

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**LOCAL PANDEMIC INFLUENZA
PREPAREDNESS:
VACCINE AND ANTIVIRAL DRUG
DISTRIBUTION AND DISPENSING**



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Inspector General

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OBJECTIVES

To determine the extent to which 10 selected localities:

1. addressed in their planning documents the vaccine and antiviral drug distribution and dispensing components and preparedness items that we identified based on Department of Health and Human Services (HHS) pandemic influenza guidance,
2. conducted exercises related to vaccine and antiviral drug distribution and dispensing and documented these exercises with After Action Reports and Improvement Plans, and
3. collaborated with community partners to develop and exercise their plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic.

BACKGROUND

An influenza pandemic is a global outbreak of a highly infectious influenza virus that can cause serious illness in humans. HHS estimates that even a mild pandemic could cause between 2 million and 7.4 million deaths worldwide. In June 2009, the World Health Organization raised the pandemic influenza alert level to Phase 6 and declared the start of the 2009 H1N1 influenza pandemic. Although scientists believe this pandemic will initially be moderate, its severity over time may increase.

In its review of 2008 State pandemic influenza operating plans, the Assistant Secretary for Preparedness and Response (ASPR) found “very few gaps in State-level readiness for antiviral drug distribution.” Additionally, ASPR found that States were “doing well” with respect to developing State-level pandemic influenza vaccination plans. However, its review did not assess local pandemic influenza vaccine and antiviral drug distribution and dispensing preparedness.

HHS has provided guidance to States and localities to use in planning for pandemic influenza vaccine and antiviral drug distribution and dispensing. Based on this guidance and input from the Centers for Disease Control and Prevention (CDC) and ASPR, we identified eight planning areas (i.e., components) and 89 preparedness items within the eight components that provided a framework for our evaluation. These

components are: Receiving & Staging, Dispensing, Tracking, Vulnerable Populations, Priority Groups, Security, Storage, and Transportation.

HHS recommends that States and localities exercise their vaccine and antiviral drug distribution and dispensing plans and prepare After Action Reports to document exercise objectives and recommendations. They can also use Improvement Plans to assign responsibility and timeframes for completing plan improvements. Finally, HHS recommends that States and localities collaborate with community partners to develop and exercise their pandemic influenza vaccine and antiviral drug distribution and dispensing plans.

We examined plans for distributing and dispensing vaccines and antiviral drugs during an influenza pandemic in 10 selected localities and their five respective States. We also collected data about the selected localities' exercises and collaboration with community partners.

FINDINGS

Selected localities had not addressed in their planning documents most of the vaccine and antiviral drug distribution and dispensing components and preparedness items identified in HHS pandemic influenza guidance. None of the 10 selected localities had started planning in all eight distribution and dispensing components. Across components, localities' plans generally were not actionable. For example, localities did not generally have valid and detailed formal agreements, such as a Memorandum of Agreement, with partnering agencies. Additionally, localities had generally not identified sufficient sources of staff or factored absenteeism into their staffing estimates.

Localities varied in the extent to which they addressed the distribution and dispensing components in their planning documents. Localities addressed the highest percentage of preparedness items in the components of Receiving & Staging and Dispensing. They addressed a lower percentage of preparedness items in Tracking, Vulnerable Populations, and Priority Groups. Finally, localities addressed the lowest percentage of preparedness items in Security, Storage, and Transportation.

All selected localities conducted exercises related to vaccine and antiviral drug distribution and dispensing; however, most did not create After Action Reports and Improvement Plans for these exercises. Between September 2006 and July 2008, the 10 selected localities conducted a total of 63 exercises related to distributing and dispensing vaccines and antiviral drugs, ranging from 2 to 12 exercises within a locality. Most of the exercises tested more than one component of vaccine and antiviral drug distribution and dispensing. All selected localities conducted at least one exercise to test their ability to receive and stage, provide security for, and transport medications. In addition, seven localities conducted exercises to test their ability to dispense these medications to priority groups or store them during the distribution and dispensing process. Further, localities did not create both After Action Reports and Improvement Plans for 80 percent of all exercises they conducted.

All selected localities collaborated with community partners to develop and exercise their plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic.

The 10 selected localities worked with different types of community partners to develop and test their plans for distributing and dispensing vaccines and antiviral drugs during an influenza pandemic. To develop these plans, all localities collaborated with partners such as educational institutions, emergency management agencies, and hospitals. To test these plans, most localities collaborated with educational institutions, law enforcement agencies, and the medical community.

RECOMMENDATIONS

While the majority of selected localities had begun planning to distribute and dispense vaccines and antiviral drugs, more needs to be done to improve local preparedness. Therefore, we recommend that CDC work with States to:

Improve local pandemic influenza vaccine and antiviral drug distribution and dispensing preparedness. CDC, in coordination with States, could improve pandemic influenza vaccine and antiviral drug distribution and dispensing preparedness at the local level by taking the following actions:

E X E C U T I V E S U M M A R Y

- Determine why localities appear to be in the early stages of planning for pandemic influenza vaccine and antiviral drug distribution and dispensing, and provide assistance to improve their preparedness.
- Prioritize the planning areas where States should focus any carryover or future pandemic influenza funding to quickly improve local preparedness to distribute and dispense vaccines and antiviral drugs.
- Place special emphasis on ensuring localities develop actionable vaccine and antiviral drug distribution and dispensing plans. Specifically, plans should identify the organizations or individuals responsible for carrying out specific actions and the sources that would be necessary to staff distribution and dispensing positions and should be supported by valid, detailed formal agreements with partnering agencies.

Ensure that localities consistently create both After Action Reports and Improvement Plans to enhance their preparedness to distribute and dispense vaccines and antiviral drugs during an influenza pandemic.

Facilitate the sharing of pandemic influenza planning and response information and emerging promising practices.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CDC agreed with two of our three recommendations. Specifically, CDC agreed to work with States to encourage localities to develop After Action Reports and Improvement Plans that comply with the Homeland Security Exercise and Evaluation Program. CDC also agreed that States and localities should use the Lessons Learned Information Sharing Web site to facilitate the sharing of planning resources.

CDC did not indicate whether it agreed with the first recommendation, but noted that it plans to use some of the Office of Inspector General's (OIG) suggested actions to address this recommendation. For example, CDC acknowledged the need for States to prioritize some of the planning areas OIG identified, which include receiving and storing vaccines and antiviral drugs and identifying dispensing sites and staffing requirements. Finally,

E X E C U T I V E S U M M A R Y

CDC agreed that localities need to develop actionable vaccine and antiviral drug distribution and dispensing plans.

We addressed CDC's comments in the Background and Methodology sections of the report. We ask that in its final management decision, CDC more clearly indicate whether it concurs with our first recommendation.



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BACKGROUND

An influenza pandemic is a global outbreak of a highly infectious influenza virus that can cause serious illness in humans.¹ HHS estimates that even a mild pandemic could cause between 2 million and 7.4 million deaths worldwide.² In June 2009, the World Health Organization raised the pandemic influenza alert level to Phase 6 and declared the start of the 2009 H1N1 influenza pandemic. Although scientists believe this pandemic will initially be moderate, its severity over time may increase.

In February 2008, the Assistant Secretary for Preparedness and Response (ASPR) within HHS asked the Office of Inspector General (OIG) to evaluate State and local preparedness for an influenza pandemic, particularly with regard to distributing and dispensing vaccines and antiviral drugs and medical surge at the local level. ASPR annually reviews State-level pandemic influenza operating plans and

¹ HHS, "Flu Terms Defined." Available online at <http://www.pandemicflu.gov>. Accessed on February 17, 2009.

² HHS, "Why are pandemics such dreaded events?" Available online at <http://www.pandemicflu.gov/faq/pandemicinfluenza/1108.html>. Accessed on February 17, 2009.

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identifies planning strengths and deficiencies.³ In its review of the 2008 plans, ASPR found “very few gaps in State-level readiness for antiviral drug distribution” and that States were “doing well” with respect to developing State-level pandemic influenza vaccination plans.⁴ However, its review did not assess local pandemic influenza vaccine and antiviral drug distribution and dispensing preparedness.

This evaluation focuses on the extent to which selected localities have prepared to distribute and dispense vaccines and antiviral drugs during an influenza pandemic. A second OIG evaluation focuses on the extent to which selected States and localities have prepared for medical surge during an influenza pandemic.⁵ In addition, OIG has audited two States and is auditing one other to determine whether expenditures used to prepare for an influenza pandemic complied with Federal requirements.⁶

HHS Support of State and Local Preparedness Efforts

Since 2002, HHS has provided more than \$8 billion to awardees (hereinafter referred to as “States”) for programs to enhance their

³ While ASPR coordinates the review of States’ pandemic influenza operating plans, the Centers for Disease Control and Prevention (CDC) reviews the sections related to vaccine and antiviral drug distribution and dispensing.

⁴ Assessment of States’ Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council, January 2009. Available online at http://www.pandemicflu.gov/plan/states/state_assessment.pdf. Accessed on April 23, 2009.

⁵ OIG, “State and Local Pandemic Influenza Preparedness: Medical Surge,” OEI-02-08-00210.

⁶ OIG, “Review of Vermont’s Pandemic Influenza Expenditures for the Period August 31, 2005, Through June 30, 2008,” A-01-08-01500, June 25, 2009. OIG, “Review of Washington State’s Pandemic Influenza Expenditures for the Period August 31, 2005, Through June 30, 2008,” A-09-08-01006, August 21, 2009. OIG is also auditing pandemic influenza expenditures in Georgia.

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emergency preparedness for large-scale public health emergencies.^{7 8} HHS has distributed these funds primarily through cooperative agreements under programs such as the PHEP, which is administered by the CDC.

Beginning in 2005, Congress appropriated supplemental funding specifically for pandemic influenza preparedness. Through the existing PHEP cooperative agreements, CDC awarded \$500 million in pandemic influenza funding in three phases:^{9 10}

- In Phase I (August 31, 2005, through August 30, 2006), States were to identify unmet needs and develop and exercise a pandemic influenza preparedness plan and an antiviral drug distribution plan.
- In Phase II (August 31, 2006, through August 30, 2007), States were to complete and submit to CDC a work plan and progress reports and develop a pandemic influenza exercise schedule.

⁷ In a 2007 press release, HHS described providing more than \$7 billion in funding since 2002 through various HHS agencies. HHS, “HHS Announces \$896.7 Million in Funding to States for Public Health Preparedness and Emergency Response.” Available online at <http://www.hhs.gov/news/press/2007pres/07/pr20070717c.html>. Accessed on July 20, 2009. Then, in 2008, HHS provided an additional \$1 billion in Public Health Emergency Preparedness Program (PHEP) and Hospital Preparedness Program funds. See HHS, “HHS Provides More Than \$1 Billion to Improve All Hazards Public Health.” Available online at <http://www.hhs.gov/news/press/2008pres/06/20080603a.html>. Accessed on May 12, 2009.

⁸ Awardees include all 50 States; Washington, DC; five territories (Puerto Rico, the Virgin Islands, American Samoa, the Commonwealth of the Northern Mariana Islands, and Guam); the Pacific Freely Associated States (Republic of the Marshall Islands, the Republic of Palau, and the Federated States of Micronesia); and the localities of Chicago, Los Angeles County, and New York City.

⁹ CDC has cited various authorities for the bioterrorism program and the pandemic influenza supplement. Initially, CDC’s grant announcements for the bioterrorism program indicated that funding was authorized under sections 301(a), 317(k)(1)(2), and 319 of the Public Health Service (PHS) Act (42 U.S.C. §§ 241(a), 247b(k)(1)(2), and 247(d)). Beginning in August 2005, CDC indicated that funding was authorized under section 319C of the PHS Act (42 U.S.C. § 247d-3), which was subsequently repealed by the Pandemic and All-Hazards Preparedness Act, P.L. No. 109-417 (Dec. 19, 2006). The pandemic influenza grant announcements and guidance do not consistently describe the statutory authorizations, but the CDC grant award documents list sections 301(a), 317(k)(1)(2), and 319 of the PHS Act for Phases I and II and sections 319(a) and 317(k) of the PHS Act for Phase III. CDC is currently relying on section 319C-1 of the PHS Act (42 U.S.C. § 247d-3a) for all of these grant awards.

¹⁰ In September 2008, CDC also awarded \$24 million to fund 55 projects in 29 State and local public health departments to develop innovative approaches for pandemic influenza preparedness.

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- In Phase III (August 31, 2007, through August 9, 2008), States were to fill gaps identified in Phases I and II.

For the most recent cooperative agreement budget year (August 10, 2008, through August 9, 2009), Congress did not appropriate additional funding specifically for pandemic influenza preparedness. However, CDC encourages States to request permission to use any unobligated funds from the previous two funding periods to continue pandemic influenza preparedness projects.¹¹ As the PHEP has evolved, the program’s guidance has become less prescriptive by allowing States to select the projects that they intend to complete to improve their preparedness.

In addition to issuing the PHEP cooperative agreement guidance, HHS has distributed supplemental pandemic influenza preparedness guidance.¹² For example, the Phase II Pandemic Influenza Guidance Supplement included planning and exercising recommendations for distributing and dispensing vaccines and antiviral drugs. It also referred to other HHS guidance documents that States and localities could use in their pandemic influenza distribution and dispensing planning, including the State and Local Pandemic Influenza Planning Checklist.^{13 14}

PHEP funding is provided to States, but localities will carry out many of the activities needed to respond to an influenza pandemic. Although not specified in PHEP cooperative agreement guidance, HHS has indicated that it provides guidance to States that are in turn “expected to provide

¹¹ Program Announcement AA154 (August 10, 2008–August 9, 2009). Available online at <http://emergency.cdc.gov/cotper/coopagreement/08/pdf/fy08announcement.pdf>. Accessed on May 12, 2009.

¹² CDC, Pandemic Influenza Guidance Supplement to the 2006 Public Health Emergency Preparedness Cooperative Agreement Phase II, 2006, Budget Period August 31, 2006–August 30, 2007, and Phase III, 2007, Budget Period August 31, 2007–August 9, 2008.

¹³ HHS, State and Local Pandemic Influenza Checklist. Available online at <http://www.pandemicflu.gov/plan/pdf/checklist.pdf>. Accessed on February 17, 2009.

¹⁴ The State and Local Pandemic Influenza Checklist identifies a number of supplements to the HHS Pandemic Influenza Plan. Two of these supplements include recommendations for State and local health departments regarding vaccine distribution and use and antiviral drug distribution and use. Available online at <http://www.hhs.gov/pandemicflu/plan/sup6.html> and <http://www.hhs.gov/pandemicflu/plan/sup7.html>. Accessed on May 18, 2009.

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guidance to their respective localities to ensure cohesion between State and local preparedness plans.”¹⁵

Local Health Department Structure

Local health departments vary considerably in structure and size of populations they serve. In 2005, the National Association of County and City Health Officials identified a total of 2,864 local health departments in the United States.¹⁶ These health departments can be a part of the State health agency, part of the local government, or some combination of these structures. Additionally, they serve both small and large populations, ranging from less than 1,000 to nearly 10 million people. These variations contribute to the complexity of providing guidance and technical assistance to prepare for an event such as an influenza pandemic.¹⁷

Vaccine and Antiviral Drug Distribution and Dispensing Components

Based on HHS pandemic influenza guidance documents and input from CDC and ASPR, we identified eight broad components of vaccine and antiviral drug distribution and dispensing planning. These components provided a framework for our evaluation. We also developed 89 preparedness items to determine the extent of preparedness within each of the components; these items are discussed at length in the “Methodology” section. The following provides a general description of the eight components and the activities that fall within each:

1. ***Receiving & Staging.*** Receiving and staging involves identifying locations where vaccines and antiviral drugs will be received and staged and developing procedures necessary to deliver them to dispensing sites. These receiving and staging systems may differ for vaccines and antiviral drugs. Vaccines will be delivered by the manufacturer to a central State-controlled location or to multiple “ship-to” locations throughout the State. Antiviral drugs are available in State caches (i.e., State or local stockpiles) and will be delivered through CDC’s Strategic

¹⁵ ASPR, CDC, Final Report Technical Comments, issued to OIG on June 11, 2009.

¹⁶ National Association of County and City Health Officials, 2005 National Profile of Local Health Departments. Available online at http://www.naccho.org/topics/infrastructure/profile/upload/NACCHO_report_final_000.pdf. Accessed on June 24, 2009.

¹⁷ ASPR/CDC, Final Report Technical Comments, issued to OIG on June 11, 2009.

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National Stockpile (SNS) program to a State-designated location.¹⁸ Localities may further distribute the vaccines and antiviral drugs to other local receiving and staging locations or dispensing sites, as needed.

2. *Dispensing.* Dispensing involves administering medications, such as vaccines and antiviral drugs. It includes identifying facilities at which dispensing will occur and developing procedures to operate and staff these sites. For example, localities can identify facilities, such as local schools, to serve as dispensing sites. They can also identify the individuals who would be authorized to receive medications as well as ensure that they have sufficient personnel to staff other necessary positions.

3. *Tracking.* Tracking involves managing vaccine and antiviral drug inventories by implementing inventory management systems at State or local stockpiles, receiving and staging locations, and dispensing sites and during transport between these facilities.

4. *Vulnerable Populations.* Vulnerable populations refer to groups, such as the homeless, prison inmates, and nursing home residents, which may not have access to traditional dispensing sites. Localities have flexibility in defining these groups according to local circumstances. They can also estimate the size of each vulnerable population and develop specific dispensing plans for them.

5. *Priority Groups.* Priority groups are typically defined by occupation or health status, such as health care and law enforcement personnel and pregnant women. HHS has developed preliminary guidance regarding priority group definitions, but localities and States are responsible for determining how to best implement this guidance according to local and State circumstances.¹⁹ They can also estimate the size of each priority group, create specific dispensing plans for them, and identify which groups will be the first to receive the limited supplies of vaccines and antiviral drugs.

¹⁸ SNS is an HHS program that stores and delivers medicines and medical supplies from Federal storage facilities to State receiving and staging locations. Available online at <http://www.bt.cdc.gov/stockpile/>. Accessed on February 17, 2009.

¹⁹ HHS, Guidance on Allocating and Targeting Pandemic Influenza Vaccine. Available online at <http://www.pandemicflu.gov/vaccine/allocationguidance.pdf>. Accessed on July 7, 2009. HHS, HHS Pandemic Influenza Plan. Available online at <http://www.hhs.gov/pandemicflu/plan/appendixd.html>. Accessed on July 7, 2009.

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6. **Security.** Providing security for the vaccines and antiviral drugs involves protecting these medications at State or local stockpiles and receiving and staging locations through the point of dispensing. Security may be an important component of a distribution and dispensing plan because the vaccines and antiviral drugs will be limited in quantity, yet high in demand, during an influenza pandemic. Localities and States can develop detailed security plans for their own stockpiles, receiving and staging locations, and dispensing sites and during transport between these facilities.

7. **Storage.** Storing the vaccines and antiviral drugs involves ensuring that the proper environmental conditions are maintained at State or local stockpiles and receiving and staging locations until they are dispensed. Vaccines and antiviral drugs may become less effective if they are not stored in the environmental conditions specified by their labeling. Vaccines typically require refrigeration, while antiviral drugs should be stored at controlled room temperature. Localities and States can develop detailed storage plans to ensure these conditions are maintained at their own stockpiles, receiving and staging locations, and dispensing sites and during transport between these facilities.

8. **Transportation.** Transporting the vaccines and antiviral drugs involves moving them from State or local stockpiles and receiving and staging locations to dispensing sites. Generally, States are responsible for transportation to the localities. However, localities with distribution responsibilities also need to provide local transportation. Localities and States can develop detailed transportation plans, such as those that specify routes and frequency of delivery.

Developing Plans for Vaccine and Antiviral Drug Distribution and Dispensing

Localities and States may develop their plans for distributing and dispensing vaccines and antiviral drugs during an influenza pandemic by building on existing systems. For example, they may develop these plans by building on existing local and State emergency preparedness

systems, such as those developed to receive and distribute medications from CDC's SNS program.²⁰

In addition, the entity (i.e., locality or State) responsible for implementing plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic can differ by State. Localities within the same State can also be responsible for implementing different aspects of the plan. For example, one locality may have transportation responsibilities while another locality within the same State may rely on the State to transport medication to its dispensing sites. Localities and States can also share the responsibility for implementing a certain aspect of the plan (e.g., they both may share responsibility for transporting vaccines and antiviral drugs to local dispensing sites).

Ensuring That Plans for Vaccine and Antiviral Drug Distribution and Dispensing Are Actionable

HHS, in conjunction with the Department of Homeland Security, encourages States to develop emergency operating plans, in general, and pandemic influenza operating plans, in particular, that are actionable.^{21 22} That is, plans should specify the organization and/or individuals responsible for carrying out specific actions; identify personnel, equipment, facilities, and supplies available for use in a disaster; and outline how all actions will be coordinated.

HHS recommends that States and localities identify sources of personnel to staff positions in their plans for distributing and dispensing vaccines and antiviral drugs during a pandemic.^{23 24}

²⁰ CDC, "Public Health Preparedness: Mobilizing State by State: A CDC Report on the Public Health Emergency Preparedness Cooperative Agreement," February 2008. Available online at <http://emergency.cdc.gov/publications/feb08phprep/pdf/feb08phprep.pdf>. Accessed on February 17, 2009.

²¹ HHS and Department of Homeland Security, "Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council," January 2009, pp. 6-7.

²² Federal Emergency Management Agency, State and Local Guide (SLG) 101: Guide for All-Hazard Emergency Operations Planning, p. 1-1, September 1996. Available online at <http://www.fema.gov/pdf/plan/slg101.pdf>. Accessed on May 12, 2009.

²³ HHS, HHS Pandemic Influenza Plan, Supplement 6 Vaccine Distribution and Use, B. Preparedness planning for vaccination against a pandemic influenza virus, 2. Vaccine production, procurement, and distribution. Available online at <http://www.hhs.gov/pandemicflu/plan/sup6.html>. Accessed on May 18, 2009.

²⁴ Sources of personnel could include volunteers from community emergency response teams, the Medical Reserve Corps, and the National Disaster Management System.

Additionally, in their staffing estimates, localities can consider factoring in an absenteeism rate that could reach 40 percent during an influenza pandemic.²⁵ Localities and States can also train personnel prior to performing their assigned duties.

Establishing formal agreements with partnering agencies is another mechanism to ensure that plans are actionable and that the responsible partnering agencies understand their roles and responsibilities. For example, HHS uses the presence of written specific strategies and a Memorandum of Agreement (MOA) or other type of formal agreement with private and/or public agencies as a criterion when it evaluates State-level pandemic influenza operating plans.²⁶ Similarly, when CDC reviews local SNS planning, it expects localities to provide written documentation of local partnering agencies, acknowledging their roles and responsibilities.²⁷

Exercises To Address Vaccine and Antiviral Drug Distribution and Dispensing

Exercises can test and improve localities' and States' preparedness to distribute and dispense vaccines and antiviral drugs.²⁸ Starting in fiscal year 2007, CDC required that States' exercise strategies build on previous work and reflect Homeland Security Exercise and Evaluation Program principles.^{29 30}

²⁵ HHS estimates that absenteeism because of illness, fear of infection, school closures, and/or quarantining infected individuals' contacts could reach 40 percent in a severe pandemic. Available online at <http://www.pandemicflu.gov/plan/pandplan.html>. Accessed on April 22, 2009.

²⁶ HHS, "Evaluation Criteria for Key Supporting Activities Linked to PHEP Funding." Available online at <http://emergency.cdc.gov/cotper/coopagreement/08/pdf/evaluation.pdf>. Accessed on June 30, 2009.

²⁷ CDC conducts annual Technical Assistance Reviews of each State to determine its level of preparedness to receive and distribute SNS assets. SNS program preparedness requires States to distribute stockpile items, including antiviral drugs, during certain types of emergencies. CDC, "Public Health Preparedness: Mobilizing State by State: A CDC Report on the Public Health Emergency Preparedness Cooperative Agreement," February 2008.

²⁸ CDC, Pandemic Influenza Guidance Supplement to the 2006 Public Health Emergency Preparedness Cooperative Agreement Phase II, 2006, Budget Period August 31, 2006–August 30, 2007, op. cit., p. 6.

²⁹ Program Announcement AA154 (August 31, 2007–August 9, 2008). Available online at <http://www.bt.cdc.gov/cotper/coopagreement/pdf/fy07announcement.pdf>. Accessed on June 29, 2009.

³⁰ Homeland Security Exercise and Evaluation Program. Available online at https://hseep.dhs.gov/pages/1001_HSEEP7.aspx. Accessed on March 6, 2009.

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Initial preparedness exercises are generally discussion based to enable participants to become familiar with the plan or role-play. Discussion-based exercises include seminars, workshops, games, and tabletop exercises. More advanced exercises are generally operations based and enable participants to execute and validate plans and clarify roles. Operations-based exercises include drills, full-scale exercises, and functional exercises.³¹ Exercises can also test the functionality of one or several components of the plan (e.g., security, transportation).

Once a preparedness exercise is completed, participants should create an After Action Report to document the exercise.³² These reports typically include the exercise objectives, participant observations, and general recommendations to improve future performance. To incorporate the lessons learned during the exercise, participants should also develop an Improvement Plan that identifies specific corrective actions necessary to improve the plan, assigns the actions to responsible parties, and establishes target completion dates.³³ Finally, participants should test the corrective actions in subsequent exercises and update their planning documents accordingly.³⁴

Collaborating With Community Partners To Plan for and Conduct Exercises Related to Vaccine and Antiviral Drug Distribution and Dispensing

HHS recommends that States and localities collaborate with community partners to develop and exercise their pandemic influenza plans.³⁵ A successful response to an influenza pandemic depends on established partnerships and collaborative planning by public health officials, law enforcement officials, hospital administrators, tribal

³¹ Ibid.

³² CDC, Pandemic Influenza Guidance Supplement to the 2006 Public Health Emergency Preparedness Cooperative Agreement Phase II, loc. cit.

³³ Ibid.

³⁴ Ibid.

³⁵ CDC, Pandemic Influenza Guidance Supplement to the 2006 Public Health Emergency Preparedness Cooperative Agreement Phase II, op. cit., p. 34.

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nations, and other community leaders (hereinafter referred to as “community partners”).^{36 37}

CDC requires all State and local public health exercises to be entered into the Lessons Learned Information Sharing Web site or into the National Exercise Schedule, which is maintained by the Department of Homeland Security.³⁸ This Web site also enables State and local planners to share planning documents, lessons learned, and innovative practices, as well as comments, experiences and observations.³⁹

Related Work

In February 2009, the Government Accountability Office (GAO) identified major gaps in domestic pandemic influenza planning and exercising, such as insufficient capacity to acquire and distribute medical supplies and inadequate vaccine production, distribution, and dispensing capacities.⁴⁰

In December 2002, OIG reported that State and local public health infrastructure was underprepared to detect and respond to bioterrorism.⁴¹ Specifically, OIG found that some States and localities did not have complete SNS receipt and deployment plans and had not tested some of their existing response protocols.

METHODOLOGY

Scope

We assessed 10 selected localities’ preparedness to distribute and dispense vaccines and antiviral drugs during an influenza pandemic as of late summer 2008. Through conducting onsite interviews and

³⁶ Ibid, p. 3.

³⁷ The Pandemic Influenza Guidance Supplement does not list the community partners that States and localities should collaborate with when developing and exercising their plans.

³⁸ CDC, Program Announcement AA154 (August 31, 2007–August 9, 2008), p. 17. Available online at <http://www.bt.cdc.gov/cotper/coopagreement/pdf/fy07announcement.pdf>. Accessed on May 21, 2009.

³⁹ Federal Emergency Management Agency. Lessons Learned Information Sharing. Available online at <https://www.llis.dhs.gov/index.do>. Accessed on May 21, 2009.

⁴⁰ “Influenza Pandemic: Sustaining Focus on the Nation’s Planning and Preparedness Efforts,” GAO-09-334.

⁴¹ OIG, “State and Local Bioterrorism Preparedness,” OEI-02-01-00550.

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reviewing planning documents, we determined the extent to which these 10 localities had prepared to distribute and dispense vaccines and antiviral drugs by addressing the eight components and 89 preparedness items that we identified based on HHS guidance. We also determined the extent to which localities conducted and documented exercises to test their plans to distribute and dispense vaccines and antiviral drugs. Finally, we identified the community partners with which the localities collaborated to develop and/or exercise these plans.

Selection of Localities

We first selected a purposive sample of five States based on variability in the following factors: health department structure, population density, geographic distribution, tribal representation, number of incoming travelers from Asia, information gathered from preinspection site visits, SNS Technical Assistance Review scores, and CDC recommendations.⁴² We eliminated States included in recent GAO pandemic influenza preparedness work related to this evaluation, and we selected one State included in companion OIG studies.

We then selected two localities within each State based on variability in population density, geographic distribution within the State, and receipt of Cities Readiness Initiative funding.⁴³ See Appendix A for a list of selected States and localities.

Selection of Vaccine and Antiviral Drug Distribution and Dispensing Components and Preparedness Items

We identified eight broad components of vaccine and antiviral drug distribution and dispensing planning and identified a total of 89 preparedness items within these components to include in our evaluation. We identified the components and preparedness items based on our review of HHS pandemic influenza guidance and input from CDC and ASPR. Table 1 lists the number of preparedness items we developed

⁴² According to a June 2007 GAO report, U.S. agency officials consider Egypt, Nigeria, and some Southeast Asian countries such as Indonesia to pose high levels of pandemic risk. "Influenza Pandemic Efforts to Forestall Onset Are Under Way: Identifying Countries at Highest Risk Entails Challenges," GAO-07-604. Available online at <http://www.gao.gov/new.items/d07604.pdf>. Accessed on February 17, 2009.

⁴³ CDC provides funding to major United States cities through the Cities Readiness Initiative. The Cities Readiness Initiative helps cities prepare to quickly dispense medicines and medical supplies during a public health emergency. Available online at <http://www.bt.cdc.gov/cri/facts.asp>. Accessed on February 17, 2009.

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to determine the level of preparedness within each of the eight components.

Table 1: Number of Preparedness Items We Developed for Each Vaccine and Antiviral Drug Distribution and Dispensing Component

Component	Number of Preparedness Items We Developed
Receiving & Staging	15
Dispensing	23
Tracking	6
Vulnerable Populations	3
Priority Groups	5
Security	15
Storage	13
Transportation	9
Total	89

Source: OIG review of HHS pandemic influenza guidance documents and input from CDC and ASPR, 2008.

Data Collection

We developed an interview guide based on the eight components and 89 preparedness items. The interview guide included questions about the types of exercises localities and States conducted, the components tested during the exercises, and whether the exercises were documented with After Action Reports and/or Improvement Plans. In addition, we included a checklist of community partners to determine which partners each of the selected localities collaborated with to plan for and/or conduct exercises related to distributing and dispensing vaccines and antiviral drugs in response to an influenza pandemic.⁴⁴

Structured interviews. Between July and September 2008, we conducted structured interviews with local and State health department officials and other officials involved with pandemic influenza preparedness and response (e.g., representatives from the State departments of homeland security, law enforcement agencies, and emergency management agencies). During the interviews, we asked local and State officials to identify which entity (e.g., the local or State health department) was responsible for implementing each of the components and/or

⁴⁴ We developed the checklist based primarily on the collaboration checklist in the SNS Technical Assistance Review.

preparedness items in our review. We used this information to identify the relevant components and preparedness items for each entity.

For each preparedness item, we generally requested two types of documentation: planning documentation (e.g., Pandemic Influenza and SNS plans and any other planning documents that addressed the eight components) and supporting documentation (e.g., formal agreements, such as MOAs, interagency agreements, and contracts). We expected the formal agreement to be both valid (i.e., current and signed by both parties) and detailed (i.e., specifying the terms, such as the resource or service, that the partnering agency would provide).

For example, for the preparedness item regarding whether the locality had a plan to ensure security at the dispensing site, we asked for:

- a general description of the security plan in a planning document (e.g., identification of the partnering agency responsible for ensuring security during the event specified in the planning document);
- a detailed plan, such as a security site assessment; and
- a valid and detailed formal agreement, where applicable.

We also asked local and State officials to identify all exercises related to distributing and dispensing vaccines and antiviral drugs that they conducted between September 2006 and July 2008. Then we asked them to identify the exercise type and component(s) tested. They provided After Action Reports and Improvement Plans for these exercises, when available. In addition, we asked local officials to identify on the collaboration checklist we provided which partners they collaborated with to develop and/or exercise their plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic.

We followed up with localities and States to clarify interview responses and to request additional planning and supporting documentation, as needed.

Data Analysis

We reviewed each locality's and State's documentation and determined whether the plans were actionable for each preparedness item. That is, we looked to see whether plans identified the organizations or individuals responsible for carrying out specific actions; the sources of personnel that would be necessary to staff distribution and dispensing

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positions; and whether they included valid, detailed formal agreements with partnering agencies.

The results we report reflect the extent to which the locality and its respective State addressed the components and preparedness items. Specifically, for preparedness items where the State was the only responsible entity, we considered the locality to have addressed those items if the State provided an actionable plan.

For preparedness items where the locality and the State were jointly responsible for aspects of the plan, both the locality and the State needed to provide actionable plans. For example, we considered localities that shared distribution responsibilities with the State to have planned for identifying receiving and staging locations if both the locality and State had all the necessary documentation. That is, (1) the locality had to refer to local receiving and staging locations in its planning documents and provide valid and detailed formal agreements with the facilities and (2) the State had to refer to State-level receiving and staging locations in its planning documents and provide valid and detailed formal agreements with those facilities.

For preparedness items that applied to both vaccines and antiviral drugs, localities and States needed to provide actionable plans for both vaccines and antiviral drugs. For example, for a locality to receive credit for defining dispensing priority groups in its plan, it needed to include both a general description and detailed lists of these groups for both vaccines and antiviral drugs.

During the interviews, we asked about plans for distributing or dispensing vaccines and antiviral drugs separately. Even though localities and States typically had different distribution and dispensing plans for vaccines and antiviral drugs, there were not many differences in whether these plans were actionable. For example, if a locality had an actionable plan for vaccines, it generally also had an actionable plan for antiviral drugs. Therefore, for ease of presentation, we combined the vaccine and antiviral responses and provided a cumulative response in favor of presenting the vaccine and antiviral drug results separately. In other words, the number of localities that we report in Appendix B as having planning and supporting documentation for each preparedness item reflects the number of localities that provided actionable plans for both vaccines and antiviral drugs, where applicable.

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Once we reviewed the planning and supporting documentation, we analyzed it by component, preparedness item, and locality. We determined the number of components for which each locality addressed at least one preparedness item. Similarly, we determined the number of localities that addressed at least one preparedness item in each of the eight components.

Next, we determined the range, average, and average percentage of items addressed in each component across localities. We did this by summing the total number of items that localities addressed in a component and dividing by the total number of items in that component across localities. For reporting purposes, we presented the eight components in three groups based on the average percentage of items addressed in the components and the functional similarity of the components.

Next, we determined the total number of exercises localities conducted or actual emergencies localities responded to that were related to vaccine or antiviral drug distribution and/or dispensing (pandemic influenza or otherwise) and addressed any of the eight components. Similarly, we included any State-level exercises or actual emergencies that met the above criteria in which the localities participated either directly or indirectly. We also determined the number of components for which each locality conducted exercises and the number of localities that conducted at least one exercise to test any of the eight components. Additionally, we determined the number of exercises that were documented with After Action Reports and Improvement Plans.

Finally, we determined the number of types of community partners each locality collaborated with during planning or conducting exercises for pandemic influenza vaccine and/or antiviral drug distribution and dispensing.

Limitations

This study is based on a purposive sample of five States and two localities within each State. The findings cannot be projected to other States and localities.

We identified the eight components of vaccine and antiviral drug distribution and dispensing planning and the 89 preparedness items to serve as indicators of local preparedness from a number of HHS guidance documents and with input from CDC and ASPR. However,

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there are other vaccine and antiviral drug distribution and dispensing preparedness items that we did not review. For example, we did not include items regarding legal preparedness that HHS recommends States and localities resolve prior to an influenza pandemic.

We assessed localities' preparedness to distribute and dispense vaccines and antiviral drugs in response to an influenza pandemic based on their formalized planning documents and agreements with partnering agencies. We did not give localities credit for preparedness items that were not documented at the time of our review. In addition, some State and local emergency managers may have the authority to dictate support for their pandemic influenza response efforts from partnering agencies without having formal agreements with them in advance.

Most of the exercise and collaboration data were self-reported. We did not determine the extent to which localities collaborated with the community partners they identified.

Standards

This evaluation was conducted in accordance with the "Quality Standards for Inspections" approved by the Council of the Inspectors General on Integrity and Efficiency.

► FINDINGS

Selected localities had not addressed in their planning documents most of the vaccine and antiviral drug distribution and dispensing components and preparedness items identified in HHS pandemic influenza guidance

As of late summer 2008, the 10 selected localities had not addressed most of the eight vaccine and antiviral drug distribution and dispensing components and 89 preparedness items that we

identified based on our review of HHS pandemic influenza guidance and input from CDC and ASPR. That is, none of the selected localities had started planning in all eight components. Further, on average, the selected localities had not addressed more than half of the preparedness items in any of the components.

Specifically, across components, selected localities' plans to distribute and dispense vaccines and antiviral drugs generally were not actionable. For example, the selected localities typically had not estimated staffing needs, and when they did, they had not factored absenteeism rates into their estimates. Further, across components, localities did not have valid and detailed formal agreements with the partnering agencies that would be responsible for carrying out various distribution and dispensing responsibilities.

Selected localities varied in the extent to which they addressed the vaccine and antiviral drug distribution and dispensing components in their planning documents

The 10 selected localities varied in the extent to which they addressed the eight vaccine and antiviral drug distribution and dispensing components. That is, these localities varied in the number of components in which they addressed at least one preparedness item. Table 2 presents the localities that addressed at least one preparedness item in each of the eight components.

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Table 2: Selected Localities That Addressed in Their Planning Documents At Least One Preparedness Item in the Eight Vaccine and Antiviral Drug Distribution and Dispensing Components

Locality	Receiving & Staging	Dispensing	Tracking	Vulnerable Populations	Priority Groups	Security	Storage	Transportation	TOTAL
A	X	X	X	X		X	X	X	7
B	X	X	X	X	X			X	6
C	X	X	X		X	X	X		6
D	X	X	X		X	X	X		6
E	X	X	X			X	X		5
F	X	X	X			X	X		5
G	X	X	X			X	X		5
H	X	X	X					X	4
I	X			X	X		X		4
J	X			X					2
TOTAL	10	8	8	4	4	6	7	3	

Source: OIG analysis of 2008 data from selected States and localities, 2009.

All localities addressed at least one preparedness item in two or more of the vaccine and antiviral drug distribution and dispensing components. However, no locality addressed at least one preparedness item in all eight components.

All 10 localities addressed at least one preparedness item within the component of Receiving & Staging. Most localities addressed at least one preparedness item in the components of Dispensing and Tracking. Conversely, fewer than half of localities addressed at least one preparedness item in the components of Vulnerable Populations, Priority Groups, and Transportation.

Selected localities addressed the highest percentage of preparedness items in the Receiving & Staging and Dispensing Components

The 10 selected localities' planning documents addressed the highest percentage of preparedness items in the Receiving & Staging and Dispensing components. Table 3 presents the number of preparedness items we reviewed in each component and the average number, average percentage, and the range of items addressed. See Appendix B for the number of localities that addressed each preparedness item, by component.

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Table 3: Average Number, Average Percentage, and Range of Preparedness Items Addressed by Selected Locality Planning Documents in the Eight Components

Component	Number of Items in Component	Average Number of Items Addressed	Average Percentage of Items Addressed	Range of Items Addressed
Receiving & Staging	15	6.2	41%	1-10
Dispensing	23	6.8	30%	0-13
Tracking	6	1.4	23%	0-5
Vulnerable Populations	3	0.5	17%	0-2
Priority Groups	5	0.6	12%	0-2
Security	15	1.7	11%	0-6
Storage	13	1.1	8%	0-3
Transportation	9	0.3	3%	0-1
Total	89	18.2	20%	2-31

Source: OIG analysis of 2008 data from selected States and localities, 2009.

Localities addressed a higher percentage of preparedness items in Receiving & Staging than in Dispensing. Again, Receiving & Staging refers to receiving, organizing, and preparing vaccines and antiviral drugs for delivery to dispensing sites, while dispensing refers to administering these medications. All five States we reviewed were responsible for initial receipt of antiviral drugs from the SNS. Four of the five States we reviewed were responsible for initial receipt of vaccines from the manufacturer. The following sections present data related to identifying receiving and staging locations and dispensing sites, developing procedures, and staffing positions at receiving and staging locations and dispensing sites.

Identifying receiving and staging locations and dispensing sites. Five localities identified health department facilities as vaccine and antiviral drug receiving and staging locations or had valid and detailed formal agreements with private distributors. However, only three localities identified vaccine dispensing sites and had valid formal agreements with these facilities, which typically were schools and community centers.

Generally, localities planned to dispense antiviral drugs only to sick individuals seeking treatment at hospitals rather than provide them as part of a mass dispensing scenario to prevent illness. Therefore, we did not include antiviral drug dispensing in our review of documentation for the Dispensing component.

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Receiving, staging, and dispensing procedures. Approximately half of the localities addressed three items we reviewed regarding receiving and staging procedures. These items included identifying the procedures for: receiving vaccines and antiviral drugs at the receiving and staging location, requesting additional supplies of antiviral drugs if local supplies are depleted, and transfer of authority for the vaccines and antiviral drugs from officials at the receiving and staging location to officials at local dispensing sites. However, only three localities identified the officials who would be authorized to receive vaccines at local dispensing sites.

Staffing positions at receiving and staging locations and dispensing sites.

Localities primarily relied on a combination of health department officials and personnel from the receiving and staging location to staff receiving and staging positions. Five localities identified these sources of personnel and had valid and detailed formal agreements with the partnering agencies. However, only two localities' planning documents identified the number of personnel each source would provide. Additionally, no locality took absenteeism into account, which could be as high as 40 percent, when estimating the number of personnel needed at the receiving and staging location.

To staff positions at local dispensing sites, localities generally planned to use individuals from the local health department, local or county school districts, the Medical Reserve Corps, the American Red Cross, and spontaneous volunteers. Three localities had valid and detailed formal agreements with each partnering agency they identified to provide dispensing site personnel. However, even though most localities estimated the number of individuals they would need to staff one dispensing site, no locality's planning documents identified the number of personnel each source of staff would provide. Finally, no locality took absenteeism into account when estimating the number of personnel needed at dispensing sites.

Selected localities addressed a lower percentage of preparedness items in the Tracking, Vulnerable Populations, and Priority Groups Components

The 10 selected localities' pandemic influenza plans addressed a lower percentage of preparedness items in the components of Tracking, Vulnerable Populations, and Priority Groups than in Receiving & Staging and Dispensing.

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Tracking. Localities differed in the extent to which they documented inventory management systems for various segments of their vaccine and antiviral drug distribution and dispensing plans. A few localities provided documentation of tracking systems at the receiving and staging locations, during transit from these locations, and at dispensing sites. These tracking systems included the SNS Resource Inventory Tracking System, systems used by private distributors, and various electronic systems that would be used to track patients after they received a vaccine at dispensing sites. However, only 1 of the 10 localities provided documentation of a tracking system at the State or local stockpile and during transit from that location.

Vulnerable Populations. Four localities included specific definitions of vulnerable populations in their planning documents. In addition, one locality included a detailed plan describing how it would reach these groups and dispense vaccines and antiviral drugs to them. However, no locality estimated the size of each vulnerable population it identified.

Priority Groups. Three localities developed plans to dispense vaccines to priority group members. These plans included vaccinating priority group members at hospitals, police stations, and/or fire departments. However, only one locality's plan defined priority groups for both vaccine and antiviral drug dispensing. Finally, none of the localities estimated the size of these groups, so they would not know when to move from one priority group to the next.

Selected localities addressed the lowest percentage of preparedness items in the Security, Storage, and Transportation Components

The 10 selected localities addressed the lowest percentage of preparedness items in the components of Security, Storage, and Transportation. Specifically, they did not address any of the preparedness items regarding security, storage, or transportation plans at the State or local stockpiles, receiving and staging locations, or dispensing sites or during transport between these facilities. Additionally, very few localities addressed the staffing items we reviewed for these components, including taking absenteeism into account when estimating the number of personnel needed to implement security, storage, and transportation plans.

Security. Although no locality provided an actionable security plan, most localities had some documentation. Those localities having partial documentation generally listed the partnering agencies they would rely

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on to provide security and outlined areas of responsibility for these agencies. The agencies generally included local law enforcement groups, such as the police or sheriff's department. However, most localities did not have valid and detailed formal agreements with these agencies. Additionally, most localities lacked detailed site and route assessments for the State or local stockpiles, receiving and staging locations, and dispensing sites and during transit between these sites. Finally, while a few localities estimated the number of security staff they would need for a portion of their plan, none identified the number of personnel the partnering agency would provide.

Storage. Although no locality provided an actionable storage plan, several localities had some documentation. Those localities having partial documentation generally noted in their planning documents the need to ensure appropriate environmental conditions for the vaccines and antiviral drugs. These documents typically included statements about providing refrigeration for vaccines and storing antiviral drugs in temperature-controlled environments. However, the majority of localities did not identify how the appropriate environmental conditions would be maintained throughout the distribution and dispensing process. For example, their planning documents lacked standard storage protocols and site assessments to indicate whether a facility had controlled room temperature or refrigeration capabilities.

Transportation. Although no locality provided an actionable transportation plan, several localities had some documentation. Those localities having partial documentation generally addressed transportation in their planning documents by identifying the partnering agencies responsible for transportation. These agencies typically included private carriers and school districts. However, the majority of localities did not have detailed transportation plans (i.e., plans that specify routes and frequency) or valid and detailed formal agreements with the partnering agencies responsible for transportation. Finally, no locality estimated the number of drivers it would need to transport the vaccines and antiviral drugs.

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All selected localities conducted exercises related to vaccine and antiviral drug distribution and dispensing; however, most did not create After Action Reports and Improvement Plans for these exercises

All 10 selected localities conducted exercises related to vaccine and antiviral drug distribution and dispensing, but 9 localities did not create both After Action Reports and Improvement Plans for all of

their exercises.

Between September 2006 and July 2008, the 10 selected localities conducted a total of 63 exercises to test their distribution and dispensing plans, ranging from 2 to 12 exercises within a locality.

Selected localities varied in the extent to which they exercised the vaccine and antiviral drug distribution and dispensing components

The 10 selected localities varied in the extent to which they addressed the eight vaccine and antiviral drug distribution and dispensing components in their exercises. That is, localities varied in the number of components tested during these exercises, ranging from four components in one locality to all eight components in five localities.

Overall, localities conducted the most exercises to test the components of Security (42 exercises) and Dispensing (39 exercises). Table 4 presents the total number of exercises that addressed each component. It also identifies the number of localities that conducted at least one exercise to address each component.

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Table 4: Selected Localities That Conducted At Least One Exercise To Test the Vaccine and Antiviral Drug Distribution and Dispensing Components* **

Locality	Receiving & Staging (n=32 Exercises)	Dispensing (n=39 Exercises)	Tracking (n=30 Exercises)	Vulnerable Populations (n=27 Exercises)	Priority Groups (n=27 Exercises)	Security (n=42 Exercises)	Storage (n=25 Exercises)	Transportation (n=29 Exercises)	TOTAL
A	X	X	X	X	X	X	X	X	8
B	X		X			X		X	4
C	X	X	X	X	X	X	X	X	8
D	X	X	X	X	X	X	X	X	8
E	X	X	X	X		X	X	X	7
F	X	X		X	X	X	X	X	7
G	X	X	X	X		X		X	6
H	X	X		X	X	X		X	6
I	X	X	X	X	X	X	X	X	8
J	X	X	X	X	X	X	X	X	8
TOTAL	10	9	8	9	7	10	7	10	

Source: OIG analysis of 2008 data from selected States and localities, 2009.

*One locality did not indicate the components that it tested in two exercises.

** Most of the 63 exercises tested more than one component.

All 10 localities conducted at least one exercise to test their ability to receive and stage, provide security for, and transport vaccines and antiviral drugs. In addition, seven localities conducted exercises to test their ability to dispense these medications to priority groups or store them during the distribution and dispensing process.

Selected localities conducted a similar number of discussion-based and operations-based distribution and dispensing exercises

The 10 selected localities conducted a similar number of discussion-based and operations-based distribution and dispensing exercises between September 2006 and July 2008. These localities also responded to two actual emergencies that tested some aspect of their plans to distribute and dispense medications. Table 5 presents the number and percentage of these exercises that selected localities conducted, by exercise type.

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Table 5: Number and Percentage of Exercises Related to Vaccine and Antiviral Drug Distribution and Dispensing That Selected Localities Conducted Between September 2006 and July 2008, by Type of Exercise

Type of Exercise	Number of Exercises	Percentage of Exercises
Discussion-based	31	49%
Operations-based	30	48%
Actual Emergency	2	3%
Total	63	100%

Source: OIG analysis of data from selected States and localities, 2009.

Discussion-based exercises are generally used to familiarize participants with the overall preparedness plan. Most (22 of 31) of the discussion-based exercises were tabletop exercises. Localities also conducted five workshops and four seminars.

Operations-based exercises are generally used to validate the preparedness plan and clarify participant roles. Most (20 of 30) of the operations-based exercises that localities conducted were full-scale exercises. Localities also conducted five functional exercises and five drills.

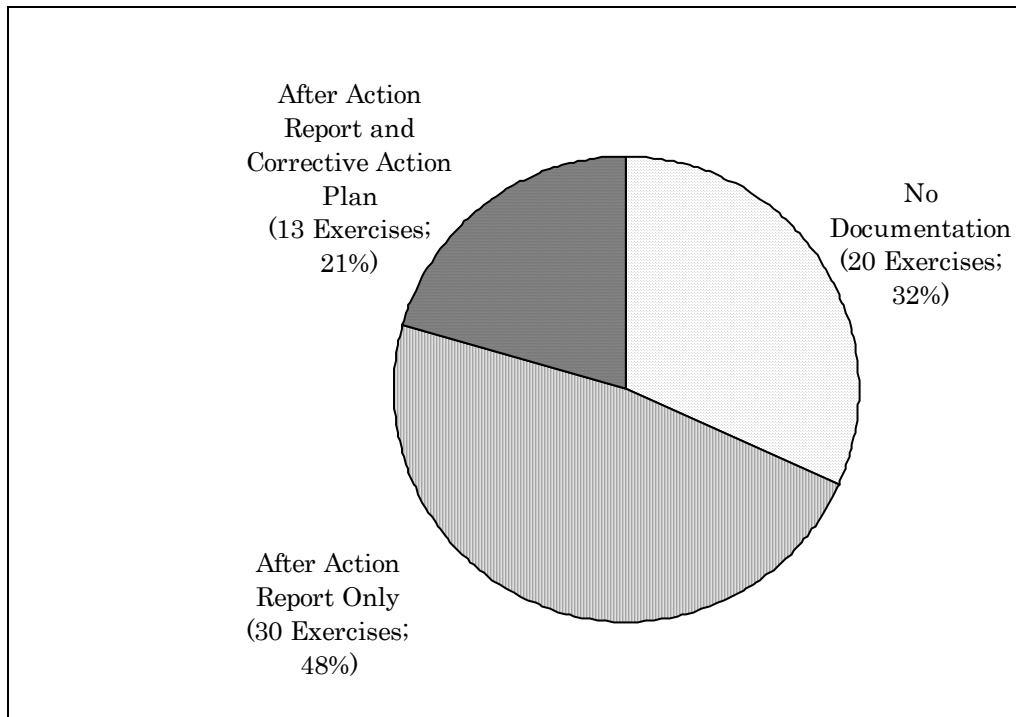
Selected localities did not create both After Action Reports and Improvement Plans for 80 percent of all distribution and dispensing exercises they conducted

The 10 selected localities did not always create both After Action Reports and Improvement Plans for the distribution and dispensing exercises they conducted. Localities were more likely to document these exercises with just After Action Reports. In addition, only one locality tested a proposed solution identified in an Improvement Plan.

Figure 1 provides the number and percentage of distribution and dispensing exercises for which selected localities provided no documentation, After Action Reports only, and both After Action Reports and Improvement Plans.

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Figure 1:
Number and
Percentage*
of Localities'
Distribution
and Dispensing
Exercises
With No
Documentation,
After Action
Reports Only,
and Both
After Action
Reports and
Improvement
Plans



Source: OIG analysis of data from selected States and localities, 2009.

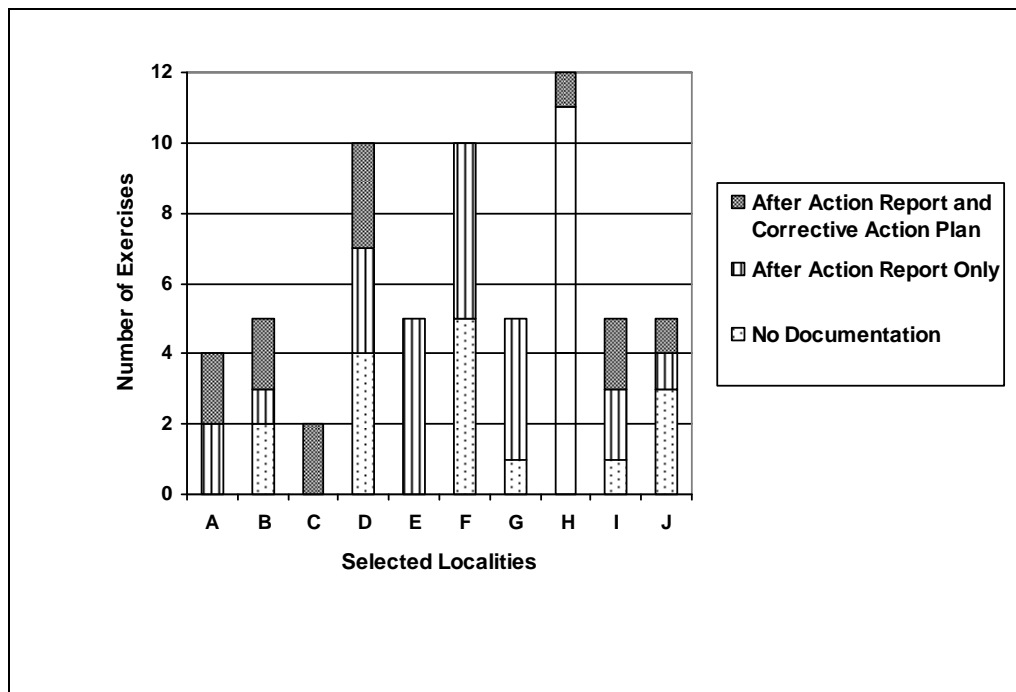
*Percentages in figure do not sum to 100 percent because of rounding.

Localities varied in the extent to which they documented their distribution and dispensing exercises with After Action Reports and Improvement Plans. Seven localities developed both After Action Reports and Improvement Plans for at least one of their exercises. However, an equal number of localities did not provide any documentation for at least one exercise.

Figure 2 presents the total number of distribution and dispensing exercises each locality conducted and the number of exercises for which selected localities provided no documentation, After Action Reports only, and both After Action Reports and Improvement Plans.

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Figure 2:
Number of
Distribution and
Dispensing
Exercises
Each Selected
Locality
Conducted
by the Number
of Exercises
With No
Documentation,
After Action
Reports Only,
and Both
After Action
Reports and
Improvement
Plans



Source: OIG analysis of data from selected States and localities, 2009.

All selected localities collaborated with community partners to develop and exercise their plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic

All 10 selected localities worked with different types of community partners (e.g., hospitals, educational institutions) to develop and exercise their plans to distribute and dispense vaccines and antiviral drugs during an influenza

pandemic. See Appendix C for a list of community partners and the number of selected localities that collaborated with each partner during planning and exercising.

Collaboration in planning. On average, localities collaborated with 16 types of partners (ranging from 12 to 22) to develop their plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic. All selected localities collaborated with educational institutions, the State or local emergency management agencies, and hospitals. Localities did not generally collaborate in planning with the National Disaster Medical System, community

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emergency response teams, the regional HHS Liaison, the Department of Transportation, or the Department of Homeland Security.

Collaboration in exercises. Localities collaborated with an average of 13 types of partners (ranging from 5 to 19) to exercise their plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic. These partners generally included educational institutions, law enforcement agencies, and the medical community. Localities generally did not collaborate with the Department of Homeland Security, the regional HHS Liaison, the National Disaster Medical System, home health or visiting nurses agencies, and community emergency response teams to exercise their plans.

The World Health Organization’s recent declaration of the start of the 2009 H1N1 influenza pandemic highlights the need for the Nation to be prepared to distribute and dispense vaccines and antiviral drugs. In its review of 2008 State pandemic influenza operating plans, ASPR found “very few gaps in State-level readiness for antiviral drug distribution.” Additionally, ASPR found that States were “doing well” with respect to developing State-level pandemic influenza vaccination plans. However, their review did not assess local preparedness to distribute and dispense vaccines and antiviral drugs in response to an influenza pandemic.

We found that while the majority of selected localities had begun planning to distribute and dispense vaccines and antiviral drugs, their plans were generally not actionable. Specifically, we found that localities had not addressed in their planning and supporting documentation most of the vaccine and antiviral drug distribution and dispensing components and preparedness items we identified in HHS pandemic influenza guidance. Localities addressed the highest percentage of preparedness items within the Receiving & Staging and Dispensing components and the lowest percentage of items within Security, Storage, and Transportation. In addition, all localities had conducted exercises related to distributing and dispensing vaccines and antiviral drugs. However, localities did not consistently create After Action Reports and Improvement Plans for these exercises or test solutions identified in the Improvement Plans. Finally, all localities collaborated with community partners to develop and test their plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic.

While the majority of selected localities had begun planning to distribute and dispense vaccines and antiviral drugs, more needs to be done to improve local preparedness. Therefore, we recommend that CDC work with States to:

Improve local pandemic influenza vaccine and antiviral drug distribution and dispensing preparedness

CDC, in coordination with States, could improve pandemic influenza vaccine and antiviral drug preparedness at the local level by taking the following actions:

R E C O M M E N D A T I O N S

- Determine why localities appear to be in the early stages of planning for pandemic influenza vaccine and antiviral drug distribution and dispensing, and provide assistance to improve their preparedness.
- Prioritize the planning areas where States should focus any carryover or future pandemic influenza funding to quickly improve local preparedness to distribute and dispense vaccines and antiviral drugs.
- Place special emphasis on ensuring localities develop actionable vaccine and antiviral drug distribution and dispensing plans. Specifically, plans should identify the organizations or individuals responsible for carrying out specific actions and the sources that would be necessary to staff distribution and dispensing positions and should be supported by valid, detailed formal agreements with partnering agencies.

Ensure that localities consistently create both After Action Reports and Improvement Plans to enhance their preparedness to distribute and dispense vaccines and antiviral drugs during an influenza pandemic

Exercises are an important aspect of strengthening preparedness. Therefore, localities should consistently document their distribution and dispensing exercises with After Action Reports, develop Improvement Plans, and test the proposed solutions to improve their pandemic influenza plans. CDC could also consider providing additional guidance or technical assistance to States and localities to ensure that they meet Homeland Security Exercise and Evaluation Program requirements.

Facilitate the sharing of pandemic influenza planning and response information and emerging promising practices

CDC should continue to develop strategies to facilitate collaboration and information sharing about existing pandemic influenza planning practices and encourage the use of existing resources. For example, CDC should encourage States and localities to use the Lessons Learned Information Sharing Web site to share not only After Action Reports but also planning documents and promising practices. These strategies could also assist States and localities in collaborating with community partners in pandemic influenza planning and exercising.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CDC agreed with two of our three recommendations. Specifically, in response to the second recommendation, CDC agreed to work with States to encourage localities to develop After Action Reports and Improvement Plans that comply with the Homeland Security Exercise and Evaluation Program. In response to the third recommendation, CDC agreed that States and localities should use the Lessons Learned Information Sharing Web site to facilitate the sharing of planning resources. CDC is using this Web site to create a national public health exercise calendar and encourage the dissemination of national trends and promising practices.

CDC did not indicate whether it agreed with the first recommendation, but noted that it plans to use some of OIG's suggested actions to address this recommendation. For example, CDC agreed that local vaccine and antiviral drug distribution and dispensing preparedness can and should be improved. Additionally, CDC acknowledged the need for States to prioritize some of the planning areas OIG identified, which include receiving and storing vaccines and antiviral drugs and identifying dispensing sites and staffing requirements. Finally, CDC agreed that localities need to develop actionable vaccine and antiviral drug distribution and dispensing plans.

CDC also identified other ways in which it continues to work with States and localities to improve their preparedness. Specifically, CDC released a gap analysis tool to States in mid-August 2009, which it will use to provide targeted technical assistance to States as they prepare to respond to the H1N1 pandemic. Additionally, CDC acknowledged that the funding provided through the June 2009 Supplemental Appropriations Act to help States and localities prepare for and respond to the H1N1 pandemic will enable them to improve preparedness and address OIG's recommendations.

CDC also provided other general comments on our draft report. Specifically, CDC noted that the lack of site-specific information in local and State plans reported by OIG may be because States and localities considered this to be sensitive information and intentionally excluded it. Additionally, CDC noted that there are distinct differences in vaccine and antiviral drug storing, distributing and dispensing requirements and in the division of State and local responsibilities for these functions.

R E C O M M E N D A T I O N S

Therefore, CDC encouraged OIG to present the vaccine and antiviral drug results separately and disaggregate the data by State and local functions.

OIG acknowledges that the delivery systems for vaccines and antiviral drugs differ and we clarified these differences in the Background. We present combined results for vaccines and antiviral drugs because we did not find substantial differences in the availability of documentation provided for each delivery system; see the Methodology for a more thorough explanation. Additionally, OIG requested and reviewed all available site-specific information, including that which may not have been incorporated in planning documents for security reasons. Finally, we combined State and local results for shared preparedness items because both the State and locality must be able to execute these items for the distribution and dispensing system to operate as intended.

We ask that in its final management decision, CDC more clearly indicate whether it agrees with our first recommendation. For the full text of CDC's comments, see Appendix D.

▶ A P P E N D I X ~ A

Selected States and Localities

State	Locality
Hawaii	Hilo
	Honolulu
Massachusetts	Boston
	Springfield
Nevada	Las Vegas
	Reno
Tennessee	Knoxville
	Memphis
Washington	Seattle
	Spokane

Source: Office of Inspector General selection of states and localities for the evaluation of local pandemic influenza preparedness: vaccine and antiviral drug distribution and dispensing, 2008.

► A P P E N D I X ~ B

Table B-1: Number of Selected Localities With Planning and Supporting Documents for the Receiving & Staging Component, by Preparedness Item

Receiving & Staging Item (n=15)	Number of Localities With Planning and Supporting Documentation for Vaccines and/or Antiviral Drugs
1. Estimated the quantities of vaccines and antiviral drugs that State/locality would need.	2
2. Determined the quantities of antiviral drugs currently available in the State/locality.	10
<i>Identifying Receiving and Staging Locations</i>	
3. Identified a receiving and staging location for assets coming from Federal agencies.	5
4. Identified an initial State/local stockpile.	2
5. Identified alternate receiving and staging locations.	2
<i>Receiving and Staging Procedures</i>	
6. Developed procedures for receiving vaccines and antiviral drugs at receiving and staging location.	5
7. Developed procedures for requesting additional supplies of antiviral drugs.	4
8. Developed transfer-of-authority procedures for distributing vaccines and antiviral drugs.	5
9. Is prepared to give the names and locations of all end-point recipients (i.e., vaccine clinics and other dispensing locations) to the distributor.	7
10. Updates end-point recipient contact information at least annually.	1
<i>Staffing Positions at Receiving and Staging Locations</i>	
11. Identified where receiving and staging staff will come from (i.e., agency, affiliation).	5
12. Estimated the number of personnel/volunteers needed for receiving and staging.	4
13. Factored absenteeism into estimated number of receiving and staging staff.	0
14. Identified number of personnel each source of staff would provide.	2
<i>Training Receiving and Staging Staff</i>	
15. Developed training materials for receiving and staging staff.	8
Total Number and Percentage of Items Addressed (out of 150 items)	62 (41%)

Source: Office of Inspector General (OIG) analysis of 2008 data from selected States and localities, 2009.

Table B-2: Number of Selected Localities With Planning and Supporting Documents for the Dispensing Component, by Preparedness Item (continued on next page)

Dispensing Item (n=23)	Number of Localities With Planning and Supporting Documentation for Vaccines*
<i>Identifying Dispensing Sites</i>	
1. Identified vaccine-dispensing sites.	3
2. Identified alternate vaccine-dispensing sites.	2
<i>Dispensing Procedures</i>	
3. Identified the officials who are authorized to receive vaccines at dispensing sites.	3
4. Planned to provide identification (i.e., badges) to dispensing staff upon entrance at dispensing sites.	5
5. Planned to keep symptomatic and nonsymptomatic people separated at dispensing sites.	7
6. Estimated patient throughput** at dispensing sites.	1
7. Determined time to vaccinate entire population based on throughput estimate.	1
8. Planned to collect data regarding number of doses received; date of dispensing; age, priority group, State, county, and ZIP Code of recipient.	0
9. Documented a data entry system for dispensing sites.	0
10. Ensures that data entry keeps pace with throughput.	0
11. Developed a process to dispense vaccines to individuals that have trouble communicating.	5
<i>Staffing Positions at Dispensing Sites</i>	
12. Identified where dispensing staff will come from (i.e., agency, affiliation).	3
13. Estimated the number of personnel/volunteers needed for dispensing.	7
14. Factored absenteeism into estimated number of dispensing staff.	0
15. Identified number of personnel each source of staff would provide.	0
16. Has contingency plans for volunteer absenteeism.	0
17. Has a system to maintain contact information for dispensing staff.	6
18. Ensures that contact information for dispensing staff is up-to-date (i.e., updated at least every 6 months).	4

Table B-2: Number of Selected Localities With Planning and Supporting Documents for the Dispensing Component, by Preparedness Item (continued)

Dispensing Item (n=23)	Number of Localities With Planning and Supporting Documentation for Vaccines*
<i>Staffing Dispensing Sites</i>	
19. Has a system to ensure that dispensing staff is qualified to administer vaccines.	4
20. Ensures that dispensing staff's qualifications are up-to-date (i.e., updated at least every 6 months).	4
21. Has a process to allow nonlicensed personnel/volunteers to dispense vaccines, when and if needed.	4
22. Has a process to allow health care workers from other jurisdictions to dispense vaccines, when and if needed.	1
<i>Training Dispensing Staff</i>	
23. Has training materials for dispensing staff.	8
Total Number and Percentage of Items Addressed (out of 230 items)	68 (30%)

Source: OIG analysis of 2008 data from selected States and localities, 2009.

*Generally, localities planned to dispense antiviral drugs only to sick individuals seeking treatment at hospitals rather than provide them as part of a mass dispensing scenario to prevent illness. Therefore, we did not include antiviral drug dispensing in our review of documentation for the Dispensing component.

**Throughput generally refers to the number of people that can be vaccinated in a given amount of time.

Table B-3: Number of Selected Localities With Planning and Supporting Documents for the Tracking Component, by Preparedness Item

Tracking Item (n=6)	Number of Localities With Planning and Supporting Documentation for Vaccines and Antiviral Drugs
1. Has system to track antiviral drugs at the State or local stockpile.	1
2. Has system to track antiviral drugs during transport from the State or local stockpile.	1
3. Has system to track vaccines and antiviral drugs at the receiving and staging location.	3
4. Has system to track vaccines and antiviral drugs during transport from the receiving and staging location.	5
5. Has system to track vaccines and patients at the dispensing sites.	4
6. Has tracking system that includes variables for doses dispensed; lot number; date of dispensing; age and priority group of recipient.	0
Total Number and Percentage of Items Addressed (out of 60 items)	14 (23%)

Source: OIG analysis of 2008 data from selected States and localities, 2009.

A P P E N D I X ~ B

Table B-4: Number of Selected Localities With Planning and Supporting Documents for the Vulnerable Populations Component, by Preparedness Item

Vulnerable Populations Item (n=3)	Number of Localities With Planning and Supporting Documentation for Vaccines and Antiviral Drugs
1. Defined vulnerable populations.	4
2. Estimated the size of each vulnerable population.	0
3. Developed plan to dispense to vulnerable populations.	1
Total Number and Percentage of Items Addressed (out of 30 items)	5 (17%)

Source: OIG analysis of 2008 data from selected States and localities, 2009.

Table B-5: Number of Selected Localities With Planning and Supporting Documents for the Priority Groups Component, by Preparedness Item

Priority Groups Item (n=5)	Number of Localities With Planning and Supporting Documentation for Vaccines and Antiviral Drugs
1. Defined priority groups.	1
2. Estimated the size of each priority group.	0
3. Developed plan to dispense to priority groups.	3
4. Developed protocols to screen and identify persons in priority groups at dispensing sites.	2
5. Developed method to determine when it is appropriate to provide vaccines and antiviral drugs to the next priority group.	0
Total Number and Percentage of Items Addressed (out of 50 items)	6 (12%)

Source: OIG analysis of 2008 data from selected States and localities, 2009.

Table B-6: Number of Selected Localities With Planning and Supporting Documents for the Security Component, by Preparedness Item

Security Item (n=15)	Number of Localities With Planning and Supporting Documentation for Vaccines and Antiviral Drugs
<i>Security Procedures</i>	
1. Has plan to ensure security for the antiviral drugs at State or local stockpile.	0
2. Has plan to ensure security for the antiviral drugs during transport from State or local stockpile.	0
3. Has plan to ensure security for the vaccines and antiviral drugs at the receiving and staging location.	0
4. Has plan to ensure security for the vaccines and antiviral drugs during transport from the receiving and staging location.	0
5. Has plan to ensure security for the vaccines at the dispensing sites.	0
6. Has a contingency plan to provide security for the vaccines and antiviral drugs.	0
<i>Staffing Security Positions</i>	
7. Identified where security staff will come from (i.e., agency, affiliation).	0
8. Estimated number of personnel/volunteers needed to ensure security for the antiviral drugs at State or local stockpile.	0
9. Estimated number of personnel/volunteers needed to ensure security for the antiviral drugs during transport from State or local stockpile.	4
10. Estimated number of personnel/volunteers needed to ensure security for the vaccines and antiviral drugs at receiving and staging location.	3
11. Estimated number of personnel/volunteers needed to ensure security for the vaccines and antiviral drugs during transport from receiving and staging location.	2
12. Estimated number of personnel needed to ensure security for vaccines at dispensing sites.	4
13. Factored absenteeism into estimated number of security staff.	0
14. Identified number of personnel each source of staff would provide.	0
<i>Training Security Staff</i>	
15. Has training materials for security staff.	3
Total Number and Percentage of Items Addressed (out of 150 items)	16 (11%)

Source: OIG analysis of 2008 data from selected States and localities, 2009.

Table B-7: Number of Selected Localities With Planning and Supporting Documents for the Storage Component, by Preparedness Item

Storage Item (n=13)	Number of Localities With Planning and Supporting Documentation for Vaccines and Antiviral Drugs
<i>Storage Procedures</i>	
1. Has plan to ensure proper storage conditions for the antiviral drugs at the State or local stockpile.	0
2. Has plan to ensure proper storage conditions for the antiviral drugs during transport from the State or local stockpile.	0
3. Has plan to ensure proper storage conditions for the vaccines and antiviral drugs at the receiving and staging location.	0
4. Has plan to ensure proper storage conditions for the vaccines and antiviral drugs during transport from the receiving and staging location.	0
5. Has plan to ensure proper storage conditions for the vaccines at the dispensing sites.	0
6. Has contingency plans for the vaccines and antiviral drugs in adverse storage conditions.	0
7. Ensures that antiviral drugs in State/local stockpiles have not expired.	7
<i>Staffing Storage Positions</i>	
8. Designated responsibility for ensuring proper storage conditions for the antiviral drugs at the State or local stockpile.	0
9. Designated responsibility for ensuring proper storage conditions for the antiviral drugs during transport from the State or local stockpile.	0
10. Designated responsibility for ensuring proper storage conditions for the vaccines and antiviral drugs at the receiving and staging location.	0
11. Designated responsibility for ensuring proper storage conditions for the vaccines and antiviral drugs during transport from the receiving and staging location.	0
12. Designated responsibility for ensuring proper storage conditions for the vaccines at the dispensing sites.	2
<i>Training Staff Responsible for Storage</i>	
13. Has training materials for staff responsible for storage.	2
Total Number and Percentage of Items Addressed (out of 130 items)	11 (8%)

Source: OIG analysis of 2008 data from selected States and localities, 2009.

A P P E N D I X ~ B

Table B-8: Number of Selected Localities With Planning and Supporting Documents for the Transportation Component, by Preparedness Item

Transportation Item (n=9)	Number of Localities With Planning and Supporting Documentation for Vaccines and Antiviral Drugs
<i>Transportation Procedures</i>	
1. Has plan to transport the antiviral drugs from the State or local stockpile.	0
2. Has plan to transport the vaccines and antiviral drugs from the receiving and staging location.	0
3. Has contingency plans to transport the vaccines and antiviral drugs.	0
<i>Staffing Transportation Positions</i>	
4. Identified where transportation staff will come from (i.e., agency, affiliation).	2
5. Estimated number of personnel/volunteers needed to transport the antiviral drugs from the State or local stockpile.	0
6. Estimated number of personnel/volunteers needed to transport the antiviral drugs from the receiving and staging location.	0
7. Factored absenteeism into estimated number of transportation staff.	0
8. Identified number of personnel each source of staff would provide.	0
<i>Training Transportation Staff</i>	
9. Has training materials for transportation staff.	1
Total Number and Percentage of Items Addressed (out of 90)	3 (3%)

Source: OIG analysis of 2008 data from selected States and localities, 2009.

▶ A P P E N D I X ~ C

Number of Selected Localities Collaborating With Each Type of Community Partner During Pandemic Influenza Vaccine and Antiviral Drug Distribution and Dispensing Planning and Exercising**

Community Partner**	Number of Localities Collaborating With Partner During Planning	Number of Localities Collaborating With Partner During Exercising*
1. Educational institutions	10	9
2. Emergency management agencies	10	7
3. Hospitals	10	7
4. State health departments	9	7
5. Law enforcement	9	8
6. Fire departments	9	5
7. Emergency medical services	9	7
8. Medical Reserve Corps	9	7
9. Medical community	9	8
10. Military installations	8	4
11. Mental health/crisis professionals	8	6
12. Private industry	8	6
13. Volunteer organizations	8	3
14. Critical infrastructure/public works	7	4
15. Home health/visiting nurses	7	2
16. Organizations serving at-risk populations	7	3
17. Metropolitan Medical Response System	5	6
18. Departments of Correction	4	3
19. Professional associations	4	4
20. Department of Homeland Security	3	0
21. Department of Transportation	3	3
22. Regional health and human services liaisons	3	1
23. Community emergency response teams	3	2
24. National Disaster Medical System	2	1

Source: Office of Inspector General analysis of 2008 data from selected States and localities, 2009.

* One locality did not provide the types of partners it collaborated with during its exercises.

** In addition, three out of the four localities with tribal populations collaborated with tribal governments during planning. Two of three localities also collaborated with tribal governments to exercise their plans; the fourth locality did not provide information about whether it collaborated with the tribal governments to exercise the plan.

▶ A P P E N D I X ~ D

A G E N C Y C O M M E N T S



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

AUG 25 2009

TO: Daniel R. Levinson, Inspector General
Department of Health and Human Services

FROM: Thomas R. Frieden, M.D., M.P.H., Director
Centers for Disease Control and Prevention

SUBJECT: Office of Inspector General's Draft Report: "Local Pandemic Influenza Preparedness:
Vaccine and Antiviral Drug Distribution and Dispensing."
OEI-04-08-00260

The Centers for Disease Control and Prevention (CDC) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report, "Local Pandemic Influenza Preparedness: Vaccine and Antiviral Drug Distribution and Dispensing." Thank you for your review of this important and timely issue.

The objectives of the review were to determine the extent to which the selected localities 1) addressed in their planning documents the vaccine and antiviral drug distribution and dispensing components and preparedness items OIG identified based on Department of Health and Human Services' (HHS) pandemic influenza guidance; 2) conducted exercises related to vaccine and antiviral drug distribution and dispensing and documented these exercises with after-action reports and improvement plans; and 3) collaborated with community partners to develop and exercise their plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic. The OIG completed their data collection in September 2008.

As stated in the draft report, this evaluation focuses on the extent to which 10 selected localities in Hawaii, Massachusetts, Nevada, Tennessee, and Washington have prepared to distribute and dispense vaccines and antiviral drugs during an influenza pandemic.

The report's findings provide important information regarding the readiness of these selected localities to respond to an influenza pandemic. CDC is conducting a gap analysis of state pandemic preparedness and response related to the current novel H1N1 influenza outbreak, which should yield valuable information about some of these issues and should help to prioritize local efforts.

Local Planning Important to Pandemic Influenza Response

Thank you for drawing attention to these gaps. CDC is working hard to address local gaps in pandemic planning. CDC agrees that while states, overall, are doing well with antiviral drug distribution and development of vaccination plans, local pandemic preparedness can and should be improved. While development of local plans and capabilities is the responsibility of the states, CDC provides resources and guidance to the states to enhance their ability to improve preparedness at the local level.

Recognizing the critical importance of state and local pandemic H1N1 response, Congress appropriated funding in June 2009 through the 2009 Supplemental Appropriations Act to prepare for and respond to the novel H1N1 influenza outbreak in the United States. To date, CDC has provided \$508 million through the Public Health Emergency Response (PHER) grant to upgrade state and local pandemic influenza preparedness and response capacity, including vaccination and antiviral drug distribution and dispensing.

While the majority of the PHER funds are distributed to state health departments, CDC guidance in the PHER funding opportunity announcement states that CDC expects a significant portion of the PHER funds to be distributed to and utilized at the local level for activities related to antiviral distribution/dispensing, community mitigation, and mass vaccination. The guidance also strongly encourages states to work closely with local and tribal entities and governments to assure access to the funding necessary to achieve preparedness at all levels of government.

In addition, recipients of PHER funding must conduct a pandemic preparedness gap assessment to identify gaps that are most critical or of highest priority for their jurisdictions, develop work plans and program goals that address the prioritized gaps, and build detailed budgets that reflect how funding will be directed to address gaps and achieve the program goals. CDC expects states to direct appropriate funds to their localities to address local pandemic preparedness gaps that they identify in these gap assessments. Furthermore, PHER awardees are required to have comprehensive, up-to-date plans in place no later than September 15, 2009, for a potential mass vaccination campaign. These plans should incorporate local activities.

Specific Recommendations and CDC's Response

OIG Recommendation: Improve local pandemic influenza vaccine and antiviral drug distribution and dispensing preparedness. CDC, in coordination with states, could improve pandemic influenza vaccine and antiviral drug distribution and dispensing preparedness at the local level by taking the following actions:

- Determine why localities appear to be in the early stages of planning for pandemic influenza vaccine and antiviral drug distribution and dispensing, and provide assistance to improve their preparedness.
- Prioritize the planning areas where states should focus any carryover or future pandemic influenza funding to quickly improve local preparedness to distribute and dispense vaccines and antiviral drugs.
- Place special emphasis on ensuring localities develop actionable vaccine and antiviral drug distribution and dispensing plans. Specifically, plans should identify the

- organization or individuals responsible for carrying out specific actions; the sources of personnel that would be necessary to staff distribution and dispensing positions; and be supported by valid, detailed formal agreements with partnering agencies.

CDC Response: CDC continues to work with states to provide assistance to improve their preparedness. Specific to H1N1 influenza, CDC provided the states with a gap analysis tool on August 12, 2009, which will result in targeted technical assistance to prepare states for H1N1 response this fall.

States and localities initiated pandemic influenza planning in 2005 and 2006 after receiving the first of three phases of pandemic influenza funding through CDC’s Public Health Emergency Preparedness (PHEP) cooperative agreement. However, many of those planning activities were not sustained when the supplemental pandemic influenza preparedness funding ended in 2008. While CDC encouraged states to continue pandemic influenza preparedness projects, many states simply did not have the resources to maintain their pandemic influenza staffing and related activities.

The OIG findings reinforce CDC concerns regarding the need for states to prioritize planning efforts to quickly improve local preparedness to distribute and dispense vaccines and antiviral drugs, particularly the ability of local health departments to receive and store vaccine and to identify vaccine clinic sites and staffing requirements before an influenza pandemic occurs. The OIG report provides CDC with a useful snapshot of the 10 localities’ gaps that, as discussed earlier, will inform our plans with states and localities for likely distribution and administration of H1N1 vaccine in the current public health emergency.

CDC agrees that localities need to develop actionable vaccine and antiviral drug distribution and dispensing plans that identify those responsible for carrying out specific actions; the sources of personnel needed to staff distribution and dispensing positions; and be supported, if necessary, by valid, detailed formal agreements with partnering agencies.

CDC provided broad guidance to states on the development of their comprehensive, up-to-date vaccination campaign plans that they must complete by September 15, 2009. CDC also recognized that a significant portion of the activities related to antiviral distribution and dispensing, community mitigation, and mass vaccination are operationalized at the local level. Therefore, CDC strongly encouraged states to work closely with local and tribal entities and governments to assure preparedness at all levels of government and access to supplemental funding necessary to achieve this goal.

Supplemental funding appropriated by Congress in June 2009 to prepare for and respond to an influenza pandemic should provide the additional resources states need to meet these OIG recommendations. To date, CDC has provided \$508 million in supplemental funding through the PHER grant to upgrade state and local pandemic influenza preparedness and response capacity. Funding is intended to help awardees assess their current capabilities in pandemic influenza response, using a gap analysis tool similar to that used by OIG, and to address remaining gaps in

two focus areas, including vaccination and antiviral distribution and dispensing. Funding may be used to accelerate planning for a national vaccination campaign for H1N1 influenza in fall 2009, as well as vaccine delivery, vaccine administration, and related communications planning and implementation.

To receive funding, awardees must submit to CDC detailed gap assessments, work plans, and revised budgets that are intended to 1) identify remaining gaps in state/local, territorial, and/or tribal pandemic preparedness; 2) prioritize remaining gaps, determine which gaps are the most critical/highest priority areas and develop work plans that address how these gaps will be addressed; and 3) develop detailed budgets that reflect how funding will be directed to address the identified gaps.

OIG Recommendation: Ensure that localities consistently create after-action reports and improvement plans to enhance their plans to distribute and dispense vaccines and antiviral drugs during an influenza pandemic.

CDC Response: CDC agrees that after-action reports and improvement plans are essential components of effective exercises. Accordingly, CDC requires, as part of the PHEP cooperative agreement, that states produce after-action reports and improvement plans for at least two preparedness exercises annually. Because of the nature of the cooperative agreement, this requirement applies to states rather than localities. To address OIG’s recommendation, CDC will work with states to encourage the development of after-action reports and improvement plans at the local level that comply with the Homeland Security Exercise and Evaluation Program.

OIG Recommendation: Facilitate the sharing of pandemic influenza planning and response information and emerging promising practices.

CDC Response: CDC agrees with OIG’s recommendation that states and localities should use the Lessons Learned Information Sharing (LLIS) website to share after-action reports, planning documents, and promising practices. All federally funded exercises should be posted to the National Exercise Schedule (NEXS) which is maintained by the Department of Homeland Security. However, all state and local public health departments do not have access to NEXS and the Corrective Action Program (CAP), limiting coordination between federal agencies and limiting the collaboration with community partners in pandemic influenza planning and exercising. CDC is working to facilitate collaboration and information sharing about existing pandemic influenza planning practices and encourage the use of existing resources. As a stop-gap solution, CDC has developed a Division of State and Local Readiness (DSLRL) secure channel on the LLIS.gov system and required all PHEP awardees to submit fiscal year 2009 state public health exercise schedules to CDC’s DSLRL. These schedules are being used to create a national calendar of public health exercises. This national public health exercise calendar, along with an aggregate review of after-action reports from two required preparedness exercises, will allow CDC to foster a learning exchange between PHEP awardees that encourages the dissemination of national trends and promising practices regarding pandemic influenza planning and will allow awardees to leverage existing resources between states.

A P P E N D I X ~ D

Other Comments

The OIG report findings regarding the identification of receiving and staging locations references the lack of site-specific information for receiving and staging sites in local and state plans. As a point of clarification, locations and addresses of such facilities are considered sensitive information, and in many states they are not included in plans and documentation because their plans are subject to state open records laws and public release.

There are distinct differences between the requirements for storing, distributing, and dispensing antiviral drugs and vaccines, and it is important to not confuse the two by combining them in the manner that was undertaken in this report. We encourage OIG to make these distinctions clear in the findings section of the report to ensure readers fully understand them.

- Antiviral drugs are available in state caches and come from the federally maintained Strategic National Stockpile (SNS). SNS-stored antiviral drugs are distributed to one location designated by the state. The state can further distribute antiviral drugs in nonrefrigerated vehicles to their localities for dispensing. Antiviral drugs can be stored centrally or at the receiving locations at room temperature. Antiviral drugs are dispensed at medical facilities, such as hospitals, clinics, and alternate care facilities, for the purpose of treating symptomatic patients.
- Vaccine is delivered by the manufacturer to a central state location or multiple provider sites throughout the state. Cold chain management is a factor for distribution and storage. Vaccine is targeted to priority populations and to the general public for prevention of influenza. Vaccine can be administered in various locations, such as clinics, schools, or malls, as designated by the localities.

CDC strongly encourages the OIG to break out in the data tables in the appendix not only the data in terms of antiviral drugs and vaccine but also by state and local roles and functions. CDC is concerned that aggregating disparate state and local roles and functions could confuse readers about whether the activity is a state or a local responsibility. CDC recommends this be done throughout the report, including a separate OIG analysis of each system to help readers more easily understand this distinction.

We appreciate your consideration of the comments contained in this memo as you develop the final report. We are happy to discuss any of these comments with you. Please direct any questions regarding these comments to Mr. Shaun Ratliff by telephone at (404) 639-2809 or by e-mail at iggao@cdc.gov.

Sincerely,

/S/

Thomas R. Frieden, M.D., M.P.H.
Director

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A C K N O W L E D G M E N T S

This report was prepared under the direction of Dwayne Grant, Regional Inspector General for Evaluation and Inspections in the Atlanta regional office.

Jaime Durley and Mina Zadeh served as team leaders for this study. Erica Bushong served as the Lead Analyst. Other principal Office of Evaluation and Inspections staff from the Atlanta regional office who contributed include Leila Samy; central office staff who contributed include Talisha Searcy and Kevin Farber.