Centers for Disease Control and Prevention

Dear Dr. Redfield:

On June 23, 2020, the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), the Association of Immunization Managers (AIM), and the American Immunization Registry Association (AIRA) sent a letter offering our support, expertise, experience, and partnership for planning and executing a successful COVID-19 vaccine program. The letter also included our feedback and emphasis on the importance of building on the existing vaccine delivery infrastructure.

The immunization community recognizes the critical importance of CDC, Operation Warp Speed (OWS), and other federal partners' having timely and complete access to data on doses distributed and administered. These same needs exist in each state and local jurisdiction where state health officers, governors, legislatures, immunization programs, and state-based COVID-19 task forces will need to closely track vaccine distribution and administration to carry out their mission of protecting their populations' health.

As organizations that work closely with states and local jurisdictions that will be on the front lines of vaccine distribution and administration, we've seen positive movement, such as setting vaccination priorities and decisions to use existing, centralized vaccine distribution infrastructure. Thank you for acting on these key issues. However, there continue to be areas of concern to the immunization community. The attached table outlines our concerns and recommendations. We believe these recommendations are in line with CDC's COVID Planning Assumptions, COVID Scenarios, and Early COVID Action Items Checklist.

Successful vaccine rollout in this country hinges on immediate and clear guidance that leverages the current health information technology infrastructure used nationally by both private and public health care sectors. Immunization information systems (IIS) have been used for over 25 years and have been successfully employed in outbreak and pandemic response, most recently during H1N1. Nearly all states and local jurisdictions have capacity to use their IIS

for COVID-19 vaccine rollout. IIS have established connections with over 117,000 health systems, pharmacies, and other data partners to capture administered doses in real time for a large portion of the population.

We share your belief that safe, effective, and transparent vaccine distribution and administration and reducing the risk that any one system fails or lacks capacity to scale to a national response are the most important goals. To this end, we continue to urge you to work closely with CDC, AIM, AIRA, ASTHO, NACCHO, and others to clarify roles, decision-making processes, and technical operational features of the systems that impact vaccine rollout. Without deliberate and collaborative partnerships, including engagement of public health subject matter experts, a successful vaccine rollout will be at risk. When rapid response to a nationwide emergency is required, it is critical to minimize changes to existing systems to allow an agile and seamless response. Unnecessary changes put the whole effort at risk of failure.

We look forward to working with you to resolve these concerns and help further the recommendations outlined below.

Respectfully,

Association of Immunization Managers (AIM)
American Immunization Registry Association (AIRA)
Association of State and Territorial Health Officials (ASTHO)
National Association of County and City Health Officials (NACCHO)

Cc:

Dr. Nancy Messonnier, Director, National Center for Immunization and Respiratory Diseases, CDC
Sherri Berger, Chief Operating Officer, CDC
Dr. Jay Butler, Deputy Director for Infectious Diseases, CDC
Dr. Jose Montero, Deputy Director, Center for State, Territorial, Local and Tribal Support, CDC
Dr. Brett Giroir, Assistant Secretary for Health, U.S. Department of Health & Human Services
Darcie Johnston, Director, Intergovernmental Affairs, U.S. Department of Health & Human Services
General Gustavo Perna, Chief Operating Officer, Operation Warp Speed

Concerns and Recommendations

Central to all concerns and recommendations noted below is the need to **ensure CDC experts, state and local health departments, and partners are involved and contribute their expertise and experience for planning and executing a successful COVID-19 vaccine program.** Recommendations may be relevant to multiple concerns.

Concerns	Recommendations
<p>States and local jurisdictions are concerned about sharing identified data with CDC and other federal entities.</p> <p>The proposed CDC data extract requirements from IIS include identified data to populate the IZ Data Clearinghouse, including name, address, date of birth, etc. Requests for identified data will create significant challenges for immunization programs. Due to jurisdictional laws and policies, many states and local jurisdictions, including California, Colorado, Minnesota and others, have voiced concerns that they may not be able to sign a data use agreement that requires them to send identified data to CDC, particularly when system requirements, system access, and security provisions have not been published.</p> <p>At the September 23, 2020, Advisory Committee on Immunization Practices (ACIP) meeting, CDC shared information on the Vaccine Safety Assessment for Essential Workers (V-SAFE). It was noted that essential workers would receive a text message following the receipt of a COVID-19 vaccine. While this effort is commendable, it is not clear how essential workers will be informed of and/or consent to this use of their data or where mobile phone numbers may be gathered, as they are not listed on CDC's required or optional data elements for COVID-19.</p> <p>Additionally, recent polls suggest as many as 50 percent of Americans may refuse a COVID-19 vaccine. Requiring states and local jurisdictions to share identified data with the federal government as a condition of getting vaccinated may further erode patients' willingness to get COVID-19 vaccine. It is also unclear what role patient consent may play as a precursor to receiving vaccine and how current consent</p>	<ol style="list-style-type: none">1. Support the submission of deduplicated, deidentified or aggregate data from IIS to CDC. Publish the CDC-IIS data use agreement as soon as possible to ensure states and local jurisdictions can secure approval and share deidentified or aggregate data as soon as a COVID-19 vaccine is available.2. Clearly articulate how data will be used and for what purposes. Transparency with the states and local jurisdictions and the public is paramount in establishing and maintaining the public's trust.

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<p>laws and policies may be affected by these new systems/data pathways. Groups of people who would likely be prioritized as essential workers, such as people who are undocumented, migrant farmworkers, food processing plant workers, etc., may be most apprehensive about sharing their information. States and local jurisdictions, particularly those with legal and regulatory hurdles and/or public distrust or hesitancy to share personal information, need <u>immediate</u> information detailing the need for personal identifiable information and how it will be used.</p>	
<p>States and local jurisdictions, regardless of whether they are a directly funded entity or not, are unclear and urgently need published, actionable and timely guidance about how to plan for COVID-19 vaccine response and the role of IIS.</p> <p>The recently released CDC Playbook lacks key guidance, requirements, and detailed specifications regarding data flow and system interfaces, particularly regarding the Immunization Clearinghouse and Data Lake. In the absence of clear specifications, IIS cannot move forward with enhancements for capturing data such as serology (e.g., Clinically verified results? Patient self-report?) or extracting data to meet federal partner needs. Furthermore, it is not clear if some COVID-19 administered data will flow directly into the Clearinghouse and, if so, how jurisdictions will bring these data back into their IIS to meet the needs of jurisdictional public health, governors, legislatures, and others.</p>	<p>3. Develop, pilot, and finalize all technology workflows and solutions no later than October 30, 2020. States and local jurisdictions need time to ensure new technology solutions can be integrated into their existing workflows. This may include modification of existing systems, implementation of any new systems, and onboarding and training new users, all before a vaccine is available.</p>
<p>Multiple states and local jurisdictions have already made investments to collect and report key data elements.</p> <p>Due to the lack of clarity in the guidance about how data should be transmitted, states and local jurisdictions are unsure if their technology investments and solutions will meet the reporting requirements of the federal government.</p>	<p>4. Thoroughly respond to questions from states and local jurisdictions. Many questions have been asked of CDC by states and local jurisdictions about all aspects of the COVID-19 response, and most questions are still yet to be answered. The frequently asked questions document on CDC's SharePoint site hasn't been</p>

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	<p>updated since mid-August. States and local jurisdictions can't fully move forward or finalize their plans until their questions get answered.</p>
<p>IIS and their existing interfaces with providers and pharmacists are not being fully leveraged and maximized during the COVID-19 vaccine response.</p> <p>Most IIS allow electronic health record (EHR) and pharmacy systems to query them to access a patient's consolidated record and forecast of immunizations due, with many IIS receiving an average of 11 million queries in 2019, equating to 32,000 queries a day from providers using their EHR at the point of care. This query feature saves providers time and effort since (1) patient immunization needs, along with comorbidities and other conditions, are contained in the patient record and (2) providers are already accustomed to using IIS query functions. Where established connections are not currently in place, new immunizers can still leverage the IIS user interface for reporting and querying.</p> <p>Nearly all IIS—and, by extension, provider sites ordering public vaccine—use CDC's VTrckS system to order, distribute, and account for vaccine. IIS, in recording administered doses, can then link doses distributed with doses administered. Yet the message that IIS must be leveraged rather than using untested vaccine distribution and administration tracking systems has not been embraced.</p> <p>The current COVID-19 data strategy relies on multiple new and yet-to-be-tested or scaled systems to track vaccine distribution and administration—VAMS, the IZ Gateway, the emerging IZ Data Clearinghouse/Data Lake/Data Storefront, and Tiberius.</p> <p>Introducing new systems creates significant risk within a national public health response system already spread thin and under-resourced. Even though the</p>	<p>5. Position IIS as the primary jurisdictional repository of complete COVID-19 data. Ensure adequate resources exist for IIS programs to collect, deduplicate, and report on comprehensive COVID-19 vaccine administration and distribution activities. It is essential that CDC publish documentation on data flows, requirements, functionality, specifications, and expectations of all partners and systems anticipated to play a role in vaccine distribution and administration.</p> <p>6. These systems need to be pilot tested immediately if they are to be used in early 2021 with state and territorial engagement.</p>

Concerns	Recommendations
<p>development of these systems will be funded and operationalized outside of the current immunization infrastructure, the approach relies on states and local jurisdictions to support and/or interface with them. Currently, it is not clear how these new systems would interface with existing IIS or through the IZ Gateway. Not only does the interface between systems need to be specified, developed, and tested, it also needs to include clear guidance to states and local jurisdictions so they can successfully and seamlessly exchange data between the systems. As recently as September 23, 2020, new systems were announced, yet no guidance on the role these systems will play, how data will flow between them, and training requirements necessary to access/operate them have been released. We would like to see IIS have a more prominent role in data collection, consolidation, and use, rather than relying on several brand-new and unproven systems.</p>	