

## Introduction

To protect all Americans during an influenza pandemic, it is estimated that thousands of healthcare providers would need to administer 600 million vaccinations to 300 million patients.<sup>1</sup> Such a campaign would require extensive tracking of patients and vaccine doses to monitor coverage and readiness. Countermeasure and response administration (CRA) systems track countermeasures and patients that receive them during a public health event. Recently, the focus on CRA has been on its role in the “seamless preparedness network” needed for influenza pandemic preparation and response.<sup>2</sup> However, CRA is important in preparing for and responding to all disasters and outbreaks requiring detailed monitoring of patients and countermeasures. This issue brief describes how State Public Health Agencies are achieving CRA capacity and the role of CRA in pandemic influenza preparation and response.

## Defining CRA

In this issue brief, CRA refers to the Centers for Disease Control and Prevention (CDC) CRA Public Health Information Network (PHIN) Preparedness Functional Area, one of six areas identified by the PHIN Preparedness Initiative as components of public health preparedness.

CRA is the management of “measures taken to contain an outbreak or event and to provide protection against a possible outbreak or event.”<sup>3</sup> Measures include:

- Vaccine.
- Drug prophylaxis.
- Patient follow-up.
- Isolation and quarantine.

CRA occurs when the outbreak or event requires more thorough monitoring than normal public health operations. First responders, public health and clinical professionals, community members exposed to a disease or agent, and the general public are all potential participants in CRA campaigns.

Tracking patients who have received countermeasures is important in detecting adverse reactions to countermeasures and modifying response strategies to better protect the populations affected by an outbreak or disaster. During the Smallpox Vaccination Program, three patients who had been immunized against smallpox died of heart attacks within weeks of their immunizations. Concern about adverse events prompted two national responses. The National Immunization Program Advisory Committee on Immunization Practices recommended additional cardiac exclusion criteria for smallpox vaccination, and the CDC issued a health advisory to avoid vaccinating people with cardiac risk factors.<sup>4</sup> CRA systems are needed to support the public health response during all phases of an emergency.

## Background

The CDC Pre-event Vaccination System (PVS) was a precursor of the CRA systems. PVS was used to track vaccinations during the Smallpox Vaccination Program. Many state public health agencies found obtaining useful data from PVS difficult. It lagged in providing real-time data; both line listed and aggregate reporting were required.<sup>5</sup> Mixed opinions exist about whether the value offered by PVS outweighed the data-reporting burden.<sup>6</sup>

CDC and state and local public health agencies seek to apply lessons learned from experience with PVS toward current CRA activities. The

current focus of the developing CRA system is on providing flexibility at the state and local level and simplifying the system for ease of implementation. Another objective is to facilitate the alignment and interoperability of all information systems that might be employed during a public health event. Strong CRA, laboratory, and outbreak management systems strengthen public health preparation and response to emergencies.

## Functional Requirements and Key Performance Measures

The CRA PHIN Preparedness Functional Area has a set of functional requirements and key performance measures that describe the minimum capabilities necessary to manage CRA actions taken to prepare for or respond to public health events.

The CRA functional requirements stress flexibility of operations. An ideal CRA system has the capacity to support multiple and simultaneous campaigns that involve multiple agents, countermeasures, populations, and jurisdictions. It captures roles and other information about the organizations and staff that participate in a campaign. It logs fields such as lot number, manufacturer, and expiration date of pharmaceuticals. Additionally, it links inventories of pharmaceutical products at sites with pharmaceutical stockpiles, such as the Strategic National Stockpile (SNS). An ideal CRA system also supports the allocation and tracking of pharmaceuticals. Data on patient demographics, medical history, and follow-up are collected in addition to the specific countermeasures administered. Finally, isolation and quarantine activities and adverse reactions to administered pharmaceuticals are documented.<sup>7</sup>

According to the CDC, key performance measures are discrete, testable, technical or operational capabilities used to assess the effectiveness of the integration and exchange of data, information, and alerts among the systems that support the PHIN Preparedness Functional Requirements.<sup>8</sup> For the CRA PHIN Preparedness Functional Area, the key performance measures focus on the protocols for sending and receiving

messages related to CRA. Messages include those used for transmitting information on:

- Administration of countermeasures.
- Follow-up observations.
- Associated non-substance treatments or protocols.
- Interventions to be managed.
- Adverse events identified during active surveillance.

## PHIN Certification

PHIN Certification involves CDC grantees working through steps to verify the functionality of non-certified applications. The grantees review the PHIN specifications and documentation and conduct self assessments of current systems. They demonstrate that the systems meet the capabilities described in the PHIN documents and receive feedback from the certification team. Once functional requirements and key performance measures are satisfactorily met and demonstrated, a grantee receives PHIN Certification. The CDC supports this process through technical assistance. Grantees have until August 30, 2010, to be certified in all PHIN Preparedness Functional Areas.<sup>9</sup>

## Methods of Achieving CRA Functionality

As with all PHIN Preparedness Functional Areas, states have three options for meeting CRA PHIN Functional Requirements:

- Build the functionality described in the functional requirements and key performance measures into existing systems or develop a state CRA system or systems.
- Purchase a commercial product.
- Use a CDC-developed system.

State-developed systems would need the capacity to send requisite data to the CDC.

## Immunization Information Systems

State public health agencies are incorporating CRA functionality into their state immunization information systems (IIS)/immunization registries as part of their influenza pandemic planning. In a survey conducted by the American Immunization Registry Association (AIRA) in February 2006, 83 percent of responding jurisdictions said that they would use their IIS for the collection of data on vaccine doses administered during an influenza pandemic.<sup>10</sup> Fifty-one percent of the respondents stated that their IIS is currently capable of reporting aggregated summary data on patients, providers, vaccines, and immunizations to the CDC within one week of receipt of data from providers.<sup>11</sup>

States are also integrating several information systems, including their immunization information system and state-developed CRA applications, to achieve the full functionality described in the CRA PHIN Function Requirements and Key Performance Measures. The following three examples illustrate how states are meeting the challenge of developing CRA capacity.

### More than Just Kids: The Michigan Care Improvement Registry Supports CRA

The Michigan Care Improvement Registry, formerly the Michigan Childhood Immunization Registry (MCIR), is used in local public health agencies, health plan offices, and more than 3,000 healthcare provider offices to record information about immunizations statewide. In June 2006, an all-hazards module to MCIR will be rolled out.<sup>12</sup> This module will, in the event of a public health emergency, allow MCIR users to enter data via screens customized to the response campaign. The module will track the administration of countermeasures such as influenza vaccine, antibiotics, and antiviral medications. Data on these CRA activities will be sent electronically to the CDC.

The objective with this new module is to allow MCIR users, such as physicians, to continue to use an existing, familiar system; CRA reporting then occurs seamlessly and electronically, via

MCIR. Future additions to MCIR include the ability to report adverse events. MCIR may also be enhanced to add a breakthrough disease field that would trigger a message to the Michigan Disease Surveillance System (MDSS). This message would pre-populate MDSS with MCIR data, and the appropriate local public health agency could respond to the reported case.<sup>13</sup>

## Integrating New and Existing Systems

Ohio and Montana are examples of two states that are building CRA capacity into existing systems and integrating new systems with established ones.

### Moving Patients Quickly: Ohio CRA

The Ohio Department of Health is using multiple tools to achieve CRA functionality. The state IIS aggregates data prior to submission to the CDC. A state-developed CRA application is available on laptops, servers, and in wireless environments in clinics, also called points of distribution (PODs). PODs are where countermeasures would be administered during a public health emergency.

During a recent pandemic influenza exercise, providers used the CRA application to quickly and efficiently collect information at PODs about patients, vaccines, and antiviral medications. Many patients went through PODs in minutes, receiving the appropriate countermeasures for the hypothetical scenario.<sup>14</sup> Data on the patients were then forward to the state IIS via Health Level 7 (HL7) messages where they could be aggregated and forwarded to the CDC. Data on inventory in PODs, such as lot numbers of vaccines and antiviral medications, were also recorded using the CRA application. The information was also sent to the state IIS.

Ohio is also integrating a geographic information system (GIS) component that would create maps identifying the location of PODs, the location of the outbreak or event, and the population affected in order to apportion supplies from the Strategic National Stockpile.<sup>15</sup>

## Building on Existing Capacity: Montana

The Montana Department of Public Health and Human Services is following a similar path, using multiple systems to achieve CRA functionality. The Montana IIS will be the CRA base in terms of recording information about populations and individuals. Other related functionalities, not provided by the IIS, are also needed, such as logistics, resource management, isolation and quarantine management, and small modules to track small pharmaceuticals from the SNS. Systems developers in Montana are in the design phase of creating products that will perform the CRA functions beyond the scope of the state IIS.<sup>16</sup>

### CDC CRA Application

The CDC is developing a web-based application for states to accomplish CRA functions. It contains modules for smallpox, monkeypox, and Investigational New Drug (IND) influenza vaccine administration. Future releases will include modules for antiviral and antibiotic administration, tracking novel influenza vaccine administration, and tracking isolation and quarantine activities.<sup>17</sup>

The CRA application replaces PVS and the Investigational New Drug Application for Influenza. Investigational New Drug is a status given by the Food and Drug Administration to drugs being tested. Investigational New Drug Application for Influenza was designed to track vaccine administration in the event of the need for rapid roll-out of an influenza vaccine not licensed in the United States.

A demonstration model of the CRA application is available for viewing on the CDC PHIN Web site. It records information by patient and pharmaceutical products. Demographic information, including occupation, on patients is collected. Information about the location, time, and staff participating in the administration of the countermeasure is also recorded, as is information on the take response, the physical reaction that a patient has that demonstrates successful vaccination (e.g., the lesion that forms at the site of smallpox vaccination). The CRA

application supports three user roles: public health administrators, data entry specialists, and global administrators. Public health administrators manage data for the partner jurisdiction and prepare reports on data entered. Data entry specialists are assigned to an organization or point-of-delivery in a campaign and are tasked with managing data. Global administrators manage the CRA application and assist users in their roles.<sup>18</sup>

The CRA application is being designed to be flexible and responsive, specifically to allow the quick creation and customization of a new campaign. In addition, it is being created to work with the Strategic National Stockpile. With SNS, shipments of supplies, including pharmaceutical products, are deployed in areas affected by outbreak or disaster. A CRA application could be sent with the shipments to assist in tracking administration of the pharmaceutical products.<sup>19</sup>

The CDC will be testing the new CRA application and working closely with public health users and diverse stakeholders within CDC to ensure that the system meets the priority needs of individuals involved with CRA activities at the federal, state, and local level. The demonstration model of the CRA application is being presented to partners and revised based on feedback.

The first priority function for a CRA system is aggregate reporting that allows information on CRA activities to be sent to the CDC. The second is individual level data entry and reporting for both influenza vaccines and antiviral medications at points of distribution at the state and local level. Both vaccines and antiviral medications may be needed in a potential influenza pandemic. The final priority function is tracking of the administration of drug prophylaxis, as might be needed during an anthrax attack.<sup>20</sup>

The CDC is planning to have a CRA system that meets the first priority of aggregate reporting by early summer 2006. The second priority—individual data entry and reporting—is expected to be achieved by late summer/early fall 2006.



The target is to have a CRA system that meets these priorities available for use during the 2006-2007 influenza season. Modules that track the administration of drug prophylaxis—focusing initially on the drugs doxycycline and ciprofloxacin—are slated to be available by September 30, 2006.

## Next Steps

Next steps in CRA include developing definitions and documentation of the data elements required of states to submit to the CDC in an influenza pandemic. Some states will be using the CDC CRA application released in summer and fall 2006 while others will continue to enhance existing IIS systems and/or build new CRA systems based on PHIN standards. Once software applications are implemented, it will be necessary to ensure that state public health agencies have the hardware systems needed for deployment during a public health event.

In the short term, public health agencies will be building systems that could be deployed when needed to track the delivery of vaccine, antiviral medications, or other pharmaceutical products necessary during a pandemic influenza outbreak. These systems will be able to aggregate nationally the delivery of similar antiviral medications and vaccines in order to share that information.<sup>21</sup>

## Conclusion

State public health agencies are building new CRA systems, building on existing systems, such as IISs, and awaiting the release of the CDC CRA application to achieve CRA functionality. This functionality is vital to influenza pandemic preparation and response and overall public health preparedness.

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<sup>1</sup> CDC Overview: Use of the CDC's CRA System for Pandemic Influenza. [Powerpoint] At: [www.immregistries.org/docs/AIRA\\_PanFluWorkshop\\_CRA\\_030506.ppt](http://www.immregistries.org/docs/AIRA_PanFluWorkshop_CRA_030506.ppt). Accessed: 03-20-06.

<sup>2</sup> Department of Health and Human Services. Pandemic Influenza Plan. At: [www.hhs.gov/pandemicflu/plan/](http://www.hhs.gov/pandemicflu/plan/). Accessed 05-08-06.

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<sup>3</sup> PHIN: Countermeasure and Response Administration Overview. At: [www.cdc.gov/phिन/preparedness/cra\\_overview.html](http://www.cdc.gov/phिन/preparedness/cra_overview.html). Accessed 03-13-2006.

<sup>4</sup> Institute of Medicine of the National Academies. *The Smallpox Vaccination Program: Public Health in an Age of Terror*. National Academies Press. Washington, DC. 2005.

<sup>5</sup> Association of State and Territorial Health Officials (ASTHO). *Remembering Smallpox: Lessons Learned from the State Experience*. October 2004. At: [www.astho.org/pubs/SmallpoxLessonsLearned20.pdf](http://www.astho.org/pubs/SmallpoxLessonsLearned20.pdf). Accessed 04-17-06.

<sup>6</sup> Institute of Medicine of the National Academies. *The Smallpox Vaccination Program: Public Health in an Age of Terror*. National Academies Press. Washington, DC. 2005.

<sup>7</sup> PHIN Preparedness Countermeasure/Response Administration Functional Requirements. Version 1.0. April 2005. At: [www.cdc.gov/phिन/preparedness/CRA\\_RSv1.0.pdf](http://www.cdc.gov/phिन/preparedness/CRA_RSv1.0.pdf). Accessed 04-18-06.

<sup>8</sup> PHIN Preparedness Key Performance Measures Version 1.0 April 2005. At: [www.cdc.gov/phिन/kpm/KPM\\_RSv1.0.pdf](http://www.cdc.gov/phिन/kpm/KPM_RSv1.0.pdf). Accessed 04-18-06.

<sup>9</sup> Cicchinelli, M (personal communication 05-10-06).

<sup>10</sup> American Immunization Registry Association. IIS Pandemic Influenza Survey. February 15, 2006.

<sup>11</sup> Ibid.

<sup>12</sup> Swanson, B (personal communication 05-04-06).

<sup>13</sup> Pandemic Flu Preparedness: Michigan Childhood Immunization Registry. [Powerpoint] March 5, 2006. At: [www.immregistries.org/docs/AIRA\\_PanFluWorkshop\\_MI\\_030506.ppt](http://www.immregistries.org/docs/AIRA_PanFluWorkshop_MI_030506.ppt).

Accessed: 04-07-06.

<sup>14</sup> Meeting Notes. Pandemic Flu Vaccination Tracking Users Working Group. November 22, 2005.

<sup>15</sup> Ware, K (personal communication 05-04-06).

<sup>16</sup> Aspevig, J. (personal communication 05-04-06).

<sup>17</sup> PHIN: Countermeasure and Response Administration. At: [www.cdc.gov/phिन/preparedness/cra.html](http://www.cdc.gov/phिन/preparedness/cra.html). Accessed 04-17-06.

<sup>18</sup> CDC Overview: Use of the CDC CRA System for Pandemic Influenza. [Powerpoint] March 5, 2006. At: [www.immregistries.org/docs/AIRA\\_PanFluWorkshop\\_CRA\\_030506.ppt](http://www.immregistries.org/docs/AIRA_PanFluWorkshop_CRA_030506.ppt). Accessed: 03-20-06.

<sup>19</sup> Steele L (personal communication 05-10-06).

<sup>20</sup> Ibid.

<sup>21</sup> Ibid.

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