Survey of State Practices During the 2004–2005 Influenza Vaccine Shortage

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SYNOPSIS

To describe state-level actions and policies during the 2004–2005 influenza vaccine shortage and determine whether these or other factors were related to vaccination coverage, we surveyed all state health departments (including the District of Columbia). We included 2004–2005 Behavioral Risk Factor Surveillance System data to examine whether state-level actions, policies, or other factors like vaccine supply were related to changes in vaccination coverage in adults aged ≥65 years from the previous non-shortage year. We found that 96% (n=49) of states reported adopting or recommending adherence to the initial national interim influenza vaccination recommendations. Of these, at some point during the season, 22% (n=11) reported local public health agencies issued prioritization recommendations that differed from the state health department's guidance. Eighty percent (n=41) initiated at least one emergency response activity and 43% (n=22) referred to or implemented components of their pandemic influenza plans. In 35% (n=18), emergency or executive orders were issued or legislative action occurred.

In a multivariable linear regression model, the availability and use of practitioner contact lists and having a relatively high vaccine supply in early October 2004 were associated with smaller decreases in coverage for adults aged ≥65 years from the previous non-shortage season (p=0.003, r^2=0.26). States overwhelmingly followed national vaccination prioritization guidelines and used a range of activities to manage the 2004–2005 vaccine shortage. The availability and use of practitioner contact lists and having a relatively high vaccine supply early in the season were associated with smaller decreases in coverage from the previous non-shortage season.

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On October 5, 2004, Chiron Corporation notified the Centers for Disease Control and Prevention (CDC) that the Medicines and Healthcare Products Regulatory Agency of the United Kingdom, citing manufacturing deficiencies, had suspended its license to produce the trivalent inactivated influenza vaccine Fluvirin®.[1,2] As a result, Chiron was unable to supply any of its anticipated 48 million doses destined for the U.S. market—approximately half of the originally expected 102 million total doses.[3] In response, CDC, in coordination with the Advisory Committee on Immunization Practices (ACIP), issued interim influenza vaccination recommendations, which prioritized the following groups: children aged 6–23 months; adults aged ≥65 years; people aged 2–64 years with underlying chronic medical conditions; all women who would be pregnant during the influenza season; residents of nursing homes and long-term care facilities (LTCFs); children aged 6 months to 18 years on chronic aspirin therapy; health-care workers involved in direct patient care; and out-of-home caregivers and household contacts of children aged <6 months. Individuals not in these priority groups were initially asked to defer vaccination.[4]

CDC, in cooperation with state and local as well as private sector partners,[5] assumed an active role in managing vaccine supply and distribution. Additionally, the U.S. Food and Drug Administration, citing emergency medical reasons, authorized local redistribution of vaccine.[6] Throughout the 2004–2005 influenza season, CDC monitored vaccination coverage and periodically issued updated interim influenza vaccination recommendations.[7,8]

During the influenza vaccine shortage of the 2004–2005 season, states expended unprecedented efforts to manage vaccine procurement, allocation, and prioritization in order to reach those at highest risk for complications from influenza. It is important to examine state-level responses and determine whether specific practices were more effective in managing the shortage, especially because vaccine shortages are anticipated in the event of an influenza pandemic. Some problems faced by states, particularly those pertaining to sub-prioritization of high-risk groups, may provide lessons learned with respect to planning for pandemic influenza. The objectives of this study were to *(1)* describe the array of state-level actions taken and policies implemented in response to the 2004–2005 influenza vaccine shortage and *(2)* determine whether state actions or policies, or other factors such as vaccine supply, were related to influenza vaccination coverage levels.

METHODS

Survey respondents

We surveyed state health departments and the District of Columbia Department of Health. We recommended that the survey be completed by the state immunization manager or whomever had primary responsibility for responding to and managing issues related to the 2004–2005 influenza vaccine shortage, and encouraged collaboration with other staff as appropriate.

Survey content and administration

The 30-question Web-based survey was developed as a collaborative effort between the CDC's National Center for Immunization and Respiratory Diseases (proposed) and representatives from the Council of State and Territorial Epidemiologists, the Association of State and Territorial Health Officials, and the Association of Immunization Managers. It focused on vaccine prioritization, executive and legislative action, needs assessment, emergency preparedness, and redistribution and reallocation of vaccine. Respondents had the option to e-mail electronic documents or URLs linking to the documents and provide general comments regarding the 2004–2005 influenza vaccine shortage that they wished to share with investigators. The six-week survey administration period ran from the latter half of March through April 2005.

ANALYSIS

We conducted descriptive analysis, bivariate analysis, and multivariable linear regression. We examined whether certain state-level actions, policies, or vaccine supply in a state during the 2004–2005 season were associated with the magnitude of change in vaccination coverage from the previous non-shortage season. For the bivariate and multivariable analyses, independent variables included selected state actions and policies as well as vaccine supply in the state in early October 2004. We used previously determined CDC estimates of vaccine supply, which were calculated by taking the number of vaccine doses distributed in a state divided by the estimated number of ACIP-defined priority adults in that state. Vaccine doses distributed included direct orders from Aventis Pasteur Inc. (now Sanofi Pasteur) as well as doses ordered through CDC. Supply was stratified into three groups: *(1)* 75(+) doses per 100 priority adults, *(2)* 50 to 74.9 doses per 100 priority adults, and *(3)* <50 doses per 100 priority adults. The outcome measure was the percentage point difference in state influenza vaccination coverage from the first half of 2004 vs. the first half of 2005. We used Behavioral Risk Factor Surveillance System

(BRFSS) data to examine coverage in adults ≥65 years because this priority group was surveyed in both 2004 and 2005. BRFSS calculates vaccination status based on responses to the following question: "During the past 12 months, have you had a flu shot?" Therefore, the great majority of people surveyed in the first half of a year represent vaccination status the preceding fall. We used SAS version 9.1[9] and SUDAAN version 9.0[10] for data management and analysis with statistical significance assumed at $p<0.05$.

RESULTS

Respondents

All 50 states and the District of Columbia responded (for reporting purposes, the District of Columbia is treated as a state). Eighty percent of respondents (n=41) were state immunization managers or immunization officials, 6% (n=3) were state epidemiologists, 4% (n=2) were state health officers, and the remaining 10% (n=5) were primarily infectious or respiratory disease staff.

State responses to survey questions (Figure)

The vast majority, 96% of states (n=49), reported adopting or recommending adherence to the initial ACIP/CDC interim influenza vaccination recommendations in response to Chiron's October 5, 2004, announcement that it would not supply vaccine for the 2004–2005 influenza season. Of these 49 states, at some point during the season 22% (n=11) reported that local public health agencies issued vaccination prioritization that differed from that of the state health department. Overall, 35% (n=18) had a policy or recommendation for sub-prioritization of patients and staff in LTCFs beyond the ACIP/CDC recommendations. Of these, 12 specified residents should receive priority over staff, one specified staff with direct resident contact should receive priority over residents, one specified vaccinating either all residents or all staff, and the remaining four did not specify their sub-prioritization scheme. A majority of states (n=30) issued at least two changes in vaccine prioritization over the course of the season. Changes largely mirrored the ACIP/CDC updated interim influenza vaccine recommendations.

In 35% of states (n=18), the state health officer or governor issued an emergency or executive order, or the state legislature passed a law or statute related to influenza vaccine prioritization. For these states, consequences for nonadherence included civil penalties (six states), criminal penalties (five states), and both civil and criminal penalties (one state). In the remaining six states, neither civil nor criminal penalties were specified. Seven states reported conducting investigations, but enforcement action occurred in only one state. For the 65% of states (n=33) in which the health officer or governor did not issue an emergency or executive order, 12 did not consider the situation an emergency, three lacked the authority to do so without legislative action, three deferred action to local government, and 15 primarily cited adequate initial cooperation from providers and health-care facilities and the belief that official communication from the governor's office or health department was sufficient to address the situation.

In 86% of states (n=44), state and/or local governments conducted an assessment of the amount and location of Aventis Pasteur vaccine that had already been distributed prior to Chiron's October 5, 2004, announcement that it would not supply vaccine for the 2004–2005 influenza season. Thirty-three percent (n=17) reported having either on hand or readily available a complete or near-complete contact list of individual practitioners, which was used during the 2004–2005 season. These lists were obtained primarily through combinations of Health Alert Network (HAN) recipient lists (12 states), Vaccines for Children (VFC) program provider lists (11 states), state licensing agencies (nine states), and state medical societies or organizations (six states). The HAN is an electronic notification system designed to rapidly alert public health officials, clinicians, health-care administrators, first responders, key policy makers, and stakeholders to emergent health-related information, while the VFC program is a federally funded vaccine program for poor children. Seventy-one percent (n=36) reported the HAN was an effective way to keep individual practitioners up-to-date with influenza-related information. For states reporting that the HAN was not effective for communicating at the individual practitioner level, most cited an incomplete HAN listing as well as uncertainty about provider awareness of and access to the HAN. However, these states generally reported that the HAN was useful for communicating with local health departments and public health officials.

Eighty percent of states (n=41) initiated at least one emergency response activity and 43% of states (n=22) referred to or implemented components of their pandemic influenza plan. Components implemented included initiating public health emergency operations and incident command procedures; activating pre-identified partnerships; alerting health-care providers using the state HAN; reviewing vaccine prioritization schemes; utilizing checklists and communication templates; and initiating and encouraging mass vaccination activities. Furthermore, 63% (n=32) activated a

Figure. State actions taken and policies implemented in response to the 2004–2005 influenza vaccine shortage

	Percent[a] *(n)*
Influenza vaccination prioritization	
State influenza vaccination prioritization policy or recommendation in response to Chiron's October 5, 2004, announcement that it would not supply vaccine for the 2004–2005 season	
Adopted initial ACIP/CDC interim recommendations	96 (49)
No official policy or recommendation	4 (2)
At some point during the 2004–2005 season, local public health agencies issued influenza vaccination prioritization that differed from that of the state health department (of the 49 states)	22 (11)
State had a policy or recommendation for sub-prioritization of residents and staff in long-term care facilities	35 (18)
Executive and legislative action	
State health officer or governor issued an emergency or executive order, or the state legislature passed a law or statute related to influenza vaccine prioritization/subprioritization	35 (18)
Penalties for nonadherence in states with orders, laws, or statutes (of the 18 states)	
Civil penalties	33 (6)
Criminal penalties	28 (5)
Both civil and criminal penalties	6 (1)
Neither civil nor criminal penalties	33 (6)
Needs assessment	
State and/or local assessment conducted of the amount and location of influenza vaccine that had already been distributed prior to October 5, 2004	86 (44)
State had a complete or near-complete contact list of individual practitioners and used the list to contact practitioners	33 (17)
The contact list for the above states (n=17) was obtained through:[b]	
Health Alert Network (HAN) recipient list	71 (12)
Vaccines for Children program provider list	65 (11)
State licensing agency	53 (9)
State medical societies or organizations	35 (6)
Medicaid/Medicare provider lists	18 (3)
State reported that the HAN was an effective way to keep individual practitioners up-to-date	71 (36)
Emergency preparedness	
State referred to or implemented components of pandemic influenza plan	43 (22)
Activities that occurred at the state level	
Influenza hotline or influenza communications center activated	63 (32)
Incident command procedures initiated	41 (21)
Public health emergency operations or coordinating center activated	22 (11)
After-action review or post-event analysis conducted or planned	69 (35)
State planned to revise or considering revisions to pandemic influenza plan	63 (32)
Redistribution and reallocation	
Private facilities or individual practitioners who notified public health agencies that they had excess influenza vaccine were told to:	
Contact colleagues to see if vaccine needed elsewhere	71 (36)
Hold onto supply and continue to vaccinate	57 (29)
Wait for state/local health officials to pick it up	57 (29)
Post excess supply on the state's Web-based system	16 (8)
State or local health departments participated in or assisted in redistributing private sector Aventis Pasteur vaccine that had already been delivered to end users prior to October 5, 2004	76 (39)

[a]Totals for percentages may contain rounding errors.

[b]Not mutually exclusive categories

ACIP = Advisory Committee on Immunization Practices

CDC = Centers for Disease Control and Prevention

specific influenza hotline or influenza communications center and 69% (n=35) planned to conduct an after-action review or post-event analysis. Sixty-three percent (n=32) plan to revise or are considering revisions to their pandemic influenza plans as a result of their experiences. Proposed revisions include reviewing and clarifying subprioritization of high-risk individuals for vaccine and antiviral drugs; refining and enhancing vaccine distribution, redistribution, and mass vaccination activities; modifying procedures for public, partner, and media communications to improve timeliness and efficiency of information transfer; and increasing hotline and Web-based communication capacity.

Guidance issued by state health departments on how to manage excess vaccine supply is listed in the Figure. In 76% of states (n=39), the state or local health departments participated or assisted in redistributing private sector Aventis Pasteur vaccine that had already been delivered to end users prior to October 5, 2004. Thirty-six states were able to estimate what percent of Phase II vaccine, including direct shipments and redistribution, ultimately went to LTCFs. Phase II vaccine consisted of approximately 12 million doses available in November 2004 for distribution to states based on CDC's nationwide unmet need formula.[11] Of the 36 states, 11% (n=4) reported LTCFs received no Phase II vaccine, 42% (n=15) reported LTCFs received 1% to 20% of Phase II vaccine, and 33% (n=12) reported LTCFs received 21% to 40% of Phase II vaccine. Only 14% (n=5) reported LTCF received more than 40% of Phase II vaccine.

Open-ended comments

General comments by states regarding the 2004–2005 influenza vaccine shortage, not in response to any specific questions, primarily focused on five topic areas:

Lack of ACIP/CDC influenza vaccine subprioritization recommendations. States expressed a desire for specific guidance from ACIP/CDC regarding vaccine subprioritization within priority groups during times of inadequate supply. States indicated that the interim ACIP/CDC recommendations would have been more meaningful and practical if they had included at least some subprioritization of high-risk individuals.

Vaccine demand and timeliness of federal response. Public demand for vaccine appeared to be linked to timing rather than supply. States noted that regardless of available supply, the initial high demand early in the season declined sharply after November and by year's end had slowed substantially. Decisions about vaccine distribution and administration need to be made well in advance of the winter holiday season otherwise interest in getting vaccinated wanes, resulting in wastage. States also indicated that ACIP/CDC interim recommendations should have reverted back to preshortage guidance and VFC vaccine use for adults be allowed much earlier in the season. The delay in making these changes until after demand had dropped resulted in wastage.

Secure Data Network (SDN) ordering and delivery. The SDN is a secure CDC-operated network that allows states to monitor vaccine distribution, communicate unmet needs, and order vaccine. States expressed frustration with delays in delivery of orders placed through the SDN, which resulted in provider reductions or cancellations of orders not received in a timely manner. When this happened, the state was left trying to locate alternate providers to receive the vaccine. In addition, states had difficulty tracking the status of orders submitted through the SDN, thus limiting their ability to respond to provider inquiries about orders.

Investigational New Drug (IND) vaccine protocol. States indicated that the IND protocol for obtaining and administering non-U.S. licensed vaccine was too cumbersome and restrictive to be effective. In addition, the process was largely out of the control of state health officials, who had the greatest knowledge of where IND vaccine could best be used.

Use of live attenuated influenza vaccine (LAIV). Some states commented that the indications for LAIV use and its safety profile were poorly understood, even by health-care providers, especially as it related to use in health-care workers. The consensus among these states was that LAIV will not reach its potential until a vigorous marketing campaign directed toward health-care workers is undertaken, its indications expanded, and its price lowered.

Bivariate and multivariable analysis

Nationally, influenza vaccination coverage in adults aged ≥65 years decreased from 74% (95% confidence interval [CI], 73% to 75%) during the previous nonshortage season to 64% (95% CI, 63% to 65%) in the shortage season. When comparing individual states, in the bivariate analysis no state-level actions or policies were significantly associated with smaller decreases in coverage, in adults aged ≥65 years, from the previous nonshortage season (Table 1), although having on hand or readily available a complete or near-complete contact list of individual practitioners, which was used to contact practitioners, was marginally significant at p=0.08. These states had a mean decrease in coverage of 7.7 percentage points compared to 10 percentage points for those that did not. States with a relatively

Table 1. Bivariate analysis of state actions, policies, and vaccine supply related to BRFSS influenza vaccination coverage: percentage point changes in coverage for adults aged ≥65 years from the 2003–2004 influenza season to the 2004–2005 influenza season

	Percentage point change 2003–2004 to 2004–2005		
Parameter	*Yes*	*No*	*P-value*
Local public health agencies issued influenza vaccine prioritization that differed from the state health department	−7.9	−9.6	0.27
Residents in long-term care facilities given priority over staff	−7.5	−9.8	0.11
Emergency or executive order issued, law or statute passed	−8.4	−9.8	0.26
Complete or near-complete contact list of individual practitioners available and used to contact practitioners	−7.7	−10.0	0.08
Initiated at least one emergency preparedness function	−9.2	−9.7	0.76
Referred to or implemented components of pandemic influenza plan	−10.4	−8.4	0.11
Assisted in redistributing private sector Aventis Pasteur vaccine that had already been delivered to end users prior to October 5, 2004	−9.0	−10.3	0.40
	75+	*<50*	*P-value*
75+ doses/100 priority adults available in October 2005 vs. <50 doses/100 priority adults	−6.2	−11.0	0.003
	75+	*50 to 74.9*	*P-value*
75+ doses/100 priority adults available in October 2005 vs. 50 to 74.9 doses/100 priority adults	−6.2	−8.5	0.16
	50 to 74.9	*<50*	*P-value*
50 to 74.9 doses/100 priority adults available in October 2005 vs. <50 doses/100 priority adults	−8.5	−11.0	0.052

BRFSS = Behavioral Risk Factor Surveillance System

large amount of vaccine (75+ doses per 100 priority adults) in early October 2004 had significantly smaller decreases in coverage from the previous nonshortage season compared to states with a relatively small amount of vaccine (<50 doses per 100 priority adults), a mean 6.2 percentage point decrease vs. 11.0% (p=0.003).

The final multivariable linear regression model included two variables: *(1)* having on hand or readily available a complete or near-complete contact list of individual practitioners, which was then used to contact practitioners, and *(2)* vaccine supply in early October 2004. The model was significant at p=0.003 with an r^2=0.26 (Table 2). Within the model, states that had a practitioner contact list available and used the list had a mean decrease in coverage of 6.8 percentage points vs. 9.3 for those that did not (p=0.04). When comparing states with high and medium vaccine supply to states with low supply, those with 75+ doses per 100 priority adults in early October 2004 had a mean 5.8 percentage point decrease, while those with 50 to 74.9 doses per 100 priority adults had a mean 7.8 percentage point decrease, vs. a 10.6 percentage point decrease for those with <50 doses per 100 priority adults, p=0.002 and p=0.03, respectively.

DISCUSSION

Our results indicate that during the 2004–2005 influenza vaccine shortage, states overwhelmingly followed national vaccination prioritization guidelines and used a range of activities to manage shortage issues. Most states took steps to assess vaccine supply in the community, provide information and support services to clinicians and the general public, and actively assist in distribution/redistribution of vaccine. Of the range of actions taken and policies implemented, the availability and use of practitioner contact lists was significantly associated with smaller decreases in influenza vaccination coverage from the previous nonshortage season in adults aged ≥65 years, as was having a relatively high vaccine supply early in the season. Among states with a contact list, the HAN was most frequently cited as a source, underscoring the value of maintaining a comprehensive, up-to-date HAN listing. Since its inception and especially since September 11, 2001, the HAN has become an increasingly important medium for rapidly communicating health information, particularly in emergent situations.[12,13] Of note, states that issued emergency or executive orders or passed legislation in response to the shortage (35%) did no better at vaccinating adults aged ≥65 years than those that did

Table 2. Multivariable linear regression of state actions, policies, and vaccine supply related to BRFSS influenza vaccination coverage: percentage point changes in coverage for adults aged ≥65 years from the 2003–2004 influenza season to the 2004–2005 influenza season, r^2=0.26 (p=0.003)

	Percentage point change 2003–2004 to 2004–2005		
Parameter	*Yes*	*No*	P-*value*
Complete or near-complete contact list of individual practitioners available and used to contact practitioners	−6.8	−9.3	0.04
	75+	*<50*	P-*value*
75+ doses/100 priority adults available in October 2005 vs. <50 doses/100 priority adults	−5.8	−10.6	0.002
	50 to 74.9	*<50*	P-*value*
50 to 74.9 doses/100 priority adults available in October 2005 vs. <50 doses/100 priority adults	−7.8	−10.6	0.03
<50 doses/100 priority adults available in October 2005	Referent group		

BRFSS = Behavioral Risk Factor Surveillance System

not, when compared to the previous nonshortage year. This statistic indicates that these kinds of directives were not particularly useful at managing the 2004–2005 influenza vaccine shortage. Almost one-quarter of states that issued a prioritization policy or recommendation reported that at some point during the season there was discordance between state and local guidance. Judging from comments by state immunization officials, lack of national subprioritization guidelines was the primary reason for this observed divergence. The extent to which this would reflect adherence to national pandemic influenza vaccination prioritization recommendations is unclear given that vaccination prioritization will be more clearly defined for a pandemic.[14]

Among the strongest and most numerous comments from states concerned the lack of ACIP/CDC influenza vaccine subprioritization recommendations. To address this issue, ACIP/CDC has issued updated guidance on the prevention and control of influenza and taken the step of recommending tiered use of inactivated influenza vaccine in the event of future vaccine shortages.[15,16] Attitudes, beliefs, and resistance among health-care workers to LAIV were consistent with other published work.[17] Finally, our survey confirms the observation that demand for influenza vaccine drops substantially toward the end of the year and does not appear to rebound. (Personal communication, Joanne Lynn, RAND Corporation, and Barbara Bardenheier, CDC, June 2006.) Perhaps educational campaigns or other initiatives targeted at both the public and vaccine providers may be indicated to maintain demand throughout the season.

This study has both strengths and limitations. We achieved a 100% response rate and the survey was developed with input from multiple state-level stakeholders. However, it lacked a local perspective because it did not include county and city health departments, and the survey instrument did not account for the fact that states have varying governmental structures and lines of authority with respect to public health. In addition, the survey was most frequently completed by a single individual and provided only crude measurements of complex, multilevel public health activities. Finally, we did not adjust for baseline influenza vaccination coverage when comparing changes from the 2003–2004 nonshortage season to the 2004–2005 season. We believed the year-by-year variability, both among states and within individual states, would limit the utility of adjusting for baseline coverage.

The 2004–2005 influenza vaccine shortage gave many states an opportunity to initiate some basic emergency response functions. The observation that most states planned to conduct a review of their actions and were also planning to revise or were considering revisions to their pandemic influenza plans, indicates that managing the 2004–2005 influenza vaccine shortage provided valuable experience for responding to an influenza pandemic and other future public health crisis situations. To our knowledge, this is the first study that attempts to categorize and quantify state-level actions in response to the 2004–2005 influenza vaccine shortage. It provides insight into how states would respond to public health emergencies and coordinate operations with individual providers, health-care facilities, and policy makers when resources are scarce. It also gives state health departments an opportunity to examine how their peers responded and may provide them with valuable information as they continue to refine their pandemic influenza and emergency response plans. In addition, it may assist federal health authorities in

pandemic influenza and emergency response planning, particularly as it relates to issuing recommendations and practice guidelines as well as ordering, distributing, and tracking vaccine.

Vaccine shortages and imbalances in supply and demand have occurred frequently in the recent past.[18,19] To cope with uncertainty for the 2005–2006 influenza season, CDC and vaccine manufacturers cooperated in developing supply projections, distribution strategies, and prebooking (i.e., ordering in advance of availability) and partial shipment procedures.[20] Normally, adult influenza vaccination is a private sector function, but the 2004–2005 experience demonstrated that during shortages, much supply and distribution management shifts to the public sector. Most seasonal influenza vaccine is purchased by, delivered to, and administered in the private sector, and vaccine manufacturers vary in their use of direct shipments vs. secondary distributors. These transactions constitute proprietary information, which is generally not available to federal, state, or local health agencies. Federal, state, and local health officials have indicated that access to more specific manufacturer-level information on vaccine production and private sector distribution would assist in managing influenza vaccine shortages. (Personal communication, Jeanne Santoli, CDC, and Paul Robinson, Science Applications Corporation contractor, April 2006.) Without this knowledge, states have limited ability to ensure that scarce supplies of vaccine reach targeted populations. This limitation highlights the need to continue research and development into a system to track and monitor vaccine supply up to the point of administration, which is essential if informed decisions are to be made about allocation and redistribution, should shortages occur in the future.

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