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EXECUTIVE SUMMARY

Antiviral distribution and dispensing are critical to reducing the number of cases and deaths from an influenza pandemic. This report summarizes the antiviral distribution and dispensing activities conducted by state and local health departments in response to the 2009 H1N1 influenza pandemic. This report is the first stage in a larger project that the Centers for Disease Control and Prevention (CDC), the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and other partners are conducting to explore alternative models for antiviral management during an influenza pandemic.

ASTHO and NACCHO used multiple approaches to gather information from state and local public health representatives about antiviral distribution and dispensing during the H1N1 outbreak. Both organizations conducted literature reviews, evaluated health department after-action reports (AARs) for the 2009 H1N1 pandemic influenza, and examined key informant interviews, with NACCHO focusing on local health officials and ASTHO addressing state and territorial officials. Additionally, NACCHO and ASTHO convened advisory groups comprised of state or local public health officials, respectively, to provide subject matter expertise, guidance, and leadership for the project. ASTHO and NACCHO jointly hosted roundtable discussions during the July 2011 Strategic National Stockpile (SNS) Summit to gather additional information from federal, state, territorial, local, and tribal representatives.

This report synthesizes information and anecdotal experiences from the state/territorial and local health department (LHD) perspectives. This review is not a comprehensive analysis and may not represent all experiences or viewpoints. Each state, territorial, and local health department managed how it released (for downstream distribution and dispensing) the stockpiled antiviral medications differently, which allowed for varied early successes and challenges in response to the 2009 H1N1 pandemic. At the onset of the 2009 H1N1 pandemic, most state and some local health departments already had some stockpiles of antivirals through a federal subsidy purchase program. This report focuses on antiviral distribution and dispensing from the CDC’s SNS to state/territorial health departments (S/THDs) and then subsequently from state to LHDs during the pandemic.

Eleven key themes were identified for antiviral distribution and dispensing activities during the 2009 H1N1 pandemic and will be explored in this report:

**Process Themes**
1. Allocation
2. Receiving and Staging
3. Storage
4. Distribution
5. Dispensing
6. Returning, Redistributing, Relabeling, and Disposing of Unused Antiviral Medications

**Overarching Themes**
7. Communication
8. Legal and Policy Considerations
9. Security
10. Tracking and Reporting
11. Population Considerations
Process Themes

1. Allocation
The 2009 H1N1 pandemic emerged as a threat to U.S. citizens and prompted the federal government to release antiviral medications from the SNS to states based on predetermined pro rata (population-based) allocations. State and local health departments then managed and allocated these critical resources to their populations. Allocation decisions varied in state and local health departments, ranging from strict pro rata appropriations to allocation based on clinical need. In making allocation decisions, health officials worked to balance equity with clinical need and commercial product scarcity by assessing population demographics, epidemiological data, and healthcare sector distribution.

Allocation Planning—Considerations
• Consider ethical principles when making allocation decisions to ensure equitable access to antivirals.
• Explore and consider alternative allocation schemes that are flexible and equitable. Per capita allocation may not account for a population’s clinical need.
• Consider alternative, more time-efficient allocation schemes. Allocation decisions based on epidemiological data are arduous and may prevent supplies from reaching populations in a timely manner.
• Properly communicate allocation decisions and rationale to all partners to increase efficiency in the response.
• Improve decision-making capabilities at the state and local levels by increasing dialogue between states and the federal government concerning the decision to release antivirals, proposed allocation methodologies, and guidance around distribution and dispensing practices.

2. Receiving and Staging
The phrase “receiving and staging” describes state and local public health departments’ ability to secure locations and personnel to receive antivirals, conduct warehouse operations, and prepare these antivirals for delivery to dispensing sites. Many state and local health departments planned and exercised how to receive and stage medical countermeasures prior to the outbreak, which contributed to the many successes of these operations during H1N1. There were, however, some jurisdictions that had challenges, particularly with discrepancies in communicating the timing and contents being delivered to the jurisdiction.

Receiving and Staging—Planning Considerations
• Delays in receiving antivirals by either the state or local health departments can quickly result in community shortages.
• Effective and accurate communication around deliveries’ timing and contents is essential for S/THDs and LHDs to receive and stage materiel smoothly.
• Conduct exercises that allow state and local health departments to test their receiving and staging capabilities for pandemic influenza preparedness.
• Having volunteers or dedicated personnel experienced in warehouse operations can decrease the burden on S/THD and LHD staff tasked with other response roles.

3. Storage
Storing medical countermeasures is a significant component of preparedness planning. For many states and localities, the 2009 H1N1 pandemic was the first event in which storage for antivirals had to be readily available; those storage facilities also had to retain stockpiles for longer than anticipated. Although storing antiviral supplies was a smooth process for most state and local health departments, the cost of long-term storage was burdensome.
Storage—Planning Considerations
- Continue to evaluate storage options and capabilities, including external and internal partnerships, because they could be beneficial in future preparedness planning efforts.
- Because the cost to store antivirals can be burdensome, federal, S/THD, and LHD partners should discuss careful and practical decision-making around initial distribution or consider initial supply/resupply models to mitigate costs.
- Consider ways for state and local health departments to leverage public or private entities’ expertise regarding storage.

4. Distribution
The 2009 H1N1 pandemic was the first time many states and localities engaged in large-scale distribution. Distribution went well for most S/THDs and LHDs, particularly those that were able to harness both private and public resources.

Distribution—Planning Considerations
- Consider ways for S/THDs and LHDs to leverage the expertise of public or private entities in the business of distribution, which can be a large asset to public health.
- Consider establishing agreements with multiple entities (e.g., establish contingency plans) to ensure that S/THDs’ and LHDs’ needs are met even if some assets are not available during public health emergencies.

5. Dispensing
Dispensing is the process of providing medical countermeasures directly to the end-user. Although planning for large-scale exercises regarding dispensing medical countermeasures has been underway for some years, the 2009 H1N1 response was the first event in which this function had to be put into operation by S/THDs and LHDs around the country. S/THDs are not typically responsible for dispensing; they are, however, involved with disseminating guidance to dispensing entities, and they worked with many community partners on antiviral dispensing during the 2009 H1N1 pandemic. LHDs are typically responsible for dispensing; however, given the low severity of H1N1 and availability of antivirals in the commercial sector, LHDs dispensed limited amounts of antiviral drugs.

Dispensing—Planning Considerations
- Develop clear triggers for dispensing antivirals before an emergency so that S/THDs and LHDs can plan and respond appropriately. The low severity of the 2009 H1N1 virus and availability of antivirals in the commercial sector limited the need to dispense government stockpiles.
- Receiving increased assistance from both federal and national private sector associations in establishing memorandums of agreement (MOAs) with pharmacies or other dispensing partners could greatly benefit S/THDs and LHDs.

6. Returning, Redistributing, Relabeling, and Disposing of Unused Antiviral Medications
As the response to the 2009 H1N1 pandemic began to wane, many S/THDs and LHDs were left with large quantities of antiviral medications to manage. At the local level, unused antivirals were typically returned to S/THDs, which then determined further action. Although some of these antivirals were disposed of, most still continue to be stored in state managed stockpiles as of summer 2011.

Returning, Redistributing, Relabeling, and Disposing of Unused Antiviral Medications—Planning Considerations
- Increased planning should occur to ensure all assets are used, redistributed to populations in need, or given to entities (such as SNS or pharmaceutical distributors) that are better equipped
to handle long-term storage. Long-term storage of antivirals by state, local, or partner organizations can be expensive and complicated for some entities.

- Address legal and regulatory issues regarding redistributing and disposing of antivirals for each jurisdiction before an event.
- Consider the possibility of S/THDs redistributing supplies early in an event. Specifically, state and local jurisdictions must weigh the pros and cons of distributing all supplies too early in an event and build in the capacity to adjust distribution, if needed, as the event unfolds to best address the community’s changing needs.

Overarching Themes

7. Communication
Communication is an essential activity during any response. Strong internal communication at state and local levels was essential during H1N1. However, federal, state, and local coordination and communication could be improved for the future.

Communication—Planning Considerations
- Consider ways for S/THDs and LHDs to improve internal communications, including using the incident command structure (ICS), before an emergency.
- Improve federal, state, and local coordination and communication by increasing visibility and information sharing among all stakeholders.
- Be cognizant of S/THD and LHD stakeholders’ communication capabilities and incorporate alternative communication strategies into preparedness planning.
- Streamline messaging and requests at the federal, state, and local levels and establish a single point of contact to ease information exchange and improve response.

- Establish databases with the contact information for the medical community partners in the respective S/THDs’ and LHDs’ jurisdictions.
- Foster relationships with community partners that can share information with community members who do not access public health information through traditional mechanisms.
- Consider ways to increase staff training and develop more coordinated plans for how best to communicate with the public, media, and outside stakeholders during an emergency.
- Garner support from the national level of large private sector organizations (e.g., pharmacy chains, insurance companies) so local partnership activities between public health and local corporate branches can develop plans and boost confidence.

8. Legal and Policy Considerations
State and local health departments encountered many legal and policy challenges regarding antiviral distribution and dispensing during the H1N1 pandemic. As part of this review, James G. Hodge, Jr., JD, LLM, analyzed legal and policy issues encountered by federal, state, and local public health organizations during the 2009 H1N1 response.

Legal—Planning Considerations
- Increase S/THD and LHD staff awareness of their legal authorities during a declared public health emergency.
- Establish, where possible, contracts and MOAs with both public and private sector partner organizations before a public health emergency.
- Resolve legal barriers, where possible, to effectively manage antivirals before a public health emergency.
9. Security
Securing medical countermeasures during a public health emergency is an important consideration in preparedness planning. Because the severity of the 2009 H1N1 pandemic was lower than that of historical influenza outbreaks, the event did not create a large enough demand for medical countermeasures to elicit a security risk to state-held or locally held antiviral drug stockpiles. The response did, however, give many states and localities an opportunity to test their security plans. Most security plans for antivirals focused on ensuring product safety during transportation and storage. Because antivirals were stored longer than anticipated, security also remained in place for that duration.

Security—Planning Considerations
- Consider future security plans that are more scalable and easy to adapt depending on the severity of the event.
- Preparedness planning efforts should consider the need for long-term security because S/THDs and LHDs were responsible for storing antivirals longer than anticipated; therefore, security remained in place longer than anticipated.

10. Tracking and Reporting
Tracking and reporting inventory levels of antiviral drugs was an integral part of antiviral management during the 2009 H1N1 response. Maintaining situational awareness on product inventory at the state and local levels is critical to ensure that medications are available in the right place at the right time. During the 2009 H1N1 response, tracking and reporting processes and requirements varied greatly among S/THDs and LHDs.

Tracking and Reporting—Planning Considerations
- Develop a standardized set of data elements for tracking distribution and dispensing to minimize burden across organizations and more readily provide a common reporting method.
- Develop tracking and reporting systems that are easy for all partners to use and compatible with existing systems.
- Maintain situational awareness during an emergency by managing data regarding antiviral distribution and dispensing.

11. Population Considerations
During the 2009 H1N1 response, state and local health departments worked to ensure that certain populations were able to obtain information and access to antivirals. S/THDs and LHDs defined these populations to include the following groups: first responders/medical professionals; those at high risk for severe illness, complications, or death from the virus (pregnant woman, immunocompromised patients, etc.); those with limited or no access to healthcare (uninsured, underinsured, homeless, etc.); and those who may have challenges accessing needed health information (non-English speakers, those with visual, auditory, or cognitive impairment, etc.). S/THDs and LHDs should continue to consider the needs of these populations in their community and ensure they have access to medical countermeasures during an emergency.

Population—Planning Considerations
- Consider the role of first responders, medical professionals, and other critical infrastructure when planning all public health preparedness efforts; however, not all emergencies may warrant special provisions for these populations. Additional discussions regarding when such provisions may or may not be warranted should occur with these groups before an emergency.
- Develop better strategies for reaching priority groups, high-risk populations, or those with communications challenges before a public health emergency. It is particularly important to establish relationships with providers...
or entities that already have strong relationships with these populations.

- Continue to consider the special needs of the populations with limited or no access to healthcare in their communities, and work to ensure these populations have access to medical countermeasures during an emergency.

**Conclusion**

Managing medical countermeasures during a public health emergency, particularly a pandemic, is a critical public health function during a response. Although there was considerable variability in how antiviral medications were managed at the state and local level during the 2009 H1N1 response, this report highlights 11 key areas that represent the common themes, experiences, successes, and challenges of both state and local public health departments during the H1N1 response.

Each section of the following report highlights planning considerations for federal, state, and local public health officials. Overall, many of these considerations point to the need for ongoing investment in a robust public health system. Many of the challenges discussed in this report resulted from eroding public health infrastructure. Although this report focuses on antiviral management, S/THDs and LHDs have many other roles during a response, including surveillance, epidemiology, and communication. Without solid investment in public health infrastructure (staff, information technology, equipment, etc.), it will grow increasingly difficult for S/THDs and LHDs to mount the proper response to an influenza pandemic. Federal, state, and local public health officials need to consider their essential roles during a response and what resources will be necessary to accomplish their mission to protect the health of their communities.
MAIN REPORT

Introduction

During the 2009 H1N1 influenza pandemic, the Centers for Disease Control and Prevention (CDC), through the Strategic National Stockpile (SNS), released 11 million courses of antiviral medication to state/territorial health departments (S/THDs), four directly funded cities, and the U.S. territories. These antiviral medications were then further distributed to local health departments (LHDs), hospitals, clinics, pharmacies, and other organizations responsible for directly dispensing medications to the public. Although antiviral distribution and dispensing during an influenza pandemic are critical public health functions required to help mitigate the disease’s effects, little to no data exist regarding how best to distribute and dispense antivirals in such an emergency. This report summarizes the S/THDs’ and LHDs’ activities regarding antiviral distribution and dispensing in response to the 2009 H1N1 influenza pandemic, in an effort to collect and analyze data to assist decision-makers in future pandemics.

This report was coauthored by the Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officials (NACCHO), and funded through a non-restricted cooperative agreement provided by the CDC’s Influenza Coordination Unit. ASTHO and NACCHO are national-level organizations that promote sound public health policy and strengthen public health practice in support of their respective memberships. ASTHO represents the 50 state public health departments, the District of Columbia, and the eight territorial or freely associated state health departments. NACCHO represents the approximately 2,800 local public health departments in the United States.

This report is the first stage in a larger project that the CDC, ASTHO, NACCHO, and other partners have undertaken to explore alternative models for antiviral distribution and dispensing. The full project goals are to expand the understanding of how state and local public health systems manage antiviral distribution and dispensing, explore more efficient ways to distribute and dispense antivirals during a public health emergency by leveraging existing private sector systems, and contribute to the knowledge base regarding effective countermeasure enterprise, as called for by the National Health Security Strategy.

Background

Although medical countermeasure planning has been underway for more than a decade, its significance became heightened following the 2001 anthrax attacks in the United States and has remained in the forefront of public health preparedness planning through numerous federal reports, presidential executive orders, and legislation. From 2001 to 2011, billions of dollars and personnel time were devoted to ensuring the availability of medical countermeasures during a public health emergency. Historically, antiviral stockpiling and planning emerged in response to concerns about H5N1 influenza, which circulated in other parts of the world and contributed to the urgency for the federal government to increase pandemic disease preparedness activities, including stockpiling critical countermeasures. To ensure medical countermeasures would be available, the National Pharmaceutical Stockpile (NPS) was created in 1999 with a mission to provide large quantities of essential medications and supplies to states and territories during an emergency. In 2003, NPS became the Strategic National Stockpile (SNS).

The CDC manages this division, whereby medical supplies and pharmaceuticals are stockpiled and poised for deployment to areas where an emergency has occurred. The stockpile is designed to help supplement or resupply state and local assets during an emergency. Information on the stockpile’s exact location, size, and composition is not publicly available; however, a large quantity of antivirals is known to be stored in
SNS. In addition to federal supplies, as part of the United States Homeland Security Council’s National Strategy for Pandemic Influenza Implementation Plan,\(^1\) and the Department of Health and Human Services’ (HHS’) Pandemic Influenza Plan,\(^2\) states were also strongly encouraged to stockpile antivirals through a federal subsidy antiviral drug purchase program.\(^3\)

Antiviral distribution and dispensing plans were implemented in spring 2009 when the CDC reported the first cases of a novel influenza virus with potential to become a pandemic and circulate throughout the United States and other countries. The response to the CDC’s announcement marked an unprecedented collaborative effort by the public health and medical communities, government, the private sector, and the public to understand and prepare for the H1N1 influenza pandemic. One of the initial response efforts included releasing supplies, including antivirals, from the SNS.

On April 26, 2009, five days after the first reported cases of H1N1 influenza in the United States, the SNS released 11 million courses of antiviral medications, in addition to other medical supplies, for distribution to state and territorial public health authorities. By May 3, 2009, all state and territorial public health authorities had received their allocation of SNS supplies.\(^4\)

Each state and local public health department managed SNS antiviral medications differently, which led to some early successes and challenges in response to the H1N1 pandemic. Figure 1 provides an overview of how federal, state, and local agencies moved antivirals during the 2009 H1N1 response. CDC released the SNS supplies to the 50 states, eight territories, and the four directly-funded cities (Chicago, Los Angeles, New York City, and Washington, DC). Each jurisdiction that received SNS supplies could then

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2 See http://www.flu.gov/planning-preparedness/federal/hhs-pandemic-influenza-plan.pdf. In 2005, the White House Homeland Security Council’s National Strategy for Pandemic Influenza Implementation Plan, followed by the HHS Pandemic Influenza Plan, established policy to build and maintain a stockpile of antiviral drugs for use in a pandemic. This included enough antiviral drugs to treat 75 million persons (approximately 25 percent of the U.S. population) divided between federal (44 million courses) and state (31 million courses) stockpiles. HHS met the federal stockpiling goal in 2007 and states purchased 26 million treatment courses of antiviral drugs for pandemic use, using a 25 percent federal cost share through established subsidy program contracts.


choose when, how, and to whom to distribute the supplies. The use of influenza antiviral medications from the commercial supply in response to the H1N1 influenza pandemic is estimated to have prevented 8,400 to 12,600 hospitalizations and 420 to 640 deaths.\(^5\)

Figure 1. Method for Antiviral Distribution and Dispensing during the 2009 H1N1 Influenza Pandemic

Source: Lisa Koonin, CDC, 2011. Includes territories and four directly funded cities.

The State of Public Health during the H1N1 Influenza Pandemic

It is important to understand the context in which federal, state, and local health departments were making decisions during the H1N1 response. Two key factors for the health departments were that (1) pandemic preparedness in the United States has traditionally relied on assumptions that did not apply to the H1N1 pandemic, and (2) state and local health departments were trying to address the pandemic with significantly reduced funding.

Planning for an influenza pandemic had previously been based on several key assumptions—most important, that the pandemic would emerge in other parts of the world, giving the United States time to

plan prior to its circulation in the U.S. population, and the disease would yield high morbidity and mortality rates. During the 2009 H1N1 response, however, the disease was identified in the United States before public health officials were able to obtain enough epidemiological data to understand the nature of the disease. The stress caused by the disease’s fast emergence and the lack of available data was compounded by constant news coverage, public panic, and political pressure. As a result, public health officials routinely took the most stringent precautions possible to protect and reassure the public. Officials provided anticipatory guidance that activities and policies would change as they learned more about the virus.

The effect of decreased investment in the public health enterprise’s state and local portions was evident during the 2009 H1N1 response. More than a decade of preparedness planning efforts were tested during the H1N1 influenza pandemic, but with significantly decreased numbers of public health practitioners in state and local health departments. To respond effectively to an emergency like the 2009 H1N1 pandemic and even more severe emergencies, a robust, well-trained public health staff is needed. Although state and local public health departments were able to adequately respond with decreased levels of public health resources, continued lack of investment in state and local public health may make it increasingly difficult to respond to future public health emergencies.

Methods

ASTHO and NACCHO used multiple approaches for gathering information from state and local public health representatives about antiviral distribution and dispensing during the 2009 H1N1 influenza pandemic. Both organizations conducted literature reviews, evaluated health department after-action reports (AARs) for the 2009 H1N1 pandemic influenza, and examined key informant interviews, respective of each organization’s focus on state/territorial or local health officials. Additionally, ASTHO and NACCHO both convened advisory groups comprised of state or local public health officials to provide subject matter expertise, guidance, and leadership for the project. ASTHO and NACCHO jointly hosted roundtable discussions during the July 2011 SNS Summit to gather additional information from federal, state, local, and tribal representatives.

The information presented in this report synthesizes information and anecdotal experiences from the S/THD and LHD perspective. This is not a comprehensive analysis and may not represent all experiences or viewpoints.

Literature Review

To gather initial background information for this project, ASTHO and NACCHO reviewed literature and examined existing ASTHO/NACCHO documentation related to membership experiences with the 2009 H1N1 pandemic. The literature review was limited by the lack of peer-reviewed published data in this area. The review by ASTHO/NACCHO of state and local health department’s documentation of activities during the 2009 H1N1 pandemic provided extensive data for analysis. For a full list of reports, please see the bibliography.
ASTHO H1N1 Antiviral Management Survey
In December 2010, ASTHO surveyed the 62 U.S. states, territories, and directly funded cities that received Public Health Emergency Preparedness (PHEP) Cooperative Agreement funding to ascertain their methods for managing, deploying, and monitoring their antiviral assets before and during the 2009 H1N1 influenza pandemic. ASTHO administered the survey electronically through e-mail using an online survey tool, Qualtrics. ASTHO received 37 responses from 36 states and one directly funded city. A summary of the survey results was completed in April 2011 (see Appendix IV, ASTHO H1N1 Antiviral Management Survey Summary).

After-Action Report Review
Both ASTHO and NACCHO reviewed H1N1 AARs to gain perspective into how state and local health departments managed antiviral medications. ASTHO obtained a convenience sample of 23 AARs. Twenty-one state-specific AARs were acquired from the Department of Homeland Security (DHS) Lessons Learned Information Sharing (LLIS) website; two were received from S/THDs who participated in key informant interviews (see below). The AARs were reviewed to supplement available data regarding state distribution and dispensing activities, but the sample of AARs is not a comprehensive representation of S/THDs.

NACCHO contacted more than 400 LHD representatives and invited them to share their jurisdiction’s H1N1 AARs, including members from NACCHO’s eight standing Preparedness Workgroups and the LHDs that participated in the sentinel network NACCHO established during the 2009 H1N1 pandemic. (NACCHO’s sentinel network was comprised of 168 LHDs that provided weekly data to NACCHO during H1N1.) LHDs submitted a total of 58 AARs for the 2009 H1N1 pandemic in response to this request. Additionally, NACCHO identified five LHD-specific AARs on DHS’ LLIS website. From the combined 63 AARs, NACCHO selected a sample of 30 using the following criteria: geographical representation across the country, jurisdiction size, and centralized/decentralized public health system.

Key Informant Interviews
ASTHO and NACCHO conducted a series of key informant interviews to obtain more detailed information about antiviral distribution and dispensing during the 2009 H1N1 influenza pandemic. Each organization selected 10 states or localities, respective of their membership, to interview. These participants were identified from the background information collected through the project, and institutional knowledge of individuals who played an active role in antiviral distribution and dispensing during the 2009 H1N1 pandemic. The S/THDs and LHDs that were selected represented a geographical distribution across the country, various jurisdiction sizes, and both centralized and decentralized public health systems. Interviews were conducted over the phone and lasted approximately one hour.

Antiviral Advisory Workgroups
ASTHO and NACCHO each convened a workgroup of representatives from 14 S/THDs and 11 LHDs, respectively, which provided subject matter expertise, guidance, and leadership for the overarching project. The members of each workgroup represented a geographical distribution across the country, multiple jurisdiction sizes, and both centralized and decentralized public health systems. Both workgroups provided direct experiences from the 2009 H1N1 pandemic, evaluated the key themes, and reviewed a report draft.

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SNS Summit Breakfast Roundtables
ASTHO and NACCHO held two roundtable discussions at the July 2011 SNS Summit in Atlanta to capture additional information about the 2009 H1N1 distribution and dispensing practices. The discussion topics included (1) state and local public health’s infrastructure needs for antiviral distribution and dispensing; and (2) barriers to working with pharmacies for antiviral distribution and dispensing. Each discussion was facilitated by an ASTHO Antiviral Advisory Committee member, with participants representing federal, state, local, and tribal public health organizations.

Key Themes
Based on the information collected, ASTHO and NACCHO, in conjunction with each organization’s workgroup, identified 11 key themes regarding antiviral distribution and dispensing activities during the 2009 H1N1 pandemic. Below is a description of the 11 themes and how they affected state and local health department response efforts during the 2009 H1N1 pandemic. The themes have been broken down into process themes (themes that follow the stages of antiviral management during H1N1 from the state and local perspective), and overarching themes (themes that affect the management of antivirals but are not tied to any one period during the pandemic response).

Process Themes
1. Allocation
2. Receiving and Staging
3. Storage
4. Distribution
5. Dispensing
6. Returning, Redistributing, Relabeling, and Disposing of Unused Antiviral Medications

Overarching Themes
7. Communication
8. Legal and Policy Considerations
9. Security
10. Tracking and Reporting
11. Population Considerations

Process Themes
1. Allocation
The 2009 H1N1 pandemic emerged as a threat to U.S. citizens and triggered the federal government to release antiviral medications from the SNS. The antivirals were deployed to states based on pre-determined pro rata (population-based) allocations. S/THDs and LHDs were then responsible for making additional allocation decisions. The following section describes the allocation activities of S/THDs and LHDs. Allocation for the purposes of this report covers allocation from the federal government to S/THDs, allocation from S/THDs to LHDs or other local community partners, and allocation from LHDs to other local community partners.

State Perspective
Allocation decisions that ensure equity across the states or populations have always been a challenge. During the 2009 H1N1 response, the S/THDs were confronted by the challenge of allocating antivirals in two ways: the federal government’s decision on how to allocate antivirals, and their own decisions on how to allocate antivirals to local community partners.
Federal Allocation to S/THDs

All states received their pro rata allotment of antivirals from the SNS in spring 2009. The CDC released additional supplies of countermeasures, including antiviral drugs, in fall 2009 in response to commercial shortages for specific products. For example, in October 2009, shortages of commercially available Tamiflu® suspension (commonly used in the pediatric population) compelled the CDC to release additional courses of Tamiflu® suspension from the SNS to all 62 project areas.

Although all states received their allotment from the SNS assets, not all states’ public health practitioners believed federal SNS assets were necessary to respond the pandemic. States that were hesitant about receiving SNS antiviral assets thought that, based on epidemiologic data, the needs of their respective populations could be met either through commercially available antivirals or state-owned caches. However, all states received their pro rata allotment of antivirals in anticipation of a severe pandemic through the federal “push” of assets.

Of the 37 respondents to the ASTHO 2009 H1N1 pandemic Antiviral Management Survey, five states reported that they did not have a state-owned cache of antivirals at the beginning of the pandemic. Those states that did not have a state-owned cache relied more heavily on the federal supply of antivirals. Some states that possessed state-owned assets believed that the commercial supply and state-owned caches were sufficient to address the needs of their populations. States with their own state cache and SNS antivirals had more flexibility to determine allocation strategies to meet the needs of their respective populations. Based on the survey results and interviews, SHDs indicated more guidance on allocation strategies should be developed. The information gathered indicates many thought allocation strategies used during the 2009 H1N1 pandemic may not have been the best methods in all cases. Allocating antivirals on a per capita basis may not fully consider the needs of a population. In a more severe pandemic, per capita-based allocation could cause shortages of antivirals in areas where higher infection rates or greater numbers of at-risk populations exist and, in turn, create an unnecessary surplus in other areas. Allocation strategies need to optimize use of stockpiled antiviral drugs, balancing equity as well as clinical need.

S/THDs Allocation to Community Partners

State allocation decisions were made based on population, epidemiologic data, provider requests, and the number of hospital and treatment centers in a given jurisdiction. Fifty-three percent of states that responded to the ASTHO 2009 H1N1 pandemic survey allocated antivirals based on population, 20 percent used epidemiologic data and provider requests as the basis for their allocation decisions, and 18 percent allocated antivirals based on the number of hospitals and treatment centers in the jurisdiction. Each of these decision criteria had benefits and challenges. Although allocation decisions based on epidemiologic data can be most reflective of need, they can also be the most challenging for decision-makers. Epidemiologic data are generally obtained through systems that do not allow for real-time collecting or reporting of information. The delay in information, paired with the constantly changing nature of infectious disease outbreaks, makes it difficult to rely on epidemiological data to guide allocation decisions.

Although allocation decisions based on epidemiologic data can be most reflective of need, they can also be the most challenging for decision-makers.

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7 According to the Federal Pandemic Influenza Antiviral Drug Subsidy Program, all but two states had purchased product off of these contracts by April 2009. By the time the state stockpile procurement program ended in September 2010, all states had made purchases through the subsidy program contracts.

During the 2009 H1N1 response, S/THDs distributed antiviral drugs to the following:

- Public/private hospitals.
- LHDs (for dispensing and redistribution to community providers).
- Public/community health clinics.
- Tribal health clinics/hospitals.
- College/university student health centers.
- Regional distribution sites (including pharmaceutical distributors).

Although scarcity of antiviral resources and hoarding were not major issues during the H1N1 response, most pandemic preparedness plans contain strategies to prevent inequitable distribution of antivirals. In a severe pandemic scenario, where medication shortages could occur, S/THDs must continue to be cognizant of the potential for hoarding. Additionally, S/THDs may require clear guidance from the federal level on how best to verify need and respond to provider requests for scarce resources.

**Local Perspective**

Allocation decisions have a direct effect at the local level and are, therefore, very important to LHDs who are charged with the health and well-being of the communities they serve. From LHD 2009 H1N1 pandemic AARs and interviews, the topic of allocation came up in the following areas: S/THD decisions on initial allocation, resupply and supplemental supply, and LHDs allocation decisions to other local community partners.

Not all LHDs were allocated antivirals. Three LHDs reported that their state decided not to distribute antivirals to LHDs (one state did no distribution, one distributed directly to hospitals only, and one distributed to a single pharmacy chain). The LHD that reported that the state choose a single pharmacy chain noted that there were no branches of the pharmacy in their jurisdiction and therefore, functionally, no public health supplies of antivirals were readily available to their community.

Of LHDs that received antivirals, they reported that their initial allocation of antiviral medications from the state was based on population. Most LHDs thought that this allocation method worked well for serving their community, particularly given the availability of antivirals in the commercial supply chain. A few LHDs, however, asserted that the communities they serve have more at-risk populations than some of their neighboring LHDs. Therefore, in a more severe pandemic or during a shortage of antivirals, their LHD may have a harder time serving those most in need in their community.

As the 2009 H1N1 response continued, states offered additional allotments of antivirals. Due to uncertainties around the pandemic, many LHDs continued to accept their full allotments from the state despite having a surplus of antivirals in their storage facilities. LHDs were concerned that if they forwent their additional allotments then they would lose future claim to them.

Some states allocated directly to other local level community partners, relieving the LHDs from making allocation decisions. Although most of the LHDs in these states would have preferred to make the allocation decisions for their community, the bigger challenge was the SHD not informing them about which organizations in their community had received antiviral medications.

In most states, however, each LHD was able to select which partner organizations within their community should receive antiviral medications. Many LHDs had previously established allocation plans for their community partners. Types of organizations that received antivirals from LHDs (either through pre-planning or through decisions made during the 2009 H1N1 response) included hospitals, clinics, federally qualified health centers, rural community health providers, prison health services, tribal clinics, and
pharmacies. However, LHDs typically allocated antivirals to only two or three types of organizations, with hospitals and clinics being the most commonly reported organizations. LHDs also considered several other factors to facilitate allocation decision-making, including the size of the hospital (number of beds), the size of clinic (number of patients routinely seen), hospitals/clinics/pharmacies that primarily served uninsured/underinsured, pediatric, or incarcerated populations, and hospitals/clinics reporting shortages of antiviral medications.

**Allocation—Planning Considerations**

- Consider ethical principles when making allocation decisions to ensure equitable access to antivirals.
- Explore and consider alternative allocation schemes that are flexible and equitable. Per capita allocation may not account for a population’s clinical need.
- Consider alternative, more time-efficient allocation schemes. Allocation decisions based on epidemiological data are arduous and may prevent supplies from reaching populations in a timely manner.
- Properly communicate allocation decisions and rationale to all partners to increase efficiency in the response.
- Improve decision-making capabilities at the state and local levels by increasing dialogue between states and the federal government concerning the decision to release antivirals, proposed allocation methodologies, and guidance around distribution and dispensing practices.

2. Receiving and Staging

Receiving and staging refer to the ability of state and local public health departments to secure locations and personnel to receive antivirals, conduct warehouse operations, and prepare antivirals for delivery to dispensing sites. Receiving and staging for the purposes of this report covers receiving SNS antiviral assets from the federal government by S/THDs and LHDs, and S/THDs and LHDs breakdown of SNS assets.

**State Perspective**

Receiving and staging SNS assets were large activities S/THDs engaged in as part of the H1N1 response. This section will cover S/THD activities in the following areas: S/THD receiving and staging processes, locations, and challenges.

Federal SNS assets were received at pre-designated receiving, staging, and storage (RSS) facilities. Materiel was then inventoried, sorted, and prepared for delivery to other sites. Many S/THDs reported that the activation of state RSS sites was a success. Part of the success was attributed to the CDC Division of Strategic National Stockpile (DSNS) Technical Assistance Review (TAR), in which states are required to plan and conduct exercises that include...
activating RSS sites. These exercises helped to ensure that RSS staff were adequately trained and prepared to activate RSS sites and carry out warehouse operations during the 2009 H1N1 response.

According to the ASTHO 2009 H1N1 pandemic survey results, 52 percent of project areas received their SNS allocations at government-owned and operated RSS warehouses, and more than a quarter used privately owned and operated RSS warehouses under contract to the state.9

For several states, SNS assets’ arrival at the RSS facility posed some challenges. SNS planned to send each state its 25 percent allotment, which included antivirals, within seven days of notification of release. The CDC communicated to S/THDs the estimated delivery time; however, those estimates were often unreliable. For example, one state reported receiving a truck in the middle of the night when no one was expecting it. Additional issues arose with communicating the number of trucks that should be expected to arrive at state RSS sites. S/THDs reported sometimes receiving more or fewer trucks than expected within a specified timeframe. To ensure that staff is available to provide security services and properly receive and process materiel, accurate advance notification is needed.

When trucks arrived, discrepancies in the quantity and types of materiel received were also common. Often bills of lading10 that came with SNS shipments contained details about the contents of the delivery such as name, type, and quantity of items, but did not correspond to stock received; occasionally no bills of lading were available. States reported receiving pallets of varying sizes and quantity in a shipment. One state reported receiving stock that should have been delivered to another state. Consistency when receiving materiel from the CDC was a significant challenge.

In fall 2009, SNS retooled delivery practices in an effort to increase the accuracy and delivery in response to challenges that S/THDs and LHDs reported. Although it is encouraging that the CDC responded to S/THD and LHD concerns, the acceptability and usefulness of the aforementioned changes among state and local public health partners was not assessed in the survey.11

Local Perspective

From LHD 2009 H1N1 pandemic AARs and interviews, most reported a smooth process for receiving and staging antiviral medications from the S/THDs or directly from the federal government.12 Many LHDs had never received antivirals from the state before the 2009 H1N1 response, making this a slightly different experience than receiving non-pharmaceutical materiel. In addition to receiving the antivirals, LHDs also received numerous other items, such as N95 respirators, masks, gloves, and other medical materiel. The LHDs that had trained and conducted exercises for receiving medical materiel from the state cited these experiences as essential for the smooth transition of materiel into LHD storage areas. LHDs that had never conducted exercises for receiving SNS materiel experienced greater challenges.

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10 A bill of lading is a legal document between the shipper of a particular good and the carrier detailing the type, quantity, and destination of the good being carried. The bill of lading also serves as a receipt of shipment when the good is delivered to the predetermined destination. This document must accompany the shipped goods, no matter the form of transportation, and must be signed by an authorized representative from the carrier, shipper, and receiver. Read more at http://www.investopedia.com/terms/b/billoflading.asp#ixzz1ZkBGW7kF.


12 Federal supplies are sent directly from SNS to localities if they are directly funded cities (New York City, Chicago, District of Columbia, and Los Angeles).
How the LHD received antiviral drugs varied depending on how the S/THD decided to send them. A few LHDs reported that the state sent antivirals through a delivery service, such as FedEx or the U.S. Postal Service. These LHDs found that this system worked very well. A few LHDs reported that S/THDs were unwilling or unable to deliver antiviral medications, leaving LHDs responsible for picking up their allocation from the state RSS warehouse. These LHDs cited this as an additional step in their efforts that cost them half-a-day to a full day of staff time spent going to and from the state storage facility.

Most S/THDs, however, transported antivirals themselves or through a contractor. LHDs that received antivirals through this manner reported that the process went smoothly but that a few areas could be improved. These areas for improvement included timing the receipt of materiel with S/THDs, notification of shipment contents, warehouse logistics, and staffing considerations.

LHDs said that one of the greatest challenges was timing the receipt of materiel with S/THDs. Many LHDs reported that their shipments of antiviral medications would arrive hours or days later than expected. A particular problem was that antiviral shipments would be delivered after normal business hours or in the middle of the night. This was not a challenge for larger jurisdictions that were operating 24-hour warehouses with dedicated staff. It was, however, a challenge for the medium and smaller jurisdictions that had LHD employees who received the materiel at their health department. These jurisdictions cited cost increases to cover employees working overtime as well as faster burnout rates by staff members who had already worked long hours and were asked to return to help receive the materiel. LHDs were not always aware of the contents of shipments being delivered to them because it was not always communicated prior to delivery. During the 2009 H1N1 pandemic, the federal government and states were moving very quickly and pre-notice to LHDs was not always possible. The lack of advance knowledge was, however, a challenge for a few LHDs because proper equipment or people were not always readily available, and LHDs found it difficult to pre-plan for how they would divide the supplies for distribution among their partner organizations.

Very few LHDs reported difficulty with the logistics of receiving antiviral shipments. For example, one LHD reported that the delivery truck was too large to fit into LHD’s loading bay. LHD staff had to manually unload each box from the pallets and then restack them on the pallets inside the warehouse. In another example, an LHD stated that the doorway leading to the room designated for antiviral storage was too small for the forklift used to move the pallets. Again, this required LHD staff to unpack and then repack each of the pallets within the storage room.

For LHDs that maintained warehouses as part of normal operations, staffing was not a challenge because they had designated employees. The rest of the LHDs, however, reported bringing in additional staff or volunteers to help on days when shipments were received. When supplies were received, a few LHDs reported relying on staff such as epidemiologists, health directors, and other senior level personnel, which took them away from their primary response roles.

**Receiving and Staging—Planning Considerations**

- Delays in receiving antivirals by either S/THDs or LHDs can quickly result in community shortages.
- Effective and accurate communication around the timing and contents of deliveries is essential for S/THDs and LHDs to receive and stage materiel smoothly.
- Conduct exercises that allow S/THDs and LHDs to test their receiving and staging capabilities for pandemic influenza preparedness.
- Having volunteers or dedicated personnel experienced in warehouse operations can decrease the burden on S/THD and LHD staff tasked with other response roles.
3. Storage
Storing medical countermeasures is a significant component of preparedness planning. The 2009 H1N1 pandemic was the first event in which all states and many localities had to quickly provide such storage facilities, which were used for a longer period than anticipated. Storage, for the purposes of this report, includes storage location, agreements, costs, and considerations by S/THDs and LHDs.

State Perspective
Pandemic influenza plans assumed that antiviral medications would be scarce and in high demand, thus an immediate push out of stockpile materiel to LHDs and dispensing entities would need to occur. The aforementioned assumption did not prove accurate for the 2009 H1N1 influenza pandemic. Therefore, storing antivirals became a necessity because wide-scale distribution and dispensing was not necessary. Storing the antivirals posed its own challenges, however. For example, antivirals must be stored in a secured, temperature-controlled facility. This section will discuss the S/THDs’ storage locations, public and private partnerships, and challenges encountered related to storing antivirals during the 2009 H1N1 influenza pandemic.

As a part of preparedness planning efforts, all states had a pre-identified primary and secondary RSS location; however, storage capabilities still varied among SHDs. In addition, RSS sites developed for SNS push packs (typically large locations designed for short-term use) were often not applicable to the smaller volume and long-term storage needs for antivirals. S/THDs with a state-owned cache of antivirals often had appropriate, existing storage capabilities; whereas, those without a state-cache had to secure a storage location on an ad hoc basis.

Some S/THDs used RSS sites for storage. Those S/THDs that did not leveraged both public and private partnerships to store stockpiled antivirals. Sixty-three percent of states that responded to the ASTHO H1N1 Antiviral Management Survey reported that they stored their SNS allotment of antivirals in centrally located facilities, such as state controlled locations, commercial locations, and multiple regional locations. A state-controlled location could be at the public health department itself, a state’s general services warehouse, or state pharmacies. The remainder of states forwarded SNS assets to dispensing locations, including LHDs and treatment facilities.13 For more information on distribution to community partners, please see Section 4: Distribution.

Of the 63 percent of SHDs that did not use RSS locations for storage but instead used centrally located facilities, about half of them partnered with commercial entities to meet their warehouse and storage needs. Most states did not work with commercial partners for storing and warehousing antivirals because S/THDs reported that state-owned and -managed warehouses had sufficient capacity and capabilities. Those states that teamed with outside partners reported working with pharmaceutical distributors and wholesalers, state pharmacy associations, state hospital associations, state colleges of pharmacy, state boards of pharmacy, and other private partners (e.g., moving, warehousing, and logistics companies). S/THDs that worked with commercial partners generally had positive experiences. S/THDs indicated that commercial partners were beneficial because of their experience with storage and warehousing operations, as well as their existing physical infrastructure and trained staff. Most commercial partnerships had been established prior to the 2009 H1N1 pandemic, which allowed for easier use during the response. New partnerships required S/THDs to develop MOAs with commercial partners that included adequate payment for services rendered. New and pre-existing MOAs required commercial

partners to follow the state’s maintenance and storage guidelines, such as those regarding climate-control and personnel access.

**S/THD Storage Challenges**

Whether storage occurred at a public or private location, costs were incurred as a result of unexpected long-term storage needs. The federal push of antivirals to states meant that states gained full ownership and responsibility for the materiel. Any unused antivirals either had to be stored or destroyed. States reported incurring unexpected costs due to long-term antiviral storage. These costs included space rental, cleaning, maintenance, and utilities. As of March 2011, at least 36 S/THDs still possessed SNS antivirals. S/THDs did not anticipate having to store antivirals indefinitely or incurring the associated costs. This issue continues to present a major challenge for S/THDs.

**Local Perspective**

Antiviral medication storage practices varied greatly among LHDs, with clear distinctions based on the size of the jurisdiction. Larger jurisdictions had warehouses and reported no challenges with storing antivirals. Smaller jurisdictions stored antivirals within their health departments and reported few challenges. Medium jurisdictions had the most variability in storing antivirals and reported several challenges. Most, if not all, large jurisdictions maintain warehouses year-round with LHD-owned caches of antivirals and other medical countermeasures. These warehouses have dedicated staff for receiving, staging, and storing materiel. Because these warehouses are operated year-round, there are established processes in place that allow the LHD and warehouse staff to work together easily. These large jurisdictions reported no challenges with storing antivirals received for the 2009 H1N1 response.

Small jurisdictions typically received small quantities of antivirals, which did not require a large storage space. Typically these LHDs were able to store the antivirals in a closet, office, conference room, or other space within the LHD. These jurisdictions also did not report any challenges with storage.

Medium jurisdictions had the most variability. Many of these LHDs had predetermined locations for storing medical countermeasures; however, for several reasons, these locations could not be used for antiviral storage during H1N1. Many LHDs indicated that the preselected facilities were not temperature-controlled. Many LHDs received antivirals in the spring and they feared that the temperature inside the warehouse would exceed the temperature required for safely storing antivirals as summer progressed. Another challenge with the preselected sites was space availability. A few LHDs had planned to use privately owned facilities during an emergency; however, during the H1N1 response they were notified that the space they intended to use was full and that no room could be made available in the short timeframe before the antivirals arrived.

Because predetermined storage facilities were not available for many of the medium-size LHDs, they stored their antiviral allocations with partner organizations such as hospitals, police, and fire departments.

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14 A more detailed discussion about unused antivirals can be found in Section 6: Returning, Redistributing, Relabeling, and Disposing of Unused Antiviral Medications.

15 Jurisdiction size is defined by population. Large jurisdictions have a population of 500,000 or more; medium jurisdictions have a population of 50,000–499,999; and small jurisdictions have a population of less than 50,000.
or within their own health department. LHDs that stored antivirals with partner organizations reported no problems with this arrangement. The LHDs that did not have dedicated or trained staff for storage procedures reported challenges when faced with storing antivirals (in relatively large quantities) at their facility. See Section 2: Receiving and Staging for additional information.

**Storage Future—Planning Considerations**
- Continue to evaluate storage options and capabilities, including external and internal partnerships, because they could be beneficial in future preparedness planning efforts.
- Federal, S/THD, and LHD partners should discuss careful and practical decision-making around initial distribution and/or consider initial supply/resupply models to mitigate costs, because the cost to store antivirals can be burdensome.
- Consider ways for state and local health departments to leverage public or private entities’ expertise in the business of storage.

4. Distribution
The 2009 H1N1 pandemic provided many states and localities their first opportunity for large-scale distribution of medical countermeasures as written into their preparedness plans. Distribution, for the purposes of this report, covers both distribution from states to LHDs or other local community partners, and distribution from LHDs to other community partners.

**State Perspective**
Distribution activities in S/THDs involved delivering antiviral drugs to LHDs and other dispensing sites. Distributing antivirals depended on allocation priorities and guidance received in each state. Some states followed their existing pandemic influenza plans that had been developed before the event and, because these plans were based on a severe pandemic, they called for aggressively distributing antiviral medications. For the states that chose to distribute all antiviral medications to the local level at once, several problems arose. If one county had more H1N1 cases than another, those antivirals then had to be reallocated. It was not an easy process for states that chose to redistribute product within their state. States that decided to hold back on distribution until there was need, or distributed only a portion of their antivirals, had more flexibility once the effect of the 2009 H1N1 pandemic was fully understood; they could then effectively address their populations’ needs.

S/THDs worked with agencies within state governments and private companies to distribute antivirals. S/THDs that relied on other state agencies for distribution reported using departments of transportation, emergency management, general services, civil air patrol, and other state assets. Additionally, some local community partners picked up their antiviral allotment directly.

States reported using several commercial entities to transport or distribute materiel: United Parcel Service (UPS), Federal Express (FedEx), pharmaceutical distributors (such as Amerisource Bergen, McKesson, and Cardinal Health), moving companies, local trucking companies, state pharmacy associations, and pharmacies. Some S/THDs reported that private companies focused on daily distribution were essential for smoothly distributing antivirals to local community partners.

Using public versus private partners for distribution depended on state Emergency Operations Plans, need, state size, and geography. One challenge S/THDs noted was the lack of availability of commercial trucks for distribution purposes. Although this may not have been the case in all states, some S/THDs reported that federal distribution needs took priority, thereby limiting the availability of commercial trucks for state distribution. Some S/THDs used state-owned vehicles as they were available and met the distribution needs. Others used larger companies because antivirals had to be distributed across multiple
counties in larger states. For example, Alaska has very unique distribution needs because much of their distribution must occur via airplane.

Additional issues with payment arose during the 2009 H1N1 response. For example, one S/THD had a pre-existing contract with its state department of transportation for distribution needs during a pandemic. The 2009 H1N1 pandemic was a declared public health emergency; however, not all departments and agencies throughout government were operating under emergency response protocols. In one instance, the state department of transportation requested that the S/THD reimburse them for services rendered. In the absence of emergency supplemental dollars (e.g., Stafford Act funding\(^\text{16}\)) to help implement state response plans, including MOA and contingency contracts, Public Health Emergency Response (PHER) funds had to be used to pay the transportation department, which was unexpected.

**Local Perspective**

Antiviral distribution by LHDs varied and depended on their states’ distribution decisions. Some states chose to distribute small caches of antivirals to LHDs for dispensing purposes only. Therefore, these LHDs had no role in distributing antivirals within their community. However, most LHDs received larger shipments of antivirals and were responsible for distributing to community partners. These LHDs reported having the flexibility to make decisions regarding how antiviral medications were distributed within their communities. This flexibility helped LHDs ensure that the communities most in need of antiviral medications were able to receive them, but it also resulted in significant variability in how antiviral distribution was managed at the local level. LHDs had to decide when antiviral medications should be distributed and how those antivirals should be transported.

**Distribution Timing**

LHDs had to make major decisions regarding antiviral distribution timing. After receiving antivirals from the S/THDs, LHDs either quickly distributed them to their community partners, or held them until a need was indicated in their community. Those that decided to distribute immediately then implemented their allocation and transportation plans. Of those that held the shipment of antiviral medications, many reported never having to distribute antivirals, or only having to distribute one or two units in response to spot shortages (most often for pediatric formulations). All of these LHDs, however, reported having a plan in place for how and to whom the antivirals would be distributed if a greater need was determined in their community. One LHD also reported that they held the antivirals for as long as they could to prevent their partner organizations (particularly hospitals) from incurring additional costs associated with the antiviral storage, dispensing, and disposing of expired courses (non-reimbursable expenses for hospitals or certain other partners).

**Distribution Transportation**

Transporting antiviral medications was handled in several ways at the local level. Some LHDs had government vehicles available or had made arrangements with their local law enforcement departments to transport the antivirals. This system worked well and no LHDs reported any challenges with this approach. Many LHDs, however, required that their community partners pick up the antivirals from the LHD storage location. Although having the community partners pick up the antivirals decreased the logistical burden on LHDs, it caused several other challenges. A few LHDs noted that some of the community partners did not realize the size of shipments, so the vehicles they brought for picking up could not fit all of the allocated antivirals. Other challenges that LHDs reported included scheduling

partners to pick up the antivirals, verifying who was picking up the antivirals, and ensuring that the partners could find the storage site.

**Distribution—Planning Considerations**

- Consider ways for S/THDs and LHDs to leverage the expertise of public or private entities in the business of distribution.
- Consider establishing agreements with multiple entities (e.g., establish contingency plans) to ensure that S/THDs’ and LHDs’ needs are met because some assets may not be available during public health emergencies, as expected.

5. Dispensing

Dispensing is the process of providing medical countermeasures directly to the end user. Although planning and large-scale exercises regarding dispensing medical countermeasures have been underway for some years, the 2009 H1N1 response provided the first event in which S/THDs and LHDs around the country had to put this function into operation. SNS planning has often focused on short-term, mass prophylaxis dispensing post-exposure in a biological event (e.g., anthrax attack). Although some planning elements remain the same, dispensing antivirals for treatment during a pandemic requires very different models (linking use to diagnosing disease, meeting the 24–48 hour after-symptom onset timeframes needed for antivirals to be most effective, needing ongoing mechanisms of access to medications—including after hours—for months of pandemic waves, etc.). Many health departments had plans in place to address these differences in dispensing needs (often working through routine healthcare delivery system dispensing partners), whereas others had yet to fully complete this planning and had to further develop mechanisms during the event. Dispensing, for the purposes of this report, covers issues and practices surrounding S/THDs and LHDs providing antiviral medications to individuals during the 2009 H1N1 response.

**State Perspective**

Typically states are responsible for distribution to community partners, whereas LHDs manage direct dispensing to individuals. However, there are some exceptions to this rule, which include smaller states that do not have LHDs or states where local staff are technically employees of the S/THD. For the purposes of this report, dispensing activities from the state perspective will cover issuing dispensing guidance to LHDs and other dispensing partners, and the dispensing partnerships/MOAs between the S/THDs and local entities. Not all states released their SNS assets. Of those that did, dispensing guidance from S/THDs provided to community partners varied from state to state. More than 50 percent of S/THDs followed CDC recommendations to dispense antivirals for treatment rather than prophylaxis and target uninsured and underinsured populations to receive antivirals. Only a few states made SNS antivirals available to everyone regardless of their insurance status or ability to pay. Another commonality was

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using antivirals for treatment versus prophylaxis. Very few S/THDs reported that antivirals were used for pre-exposure prophylaxis. The few instances of pre-exposure prophylactic use were in long-term care facilities where there was a higher risk of transmission and in homes with children (at the discretion of providers) or in high-risk populations. Most S/THDs partnered with commercial entities for antiviral dispensing during the 2009 H1N1 pandemic. At least 23 S/THDs reported partnering with community retail pharmacies (see Appendix IV, ASTHO H1N1 Antiviral Management Survey Summary).

Community retail pharmacies were excellent partners for dispensing because of their existing capacities including trained, expert staff; multiple locations; and familiarity within the community. Partnering with pharmacies required enacting MOAs. Those agreements formally established the parameters under which pharmacies could use government assets. A few states had pre-existing relationships with pharmacy partners, which allowed for faster and smoother negotiations. Conversely, S/THDs that did not have pre-existing relationships with pharmacy partners reported negotiating MOAs as a barrier. This issue was most often seen with larger retail pharmacy chains. For more information on MOAs, see Section 8: Legal and Policy Considerations. All S/THDs who worked with pharmacies to dispense antivirals during the 2009 H1N1 pandemic reported that they would partner with pharmacies in the future. However, S/THDs must resolve issues experienced during the 2009 H1N1 pandemic and establish pharmacies as partners before another pandemic.

**Local Perspective**

LHD antiviral dispensing practices varied greatly during the 2009 H1N1 pandemic. Many LHDs have trained staff on dispensing procedures for several public health emergencies; however, sufficient availability of antivirals in the commercial supply and the low morbidity and mortality rates associated with the pandemic limited the demand of antivirals at the local level. Even with the limited demand, LHDs still had to consider the following: triggers for dispensing, how to dispense, and which individuals were eligible to receive them.

**Triggers**

Most LHDs did not dispense antivirals to individual patients during the 2009 H1N1 pandemic, although many LHDs had plans in place to dispense if commercial supply was no longer available. Because there was no significant shortage in the commercial supply for antiviral drugs (except Tamiflu® Suspension product in fall 2009), the triggers for LHDs to start dispensing were never reached. Some LHDs also reported that they were waiting for states to authorize using the antivirals, which did not occur; therefore, those LHDs did not dispense antiviral medications (nor did partner organizations that had received SNS state antivirals).

**How LHDs Dispensed**

Many LHDs no longer offer clinical services, and even fewer maintain pharmacy services. The LHDs with pharmacy services reported dispensing antivirals to a handful of patients. Most LHDs without pharmacy services did not dispense antivirals. However, a few attempted to establish special antiviral clinics in which members of the public could come to the health department to receive their antivirals. The LHDs that established these clinics reported that there was very little interest from the public and only a few people participated.

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Managing Antiviral Medication during the 2009 H1N1 Influenza Pandemic

Antiviral Eligibility
During the 2009 H1N1 response, the federal government released guidance regarding the use of antivirals. The guidance highlighted priority groups recommended to receive available antivirals. S/THDs used this guidance to develop specific guidance to LHDs on how to dispense antivirals provided by public health. Guidance from S/THD to LHDs varied among states and localities because approaches to antiviral dispensing differed.

In general, the federal government recommended antivirals for treatment only and not prophylaxis. Many states required or recommended LHDs follow the federal recommendation, and LHDs dispensed antiviral drugs mostly for treatment; however, two LHDs reported that they dispensed antivirals to a few patients for prophylaxis. One of these reported that they dispensed only one course of antiviral medication, which was for a pregnant woman for prophylaxis.

Most individuals seen in LHD clinics were outside the treatment time of when antiviral therapy would be effective, so low numbers of antivirals were dispensed in this way. One LHD reported that it was able to dispense the entire cache of antivirals it received. To accomplish this, the LHD requested all providers and hospitals to direct all of their patients to the LHD to fill their antiviral prescription, even if the patient had insurance or could afford the medication. The LHD was, however, unsure if the cache of antivirals it received was from the federal SNS or from the state’s pre-purchased antivirals.

Dispensing—Future Planning Considerations
• Develop clear triggers for dispensing antivirals before an emergency so that S/THDs and LHDs can plan and respond appropriately. The low severity of the 2009 H1N1 virus and availability of antivirals in the commercial sector limited the need to dispense government stockpiles.
• S/THDs and LHDs could greatly benefit from receiving increased assistance from both federal and national private sector associations in establishing MOAs with pharmacies or other dispensing partners.

6. Returning, Redistributing, Relabeling, and Disposing of Unused Antiviral Medications
As the response to the 2009 H1N1 pandemic began to wane, many S/THDs and LHDs were left with large quantities of unused antivirals to manage. The following section highlights some of the issues and practices surrounding returning, redistributing, relabeling, and disposing of antivirals that were not dispensed during the 2009 H1N1 response. This section covers the activities S/THDs and LHDs engaged in to manage unused antivirals after the 2009 H1N1 response.

State Perspective
The mild nature of the 2009 H1N1 pandemic limited the need for, and use of, antivirals. At the conclusion of the pandemic, S/THDs, LHDs, and other partners still possessed antiviral stockpiles. ASTHO’s H1N1 Antiviral Management Survey found that all 36 states that participated in the survey still had unused state-owned and federal SNS antivirals as of March 2011. Prior to the 2009 H1N1 pandemic, public health preparedness planning, exercises, and drills had assumed all assets would be consumed over the course of an event; therefore, many S/THDs did not have plans in place for managing remaining antivirals. This

section will cover S/THDs’ challenges with guidance around managing unused stockpiles, the potential need to redistribute antivirals to meet community demand, returning antivirals from dispensing sites, the cost of storing unused antivirals, and relabeling or disposing of expiring antivirals.

**Flexibility to Redistribute to Meet Community Needs**
It is difficult to accurately anticipate community needs before an event. Many S/THDs and LHDs found that redistribution was necessary to meet community needs, given that consumption varied based on various local issues (e.g., vulnerable populations are not evenly distributed, healthcare delivery systems are not evenly distributed, virus spread varies across geographic areas). Although not as significant an issue with antivirals in the 2009 H1N1 event, redistribution would be especially critical in a pandemic in which there were greater shortages in government or commercial supply. This was evident in the 2003–2004 flu vaccine shortages as well as in distributing flu vaccine in 2009 while the H1N1 pandemic was occurring simultaneously. The same would hold true for antivirals in an event where shortages could be more significant than what was seen in the 2009 H1N1 response. S/THDs should consider the possibility of redistribution. Specifically, state and local jurisdictions must weigh the pros and cons of distributing all supplies too early in an event and build in the capacity to adjust distribution if needed to best address community needs as the event unfolds.

**Guidance**
Traditionally, once SNS assets are deployed to states, these assets become state property. Because the CDC no longer manages or monitors the product, these assets cannot be returned to SNS inventory. Thus, post-2009 H1N1 response, S/THDs and LHDs were responsible for managing remaining antiviral caches in their possession. The federal government did not provide adequate guidance on what to do with unused antivirals, which compounded the S/THDs’ challenges.

**Returning Unused Antivirals**
Returning unused antivirals involved states recalling and collecting antivirals distributed during the 2009 H1N1 response. Dispensing sites, such as pharmacies and LHDs, do not have the capacity to store medications for the long term. Some states also reported that they were restricted from putting state stockpile into rotation with commercial stockpile during the 2009 H1N1 pandemic, often leaving state stockpiled antivirals unused. Therefore, it was S/THDs’ responsibility to manage antivirals after the pandemic response subsided. The mechanisms for returning antivirals varied from state to state, including using FedEx and courier services, and using S/THD employees to retrieve the antivirals. Packaging the antivirals also varied greatly between jurisdictions; some S/THDs reported receiving boxes that were unopened, antivirals returned in different boxes, boxes of antivirals labeled with incorrect lot numbers, and antivirals returned in inappropriate packaging, such as plastic bags. A strategy to return unused antivirals should be a part of future S/THD pandemic planning.

**Storing Unused Antivirals**
Costs associated with long-term storage of unused antivirals presented a challenge. States that maintained warehouses to store state-owned caches of antivirals were able to use existing warehouse space; however, those that did not have existing storage had to contract for it and find funds to maintain storage capacity for an undefined time. When possible, S/THDs made arrangements with dispensing entities to store antivirals. If LHDs had the capacity to store antivirals, S/THDs asked them to continue to store them for as long as possible. Some states transferred responsibility for the antivirals to the LHDs. Thus, some LHDs were responsible for post-2009 H1N1 management of antivirals and the associated costs. Many S/THDs would prefer to send unused antivirals back to manufacturers and distributors who are better suited to maintain surplus stock.
Expired Antivirals
S/THDs also faced challenges with large quantities of state-owned caches nearing their expiration dates. In June 2010, the Food and Drug Administration (FDA) and the CDC released the following guidance:

FDA approved supplemental new drug applications for Relenza inhalation powder (May 2009) and Tamiflu® capsules (Dec. 2007), that provided an expiration dating period of seven years. Approvals of new drug applications are generally prospective. However, FDA concluded that, provided the products have been stored under the labeled storage conditions, it would be scientifically supportable for the expiry extension for a maximum of seven years to apply to lots that had been previously manufactured. Lots that exist within state stockpiles that are currently packaged with an expiration date of less than seven years may be extendable provided the products have been stored under the labeled storage conditions. Therefore, in June 2010, FDA stated that it would not take enforcement action with regard to the storage of certain lots of Relenza inhalation powder (May 2009) and Tamiflu® capsules that were retained for use in future emergencies, provided that the products have been stored under labeled storage conditions.21

Because this guidance was not issued until the end of the declaration of emergency in line with terminating Emergency Use Authorization (EUA) for these products, S/THDs were encouraged to maintain unused antivirals according to the product’s labeled storage conditions. This assumed the products were stored in appropriate facilities and environments, were monitored, and accurate records were kept.

SHD personnel often were confused by supplemental data about the extension of product expirations that had been provided by the manufacturer to the FDA and by the information from the Department of Defense-FDA shelf-life extension (SLE) program. Some state public health practitioners were under the impression that the manufacturer extension was the same as the SLE program. Additional guidance and education around the detail of these extensions (e.g., differences, FAQs) would have been beneficial to increase understanding around the regulatory framework.

Relabeling Antivirals
Under the FDA guidance described above, relabeling antiviral drugs to reflect the extended expiration dates was recommended but not required. It was also recommend that if in future emergencies S/THDs dispensed antivirals whose expiration dates had been extended but not relabeled, documentation should indicate that the drug is suitable for use beyond the manufacturer’s original labeled expiration date. S/THDs had to weigh the risk of poor public perception or misunderstandings and incurring costs for relabeling (funding for personnel, transportation, and relabeling) or destroying expired antivirals. It was unclear to S/THDs how relabeling costs would be resolved. Although PHEP funds could have been used for relabeling efforts, it was not always clear that this practice was acceptable or if the cost and time needed for relabeling was worthwhile. Furthermore, HHS indicated that limited authorized re-labelers existed in the United States to support the re-labeling activities for these antiviral drugs.

Disposing of Unused Antivirals
S/THDs had to determine if antivirals that were returned should be maintained for future use or destroyed. HHS/FDA issued guidance directing S/THDs to dispose of antivirals using the facilities’ pharmaceutical disposal procedures and in compliance with all applicable laws. This guidance applied only to products that had truly expired (with no additional product expiry extensions; for example, Tamiflu® Oral Suspension).\(^2\) S/THDs decided which and how many antivirals they could continue to manage and which products would need to be destroyed. This meant that states also incurred destruction costs. Depending on the state, LHDs or other dispensing partners may have been responsible for disposal costs instead of S/THDs. Additionally, there were questions over whether antivirals would be classified as medical or hazardous waste because there are different costs and regulations associated with each.

Local Perspective
Most LHDs that received antivirals during the 2009 H1N1 response reported that they had unused antivirals at the end of the response. Management of the unused antivirals varied among jurisdictions and depended mostly on requirements set by the S/THDs. From the 2009 H1N1 pandemic AARs and key informant interviews, LHDs reported either returning the antivirals to the S/THDs, attempting to redistribute some antivirals to partner organizations, disposing of some antivirals, or continuing to store unused antivirals as of August 2011.

Most unused antivirals were returned to S/THDs. LHDs returning the antivirals to the S/THDs varied in the following areas: timing, initiation of return, cost coverage, and transportation. A few LHDs returned the bulk of their antivirals after the spring 2009 surge had subsided, whereas most waited until after the fall and winter 2009–2010 influenza season had passed. S/THDs initiated most returns; however, a few LHDs initiated returns to decrease their storage costs. No matter which organization initiated the return of the unused antivirals, LHDs reported a successful process. About half of LHDs reported they were required to cover the cost of returning the antivirals, and the other half reported that the S/THDs covered the cost. Of the LHDs that reported having to cover the cost to return the antivirals, many had to make arrangements for returning them. These LHDs either hired a third-party contractor to return the antivirals or, for smaller quantities, shipped them through a postal carrier service. Of the LHDs that reported the S/THDs covered the return shipping costs, many reported that the S/THDs contracted with a third-party vendor to pick up the antivirals or used a courier or other services already in place to move items between the S/THD and LHD.

In addition to returning the antivirals LHDs had in storage, a few LHDs were required to gather the antivirals they had distributed to partner organizations and return those to the S/THDs as well. To accomplish this, LHDs typically arranged for a third-party vendor to pick up the antivirals and bring them to the LHD storage sites. Collecting antivirals was typically a requirement only for organizations that received a large quantity of antivirals, not for organizations that received only small quantities. Additionally, some LHDs reported that their partner organizations sent their cache of antivirals back to the S/THDs directly. Although all LHDs reported that the process went well, this extra step of returning antivirals was unaccounted for in plans and exercises.

Some LHDs tried to redistribute unused antivirals to locations that might need them instead of disposing of them. These LHDs, however, reported that the S/THDs did not allow them to redistribute the antivirals, or that there were no organizations (hospitals, clinics, etc.) interested in accepting them.

Some LHDs also reported that they were required to dispose of some of their antivirals, particularly if the antivirals expired while under the LHDs’ control. All LHDs that disposed of antivirals reported that they were responsible for this cost, and that PHER funds could be used. Additionally, a few LHDs reported that they already had disposal vendors in place, which decreased the amount of work and cost LHDs incurred in this process.

Although most LHDs reported that they stored antivirals for up to a year before returning them, other LHDs reported that, as recently as summer 2011, they still possessed antivirals. Most LHDs that continued to store antiviral medications had received only a very small amount and therefore were storing them within the LHD at no additional cost. Because there was never a high demand for antivirals in their communities, their cache of antivirals was never depleted.

**Returning, Redistributing, Relabeling, and Disposing of Unused Antiviral Medications—Planning Considerations**

- Increased planning should occur to ensure all assets are used, redistributed to populations in need, or given to entities (such as SNS or pharmaceutical distributors) that are better equipped to handle long-term storage. Long-term storage of antivirals by state, local, or partner organizations can be expensive and difficult for some entities.
- Address legal and regulatory issues regarding redistributing and disposing of antivirals for each jurisdiction before an event.
- Consider the possibility of S/THDs redistributing supplies early in an event. Specifically, state and local jurisdictions must weigh the pros and cons of distributing all supplies too early in an event and build in the capacity to adjust distribution if needed as the event unfolds to best address changing needs of the community.

**Overarching Themes**

**7. Communication**
Communication is an essential activity during any response. This section highlights some of the successes and challenges in communication during the 2009 H1N1 pandemic. Communication, for the purposes of this report, includes internal communications between S/THDs and LHDs, their federal and local partners, and the general public.

**State Perspective**
Improving internal and external communications was often listed as an area of improvement in SHD AARs. As that area related to antivirals, suboptimal communication among federal, state, local, and private partners added to the complexity of the H1N1 response. The section below provides a sample of SHDs’ communication experiences during the H1N1 response related to antiviral management.

**Internal S/THD Communication and State-to-State Communication**
Effective internal communication is critical in emergencies. ASTHO’s review of AARs, the survey findings, and background literature did not reveal many communication challenges within states. Pre-event planning efforts and implementing an incident command structure (ICS) presumably contributed to success in this area.

Communication among states was also necessary during the 2009 H1N1 response. ASTHO facilitated all-states calls with the CDC to share information. The regional level saw additional collaboration and coordination. The states within HHS Regions 1, 4, and 6 collaborated extensively, where possible, to develop consistent messaging, communications, and policies.
Communication between the Federal Government and S/THDs

S/THDs had varying experiences communicating with the federal government. Overall, the ability of CDC and HHS to communicate with S/THDs via conference calls, memos, and daily alerts was a success; however, there were a few areas where communication could be improved. For example, S/THDs had challenges with communications from the CDC regarding receiving SNS assets, supply chain visibility, and reporting requirements.

During the 2009 H1N1 response, S/THDs received messages from multiple federal agencies, such as HHS, the CDC, and FDA, at least daily, and sometimes multiple times per day. Some S/THDs considered the frequency and quantity of communications from federal partners to be cumbersome. S/THDs identified bi-directional information sharing as a need.

S/THDs expressed the need for supply chain visibility to assess their population’s demands. Some S/THDs were able to obtain data about the commercial supply chain’s ability to meet the population’s needs through relationships with dispensers or by viewing aggregate supply chain inventory data on the CDC Supply Chain Dashboard. This information was used to help guide decision-making and allocation strategies. During the 2009 H1N1 response, access to the dashboard was granted to state public health preparedness directors only if they had completed a security accreditation process. The process was required because the dashboard was housed on a federal government server. States that were not credentialed to access the CDC server may have found it cumbersome and time-consuming in the throes of an emergency to go through this security step. Unfortunately, the state’s limited access to these data and the aggregate non-granular nature of these data may have hampered response efficiencies.

As discussed in Section 2: Receiving and Staging, communication deficiencies regarding delivering SNS assets and quality control frustrated some S/THDs. Although CDC re-evaluated and revamped delivery policies during the second wave of the pandemic, given the attention this issue received in the ASTHO H1N1 Antiviral Management Survey and key informant interviews, it remains an area of concern for S/THDs. Federal level messaging should be clear and consistent to ease the burden of overwhelming S/THDs with redundant information and information requests.

Communication between S/THDs and LHDs

From the state perspective, communication between S/THDs and LHDs was generally successful. Most local jurisdictions were a part of state plans to distribute countermeasures and executed existing plans accordingly. In many states, consistent information sharing and frequent communication with LHDs went smoothly as a result of planning and relationship building efforts. However, a few communication challenges were identified.

One challenge that S/THDs heard from LHDs was about the level of consistency in communication. Some LHDs thought that messaging and guidance regarding antiviral use were not clear and consistent. Additionally, communication around allocating antivirals was inconsistent. Although some states opted to transfer allocation responsibilities to the local level, others chose to keep allocation decisions at the state level. At times, allocation decisions made at the state level were not shared with LHDs. In the future, greater information sharing between S/THDs and LHDs could alleviate some of these communications issues.

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The CDC Supply Chain Dashboard was an internal website where data on commercial supply chain inventory could be viewed.
Another area for improvement is in the communication between the state RSS warehouses and LHDs. For example, one state reported that it initially managed communications between the RSS warehouse and LHDs through its Emergency Operations Center (EOC). However, because personnel in the EOC were not well versed in the RSS’ activities, important pieces of information were sometimes not conveyed. This caused delays and miscommunication in antiviral distribution. S/THDs found that reassigning this responsibility to experienced warehouse personnel at RSS sites allowed for improved communication and increased efficiency between the warehouse and LHDs.

Communication between S/THDs and Other Stakeholders
Communication from S/THDs to stakeholders such as physicians, hospitals, pharmacies, clinics, and other dispensing sites occurred in various ways. The types of information shared with stakeholders included guidance on using antivirals, when and where antivirals were available, and who was eligible to receive SNS antivirals. All stakeholders were able to access information through the S/THD website, Health Alert Network (HAN), and e-mail distribution lists. S/THDs generally communicated with stakeholders on a weekly basis, but the frequency varied depending on the circumstances. In addition to electronic messages, some states said it was effective to send official letters from state health officials to their partners, which articulated the importance of these stakeholders in the response to the 2009 H1N1 pandemic.

With pharmacies, S/THDs used various communication methods depending on the technologies available at each individual pharmacy. Not all pharmacies had e-mail capability, especially smaller or independent pharmacies. Therefore, S/THDs had to use multiple, redundant systems for getting messages to pharmacies. These systems included using blast faxes, sending messages through state pharmacy associations, and sending messages on printed invoices from distributors.

Communication to the Public
To convey to the public when and where to receive antivirals, S/THDs maintained up-to-date information on their websites, held frequent press briefings, and used social media websites to share information. As with any large event, rumors and misinformation were prevalent and, to combat these issues, S/THDs worked to ensure that residents were provided with clear, consistent messages from official sources. S/THDs also used call centers and hotlines to communicate antivirals’ availability directly to the public. Some states used public health personnel to staff call centers while others leveraged poison control centers or contracted with private entities to provide these services. Most states organized call centers that focused on providing general information to residents; however, the Minnesota S/THD launched a call center that provided clinical triage services to residents and, when appropriate, a prescription for antiviral medications was electronically submitted to a pharmacy within close proximity to the caller.

Local Perspective
Communication is a complex and challenging area when responding to a public health emergency. This was no different for the H1N1 response, in which AARs and interviews with LHDs highlighted both successes and challenges in all areas of communication. Below is a breakdown of the four major areas in which LHDs communicated. A common feature among all areas of communication was the large burden created by the volume of information and rate at which it changed during the response.

Internal Communication
Many LHDs reported that internal communication went well. Implementing an ICS structure within LHDs helped streamline information sharing and prevent miscommunication between the different LHD response groups. LHDs cited daily/weekly meetings and calls, EOC response boards, and group electronic workspaces (such as WebEOC and Sharepoint) as vital to sharing information internally. Many LHDs appointed a single person or team in charge of ordering and coordinating all supplies, including antivirals.
The LHDs that implemented this approach praised it for helping streamline the process and reducing the breakdown in communication regarding supplies.

Not all LHDs, however, reported good internal communication. LHDs cited numerous reasons for difficulties in communicating with internal staff, which included breakdown in the reporting structure, competing staff priorities (H1N1 response versus daily job requirements), and isolated planning among different groups within the LHD. LHDs that decided not to fully implement ICS for the 2009 H1N1 response typically reported more challenges with reporting structure. Among these LHDs, staff indicated that they reported to multiple supervisors or were unsure what information needed to go to whom. Competing staff priorities was another major challenge as staff tried to maintain their routine activities. On occasion, this resulted in lapses and delays in communication about the response to the rest of the staff. Planning that occurred in silos became a substantial challenge for some LHDs. Although LHDs did not provide a specific example that related to antivirals, one LHD reported that staff members planning mass vaccine clinics were completely unaware that community sites (points of distribution or PODs) had been pre-screened as part of the LHD’s preparedness activities. This miscommunication led to a lot of duplicated work and time lost by many LHD staff.

Communication between the S/THDs and LHDs

Because the public health system’s structure is different in each state, the communication between state and local health departments varied greatly. Many LHDs have strong relationships with their S/THDs. Of these LHDs, many reported that two of the greatest successes during the response were the state’s dissemination of information to LHDs and their willingness to discuss the 2009 H1N1 response with local health officials. Many LHDs reported having a single point of contact within the S/THDs, which facilitated the exchange of information among the appropriate individuals within the two agencies. LHDs indicated that having a clear point of contact within the S/THDs contributed to the success of the 2009 H1N1 response. Another success that one LHD reported was having one assigned person sit in on all state and federal calls, webinars, and meetings. This person was then responsible for disseminating the information to the appropriate LHD staff. This approach was praised for streamlining communication and allowing for greater and more efficient integration and dissemination of information. Additionally, many LHDs reported that there was a well-organized process for requesting supplies from the S/THDs. Again, a single point of contact contributed to part of this success. Furthermore, having clear guidance and documents for ordering and using antivirals also contributed to the successful communication between S/THDs and LHDs.

Not all LHDs, however, had as much success in communicating with their S/THDs during the pandemic. Some LHDs reported miscommunication regarding antiviral ordering, shipping, guidance, and distribution to other local community partners. Some said that the ordering process could be complex and burdensome and sometimes resulted in errors in ordering and shipping antivirals and other medical countermeasures. Communication around shipping was a particular challenge for many jurisdictions that were not always informed about when the antiviral medications were arriving or what materiel were included in a shipment from the S/THD. Many LHDs also reported receiving conflicting information about how, when, and to whom they should distribute and dispense antiviral medications. Several S/THDs distributed antiviral medications directly to local community partners (such as hospitals and large clinics) without informing the LHDs. These LHDs reported that sharing this information with them up front could have saved time and energy. Many LHDs had allocation plans, but as they contacted their community partners to determine their need for antivirals, the LHDs learned that their partners already had antivirals. This resulted in the LHDs having a surplus of antivirals, which then had to be reallocated or stored.
Communication between the LHD and Local Medical Partners

LHDs reported working very closely with some medical partners in their community and indicated that the relationships they developed or strengthened were invaluable to the 2009 H1N1 response. Examples of partner organizations included hospitals, private providers, clinics, and pharmacies. LHDs reported some challenges in exchanging information with these organizations, specifically not having an efficient way to contact the medical community in their jurisdictions at the beginning of the 2009 H1N1 response. These LHDs did not have a comprehensive list of the medical providers in their jurisdictions or a way to identify the primary point of contact for each organization. To rectify these challenges, many LHDs employed volunteers or interns to call each facility/provider and create a database with the information. LHDs used these databases to call, e-mail, or fax medical providers in their jurisdiction about the 2009 H1N1 response. These communications provided guidance about how to order or receive antivirals, information on what community partners had a public supply of antivirals, and the intended target population. Many LHDs reported that their medical communities requested more guidance regarding the use of antivirals they had received. Additionally, one LHD reported that its medical director and infectious disease consultant (another physician) consulted with several providers who did not routinely prescribe antivirals.

In addition to disseminating information, some LHDs reported collecting information from their community partners. Specifically, pharmacies were willing to share information about the availability of the commercial supply of antivirals. Many LHDs found their partnerships with pharmacies to be mutually beneficial. Exchanging information between LHDs and pharmacies allowed LHDs to learn about what was being seen at the customer level as well as the commercial availability of antivirals (pharmacies reported spot shortages). Pharmacies were able to learn from LHDs about what was happening in the community, where individuals could receive the public supply of antivirals, and other information they could share with their customers about the 2009 H1N1 response. Some LHDs particularly noted that the 2009 H1N1 response helped to strengthen their relationships with smaller, independent pharmacies or those that primarily serve minority populations. These new or stronger relationships aided some LHDs in learning how certain populations with limited access to medical care were responding to the pandemic, and gave the LHDs a channel through which they could share information with those populations. Some LHDs did, however, note some challenges with working with pharmacies. One LHD stated that, despite years of planning with the chain drug stores in their community, during the 2009 H1N1 response store policies changed at the national level and prohibited them from working on certain initiatives with public health. Other LHDs noted that the local branches of chain pharmacies were willing to work with them but were unable to gain approval in a timely manner from the national-level pharmacy offices.

Communication to the Public

Communication with the public was one of the LHDs’ primary responsibilities during the 2009 H1N1 response. LHDs were flooded with questions from individuals and the media. LHDs established hotlines, disseminated frequent press releases, updated their website, and used social media platforms, such as Facebook and Twitter, to address the volume of queries. Although many LHDs reported that responding to the public’s requests was very time consuming, they also indicated that their ability to provide continuous and comprehensive information to the public was a crucial activity for the overall success of the 2009 H1N1 response. Many LHDs reported that coordination with the media was prompt, accurate, and handled very well by LHD staff.

LHDs also noted a few communication challenges, in addition to the volume of requests from the public and media, including unsanctioned personnel speaking on behalf of the LHD, personal opinions from staff being construed as facts, and the release of unapproved information. In the instance where an unsanctioned employee spoke on the LHD’s behalf, the LHD reported that the staff had responded to a media request as a citizen; however, given the person’s position as an LHD employee, the media understood the comments to be the official position of the LHD. Another challenge arose when a
sanctioned LHD spokesperson expressed personal opinions about the safety of antiviral medications that were contrary to the medical facts. Disseminating written information to the public also challenged some LHDs; one LHD reported that staff leaked important information to the media without approval of the public information officer, which then required significant damage control to rectify the situation.

For LHDs that established antiviral dispensing clinics within the health department, information about the availability of, and eligibility for, antivirals was shared with the public most commonly via the local media or LHD website. Most LHDs, however, did not have dispensing clinics. Some LHDs reported they disseminated information about antivirals only to the provider community and not with the general public to try to ensure that patients who needed treatment could receive antivirals while attempting to prevent the general public from seeking antivirals for prophylaxis.

**Communication—Planning Considerations**

- Consider ways for S/THDs and LHDs to improve internal communications, including using ICS, before an emergency. Strong internal communication at state and local levels is essential during a public health emergency.
- Improve federal, state, and local coordination and communication by increasing visibility and information sharing between all stakeholders.
- Be cognizant of S/THDs’ and LHDs’ stakeholders’ communication capabilities and incorporate alternative communication strategies into preparedness planning.
- Streamline messaging and requests at the federal, state, and local levels and establish a single point of contact to ease information exchange and improve response.
- Establish databases with the contact information for the medical community partners in the respective S/THD and LHD jurisdictions.
- Foster relationships with community partners that can share information with members of the community who do not access public health information through traditional mechanisms.
- Consider ways to increase staff training and develop more coordinated plans around who and how best to communicate with the public, media, and outside stakeholders during an emergency.
- Garner support from the national level of large private sector organizations (pharmacy chains, insurance companies, etc.) so local partnership activities between public health and local corporate branches can develop plans and boost confidence.

**8. Legal and Policy Considerations**

S/THDs and LHDs encountered many legal and policy challenges regarding antiviral distribution and dispensing during the 2009 H1N1 pandemic. Understanding these issues that could arise during a future pandemic event could help federal, state, and local public health agencies find and develop tailored solutions to address potential challenges. A high-level analysis of legal and policy issues encountered by federal, state, and local public health during the 2009 H1N1 pandemic offered possible solutions for addressing barriers, alternative antiviral distribution, and dispensing strategies for consideration. ASTHO engaged James G. Hodge, Jr., JD, LLM, a national expert on public health emergency legal and ethical preparedness and public health information privacy law and policy, to conduct this analysis.

The analysis revealed several legal and policy considerations applicable to the national strategy to distribute, dispense, and track antivirals, and provided solutions based on interpretations of law, practice, and lessons learned from prior emergencies. Several key legal and policy issues that S/THDs and LHDs encountered are presented here based on a broader report prepared by Hodge and Daniel G. Orenstein, a fellow and faculty associate in the Sandra Day O’Connor College of Law’s Public Health Law and Policy Program. Appendix V lists a more complete summary of issues identified and potential solutions for S/THDs and LHDs to mitigate legal and policy issues related to antiviral distribution and management in the future. Their legal analysis is not designed to present a comprehensive, state-by-state analysis.
Because the information presented here and in the complete legal analysis does not provide an overarching assessment of all relevant state or local laws, state actors and their local counterparts may need to conduct further assessments to identify how their particular state legal infrastructure relates to several key issues identified here and in the larger legal analysis. Appendix VI, Relevant State Law Template and Examples Regarding Antiviral Distribution and Dispensing, provides an initial tabular guide of select legal issues for which states may seek to explore.

**Pre-Emergency Strategic Planning and Preparedness**

S/THDs and LHDs agreed that pre-planning efforts were critical in the response to the 2009 H1N1 pandemic. Formal and informal agreements with public and private entities for goods and services are essential. Such agreements allowed S/THDs and LHDs to set the terms under which antiviral management, distribution, and dispensing occur. The following three examples are formal and informal agreements that S/THDs and LHDs used during the 2009 H1N1 pandemic:

- **Contracts:** Formal contracts are legally binding documents that detail exactly how each party is obligated to perform under specific terms. Contracts that are binding may not be ideal for emergencies, whereas more flexible, scalable contracts would work well in this context.

- **Memorandums of Understanding (MOUs) or Agreement (MOAs):** MOUs and MOAs may be intentionally worded to be less constrictive than traditional, binding contracts. However, MOUs can be contractually binding if certain conditions are met.

- **Multiagency Coordination Systems (MACS):** MACS establish dispatch procedures, command structures, support activities, and other advanced strategies. MACS can be less formal than MOUs or contracts while still serving the interests of response and resource transfer.

Most S/THDs and LHDs entered into MOUs or contracts with public and private partners for transportation services and pharmacies for dispensing, storage, and warehousing operations before or during the 2009 H1N1 pandemic. Although these agreements helped to facilitate business between parties, developing and executing these agreements during an event can be problematic and potentially delay effective responses. Advanced planning related to these agreements helps obviate potential legal issues.

S/THDs were particularly concerned with negotiating MOUs or MOAs with pharmacies. S/THDs reported less difficulty negotiating with independent pharmacies to dispense antivirals. However, negotiations with larger chain or “big box” pharmacies did not always go smoothly. S/THDs specifically need assistance negotiating with big box and larger chain pharmacies for antiviral dispensing.

A best practice for S/THDs and LHDs is to arrange contracts and agreements before an emergency. Developing pre-existing agreements provides an opportunity to craft and delineate terms of collaboration instead of waiting until an emergency is declared and such negotiations potentially become compromised. To be effective, these agreements must either allow for considerable flexibility or attempt to reflect actual emergency conditions in which decisions will be made.

**The Changing Legal Environment in Declared States of Emergency**

During national crises that affect the public’s health, such as the 2009 H1N1 pandemic, the federal government, every state, and many tribal governments, territories, and local governments declared either general states of “emergency,” “disaster,” or “public health emergency.” These declarations change the legal landscape, authorizing public and private sectors to respond efficiently and leverage resources to facilitate an effective response.
Federal emergency declarations typically authorize emergency management agencies, such as the Federal Emergency Management Agency (FEMA) and other partners, to coordinate emergency responses. The following laws provide the legal framework for defining various types of federal emergency declarations:

- **Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act):** An emergency can be declared under the Stafford Act by the President of the United States upon request of any state governor when federal assistance is needed “to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe.”

- **National Emergencies Act (NEA):** The President can declare an emergency under the NEA for incidents requiring a national response, as with the H1N1 pandemic.

- **Public Health Service Act (PHSA):** HHS may declare a state of “public health emergency” under the PHSA. Under this declaration, HHS can mobilize resources, waive specified federal requirements related to Medicare or Medicaid reimbursement, temporarily set aside certain provisions of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and conduct other emergency response activities (depending also on other federal declarations).

**State and Territorial Declarations**

All states and territories have the legal authority to declare states of emergency or disaster, including in relation to crises that affect the public health (e.g., pandemics, bioterrorism events, widespread foodborne illnesses). Public health emergency declarations in many states empower health officials and private entities to focus on the public health aspects of emergencies, including the need to distribute and dispense antivirals. According to the Network for Public Health Law, 26 states and Washington, DC, have legislatively crafted “public health emergencies” or like terms as part of their laws, based largely on the Model State Emergency Health Powers Act (MSEHPA)24. Although all states initiated their pandemic flu response plans in response to the spread of the 2009 H1N1 pandemic, only 12 formally declared states of emergency, disaster, or public health emergency during the first six months of the pandemic.

In the 24 states that do not formally declare states of emergency, public health officials must rely on other legal techniques and maneuvers embedded within agreements, MOUs, contracts, or existing public health laws to facilitate distributing and dispensing antivirals. This accentuates the need for adequate advance planning that is not overly reliant on declarations of emergency. In many jurisdictions, distributing and dispensing antivirals may have to proceed consistent with routine laws and policies unless the legal environment changes pursuant to an emergency declaration.

**Dual Declarations**

Regardless of when they are given, multiple emergency or disaster declarations are a challenge for S/THDs and LHDs responsible for antiviral management. During the 2009 H1N1 pandemic, HHS declared a state of public health emergency on April 26, 2009, just days after initial cases in Mexico were confirmed. President Obama declared a state of emergency months later in October 2009. The president’s declaration allowed for broader waivers of federal regulatory requirements, as well as expanded HHS’ public health emergency powers. Coupling these declarations closer in time may have ensured more timely responses at the federal level.

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24 MSEHPA’s model statutory language incorporates a series of flexible measures to facilitate emergency responses under a high threshold definition of “public health emergency,” defined as, “An occurrence or imminent threat of an illness or health condition that is (1) believed to be caused by . . . bioterrorism, the appearance of a novel or previously controlled or eradicated infectious agent or biological toxin; and (2) poses a high probability of . . . a large number of deaths in the affected population; a large number of serious or long-term disabilities in the affected population; or widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population.”
A lack of understanding of the types of powers vested in emergency or disaster declarations can become problematic. For instance, a public health emergency declaration often limits the S/THD’s powers if a broader state of emergency or disaster is not declared. Other state resources may not become available at no cost to S/THDs merely because a “public health emergency” is declared. If resources such as warehousing, transportation, or General Services Administration (GSA) resources are needed for the response, S/THDs must have agreements that they will provide services to aid in the response. S/THDs must also consider costs associated with state services. If only a public health emergency is declared, costs associated with the response may be incurred by the S/THD, not by other participating state agencies.

An influenza pandemic could trigger all three types of declarations (i.e., emergency, disaster, and public health emergency) simultaneously. The potential for overlapping declarations within and across jurisdictions can lead to confusion because divergent public and private actors, each mobilized or authorized to act under a different declaration that invokes different powers and chains of command, seek to respond in duplicative, overlapping, and at times inconsistent ways.

Legal Challenges of Antiviral Distribution
S/THDs and LHDs reported many legal challenges with antiviral distribution during the 2009 H1N1 pandemic. Specifically, licensing issues and handling unused antivirals were barriers to a timely and effective response.

Distributor Licensing
During the 2009 H1N1 pandemic, some state attorney generals required state or local governments to become licensed as wholesale drug distributors before handling antivirals or other medications. This requirement is unnecessary to distribute drugs during emergencies and was problematic for S/THDs and LHDs. Transfers of antivirals or other drugs for emergency medical reasons are not considered “wholesale distributions” and thus should not require a distributor’s license under federal and many state regulations. Some LHDs had to incur the costs of obtaining and maintaining distributor licensure to operate effectively during the 2009 H1N1 pandemic. Although S/THDs and LHDs could obtain this license in anticipation of future pandemics, prohibitive costs and the continuous need for licensure renewals may limit the use of advance licensing.

Unused Antivirals
HHS worked closely with providers and states during and after the H1N1 pandemic to return or dispose of overstock of Tamiflu® and Relenza®. The Environmental Protection Agency (EPA) may also regulate specific aspects of disposal consistent with environmental health and safety laws. Because antivirals, unlike some vaccines, do not contain thimerosal or any other “hazardous” substance (as defined by federal law), their disposal may not implicate certain environmental requirements. However, costs associated with disposing of unused antivirals became an issue. S/THDs and LHDs were often not prepared to incur disposal costs of federal antiviral assets. Federal oversight of returning excess antiviral stocks or support to pay for the associated costs may be essential to ensure that the national chain of custody standards are maintained and that there is direct delivery and receipt of unused antivirals by federal or state public health authorities.

Generally, pharmacies dispose of their excess or expired stock in two primary ways. First, they may use “reverse distributors,” which are licensed and highly regulated by the federal government, particularly the Drug Enforcement Agency (DEA), because they often handle controlled substances. Unlike wholesale distributors that deliver the product to pharmacies, reverse distributors take unused products away and destroy them safely consistent with federal or state laws. Second, pharmacies destroy expired drugs themselves. Pharmacies, wary of absorbing the expense of returning drugs, may enter agreements with a
manufacturer or distributor to offset or reimburse a portion of the costs. Similar types of agreements could be beneficial to public health departments.

S/THDs and LHDs often had to act like reverse distributors during the 2009 H1N1 pandemic, receiving unused or expired stocks from pharmacies or other entities that originally received antivirals. Not all S/THDs or LHDs had reverse distribution as a part of their planning and thus were not prepared to give formal guidance to dispensers on how the process should occur. This has been identified as an area of improvement for many health departments.

**Legal—Planning Considerations**

- Increase S/THD and LHD staff awareness of their legal authorities during a declared public health emergency.
- Establish, where possible, contracts and MOAs with both public- and private-sector partner organizations before a public health emergency.
- Resolve legal barriers, where possible, to effectively manage antivirals before a public health emergency.

**9. Security**

Securing medical countermeasures during a public health emergency has always been an important consideration in preparedness planning. Although the 2009 H1N1 pandemic was not as severe as originally contemplated, and did not create a large demand that might elicit a security risk to antivirals, it did give many states and localities an opportunity to test their security plans. Security for the purposes of this report covers security at state warehouses, transportation for moving antiviral medications, and local storage sites.

**State Perspective**

As a part of preparedness planning, S/THDs must provide security for SNS assets at RSS sites and while transporting assets. Lessons learned from the 2009 H1N1 pandemic related to security needs, including RSS sites’ security needs, transportation security, the scalability of security, and the security guidance S/THDs should provide to partner organizations.

State and local law enforcement and security guards from private firms were used to secure RSS sites. S/THD plans for security included setting up access points outside RSS sites and warehouses, providing security personnel inside and outside facilities, limiting warehouse access to key personnel who were required to present proper identification before entering secure locations, and having security available for crowd control. Additionally, some warehouses were outfitted with security alarm systems. Coordination with law enforcement was sometimes a challenge because S/THDs did not always have enough notice for deliveries to arrange for security personnel to be at the RSS sites. Deliveries during the night were also challenging in ensuring security would be present. S/THDs and law enforcement had not planned for the security needs during off-hours and were given little or no notice. Such situations should be considered for future planning efforts.

Security while transporting antivirals was also a large consideration for S/THDs. State and local law enforcement, as well as security guards from private firms, were used to provide escorts for antivirals in transit to dispensing or other distribution sites.
S/THDs also learned that security needs to be scalable. Plans assumed a widespread distribution and using scarce antivirals in a very short timeframe. As there was no scarcity of antivirals during the 2009 H1N1 pandemic, S/THDs had to reevaluate where, how much, and what level of security was needed. For example, because crowd control was not an issue, law enforcement was not needed for that purpose. Because S/THDs are responsible for the antivirals, they must set security policies for all external partners who are associated with warehousing, transporting, or distributing antivirals. These security measures include having security personnel in place, ensuring assets are in locked locations, and having measures in place to limit access to the antivirals. Additionally, staff of private partners also must be cleared for access to the S/THD’s secure locations. S/THDs should consider these required measures, and also be aware of security capabilities at dispensing locations such as LHDs, clinics, pharmacies, and hospitals.

**Local Perspective**

For LHDs, security during a pandemic has been a major concern and was written into many response plans. Although the 2009 H1N1 pandemic was not as severe as the assumptions in most planning scenarios, LHDs still took many precautions to ensure the safety of the medical countermeasures they received. From LHD 2009 H1N1 pandemic AARs and interviews, most LHDs reported enacting security measures for transporting or storing antiviral medications.

To provide security, many LHDs worked directly with their local sheriff or police departments around antiviral activities. All LHDs cited their local law enforcement agency as an essential asset to the 2009 H1N1 response, and prior exercises that incorporated law enforcement assets were the foundation for the strong working relationships experienced during the response. Law enforcement often provided security while transporting antiviral courses both from state to local facilities, and from LHDs to community partner facilities, such as hospitals or clinics. Additionally, many LHDs worked with law enforcement to provide security to protect antivirals onsite at the storage facilities. One community that was particularly concerned about security decided to store its antiviral shipment at the local sheriff’s office. The only challenge that LHDs reported regarding working with their law enforcement agencies was that long-term storage of antiviral medications had not been planned for and, therefore, neither was the long-term requirement for security. Many LHDs and police realized early in the 2009 H1N1 response that there was no large threat to the antiviral stockpile; however, because security had been written into the pandemic plans, it was hard to get approval to discontinue security services.

Other security concerns at the antiviral storage sites included complying with state security requirements and allowing access to those sites for dispensing partners. Many LHDs reported that states required them to store their antiviral shipments in secure rooms in which access could be limited or controlled. For many LHDs, limiting staff access to the antiviral shipment had the additional benefit of ensuring that no antiviral courses were distributed or dispensed without proper tracking.

An additional security consideration came from community partners picking up their allotted antiviral medications directly from the storage facility. Some LHDs reported having trouble verifying that the people who came to pick up the antivirals were from the organization they claimed, as they were often not the person with whom the LHD had been communicating about the allotment.

**Security—Planning Considerations**

- Consider future security plans that are more scalable and based on the nature of the event, depending on its severity.
- Preparedness planning efforts should consider the need for long-term security because S/THDs and LHDs were responsible for storing antivirals longer than anticipated; therefore, security remained in place longer than anticipated.
10. Tracking and Reporting

Tracking and reporting inventory, distribution, and dispensing data were an integral part of antiviral management during the 2009 H1N1 pandemic. Tracking and reporting, for the purposes of this report, cover state tracking of antiviral medications from SNS/state supply to LHDs or other local community partners, state reporting to CDC or other federal agencies, LHD tracking of antiviral medication distributed to local community partners, LHDs reporting to S/THDs, and state and local tracking of commercial supply of antiviral medications in their communities.

State Perspective

It is essential for S/THDs to know the amount and location of antivirals to make allocation decisions, when to request more supplies, and issue dispensing guidance. Therefore, it is an important process for S/THDs to oversee tracking inventories of antivirals from the time they are received at state RSS sites; while they are in transit; when they are re-inventoried at alternative storage locations, distribution centers, and dispensing sites; and then dispensed to patients. The granularity of information collected, for whom it was collected, how it was collected, and tracking requirements for community partners all varied from state-to-state during the 2009 H1N1 pandemic.

Antiviral use was an important indicator of cases, disease burden, and the outbreak’s progression. For allocation purposes, S/THDs needed to know where the demand was. Therefore, some states tracked to the county level, whereas others tracked to the end-user at dispensing sites.

S/THDs reported that data requests from the CDC changed multiple times throughout the response. States expressed concern regarding the variation in data requests. Often S/THDs were not able to provide the data requested and questioned the need for it. Given the ever-changing nature of an influenza pandemic, it is understandable that information needs may change, too. However, S/THDs reported challenges with meeting multiple, changing information requests from the CDC, state agencies, and other entities.

Therefore, having a standard set of data requirements prior to an emergency, which can be modified to fit the emergency if needed, would significantly decrease the burden on S/THDs while still actively responding to a public health emergency.

S/THDs used inventory and tracking systems, which varied from state to state, to monitor antiviral supplies. These systems included state-owned inventory management systems, CDC’s RSS Inventory Tracking System (RITS), Medicaid systems and immunization registries (modified to meet H1N1 needs), and Excel spreadsheets. Each system had advantages and disadvantages. Some states preferred using in-house systems because they were familiar and adaptable. The benefits of using the Medicare/Medicaid system were that pharmacies could access it and it allowed them to charge Medicare for administrative fees rather than pass them on to patients. Also, inventory systems that were tied into geo-based systems, such as GIS, were very useful in helping states maintain supply chain visibility.

The CDC’s Division of Strategic National Stockpile (DSNS) developed RITS for tracking and inventory management purposes. RITS is a web-based tool that DSNS maintains and is available to states and directly-funded cities for free. In some states, RITS was the primary tool for inventory tracking and management. Unfortunately, it did not function at a proper level to meet the S/THDs’ needs. Some users were kicked out of the system due to infrequent use and some lost data. Some states using RITS had to hand count inventory and resort to using Excel spreadsheets to track inventory due to the system’s inefficiencies. Because of the problems RITS had fully meeting the S/THDs’ needs, many S/THDs bought inventory management systems from private firms. These systems were costly but necessary. Tracking also had to extend beyond RSS sites so S/THDs could maintain visibility on antiviral use, as well as for reporting purposes. LHDs and dispensing entities were often required to report back to S/THDs so that S/THDs could, in turn, comply with CDC reporting requirements. States that contracted...
with commercial entities for inventory management, such as pharmaceutical distributors or pharmacy associations, were able to leverage their partners’ tracking systems. There were, however, some challenges associated with obtaining the information S/THDs required from pharmacies, including the following:

- System incompatibility.
- Burden on already overwhelmed pharmacists.
- Liability issues related to HIPAA when reporting patient-level data.
- Some pharmacists refusing to comply.

S/THDs preferred electronic reporting; however, not all pharmacies have Internet access, particularly independent pharmacies. For pharmacies without Internet, some pharmacists were able to fax reports. As a result of S/THD and retail pharmacy system incompatibility, S/THDs asked pharmacies to report using S/THD-provided forms or an Excel spreadsheet. Pharmacies reported that some of their significant challenges when reporting to S/THDs included being asked to use state-based systems, report frequently (more than once a week), and being asked for too much information.

**Local Perspective**

Prior to the 2009 H1N1 pandemic, tracking and reporting antiviral distribution and dispensing were not a large focus in preparedness planning for many LHDs. Therefore, in response to the 2009 H1N1 pandemic many LHDs had to create tracking and reporting processes and forms for antiviral management. These tracking and reporting processes were created with little to no guidance from state and federal partners. This led to variability in how much and what kind of information was being collected. LHDs’ antivirals tracking included inventory tracking at the storage site, tracking antivirals being dispensed either by the LHD or partner organizations, and in some cases, tracking the commercial supply of antivirals within the community.

Inventory tracking for receiving and storing antivirals was typically done with a paper-based system, or an Excel spreadsheet. Only the few LHDs with large warehouses used inventory management systems. No matter which tracking system they used, most LHDs reported no problems in this area. A few LHDs did, however, indicate that, while there were no problems with these systems, the only time they truly had an accurate count of the antivirals (or other supplies) was when staff manually counted everything.

Tracking antivirals being dispensed either by the LHDs or partner organizations was almost exclusively done with a paper-based system. LHDs created forms that they sent out to the providers, hospitals, clinics, and other organizations where they distributed antivirals. Then these organizations would complete them and typically fax or email them back to the LHD. Many LHDs implemented MOUs with these organizations, one part of which required that these organizations would routinely report to the LHDs about their antiviral dispensing activities. Most LHDs required the organizations to report weekly (regardless of whether or not an MOU was in place), with a few requiring daily updates in the beginning of the 2009 H1N1 response. The only challenge reported with this data collection system was that some providers would not fill out the forms in a timely manner.

Some LHDs, particularly in much smaller jurisdictions, simply called their points of contact on a weekly basis to obtain the needed tracking information. These LHDs reported that this system was slightly more time consuming but allowed the LHDs to gain situational awareness of how their community partners were operating, as well as helped maintain strong relationships throughout the 2009 H1N1 response.

The tracking information that LHDs received from the dispensing organizations were typically compiled manually into an Excel spreadsheet. These spreadsheets were then routinely (typically once a week) sent to the S/THDs to meet reporting requirements, as well as to the local EOCs to increase situational
awareness. Manually tabulating antiviral dispensing information took some time; most LHDs reported that they used volunteers to help.

In addition to tracking antivirals that the LHDs had distributed, a few LHDs reported tracking the commercial supply of antivirals available to their communities through pharmacies. The LHDs that did this reported that they either had preexisting personal relationships with the pharmacies, or the pharmacies in their jurisdictions very much supported working with the LHDs during the response. All of the LHDs reported that there were no formal agreements with these pharmacies to share this information. For further information about the relationship between pharmacies and LHDs please see Section 7: Communication.

**Tracking and Reporting—Planning Considerations**
- Develop a standardized set of data elements for tracking distribution and dispensing to minimize burden across organizations and more readily provide a common reporting method.
- Develop tracking and reporting systems that are easy to use by all partners and compatible with existing systems.
- Maintain situational awareness during an emergency by managing data regarding antiviral distribution and dispensing.

**11. Population Considerations**

As mentioned in the allocation and communications sections, during the 2009 H1N1 pandemic, S/THDs and LHDs worked to ensure that certain populations had access to antivirals or information about antivirals. S/THDs and LHDs considered individuals who needed special consideration to fall into one or more of the following groups: first responders/medical professionals; those at high-risk for severe illness, complications, or death (pregnant woman, immunocompromised, etc.); those with limited or no access to healthcare (uninsured, underinsured, homeless, etc.); and those who may have challenges accessing needed health information (non-English speakers; those with visual, auditory, or cognitive impairment, etc.).

**First Responder/Medical Professional Populations**

Prior to the 2009 H1N1 pandemic, planning for pandemic influenza had always considered the need for first responders and medical professionals to have access to antivirals. In addition, this had been discussed for other components of “critical infrastructure” within communities. A few S/THDs and LHDs reported receiving requests for antivirals from these populations. Most of these requests were based on planning protocol that stated that their unit/department/sector was designated to receive a cache of antivirals during an influenza pandemic. However, given the availability of antivirals in the commercial sector, the fact that this pandemic did not dramatically affect critical infrastructure, and that most if not all first responders, medical professionals, and other critical infrastructure staff have insurance, most public health agencies did not distribute antivirals to these populations. The experience highlighted the need to educate these groups on the spectrum of potential pandemic severity and the issues considered in whether or not to provide supplies for prophylaxis or treatment to such groups is warranted.

**High-Risk Populations**

In the event of a pandemic, some people will be more susceptible to the harmful consequences of infection than others. Addressing high-risk populations’ needs was a large concern for S/THDs and LHDs during the 2009 H1N1 pandemic. During the 2009 H1N1 pandemic, the CDC identified the following groups as high-risk and recommended antivirals if the individual was infected or, in some situations, exposed, to the 2009 H1N1 virus:
- Pregnant women.
• Individuals with chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological (including sickle cell disease), neurologic, neuromuscular, or metabolic disorders (including diabetes mellitus).
• Individuals with immunosuppression, including that caused by medications or HIV.
• People younger than 19 years of age who were receiving long-term aspirin therapy.
• Children younger than five years old. The risk for severe complications from influenza is highest among children younger than two years old.
• Adults age 65 or older.

The guidance the CDC issued regarding these high-risk groups was communicated to S/THDs, LHDs, and other community health partners. The CDC’s guidance served only as a recommendation, which allowed S/THDs, LHDs, and community partners flexibility to meet the needs within the community. Even among those included in high-risk groups, some individuals still had challenges accessing antivirals. Pregnant woman in particular faced this challenge, as many OB/GYNs do not commonly prescribe antivirals, and pharmacists were hesitant to dispense because of concerns for the safety of both mother and child. This issue highlights the need to ensure that proper guidance regarding antiviral use is communicated to all health practitioners, including pharmacists.

Health practitioners also influenced allocation decisions at the state and local level. For example, hospitals with large pediatric centers were often allocated additional antivirals. Although no LHDs specified that they did this for antivirals, for the H1N1 vaccine, many LHDs reported directly targeting Women, Infants, and Children (WIC) clinics, Head Start programs, TB or HIV Clinics, migrant workers vaccine clinics, or other initiatives that reached high-risk populations.

**Populations with Limited or No Access to Healthcare**

Although S/THDs and LHDs have similar missions to protect the health of their entire jurisdictions, many staff felt connected to their special role of serving populations without access to the healthcare system. Obtaining antivirals can be a particular challenge for those without access to the healthcare system, as a prescription is required and a five-day course typically costs more than $60. To address some of these communities’ needs, many states have programs to provide services and information, including the state-run Medicaid programs. Additionally, a few LHDs reported forming special committees to address different challenges regarding these populations. These committees focused on finding services for underserved populations and directly communicating with them.

S/THDs and LHDs developed policies and programs to dispense SNS antivirals to the uninsured and underinsured populations. ASTHO internal unpublished data showed that by November 2009 at least 50 percent of states had established programs to provide antivirals to under- and uninsured individuals. These programs varied from state to state. Some states provided antivirals only to patients who did not

have insurance, some states made antivirals available to anyone, and at least one state also provided clinical services in addition to antiviral drugs to uninsured patients if needed.

About half of the LHDs provide clinical services to underserved populations.26 One LHD reported it serves 12 percent of the population in its jurisdiction, and fills more than 200,000 prescriptions annually. Although LHDs routinely serve these populations, very few reported directly dispensing antivirals to these populations. The aforementioned health department reported only dispensing around 40 courses of antiviral medication for treatment. Most LHDs reported dispensing to even fewer patients.

In addition to direct outreach to these populations, S/THDs and LHDs reported allocating antivirals to specific providers, clinics, and pharmacies that serve uninsured/underinsured/homeless populations. LHDs targeted communication to the providers or clinics that were not provided antivirals to ensure they knew which of their patients were eligible for these antivirals and where they could direct their patients to receive them.

**Populations with Communications Challenges**

Communication with the public was a primary part of the 2009 H1N1 response. S/THDs and LHDs took particular steps to communicate with populations that may not have had access to health information through standard channels. Many jurisdictions translated 2009 H1N1 pandemic communications into multiple languages to ensure a broader audience received and understood the public health messages. Additionally, some jurisdictions worked hard to communicate with tribal or ethnic community leaders whose populations may not receive their health and medical information through mainstream media channels. One LHD reported insufficient communications and services for the blind, deaf, or other special needs populations.

During the 2009 H1N1 pandemic, LHDs worked to reach out to multiple vulnerable populations; however, some LHDs reported that they needed better strategies for reaching specific at-risk groups, particularly those that lack access to health information or care through other channels. Additionally, two LHDs reported rewriting their antiviral distribution and dispensing plans for future pandemics to specifically give greater emphasis on reaching vulnerable populations.

**Population—Planning Considerations**

- When planning all public health preparedness efforts, consider the role of first responders, medical professionals, and other critical infrastructure; however, not all emergencies may warrant the need for special provisions for these populations. Hold additional discussions with these groups before an emergency regarding when such provisions may or may not be warranted.
- Develop better strategies for reaching priority groups, high-risk populations, or those with communications challenges before a public health emergency. It is particularly important to establish relationships with providers or entities that already have strong relationships with these populations.
- Continue to consider the special needs of the populations with limited or no access to healthcare in their communities, and work to ensure these populations have access to medical countermeasures during an emergency.

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Limitations

The information presented in this report has multiple limitations, and the information within is not a representative sample of all S/THDs and LHDs. In particular, limited data were collected from LHDs compared to the approximately 2,800 LHDs in the United States. Therefore, the local perspective within each section may not be generally applied to all LHD experiences. Additionally, information collected for the S/THD perspective was taken from the 37 states that participated in the ASTHO H1N1 Antiviral Management Survey and key informant interviews. Most information for this report was collected from S/THDs and LHDs one to two years after the activities described occurred. This delay in data collection may have resulted in some recall bias from the participants. Additionally, most information in this report was self-reported data, which creates potential for reporting error or biases.

Conclusion

Managing medical countermeasures during a public health emergency, particularly a pandemic, is a critical public health function during a response. There was considerable variability in how antiviral medications were managed at the state and local level during the 2009 H1N1 pandemic; some tactics were very helpful in addressing local variability and changing needs while some presented distinct challenges. This report highlights 11 key areas that represent the accomplishments, lessons learned, and challenges of both state and local public health entities during the 2009 H1N1 response. Each state and local agency reported its own successes and challenges, which should be examined further as potential best practices that could be useful in planning for future emergencies nationwide.

Each section of the report highlights planning considerations for federal, state, and local public health officials. Although this report focuses on antiviral management, S/THDs and LHDs have many other roles to fulfill during a response. Without sustained investment in public health infrastructure, including staff, technology, supplies, and equipment, it will grow increasingly difficult for S/THDs and LHDs to mount the proper response needed for responding to an influenza pandemic. It is essential for federal, state, and local public health officials to consider their pivotal roles during a response, and what resources will be necessary to accomplish their mission to protect the health of their communities.

There were several advantages to the data collection and analysis method used in developing this report. Although there have been some efforts to understand how state and local health departments managed antivirals during the 2009 H1N1 pandemic, this was the first report that captured both perspectives and, to the extent possible, synthesized all key areas of the management process. The co-authorship between ASTHO and NACCHO provided a national-level perspective on state and local successes and challenges for antiviral distribution and dispensing. Additionally, the multiple mediums used for data collection and input from both ASTHO and NACCHO advisory groups allowed for multiple aspects to be recorded for antiviral management at both the state and local level, allowing for a more integrated cataloging of the broader public health enterprise’s experience.

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Managing Antiviral Medication during the 2009 H1N1 Influenza Pandemic


Appendices

Appendix I: Acronyms

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<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>AAR</td>
<td>After-action report</td>
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<td>ASTHO</td>
<td>Association of State and Territorial Health Officials</td>
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<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
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<td>CPA</td>
<td>Collaborative Practice Agreement</td>
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<td>Drug Enforcement Agency</td>
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<td>Department of Homeland Security</td>
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<td>Federally Qualified Health Center</td>
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<td>GSA</td>
<td>General Services Administration</td>
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<tr>
<td>HAN</td>
<td>Health Alert Network</td>
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<tr>
<td>HHS</td>
<td>U.S. Department of Health and Human Services</td>
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<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
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<tr>
<td>ICS</td>
<td>Incident command structure</td>
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<td>IRMS</td>
<td>Integrated Resource Management System</td>
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<tr>
<td>LHD</td>
<td>Local health department</td>
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<tr>
<td>LLIS</td>
<td>Lessons Learned Information Sharing</td>
</tr>
<tr>
<td>MACS</td>
<td>Multiagency Coordination Systems</td>
</tr>
<tr>
<td>MIMAL</td>
<td>Model Intrastate Mutual Aid Legislation</td>
</tr>
<tr>
<td>MOA</td>
<td>Memorandum of agreement</td>
</tr>
<tr>
<td>MOU</td>
<td>Memorandum of understanding</td>
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<tr>
<td>MSEHPCA</td>
<td>Model State Emergency Health Powers Act</td>
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<td>NACCHO</td>
<td>National Association of County and City Health Officials</td>
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<td>NEA</td>
<td>National Emergencies Act</td>
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<tr>
<td>NPS</td>
<td>National Pharmaceutical Stockpile</td>
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<tr>
<td>PBMs</td>
<td>Pharmacy benefit managers</td>
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<tr>
<td>PHEP</td>
<td>Public Health Emergency Preparedness</td>
</tr>
<tr>
<td>PHER</td>
<td>Public Health Emergency Response</td>
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<td>PHSA</td>
<td>Public Health Service Act</td>
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<tr>
<td>PODs</td>
<td>Points of distribution</td>
</tr>
<tr>
<td>RITS</td>
<td>RSS Inventory Tracking System</td>
</tr>
<tr>
<td>RSS</td>
<td>Receiving, staging, and storage</td>
</tr>
<tr>
<td>S/THD</td>
<td>State/territorial health department</td>
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<tr>
<td>SLE</td>
<td>Shelf-life extension</td>
</tr>
<tr>
<td>SNS</td>
<td>Strategic National Stockpile</td>
</tr>
<tr>
<td>Stafford Act</td>
<td>Robert T. Stafford Disaster Relief and Emergency Assistance Act</td>
</tr>
<tr>
<td>TAR</td>
<td>Technical Assistance Review</td>
</tr>
<tr>
<td>UEVHPA</td>
<td>Uniform Emergency Volunteer Health Practitioners Act</td>
</tr>
<tr>
<td>VHP</td>
<td>Volunteer health professional</td>
</tr>
<tr>
<td>VPA</td>
<td>Federal Volunteer Protection Act</td>
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<tr>
<td>WIC</td>
<td>Women, Infants, and Children</td>
</tr>
</tbody>
</table>
### Appendix II: ASTHO Antiviral Advisory Committee

<table>
<thead>
<tr>
<th>Name</th>
<th>Title/Position</th>
<th>Organization and Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thomas N. Ahrens, PharmD</td>
<td>Chief, Planning &amp; Response Branch</td>
<td>California Department of Public Health, Sacramento, CA</td>
</tr>
<tr>
<td>Susan R. Cooper, MSN, RN</td>
<td>Former Commissioner</td>
<td>Independent Consultant, Nashville, TN</td>
</tr>
<tr>
<td>Deirdre Z. Depew</td>
<td>Strategic National Stockpile Coordinator</td>
<td>New York State Department of Health, Menands, NY</td>
</tr>
<tr>
<td>Terry Dwelle, MD</td>
<td>State Health Officer</td>
<td>North Dakota Department of Health, Bismarck, ND</td>
</tr>
<tr>
<td>Shannon Callouri, PharmD</td>
<td>Director, Office of Public Health Preparedness</td>
<td>Pennsylvania Department of Health, Harrisburg, PA</td>
</tr>
<tr>
<td>Gregg Grunenfelder</td>
<td>Deputy Secretary</td>
<td>Washington State Department of Health, Olympia, WA</td>
</tr>
<tr>
<td>CDR Robert Hayes, RPh</td>
<td>Director, Indian Health Service National Supply Service Center</td>
<td>Oklahoma City, OK</td>
</tr>
<tr>
<td>Ralph M. Iler, Associate Director</td>
<td></td>
<td>New York State Department of Health, Menands, NY</td>
</tr>
<tr>
<td>Aggie Leitheiser, RN</td>
<td>Assistant Commissioner</td>
<td>Minnesota Department of Health, St. Paul, MN</td>
</tr>
<tr>
<td>A.J. Lorenzen, PharmD</td>
<td>Epidemiologist/Preparedness Pharmacist</td>
<td>State of Alaska, Anchorage, AK</td>
</tr>
<tr>
<td>Amanda Fuller Moore, PharmD</td>
<td>CHEMPACK Coordinator</td>
<td>North Carolina Department of Health and Human Services, Raleigh, NC</td>
</tr>
<tr>
<td>Michael Poole, MSPH</td>
<td>State SNS Coordinator</td>
<td>Texas Department of State Health Services, Austin, TX</td>
</tr>
<tr>
<td>Cathy Slemp, MD, MPH</td>
<td>Former Acting State Health Officer</td>
<td>Independent Consultant, Charleston, WV</td>
</tr>
<tr>
<td>Steve Wagner, JD, MPH</td>
<td>Chief, Office of Health Preparedness</td>
<td>Ohio Department of Health, Columbus, OH</td>
</tr>
<tr>
<td>CAPT. Thomas Weiser, MD</td>
<td>Medical Epidemiologist</td>
<td>Portland Area Indian Health Service/Northwest Portland Area Indian Health Board, Portland, OR</td>
</tr>
</tbody>
</table>
Appendix III: NACCHO Antiviral Advisory Workgroup—February 2012

Rachel L. Abbey, MPH
Program Manager, Advanced Practice Center for Public Health Preparedness
Montgomery County Maryland Department of Health and Human Services

Robert Einweck, BS
Emergency Preparedness Manager
St. Paul-Ramsey County Public Health Department

Michael Hill, MPH, MPA, FACHE, CNU-A
Public Health Director
City of El Paso Texas Department of Public Health

Heather Hogue, PharmD
Director of Emergency Planning and Response
Jefferson County Department of Health

Michael Loehr, MRP, CBCP
Preparedness Director
Public Health–Seattle & King County

Neal Lustig, MPH
Director of Health
Pomperaug District Department of Health

Cynthia Morgan, PhD, RN
Emergency Planner and Special Projects
Salt Lake Valley Health Department

Amy Pine, MPH
Immunization Coordinator
San Francisco Department of Public Health

Lisa A. Rosenfeld, MPH
Director
Emergency & Environmental Preparedness Solutions

Isaac Weisfuse, MD, MPH
Deputy Commissioner, Office of Emergency Preparedness and Response
New York City Department of Health and Mental Hygiene

Matt Zahn, MD
Medical Director
Louisville Metro Department of Public Health and Wellness
Appendix IV: ASTHO H1N1 Antiviral Management Survey Summary

In December 2010, ASTHO surveyed the 62 U.S. states, territories, and cities that receive Public Health Emergency Preparedness cooperative agreement funding to ascertain their methods for managing, deploying, and monitoring their antiviral assets before and during the 2009 H1N1 influenza pandemic. ASTHO received a total of 37 responses from 36 states and one large city.

Among the 37 respondents, 32 (86 percent) reported that they had a state-owned and managed supply of antivirals at the beginning of the 2009 H1N1 outbreak; five did not (NM, ME, AZ, CO, and NYC). All states were provided with a pro rata allotment of antivirals from CDC’s Strategic National Stockpile (SNS) at the beginning of the outbreak in spring 2009. Twenty-three states reported requesting additional antivirals from the SNS after this initial “push,” all of which were requests for pediatric formulations. Of these, 11 received additional pediatric doses, and 12 received adult formulation doses.

Seven states reported storing, managing, distributing, or dispensing federal-supplied antivirals differently than the state-purchased supply. Three of the seven did not use their state supply, but did use the federal supply. Three reported that different storage systems or locations were used. In North Carolina, for example, the state supply was stored in a commercial warehouse. The federal supply was delivered to the pre-designated receiving, staging, and storage (RSS) facility and needed to be moved in, sorted, and then moved out; it could not remain at that location because it was an operating warehouse that needed to continue its normal operations.

There was substantial variation in the frequency with which states worked with private/commercial entities for the five steps of antiviral management and deployment, as shown in Appendix Figure 1. States most frequently worked with commercial entities for supply monitoring (26 states), and least frequently for inventory management (10 states). Further discussion on these partnerships is provided below.

Appendix Figure 1. Frequency of Collaboration with Private/Commercial Entities

![Bar Chart]

Note: The term “state-held assets” refers to antiviral stockpiles acquired by states from private entities as well as federal SNS assets distributed to states.
Supply Monitoring
Twenty-six respondents (70 percent) worked with pharmacies and other private sector partners to monitor the supply and use of the commercial supply chain of antivirals before deciding how and when to use state/federal assets. States worked with pharmacies (12), including national chains (5) and hospital pharmacies (2); state pharmacy associations and boards of pharmacy (8); pharmaceutical wholesalers/distributors (2); and poison control centers (2). Two states said that they collaborated with pharmacies at the local level, and three reported using the CDC dashboard to supplement information gathered from these entities.

Partnership was done in a variety of ways. North Carolina formed a workgroup of the state’s major pharmacy chains, which were queried to determine supply and assess the extent of shortages. Mississippi used their state hotline for pharmacies to report shortages. Maine worked with the regional poison control center to survey hospitals and pharmacies regarding the size of their stockpiles; data were used to inform the state’s antiviral purchasing decisions. Utah created a statewide database for pharmacies to report into each week.

Seven states (19 percent) did not work with pharmacies or other private entities to monitor commercial supply. Among these, Tennessee reported using TennCare (Medicaid) utilization data to track usage trends, but said this did not affect their distribution plans. New York State and Washington used data from the CDC dashboard instead; Washington also used information from local jurisdictions to monitor supply.

Storage and Warehousing
States were more split on using commercial entities for antiviral storage and warehousing, with 15 (41 percent) responding that they worked with private entities and 22 (59 percent) responding that they did not. AmerisourceBergen, McKesson, and the state pharmacy association were mentioned as partners, along with several unnamed commercial distributors and pharmaceutical wholesalers. (Some states could not name the entity they work with due to other sensitive functions performed by the entity.) Among those that did not work with commercial entities, 17 (77 percent) reported that state-owned and managed warehouses had sufficient capacity and capabilities, and were used for this function.

Inventory Management
Ten states (29 percent) reported working with commercial entities for inventory management of state-held assets, including AmeriSource Bergen (VA, AL), McKesson (AL), pharmacies (ME), and the state pharmacy association (KY). Virginia, Maine, and Alabama used public resources in addition to their private partnerships: the state Medicaid system, Northern New England Poison Center, and the state web-based ordering/inventory program, respectively. Louisiana noted their use of the Integrated Resource Management System (IRMS) as well. As in the previous question, some states did not specify the company name.

Twenty-five states (71 percent) did not use a commercial entity for inventory management. Of these, 20 noted various ways these functions were performed in-house by the state health agency, including Excel spreadsheets (8), state immunization information system (IIS, 3), the RSS Inventory Tracking System (RITS, 4), the Countermeasure Response Administration (1), or other electronic systems developed for the state. New Mexico initially used Excel spreadsheets, then transitioned to the state IIS and integrated the SNS module into that system. New Hampshire tracked inventory in-house, but worked very closely

27 The term “states” is used throughout this document for ease of reading; it does not necessarily indicate that New York City is not among the respondents included in the statement.
with a retail pharmacy to do so, noting that they could not get a contract executed in time for the pharmacy to do the work.

Five states explained their rationale for not using commercial entities, simply stating they felt there was no need given the state’s existing capacity and plans.

Of the four states who reported using RITS, three transitioned to using Excel spreadsheets instead because the system did not meet their needs for this response. Additionally, one of the three states that used the state IIS reverted to spreadsheets for similar reasons.

**Distribution**

Twenty-four states (69 percent) worked with commercial entities for antiviral distribution of state-held assets, including UPS (4), FedEx (3), AmeriSourceBergen (2), McKesson (1), Old Dominion Freight (1), SR Moving & Storage (1), Swift Transportation (1), Quicksilver (1), MetroCourier (1), Cardinal Health (1), the state pharmacy association (1), and various pharmacies (1). Mississippi noted a transition in their distribution—the state has MOUs with private warehouses for the RSS that provides distribution while the RSS is activated; once RSS operations ceased, UPS was used for subsequent distribution. Maine used a combination of state and private resources: the Maine Army National Guard distributed 90 percent of the federal allotment to 10 hospital locations, while the state-purchased cache was distributed by the Maine Department of Transportation to one Hannaford warehouse that then redistributed it to 41 Hannaford stores, 15 independent pharmacies, and 27 federally-qualified health centers statewide. Eleven states (31 percent) did not work with commercial entities for distribution, largely due to in-state resources being used instead. Six of the eleven states reported using entities such as the state departments of transportation, emergency management, and civil air patrol, or distributing to local health departments via state-owned vehicles. New Mexico noted that the state had a commercial contract for distribution that they wanted to use. However, due to initially having insufficient funding and the state not declaring a health emergency to draw down emergency funding, the decision was made to distribute antivirals statewide via the New Mexico Bureau of Health Emergency Management with some assistance from other departments. Washington started with a commercial carrier; however, the carrier had several personnel changes and did not accomplish the deliveries as requested so distribution tasks were transferred to the Washington State Department of General Administration’s surplus program, which operates a fleet of trucks to deliver statewide. Delaware reported that the Delaware Division of Public Health utilized staff drivers because demand for distribution did not exceed their capacity; if demand had been larger, the state would have used a contract service.

**End-User Dispensing**

Twenty-two states (66 percent) partnered with commercial entities for end-user dispensing of antivirals, including Walgreens (7), Kroger (3), Fred’s (3), Hannaford (2), CVS (2), Walmart (2), Rite Aid, Target, Kmart, Publix Super Markets, and several others. Seven other states reported working with retail/chain pharmacies but didn’t specify the name and 12 states worked with local or independent pharmacies. Minnesota established contracts with approximately 600 community retail pharmacies that received a case of antivirals and a system for having their administration fee reimbursed, to be used in accordance with state policy for the un- and underinsured. They also used hospitals, clinics, and local health departments to dispense medications. Vermont sent the state stockpile and federal allotment to hospitals. They prepared plans and formalized agreements to ship to other entities, such as community health centers and commercial outlets using the state’s pharmaceutical distributor; however, this plan was never utilized. Delaware partnered with hospitals and both large and small retail pharmacies; 95 percent of the pharmacies in the state were included in the dispensing plan.

All of the states that worked with pharmacies for dispensing said they would do so again, with one saying they would do so earlier in the process. Reasons for continued partnership include:
• Pharmacies’ location and existing relationships with target audience, and ability to both store/manage the supply and provide medical counseling to patients.
• They were the only way to ensure that the medicines were dispensed by prescription according to state and federal law.
• Pharmacies were committed to assisting the delivery of antivirals without any payment to them.
• It encourages long-term relationships.
• Challenges related to dispensing through hospitals and other healthcare facilities: “[hospitals] are not used to [distributing] on such a large scale and used the provided antivirals in unexpected ways, such as providing single doses to patients, then sending them out with prescriptions to pharmacies, which didn’t reduce the pressure on the commercial supply at all”; dispensing added an additional burden on hospitals when they were already dealing with a surge in patients; and some hospitals and clinics would not dispense antivirals to non-patients of their systems. One state noted that they would likely use pharmacies again, though it was evident that, as with hospitals, pharmacies had problems with reporting and inventory reconciliation.
• “Allowed health department staff to focus on vaccination response and while allowing pharmacies to do what they do best—dispensing drugs.”
• “It was easier for us to distribute the antivirals and let the public know where they could get supplies [than] us distributing.”

North Carolina said that although the state did not directly connect with any commercial entities for dispensing, they used the state/pharmacy workgroup to assist local health departments in making contacts with many of the chains’ corporate offices, and they have not heard from any local health department that did not have success using the pharmacies in their area. Rather, many of the locals would like the state to implement agreements with the larger chains for distribution at the state level similar to what was done with the H1N1 vaccine. Vermont reported that although they did not use a commercial entity during the 2009 H1N1 pandemic, they did prepare for the potential use and noted information reporting requirements would prove to be a challenge. However, they would reassess the option as an alternative in the future.

Twelve states (34 percent) did not partner with commercial entities for dispensing. Of these, eight reported that plans and decisions for this are done at the local level. Three of these eight mentioned that local jurisdictions had worked with pharmacies. For others, information was not available.

Four states developed alternative methods of prescribing antivirals. Minnesota, New Mexico, and North Carolina all developed call-in lines; this was done at the regional or local levels in New Mexico and North Carolina. The Minnesota Flu Line was established as a public-private partnership with a medical call-in system so patients throughout the state could call in and if symptomatic, receive a prescription that was sent to their preferred pharmacy. If they were un- or underinsured, the antivirals came from the state or federal supply. Oregon wrote guidance for altered standards of care and noted that local jurisdictions in some cases used triage lists.

**Future Collaborations and Lessons Learned**

States offered a variety of lessons learned to inform future collaborations. Most frequently, states discussed the importance of improving inventory tracking and reporting from pharmacies on doses dispensed. Suggestions on how to do this include developing, testing, and providing information to pharmacies about the reporting mechanism before the event (“as it was, the system was ad hoc and ended up providing bad data”); developing a CDC-managed inventory management system; and ensuring federal supplies have unique National Drug Codes to facilitate accurate tracking. Tennessee recommended engaging pharmacy benefit managers (PBMs) to report utilizing a specific countermeasure because it took the reporting responsibility off of the individual pharmacy.
Several states also commented on the benefits of engaging with pharmacies and having agreements in place with them before the event, as well as providing education and clear guidance about the state pandemic plan and protocols for antiviral storage, tracking, use and disposal/recollection of remaining supplies after the event. One state noted the importance of engaging the state board of pharmacy early as well. Frequent communications with entities holding supplies was also recommended. Although one state emphasized that decisions regarding pharmacy engagement should be handled at the state or local levels due to disruptions in communications and planning initiatives that resulted from direct federal involvement, another state suggested that national-level interaction with the large pharmacy chains could be helpful in encouraging them to participate with states.

Payment issues were noted several times, with one state recommending using in-place invoicing systems rather than creating a new system. Another state suggested determining and standardizing the reimbursement amount for compounding and dispensing as early in the response as possible. Lastly, two states encouraged working with multiple partners—in one case, signing contracts with multiple trucking companies for distribution. The other state noted that multiple partners would be beneficial to ensure back-up options if one agency or partner experiences unforeseen issues.

**Conclusions**

States worked with private sector entities to varying degrees before and during the 2009 H1N1 pandemic. Although some states had very positive experiences, others struggled to overcome key barriers. Many states encountered the same or similar issues in their collaborations, with pharmacies in particular, including challenges regarding exchange of data, contracting and payment, and formalizing agreements. Resolving these issues will be extremely beneficial for pharmacy collaborations overall.
Appendix V: Summary of Primary Legal Issues and Solutions Relating to Antiviral Distribution and Dispensing

<table>
<thead>
<tr>
<th>Issues</th>
<th>Solutions</th>
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<tbody>
<tr>
<td><strong>I. Setting the Stage: Pre-Emergency Strategic Planning and Preparedness</strong></td>
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<tr>
<td>1. Federal, tribal, state, and local jurisdictions face logistical and legal impediments to sharing personnel, supplies, and resources.</td>
<td>Advancing contracts, compacts, and MOUs between jurisdictions and entities prior to an emergency can address and resolve anticipated needs.</td>
</tr>
<tr>
<td>2. Rigid contractual requirements may not allow sufficient flexibility for contingencies during emergencies.</td>
<td>Non-binding MOUs and compacts are flexible to promote collaboration and adjustment based on circumstances, but they may also reduce certainty as to specific performance.</td>
</tr>
<tr>
<td><strong>II. Real-Time Responses: The Changing Legal Environment in Declared States of Emergency</strong></td>
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<tr>
<td>3. Existing, routine laws and policies may thwart mass antiviral distribution and dispensing in emergencies.</td>
<td>Emergency, disaster, or public health emergency declarations change the legal landscape, often allowing for the waiver of inconsistent or conflicting laws.</td>
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<tr>
<td>4. No single declaration provides all necessary coverage, resources, or authorities.</td>
<td>Declarations are not mutually exclusive, thus allowing multiple types of declarations across all levels of government.</td>
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<td>5. Distributors, pharmacists, public health practitioners, and emergency responders may be unsure of the legality of actions or omissions.</td>
<td>Practicing “legal triage” prior to and during declared emergencies through emergency planners, practitioners, and private entities helps prioritize legal issues, develop solutions, and communicate them to relevant actors in real-time.</td>
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<tr>
<td>6. Exercise of some emergency public health powers can impede distribution plans (closures, evacuations, curfews).</td>
<td>Emergency managers, public health officials, and others can work with distributors and pharmacies to limit impact on distribution and dispensing.</td>
</tr>
<tr>
<td><strong>III. Moving the Product: The Challenges of Antiviral Distribution across Jurisdictions</strong></td>
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<tr>
<td>7. Federal and state regulations concerning wholesale distributors could impede emergency antiviral distribution.</td>
<td>Although the Prescription Drug Marketing Act and federal/state regulations could restrict distributions, federal and state laws may exempt emergency response efforts, and advance agreements may address remaining conflicts.</td>
</tr>
<tr>
<td>8. State and local governments may need to obtain distributors’ licenses to assist in distributing antivirals.</td>
<td>Federal and state laws may exempt emergency response from the definition of wholesale distribution (negating the need for a license), but licenses could be obtained in advance if required.</td>
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<tr>
<td>9. Distributors may be liable for losses or damages to antivirals in transit.</td>
<td>Advance agreements may identify standards for liability. Otherwise, there is no liability generally for losses in transit absent failure to exercise reasonable care under the circumstances.</td>
</tr>
<tr>
<td>10. Large quantities of overstock and expired antivirals need to be removed and destroyed.</td>
<td>CDC may work contractually with states to coordinate removal and disposal to avoid antiviral diversion or environmental hazards.</td>
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<tr>
<td>11. Antivirals may reach their expiration date during an emergency.</td>
<td>FDA can authorize continued use of expired antivirals based on testing via the federal Shelf-Life Extension Program.</td>
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<tr>
<td><strong>IV. Dispensing Antivirals: Roles and Responsibilities of Pharmacists</strong></td>
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<tr>
<td>12. Individuals may lack the ability to obtain prescriptions in an emergency.</td>
<td>States can waive prescription requirements or allow mass dispensing under emergency prescription drug orders.</td>
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<tr>
<td>13. Counseling, labeling, and other needs may be difficult to meet in an emergency.</td>
<td>Requirements can be relaxed or waived via executive or legislative orders or by pharmacy boards in a declared emergency.</td>
</tr>
<tr>
<td>14. Pharmacists may need to compound antivirals to address needs or shortages.</td>
<td>General compounding authority, waivers of existing legal restrictions, or EUAs can facilitate pharmacists’ compounding.</td>
</tr>
<tr>
<td>15. Dispensing costs may need to be reimbursed, including through other states’ Medicaid programs for displaced residents.</td>
<td>Agreements or contracts with CDC or other agencies providing antivirals may allow for sharing separate dispensing fees. Medicaid reimbursement restrictions in many states may be waived. Pharmacies may need to register with other states’ Medicaid agencies, but can and should do so in advance.</td>
</tr>
<tr>
<td>16. Uninsured patients may need coverage to pay dispensing fees for antivirals.</td>
<td>The Emergency Prescription Assistance Program or similar state programs may provide coverage to uninsured recipients.</td>
</tr>
<tr>
<td>17. Appropriate antivirals may not yet be FDA-approved or approved for a specific use.</td>
<td>FDA can issue an EUA to allow dispensing qualifying products from any source during the emergency and can prioritize pre-emergency advance submissions, subject to FDA restrictions.</td>
</tr>
<tr>
<td>18. Legal restrictions on allocating antivirals may depend on the product’s source.</td>
<td>Advance agreements and federal/state coordination on dispensing priorities can clarify distinctions among differing caches.</td>
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<tr>
<th><strong>V. Meeting Surge Capacity: Ensuring and Empowering Personnel</strong></th>
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<tr>
<td>19. Wholesale distributors face workforce gaps during an emergency due to predictable loss of personnel.</td>
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<tr>
<td>20. More pharmacists/technicians may be needed to assist in mass dispensing during an emergency.</td>
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<tr>
<td>21. Delays in waivers or other permissions could impede rapid deployment and use of volunteers.</td>
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### VI. Providing Incentives for Participation: Liability and Other Protections

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<td>22.</td>
<td>Meeting the routine medical standard of care is difficult during an emergency.</td>
<td>In an emergency, a “crisis” standard of care may apply, allowing legal adaptation to changing circumstances and increased demand.</td>
</tr>
<tr>
<td>23.</td>
<td>Pharmacists, technicians, and volunteers may need to act beyond their scope of practice in an emergency.</td>
<td>Emergency laws, collaborative practice agreements, and waivers of pharmacy/medical board restrictions can allow administration of drugs, adjustment or issuance of prescriptions, or other functions by qualified personnel.</td>
</tr>
<tr>
<td>24.</td>
<td>Individuals and entities participating in emergency response could be subject to malpractice or other liability claims.</td>
<td>Absent gross negligence or willful/criminal acts, many actors and entities are protected from liability claims under various laws (e.g., PREP Act, Federal Volunteer Protection Act, MSEHPA, Model Intrastate Mutual Aid Legislation, UEVHPA, Emergency Management Assistance Compact).</td>
</tr>
<tr>
<td>25.</td>
<td>Patients injured through the administration of antivirals during an emergency may require compensation.</td>
<td>The federal PREP Act establishes funds for compensating individuals injured during administration of medical countermeasures, including dispensing antivirals.</td>
</tr>
<tr>
<td>26.</td>
<td>Emergency volunteers could be injured as part of their response efforts and require compensation.</td>
<td>The UEVHPA and corresponding state laws extend basic workers’ compensation protections to licensed, vetted emergency volunteers.</td>
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### VII. Tracking Antivirals: Supplies, Prescriptions, and Patients

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<td>27.</td>
<td>Real-time tracking and reporting of antiviral distribution and dispensing are uncommon in non-emergencies.</td>
<td>Public health reporting requirements may be legally authorized under various emergency laws or under a MOU or contract with distributors or pharmacists.</td>
</tr>
<tr>
<td>28.</td>
<td>Public health agencies may need identifiable health information to uncover circumstances affecting the public’s health.</td>
<td>Public health reporting laws may require reporting unusual trends, types, or rates of prescription and diseases or conditions of public health importance using identifiable health data.</td>
</tr>
<tr>
<td>29.</td>
<td>Pharmacist reporting identifiable health information to public health authorities implicates privacy concerns.</td>
<td>Disclosures of identifiable health information to public health authorities are expressly permitted under the HIPAA Privacy Rule and multiple state laws.</td>
</tr>
<tr>
<td>30.</td>
<td>Pharmacists are not well-positioned to aggregate large amounts of patient data.</td>
<td>CDC may use de-identified patient data collected by data processing agencies without violating health privacy rules.</td>
</tr>
</tbody>
</table>

*Note: Legal analysis is still being conducted. The findings presented here are from a draft report and may change after the publication of this report.*
## Appendix VI: Relevant State Law Template and Examples Regarding Antiviral Distribution and Dispensing

<table>
<thead>
<tr>
<th>State or Jurisdiction</th>
<th>I. Emergency Declarations(^a)</th>
<th>II. Pedigree Requirements(^b)</th>
<th>III. Distributor Licensure Requirements(^c)</th>
<th>IV. Prescription Labeling(^d)</th>
<th>V. Prescription Assistance(^e)</th>
<th>VI. Liability Protections(^f)</th>
<th>VII. Workers’ Compensation for VHPs(^g)</th>
</tr>
</thead>
</table>

\(^a\) “Emergency Declarations” include legally defined public health emergencies and other emergency declarations available to state officials.

\(^b\) “Pedigree Requirements” include state prescription drug pedigree requirements that supplement or exceed federal standards.

\(^c\) “Distributor Licensure Requirements” include state-based requirements or exceptions to distributor licensure as applied to state or local governments attempting to move drugs during declared emergencies or other similar circumstances.

\(^d\) “Prescription Labeling” includes state prescription drug label content mandates that exceed federal requirements.

\(^e\) “Prescription Assistance” includes legally authorized, state-based programs that defray prescription drug costs through subsidies, Medicare gap coverage, or discount plans.

\(^f\) “Liability Protections” include statutory or regulatory liability protections for healthcare workers, volunteers, or entities during a declared emergency.

\(^g\) “Workers’ Compensation for VHPs” includes state workers’ compensation laws that apply coverage to volunteer health practitioners in a declared emergency.