

LOCAL HEALTH DEPARTMENT RESPONSES DURING THE 2004–2005 INFLUENZA VACCINE SHORTAGE

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ABSTRACT: During the 2004–2005 influenza vaccine shortage, the Centers for Disease Control and Prevention (CDC) coordinated distribution of post-October 5th 2004 doses of influenza vaccine to state and local health departments (LHDs), who subsequently distributed vaccine to community providers. The National Association of County and City Health Officials (NACCHO) conducted three Web-based surveys throughout the 2004–2005 influenza season to assess in real-time how LHDs were 1) dealing with the vaccine shortage, 2) implementing the interim recommendations from the Advisory Committee on Immunization Practices (ACIP), and 3) making efforts to reallocate and redistribute doses of influenza vaccine toward high-priority populations within their communities. This paper highlights LHD responses that alleviated adverse impacts during this public health emergency. The first survey asked LHDs to quantify their community's vaccine supply; the second survey asked them to describe their specific responses to the crisis; and the third survey asked them to reflect and evaluate the effectiveness of their efforts to vaccinate high-priority groups during the crisis. Six hundred five (605) of 717 (84%) LHDs in 44 states responded to the three surveys. Results show that LHDs leveraged preparedness plans, formed strategic community partnerships, and practiced vaccination drills to address the problems of vaccinating high-priority and hard-to-reach populations that arose out of the vaccine shortage. The practices used by LHDs during this shortage may provide valuable response lessons to minimize the impact of future influenza vaccine shortages and other public health emergencies.

KEY WORDS: Local health department; Influenza vaccine; Shortage; Preparedness.

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INTRODUCTION

Efforts to control and prevent influenza infection are ongoing. Unfortunately, influenza vaccine supply disruptions are now commonplace, compromising the effectiveness of plans to achieve Healthy People 2010 (HP2010) influenza immunization rate goals toward vaccinating high-priority persons.¹ Influenza is a potentially life-threatening illness caused by an ever-changing virus that affects humans and a spectrum of wild and domesticated animals.² Influenza infection in the U.S. kills more than 36,000 people each year and causes serious medical and social stress in communities and is associated with increased economic and societal costs.³ After the October 5, 2004, Chiron announcement that they would not be allowed to deliver 48 million doses of influenza vaccine, the National Association of County and City Health Officials (NACCHO) developed a Web-based survey (on October 6, 2004) instrument to query a subset of its members (n = 717) regarding their responses to the influenza vaccine shortage.⁴ Due to the sudden onset of the shortage, time constraints and the need for immediate information, a Web-based survey was used and selection of a sample population was based not on random selection but on selection of those LHDs that had responded to a previously administered multi-part NACCHO survey during an immunization-related public health emergency in 2003.⁵ The goals of these surveys were five-fold: 1) to provide a clearer picture of national distribution of influenza vaccine supplies to all levels of governmental public health; 2) to better inform efforts to reallocate and redistribute vaccine toward high-priority populations; 3) to quantify the impact of the shortages on LHDs' ability to vaccinate high-priority populations and implement the ACIP interim prioritization recommendations; 4) to document their responses to the crisis and their efforts to maintain routine public health programs, services, and activities; and 5) to evaluate their operational responses and provide lessons for future vaccine-related emergencies.⁶

METHODS

Between October 6, 2004, and March 8, 2005, NACCHO, which represents the nation's 2800 LHDs, conducted three Web-based surveys to capture LHD self-reported experiences with the influenza vaccine shortage and implementation of CDC and ACIP recommendations regarding prioritization and redistribution and reallocation of influenza vaccine. NACCHO developed a survey URL that was posted out via E-mail to a subset of

717 LHD immunization program managers. The second and third portions of the survey were posted the same way in December 2004 and March 2005, respectively. These E-mail addresses were unique and represented individual LHDs. NACCHO solicited participation in the survey via e-mail from a selected sample of LHD immunization managers and staff members, asking that they agree to complete the entire series throughout the 2004–05 influenza season. Replies to each part of the survey from each LHD were concatenated to create a single LHD survey for analysis. Most of the questions were open-ended and responses were analyzed for content and theme and then coded.

Shortages of influenza vaccine and distribution delays and disruptions have occurred more often than not since the 1999–2000 influenza season. Multiple recommended fixes have come from a variety of sources. Several legislative fixes have been proposed and several expert panels have been convened.⁷ These legislative fixtures were predicated on results and recommendations from numerous published studies and reports. However, published reports on the impact of the shortage on vaccinating high-priority populations have tended to focus on private providers and general-public perspectives.^{8,9} Publications have also focused on another player on the stage – vaccine manufacturers, particularly focusing on the issue of liability and its association with the shrinking vaccines marketplace.¹⁰ This paper fills a gap in the literature, as there is a lack of information on documentation of: 1) the impact that these influenza vaccine shortages and supply disruptions have on routine local public health practice and 2) broad-spectrum documentation of local responses to these influenza vaccine shortages and supply disruptions. The literature has accounts of individual agency responses or experiences, but there is a dearth of literature that characterizes the response of this particular segment of governmental public health. There have been numerous reports issued by the Institute of Medicine, the Government Accountability Office, the Advisory Committee on Immunization Practices (ACIP), and the National Vaccine Advisory Committee (NVAC) regarding vaccine supply crises and subsequent recommendations for remedying those shortcomings of our public health system.^{11–13}

RESULTS

Of the 717 LHDs contacted, 605 (84%) completed the entire series of surveys and were included in the analysis. Survey respondents represented LHDs in 44 states, ranging in size from small county to large city

health departments, serving populations ranging in number from 30,000 to more than 9 million. Results from specific questions are detailed in the following narrative.

Emergency Orders and Implementation of Prioritization

NACCHO asked if LHDs operated under emergency orders during the influenza season (Table 1).¹⁴ Of the agencies responding to that question, 407 functioned under either city, county, or state (and sometimes multiple) emergency orders. One hundred ninety-seven jurisdictions did not. All of the responding jurisdictions did an excellent job of getting vaccine to high-priority groups. However, those operating under emergency orders and exercising emergency response plans seem to have done a better job of getting vaccine to the public, as they had an average of 4% of received doses remaining in March 2005. Those not operating under emergency orders had an average of 10.3% of their received doses remaining.

Placing Orders

NACCHO asked how the agencies ordered vaccine during the 2004–05 influenza season. Two hundred forty-eight (41%) respondents ordered via a state contract, 127 (21%) ordered via a multi-state contract, 24 (4%) ordered via a federal contract, and 206 (34%) ordered independently of state, multi-state, and federal contracts. These results indicate that jurisdictions split their orders based on experiences from past influenza vaccine supply disruptions (Figure 1). Some of the other means of placing orders included ordering via local immunization coalitions, consortiums of

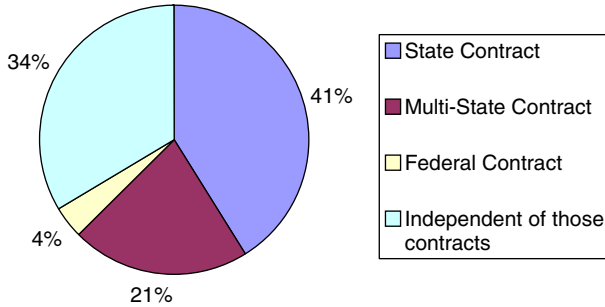
TABLE 1

Doses Received, Doses Remaining as of March 2005

<i>Status</i>	<i>n</i>	<i>Doses Received</i>	<i>Doses Remaining</i>	<i>%Unused</i>
Emergency Orders/exercised preparedness plan	407	3,212,739	128,511	4%
No Emergency Orders/no preparedness plan	197	993,067	102,450	10.3%
Totals/mean	604	4,205,806	230,961	5.5%

FIGURE 1

Local health department methods of ordering influenza vaccine



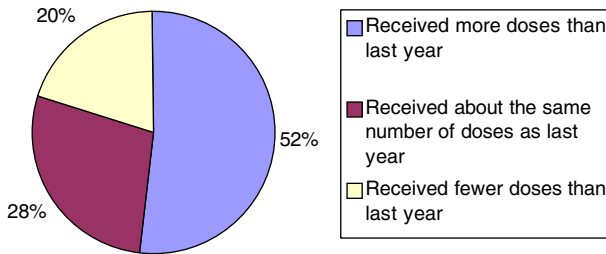
LHDs, and group orders with their emergency preparedness partners. The survey did not ask LHDs to indicate which manufacturer they ordered from, although several respondents included that information. Those data were not included in the analysis.

Doses Ordered and Doses Received

Respondents were asked to quantify the number of doses their agency ordered for the 2004–2005 season. Respondents ordered 3,364,460 doses and received 4,205,806 doses – 20% more vaccine than responding LHDs initially ordered and expected for the 2004–2005 influenza season. At the beginning of the season, most respondents reported that they had very few doses of influenza vaccine. Respondents reported receiving vaccine in allotments, with many indicating that vaccine doses came during December 2004 and later, when public demand for vaccine had waned. This is consistent with their answers to another question, as to whether the number of doses received was more than normal, about the same, or fewer doses than the previous year (Figure 2). Three hundred and nine (51%) respondents indicated that they received more doses of vaccine during 2004–05 when compared to 2003–04. One hundred sixty-nine (28%) respondents indicated that they received fewer doses during the 2004–05 season, and 121 (20%) indicated that they received about the same number of doses as the 2003–04 season. Six respondents gave indeterminate answers and were excluded from analysis for this question.

FIGURE 2

Vaccine doses received by local health departments

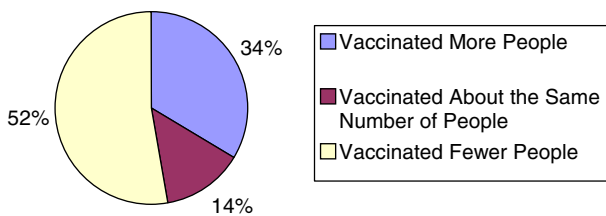


Numbers of Persons Vaccinated

NACCHO asked whether the numbers of people vaccinated by the responding agency was similar to or different from the numbers vaccinated in the previous influenza season (Figure 3). Three hundred and fourteen (52%) respondents indicated that they vaccinated fewer persons and 206 (34%) indicated they vaccinated more than the previous season. The responses were slightly skewed for smaller jurisdictions to have vaccinated more people than in previous years, as they also received more doses of vaccine than in previous years – this was predicated on the CDC reallocation formula, where vaccine doses were reallocated toward high-priority populations.¹⁵ These results are also consistent with Behavioral Risk Factor Surveillance System (BRFSS) data regarding persons vaccinated in 2004–05 versus prior influenza seasons.¹⁶

FIGURE 3

Comparison of numbers of people vaccinated at local health departments



Delivery of Public Health Services

LHDs characterized their responses to the shortage and documented the steps they took to use scarce doses of vaccine as judiciously as possible (Table 2). They also described the impact the vaccine shortage had on their routine public health programs and activities. Four hundred seventy-two (78%) respondents reported that the shortage interrupted their other public health programs and activities. LHDs reported that staff, resources, and funds were diverted from other public health activities and programs to help coordinate the response to the influenza vaccine shortage (Table 3). In addition, a significant number of LHDs reported that they deferred, delayed, or cancelled specific public health programs and activities, e.g., environmental inspections, wellness clinics, trainings, and walk-in services.

Evaluating the Response

NACCHO asked respondents to report what went well (Table 4) during this influenza season and to list the top complaints (Table 5) they heard regarding how the influenza vaccine shortage was handled. We asked them to indicate whether the complaints came from the general public, within their public health agency, or from private providers or other community partners. For things that went well, the overwhelming majority of respondents (61%) responded that developing coalitions and strategic partnerships within the community helped them tremendously. The local coalitions brought together all community stakeholders, e.g., hospitals,

TABLE 2

How did your Agency Respond to the Shortage?

<i>Action</i>	<i>n</i>	<i>%</i>
Held late-season influenza clinics	363	60
Exercised and implemented preparedness plans, including conducting mass vaccinations clinics	460	76
Rescheduled previously planned clinics	54	9
Cancelled Clinics	236	39
Redistributed vaccine to local partners	230	38
Formed Flu Coalitions/Community partnerships	569	94
Implemented priority schemes, including lotteries	115	19
Other	67	11

TABLE 3

Impact on Other Local Public Health Services and Activities

<i>Activity</i>	<i>n</i>	<i>%</i>
Delayed communicable disease investigations, including surveillance	199	33
HIV/STD/TB testing, screening, and services	54	9
Inspections	36	6
Family planning/WIC/nursing outreach services	145	24
Administrative activities	181	30
Trainings	133	22

TABLE 4

What went well During the 2004–2005 Influenza Season

<i>Item</i>	<i>n</i>	<i>%</i>
Redistribution efforts	79	13
Partnerships/Coalitions	369	61
Community outreach and public education	151	25
Increased uptake by high-priority groups	67	11
Guidance from state health department and CDC	48	8

public health, police, fire, medical societies, and non-traditional partners such as the multiple sclerosis society, to discuss response strategies. These coalitions provided the community a “place” to reach consensus, which helped eliminate barriers and facilitate faster implementation of recommendations and guidelines. As for complaints, the leading complaint by all stakeholders had to do with the ACIP recommendations for prioritization, as all parties felt that they should have been lifted earlier. Fifty-one (32%) respondents reported that the general public, providers, and public health agencies stated or indicated that the priority group restrictions should have been lifted earlier than December 2004.

Implications for Policy and Practice

The 2004–05 influenza vaccine shortage exemplifies the fragility of the nation’s influenza vaccine supply and highlights gaps in our readiness and ability to distribute vaccine doses equitably and to effectively target

TABLE 5

What did not go well During the 2004–2005 Influenza Season

<i>Complaint</i>	<i>n</i>	<i>%</i>	<i>Dominant source of complaint</i>
Distribution and access problems	157	26	Public health agencies, health care providers, nursing homes, general public
Poor communication to public	127	21	Public health staff, general public
Late, conflicting, confusing information from governmental public health	36	6	Private providers
Priority schemes – should have been subprioritized; should have been lifted earlier	193	32	All groups
Public health not prepared – no plan in place	66	11	Public health agencies, providers, general public
Billing issues – especially with Medicare	66	11	Local public health agencies
Distributors were barrier to delivering vaccine	151	25	Public health agencies; nursing homes

providers (e.g., LHDs) that reach high-priority persons for annual influenza vaccination. Those reasons contribute to the fact that despite that the nation experienced a shortage of influenza vaccine, there were doses remaining at the end of the 2004–05 season. Shortages, delays, and maldistribution of vaccine doses have happened repeatedly since 1999, and appear to grow in intensity with each subsequent season. When these shortages occur, vaccination practices are altered to deal with the particular situation. LHDs and their community partners respond in a variety of ways to conserve a limited supply of vaccine to assure that there will be ample doses available for those who need them most. The survey results and the LHDs’ experiences show the limitations of the recommendations of the various reports (e.g., IOM, GAO) that have recommended after each shortage or supply disruption actions such as stockpiling doses of vaccine or using vouchers to improve high-priority populations’ access to immunization services. However, these reports often lack recommendations on implementing those recommendations and making them operational at the local level. Results from these surveys can provide insight to those reports regarding the necessary revisions needed to make them practical and usable at the local level, where the “needle meets the arm.”

Case Studies

A number of LHDs used innovative techniques to respond to the vaccine shortage. While some of these strategies focused on clinic preparation and identifying appropriate staff and volunteer roles to ensure clinics run smoothly, others revolved around innovative methods that ensured a fair and equitable system for getting vaccine out to the community. The survey captured some of these experiences and documented them for lessons learned to inform future response plans for future emergencies. Below, we highlight four exemplary LHDs and their model responses to this complex public health emergency and challenge.

Waccamaw Public Health District, South Carolina: Identifying Roles and Responsibilities Using Incident Command

The Waccamaw Public Health District in South Carolina utilized a number of strategies to respond to the 2004 vaccine shortage.¹⁷ To the Waccamaw Public Health District, the shortage was viewed as an opportunity to work with other first responder groups and to test plans and systems already in place. Specifically, planning for mass vaccination clinics presented the Waccamaw Public Health District with the challenge of using incident command, a system that was new to public health in the district. Identifying roles and responsibilities in advance helped ensure that the clinic ran smoothly. Some of the responsibilities identified were as follows:

- Assessment and planning phase of the event;
- Clinic model development, including clinic flow, anticipating and preparing for problems, and performing role assignment of clinic staff;
- Staffing and securing employees from health service clinics, home health and environmental health programs;
- Organizing forms and supplies;
- Answering phone calls; and
- A nurse vaccinator.

Assigning these roles appropriately and ensuring that all staff acknowledged their responsibilities enabled a successful response. In addition to these roles, it became evident that logistics, management of the vaccine supply, and risk communications were also critical roles to identify ahead of time.

Crowd control issues became a major challenge, especially in relation to the special-needs populations. While the elderly, for example, faced long lines and needed a place to sit and rest, others required restroom facilities and water. To help alleviate these issues, a “logistics team” took the lead on monitoring individuals in line and addressing their needs when problems arose. “Sit zones” were set up to assist those needing rest, and water stations were prepared. Public health physicians and EMS were on standby.

To avoid having people wait in line once vaccine supplies were exhausted, a role had been created to manage the vaccine supply and project availability based on number of shots already administered and remaining crowd estimates. This method enabled all candidates who were eligible and in line to receive influenza vaccine.

With regard to the media, public health took the lead on risk communications. The incident commander (Director of Public Health Preparedness) and two physicians took the lead in responding to questions. Anticipated questions were drafted, and responses were identified in conjunction with other partners to ensure that all were in agreement and a consistent message was conveyed. In addition, this group communicated regularly through advanced communication technology (e.g., 800 MHz radios) to ensure that messages remained consistent as conditions throughout the clinic changed.

Harvey County Health Department, Kansas: The “Shots-By-Appointment” Approach

Staff at the Harvey County Health Department utilized a “shots-by-appointment” approach to avoid long lines, especially in light of the shortage.¹⁸ By prohibiting walk-ins, which are appropriate when there is a consistent supply of vaccine, the shots-by-appointment method allowed public health staff to better control the number of shots given per block of time, and prepare paperwork ahead of time. Wait times were minimized and crowd control was not an issue. There were, however, challenges with regard to setting up these appointments, as phone lines jammed once lines were opened and many individuals showed up at the health department to make an appointment, which was unanticipated. While front desk staff were assigned the role of making these appointments, administrative staff was called in to assist. Once the staffing situation was addressed, sign ups ran smoothly.

Cambridge Public Health Department, Massachusetts: A Regional Approach to Vaccinating the Public

The vaccine shortage was seen as an opportunity to further emergency preparedness planning at the Cambridge Public Health Department Advanced Practice Center.¹⁹ Massachusetts Emergency Preparedness Region 4B includes 27 communities, including Cambridge. Many of the communities within this region worked collaboratively with cross-jurisdictional partners to plan and implement collaborative, or sub-regional, influenza clinics. Planning clinics this way was beneficial in that neighboring health departments were working collaboratively to not only share resources, but also share ideas. It also helped expand the capacity to vaccinate individuals in the community. However, regionalizing also comes with challenges. With the limited time available for planning these regional influenza clinics, it was difficult coordinating certain important issues across community boundaries, including staffing, funding, and clinic locations, all of which require time to plan.

Regional clinics require some extra work given the involvement of a number of entities. However, with proper coordination and adequate time, the benefits of creating new relationships and sharing resources proved invaluable. Once the clinics were completed, the Cambridge Public Health Department Advanced Practice Center worked with the Institute for Community Health to capture lessons learned from the experience. Some recommendations are as follows:

- Ensure that there is adequate time for planning. Coordination of resources from a variety of health departments takes time;
- Identify funds for the clinics. In some cases, health departments may have limited budgets and it would be important to identify some external source, if possible;
- Clearly identify leadership roles, whether a formal incident command system is being used or not, and define standard operations procedures and practices;
- Formalize the process of resource tracking to better monitor your supplies and know when staff are available; and
- Identify a central, regional storage area to avoid having to transport supplies from various locations.

Montgomery County Department Of Health And Human Services, Maryland: A Vaccine Lottery for the Community

Staff at the Montgomery County Department of Health and Human Services in Maryland opted to create a lottery system to address the vaccine shortage as a means of providing people with more of an opportunity to apply to receive vaccine. This created a system that was fair, orderly and effective, while customers were satisfied and crowds were controlled. It was, however, very labor intensive. The demand for vaccine was far greater than the supply. Staff at the health department had to put their projects on hold to help respond to the many calls and emails from interested individuals. While under the circumstances, the lottery was the best choice at the time, it still required much staff time and energy, resources were stretched, and costs were high. High public demand was also not accurately anticipated. With only 800 doses of vaccine, 21,680 names were entered into the drawing.

The call-backs to those who won the lottery were costly and time consuming. With better technology support, human resources could have been used more effectively. Much of the time was spent entering data into computers, and looking back, the health department felt this could have been avoided had up-to-date technology been used that enabled the health department to activate a “call center” that had direct data entry, call-back features, and other interactive functions.

The vaccine lottery system has implications for addressing a possible pandemic influenza outbreak given the likelihood of having limited doses of vaccine. In addition, the Montgomery County Department of Health and Human Services also considered a “weighted lottery,” in which priority is given to “high-risk” applicants to receive the vaccine. This approach helps get the vaccine to those who really need it; however, the challenge is making judgments and defining who exactly fits in the high-risk category.

DISCUSSION

Web-based surveys are timely and provide informative data and feedback for planning during the occurrence of public health emergencies. However, there are several limitations to the use of the Internet for our assessment of local public health practices and responses during the 2004–2005 influenza vaccine shortage. Specifically, there were sampling concerns and selection of the survey participants. There were also issues that pertain to the restricted nature of such samples in that respondents must have

access to computers and be comfortable using technology and that such samples may not represent the full spectrum of LHDs. There are also concerns of confidentiality and lack of privacy, given that we informed respondents that some of their anecdotes could be shared with policy-makers and state and federal public health partners. There is also the issue of credibility and authenticity of the results from electronic surveys. Many of these surveys are open to responses from individuals outside the targeted sample. Specific safeguards were in place to verify the authenticity of respondents. We followed up via telephone with respondents whose responses or demographic information were questionable.

Manufacturing difficulties, the exit of manufacturers from the influenza vaccine market, changes in Food and Drug Administration (FDA) regulations for vaccine production, and mergers within the industry have contributed to extensive vaccine shortages in the past few years, particularly influenza vaccine. The influenza vaccine shortage of 2004–05 cut the nation's influenza vaccine supply by nearly 50% and everyone was caught off guard. LHDs' ability to deliver a critical immunization service to their most vulnerable citizens was greatly challenged by this development. Our survey results show that LHDs responded in a coordinated fashion and formed new partnerships and adopted and implemented new practices in the process. The LHDs demonstrated their adaptive capacities by leading local efforts to bring all community health care actors together and develop new and innovative partnerships to achieve a common goal of vaccinating high-priority persons, especially those in high-risk settings. The information collected in these surveys provides a compelling picture of the tremendous challenges LHDs faced during the 2004–2005 influenza season to connect scarce doses of vaccine with high-priority populations, to maintain their current levels of service, exercise preparedness plans, and develop and sustain strategic community partnerships. The lessons learned can be instructive as the nation prepares to respond to pandemic influenza outbreaks.

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