Management of Vaccine Inventories as a Critical Health Resource

Lessons Learned from Louisiana’s 2007 Mass-Immunization Exercise

BY ROBERT CONN, FRANK J. WELCH, AND MICHAEL L. POPOVICH

Currently, there are a total of 33 vaccines that target human disease, and these are produced by nine manufacturers [1]. The majority of vaccines are made by three companies: Sanofi-Pasteur (Aventis), Merck, and GlaxoSmithKline, with Sanofi-Pasteur being the largest supplier. In 2007, it shipped more than 1.6 billion doses of vaccine worldwide, including 130 million doses of influenza vaccine [2], which illustrates its global commitment to produce vaccines to meet the global demand if a pandemic were to occur.

With a limited number of vaccine manufacturers in the United States, coupled with the fact that the major supplier of pandemic vaccine is not based in the United States, vaccine production should be considered a critical resource challenge for U.S. preparedness. The probability of a major health-related event causing a disruption in the vaccine supply chain should be of concern to health officials.

The U.S. Centers for Disease Prevention and Control (CDC) has recognized the critical nature of vaccines to support the preparedness and has established specific influenza vaccine goals [3] (Table 1).

Given the importance of this resource as a component of the health infrastructure, the organizational level that will most likely be ultimately responsible for managing this resource will be state health departments. For directors, emergency coordinators, and public health officials managing state preparedness, the key questions specific to vaccine will be as follows:

- Where is the state’s current influenza vaccine inventory located?
- Is it distributed appropriately to respond to the demand?
- How do I monitor the utilization rates to redistribute or reorder?

To address this issue, health departments are examining their information infrastructure that would support the administration and utilization of vaccines in their communities. One of the most important information environments within health departments is the statewide immunization registry. Currently, 49 of 50 U.S. states have implemented a state registry [4]. These registries, which were originally developed with an emphasis on children through school age, have now evolved to include doses administered to all age groups. With this information resource, it is now possible to identify at-risk populations based on current vaccine converge rates. In turn, this provides data to public health professionals regarding the distribution and allocation of vaccines to regional locations.

In 2007, the State of Louisiana conducted a statewide influenza mass-vaccination event drill for emergency preparedness, simulating a mass-immunization event. One objective of this drill was to determine the value of using the state’s immunization registry to provide real-time information to decision makers in emergency command centers to support vaccine utilization and regional needs. The goal was to determine the value of real-time data and, in particular, to determine how the statewide registry could support these efforts.

The Louisiana Immunization Network for Kids Statewide (LINKS), developed by Scientific Technologies Corporation (STC), has been in operation for more than seven years. It was utilized extensively after Hurricane Katrina in 2005 and validated the importance of utilizing electronic immunization records to support mass-displacement events [5].

Given this rich resource and a proven history of utilization by the provider and emergency operations centers (EOCs), a project was designed for health providers at specific state-designated vaccine points of distribution (PODs) to capture vaccine utilization data with real-time reporting to command centers to determine demand and availability of vaccine supplies.

Background

Public health mass-immunization or dispensing responses to outbreaks of communicable disease have been greatly aided with the advent of secure network or Internet-accessible population-based databases. States are successfully tracking childhood and adult immunizations through access by both private and public providers to the statewide database. These immunization management systems have also proven to reduce the overimmunization of patients because of lost or incomplete hand-carried vaccination records. A second important result of this has been to reduce the total doses used for publicly or privately supplied vaccine inventories, thus reducing costs and, equally important, increasing the availability of this crucial resource in a critical event.

Statewide registries, such as the LINKS, have evolved to a robust suite of applications catering to the needs of the patients, parents, private and public providers, and CDC. The registries are feature rich, with the ability to capture hundreds of data...
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elements related to patient demographics, vaccines, inventory, and information about the participating medical organizations and the users. They are designed to provide standard and customized reports, reminder or recall processes, automated and manual patient-record matching, and algorithms to forecast vaccinations for which a patient may be due or past due.

In the case of a major health-related event in which mass immunization of individuals would be required, the use of electronic information systems to support management of critical resources is not the norm. Data collection, for example, has historically been accomplished through handwritten forms, followed by electronic data entry accomplished after the event. Manual counts by staff of onsite inventory levels, volumes of patients being served, and staffing levels at the PODs are common. Reporting to decision makers at EOCs through mobile communications is the mode for information flow. Vaccine allocation, movement of supplies, and reordering from vaccine distributors are delayed and are inefficient. In an environment of demand being greater than vaccine supply, the ability to determine exact needs would reduce the current tendency to overestimate the orders, thus potentially consuming resources that are best utilized in other locations.

With a paper-based data-collection process, the tracking of the general population patient is not shared in a real-time manner with the EOC, but the data about those considered to be first responders, including essential health-care support staff, critical infrastructure workers, public health emergency response workers, and high-risk patients, are not efficiently categorized, with the aggregated data made available to the EOC decision makers at the time of the encounters. Furthermore, after dispensing medicine or giving an immunization, there is no opportunity to easily monitor an adverse reaction or to contact an individual at a later date for a follow-up.

The Louisiana Experience

As a result of the post-Katrina response in 2005, the value of electronic data capture of patient services specific to immunizations was established within the refugee shelter environments. Since then, the Louisiana State Office of Public Health (OPH) has proactively sought to increase the capability of the statewide immunization registry to further support real-time data capture and real-time information for EOC management decision support.

Various statewide preparedness drills, including plague drill in 2005, statewide mass immunization in 2006, and the most recent mass-vaccination event drill and flu season preparation in 2007, have continued to increase the lessons learned and demonstrate the value of real-time data collection and information.

Both the 2005 and 2006 drills showed increasing levels of preparedness for public health responses to emergencies [6]. The efficiency and value of the use of electronic data collection are evident in the rapid setup of data collection at community-based PODs and in the distribution of critical resources such as vaccines and other pharmaceutical product inventories among the PODs. Past experience has also pointed to a need for a continual improvement in electronic system capabilities. Improvements are needed at two levels: the complete elimination of paper forms as backup processes to online information systems at each POD and the need for a consolidated view of the resources and event activity across all PODs at the EOC level.

### Table 1. Influenza vaccine goals.

| Vaccine goal 1 | To establish and maintain a dynamic pre-pandemic influenza vaccine stockpile available for 20 million persons: H5N1 stockpiles (40 million doses) |
| Vaccine goal 2 | To provide pandemic vaccine to all U.S. citizens within six months of a pandemic declaration: pandemic vaccine (600 million doses) |
| Antivirals goal 1 | To provide influenza antiviral drug stockpiles for treatment of pandemic illness for 25% of the U.S. population, who we estimate will become clinically ill during a pandemic (75 million treatment courses) |
| Antivirals goal 2 | To provide an influenza antiviral drug stockpile for strategic limited containment at the onset of a pandemic (6 million treatment courses) |
| Diagnostics goal 1 | To develop new high throughput laboratory and point-of-care influenza diagnostics for pandemic virus detection |

### 2007 Louisiana Drill Results

In previous preparedness exercises, the immunization registry was accessed in real time at each POD, and a specific user interface was allowed for rapid Web-based data entry to capture the minimal data set. Because there was no guarantee that online access could be provided or sustained, the backup system used was the paper form. The forms replicated the data elements collected in the mass-immunization module, a rapid data entry tool. These data would then be electronically entered once connectivity had been restored and as the POD workflow allowed.

In the 2007 drill, one of the nine statewide PODs lost connectivity for a period of several hours, and the data entry personnel reverted to paper forms. This constituted approximately 6% of the total data from the six-hour drill, and all data were in the central LINKS system within 24 h. It has been observed in past that in nearly every Louisiana mass-vaccination event, especially where PODs are quickly established in community centers, network or Internet connectivity is lost for at least some period of time, typically for an hour or less. In such cases, data collection using paper forms has been the only recourse. Paper increases the
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workload, and, hence, real-time information to support decisions is not readily accessible, and the quality of data entered after the health-care service is less accurate. As a result, it was determined that a paperless system would be a preferable means of backup.

As the drill progressed, the value of online data entry at the time of service became more apparent to the health professionals in the EOC. Real-time, accurate information is critical to EOC personnel charged with monitoring the activities of the PODs during mass events. Within a few hours of operation, the EOC staff was able to determine from the patient flow and vaccine inventory information that all PODs would deplete their inventories of flu vaccine at their then current rate of use. To alleviate the projected shortfall of vaccine, the immunization registry was used to determine locations of additional vaccines near each POD. EOC staff were able to coordinate the transfer of flu vaccine to the PODs, thereby preventing any of the PODs from running out of vaccine and having to turn away patients during the six-hour drill. This was a critical metric to manage this valuable resource.

Specific lessons focused on the fact that the EOC decision makers need access to information from all the PODs in real time as the event progresses. Decision makers required the ability to answer the following questions, without the need for numerous voice communications or extensive manipulation of data gathered from running various reports.

- **Facilities (PODs):** Are the facilities located properly? Do others need to be opened?
- **POD staff levels:** Are the intake, vaccination, and data entry personnel able to keep up with the patient flow?
- **Patients:** Is the targeted population being served? Are there geographically (or other) defined groups not being served?
- **Pharmaceutical inventory:** What is the current inventory? What is the rate of use? What or where are the sources of resupply?
- **First responders and other essential personnel:** How many and what categories of essential personnel have been vaccinated and are prepared to render services?

During the 2007 drill, the EOC staff found that they had sufficient information to determine vaccine levels and patient flow for each POD.

**The Solution**

To ensure the greatest patient coverage rate and the protection of public health in a public health emergency and to employ the most efficient utilization of resources such as responders and vaccine inventories, two problems need to be solved.

1) **Point-of-service data collection at the POD level must be done in real time, or in the case of connectivity loss, the quality of the data must be maintained, that is, all the information should be entered electronically and not collected on paper forms.**

2) The systems in use by the EOCs need to be enhanced to eliminate or reduce the need for manual manipulation to the lowest possible level.

For the 2007 drill, the solution to the point-of-service backup challenge was the migration of the current Web-based mass-immunization module to a standalone tool for local and nonconnected data entry. The tool was implemented in a USB to allow for connectivity to any computer such that the entire application and database resided on this device. Thus, no software was required on the host computer, and no special connection or hardware was necessary. This application replaces the need for paper forms, with all point-of-service data entry activity continued electronically and data uploaded to the state registry when network or Internet access is restored. This ensures the shortest possible lapse of real-time information for the EOC and, most importantly, maintains the accuracy of the patient’s demographic and vaccination information.

A solution to the second problem has not been implemented yet, as the recommendation was to establish an EOC immunization dashboard to create a consolidated view of the real-time data flowing from each POD. The proposed solution would eliminate the need for additional data consolidation at the EOC, which utilizes spreadsheets that require a labor-intensive maintenance. As a result of the most recent drill, an EOC immunization dashboard has been designed and is intended to derive and display information such as projected inventory depletion times as the data flow in from the event PODs. Figure 1 illustrates a real-time display that would be updated through information collected from each POD as these data are entered into the state immunization registry.

The hours remaining prior to depletion of the vaccine inventory would be calculated based on the beginning inventory levels, current patient volume, and the number of patients in queue at each POD. This is an essential decision support measurement.

In addition to the snapshot summary of activity at each POD, the drill illustrated the need for real-time reports to represent service delivery.

As seen for Site 4 in Figure 2, which illustrates the numbers of patients served at each POD, the St. Edmond Family Center lost network connectivity and reverted to collecting data on paper forms. This was reflected in the lagging number of vaccinations even though the patient volume was high at that POD.

Figure 3 illustrates the individuals being served at a specific POD by age group, which is valuable for the type of vaccine and staff required.

Figure 4 represents the number of patients residing in five parishes who received influenza vaccinations during the event.

**Outcome**

The 2007 drill validates the usefulness of the state’s immunization registry as an EOC management tool for the management of vaccines during a mass-immunization event. This real-time information allowed an assessment of vaccine utilization rates, assessed local stockpiles of vaccines, and prevented PODs from running out of vaccine prior to the end of the drill.
Prior to the drill, it was estimated that each POD would experience a workload of approximately 200 patients per hour, resulting in 11,000 vaccinations statewide for six hours. Surprisingly, the actual workload was more than double this number, and the 27,000 vaccinations were administered with more than 90% of the data recorded in a paperless process. This drill further demonstrated the likelihood that, in an event, the demand will outweigh the expected workload and available vaccine resources. Resources will be challenged, and only through rapid and real-time data collection can decision support staff maximize the use of resources while minimizing the burden on their time to process and analyze data.

The case study focused on the single critical resource of vaccines. Information and decision support tools to manage inventory and distributions served to maximize the ability of the state public health officials to protect individuals from vaccine-preventable diseases. Vaccine resources are a critical U.S. element to the overall infrastructure-supporting preparedness. There is no guarantee that there will be sufficient

One of the most important information environments within health departments is the statewide immunization registry.
vaccine to support all potential events, but as was demonstrated in this Louisiana Case Study, there are tools and data workflows to support and manage the use of a limited resource.

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Michael L. Popovich received his M.S. degree in systems engineering and B.S. degree in engineering mathematics from the University of Arizona. He has 35 years of engineering consulting and business experience. He founded STC in 1988 to provide information technology strategic planning, solutions, and services to local, state, and federal governments, with the primary focus on departments of health. He was instrumental in developing the U.S. technical model for immunization registries, working closely with the CDC, private foundations, and state governments. He worked with a small team of professional experts and the CDC to provide key input in the development of standardized national immunization data elements. With more than 16 years of population-based registry expertise, he has also provided the vision for the next generation of STC products to support disease outbreaks, regional disease-surveillance notifications and communications, and the integration of public health solutions within the private health sector. He is an author of more than 150 articles, white papers, and presentations. He is a founding board member of the International Council on Medical and Care Compunetics, a European-based applied technology think tank, whose mission is to support national electronic health systems and standards designed to improve the quality of health care for people throughout the world.

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References

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Fig. 4. Aggregate number of patients vaccinated by parish of residence (sample of five out of 64 parishes).