

Environmental Scan of  
H1N1 Reviews and After-Action Reports:  
Identifying Policy and Legal Issues

Prepared for the  
Association of State and Territorial Health Officials

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Logan Circle Policy Group LLC



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## Introduction

A novel influenza virus emerged in April 2009 and by June 2009 had created such widespread concern over its potential to cause global illness and death that the World Health Organization (WHO) declared an influenza pandemic. The novel H1N1 pandemic prompted a massive and coordinated response from the U.S. public health system. It provided the first opportunity for the public health system to implement the national response strategy and the states' pandemic influenza operational plans in a real-world setting. While the nation's combined response efforts were commendable, there was also acknowledgment that the policies and plans did not fully anticipate and compensate for the specific events and circumstances which unfolded.

The Centers for Disease Control and Prevention (CDC) funded the Association of State and Territorial Health Officials (ASTHO) and the National Association of County and City Health Officers (NACCHO) to conduct a special project, *Assessing Policy Barriers to Effective Public Health Response to the H1N1 Influenza Pandemic*, to systematically identify and assess key policy barriers—both legal and non-legal—encountered during the H1N1 response and offer a course of action to address these barriers. The goal of the project was to advance continued strengthening and overall improvement in the national public health system's collective capabilities to effectively respond to future pandemics and other emerging threats by addressing the barriers encountered during the H1N1 response.

The H1N1 Policy Barriers Project differed from typical after-action reviews (AARs), which look at both areas of success and areas for improvement, by focusing almost exclusively on policy and legal barriers. As such, the project did not actively seek out information about successful elements of the H1N1 response, which were many. To the extent that states' provided information about H1N1 response successes, however, it was captured in the project's various elements.

It is also important to note that the H1N1 Policy Barriers Project was not intended to be a substitute for states' and territories' H1N1 AARs nor was the timing such to capture and consider the states' and territories' AAR findings for possible inclusion in this report. All jurisdictions are in the process of completing full AARs and other evaluations in the aftermath of H1N1.

## Project Elements

There are four elements to ASTHO's H1N1 Policy Barriers Project:

- Environmental scan of in-progress reviews, after-action reviews, and other evaluations of H1N1 response activities;
- Survey of state and territorial health officials and key health agency staff;
- H1N1 response reviews conducted in five selected states; and
- H1N1 Policy Barriers Project Advisory Panel to review findings from the first three elements, identify top priorities for action, and make recommendations for mitigating the priority barriers.

Using all of these elements, ASTHO created a composite picture of the barriers identified, their impacts, and states' suggestions for mitigating the barriers' affects with the goal of improving the outcomes of future public health responses. This report is a synthesis of the many observations, comments and professional opinions on policy barriers encountered which have been shared by contributing state and territorial public health officials; it is not being represented as a consensus of the practice community.

ASTHO retained Logan Circle Policy Group LLC to assist with each phase of the project, write reports analyzing each of the project elements, and write a comprehensive final project report for ASTHO that compiled and analyzed the data and recommendations from each phase. This document, *Environmental Scan of H1N1 Reviews and After-Action Reports: Identifying Policy and Legal Issues*, is one of the project element reports.

### **Defining “Policy Barrier”**

For the purposes of the project, ASTHO defined a “policy barrier” as a plan, course of action, principle or procedure adopted by a governmental entity which impeded or impaired an agency’s/jurisdiction’s ability to more effectively respond to the H1N1 public health emergency. Barriers described through this project warrant remedial consideration since they will most likely recur in a future emergency. A policy barrier could be of a legal (e.g., a federal or state statute, regulation, or other legal authority) or non-legal (e.g., federal or state administrative order, agency guidance) nature, and of national, regional or intrastate scope. While important, it was not the primary intent of this project to capture issues of concern dealing with the operational, logistical, and administrative elements of the response; such issues were considered to the extent they revealed underlying policy and legal barriers.

To assist respondents in identifying potential policy and legal barriers, ASTHO created a list of policy barrier categories. The list provided was neither exhaustive nor was it intended to lead or narrow respondents’ identification of barriers; it was intended to prompt thought and stimulate recall of important issues that arose during states’ H1N1 response activities. (See Table 1 below for the complete categories list.)

The same list of categories was used in all project activities (scan, survey, meetings, advisory panel) to provide a common framework in which to compile and analyze the large amounts of data gathered about the public health system’s response to H1N1.

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**TABLE 1**

**ASTHO H1N1 Policy Barriers Project Potential Policy Barrier Categories**

**ICS, Command and Control, and Authority**

- H1N1 Response Command
- Emergency Declarations
- School Dismissal/Closure and Community Mitigation Measures
- Quarantine/Isolation/Travel Restrictions
- National Guidance/Standards
- Liability Protections
- PREP Act (General)

**Surveillance, Epidemiology, and Laboratory Services**

- Laboratory Services
- Epidemiology
- Surveillance Data Collection/Analysis
- Reporting of Estimated Cases, Deaths and Hospitalizations
- Surveillance Guidance/Policies
- Surveillance, Epidemiology, and Laboratory Services (General)

**Medical Care and Countermeasures**

- Identification/Formulation
- Manufacture
- Stockpiling and Distribution
- Commercial Supply Chain Visibility
- Countermeasure Response and Administration (CRA) System
- Delivery/Administering
- Emergency Use Authorization
- PPE/Infection Control Procedures and/or Requirements (including N95 Respiratory Protection)
- Adverse Events Reporting
- EMTALA and HIPAA
- HAVBED Reporting
- Countermeasures Injury Compensation
- Medical Care and Countermeasures Guidance/Policies
- Medical Care and Countermeasures General

**Workforce, Capacity, and Infrastructure**

- Flexing Existing Staff
- Surge Capacity (e.g., public health, health care, pharmacy)
- Volunteers
- Workforce Mandates (e.g., vaccination)
- Workforce/ Capacity/Infrastructure (General)

**National Vaccination Campaign**

- Formulation and Manufacture
- Allocation Approaches
- Stockpiling and Distribution
- Delivery/Administering
- Reporting of doses administered (vaccine and/or antivirals); Tracking for recall of pediatric second dose vaccination
- Liability Protection
- Vaccination Authority (e.g., efforts to expand the pool of vaccinators by including dentists or a broader age range for pharmacist vaccination)
- Inventory Management
- Reimbursement for Services (including CMS Medicaid and CHIP)
- Adverse Events Reporting
- Coverage Determination and Reporting
- Vaccination Guidance/Policies
- Vaccination (General)

**Federal/State/Local Coordination**

- Categorical Grant/Cooperative Agreement Flexibility
- Common Operating Picture/Platform
- Public Health and Health Care Sector Interaction
- Stakeholder Engagement
- PHER Grants
- Technical Assistance
- Stafford Act Applicability and Provisions
- Coordination (General)

**Communication**

- Media relations and ad campaign efforts
- Public outreach
- Stakeholders
- Policy Makers
- FOIA Requests and Disposition
- Communication (General)

**Other**

- Issues not arising under other thematic areas
- Unintended Consequences/Conflicts (areas in which a law/policy to address one issue had unintended consequences/conflicts in another area).

## I. Environmental Scan Methods

The environmental scan component of the ASTHO H1N1 Policy Barriers Project was designed to identify, compile and analyze previous observations made about the policy and legal issues that arose during the public health system's H1N1 response efforts. Data for the scan was drawn from the numerous prior in-progress reviews (IPRs), after-action reviews (AARs), other evaluations of H1N1 response, and recent general pandemic preparedness reviews conducted in 2009 and early 2010. State AARs, which are in the process of being developed, were *not* included in the environmental scan. Documents available as of May 1, 2010 were considered in this scan.

The scan encompassed approximately 30 published or distributed sources identified by ASTHO, which included IPRs, AAR, other H1N1 evaluations, reports and articles, and recent pandemic preparedness assessments. The environmental scan was not intended to be a comprehensive review or a literature review of all materials evaluating H1N1 response efforts. Priority was given to IPRs, AARs, and other evaluations by agencies and organizations involved in preparing for and responding to the outbreak. As such, the scan focused primarily on federal, state and local governmental, non-governmental organization, and academic center resources. A listing and brief description of the reviewed sources is included in Appendix 1 of this report.

Data from the resources was organized into the major categories used throughout the ASTHO H1N1 Policy Barriers Project: (A) ICS, Command and Control, and Authority; (B) Surveillance, Epidemiology, and Laboratory Services; (C) Medical Care and Countermeasures; (D) National Vaccination Campaign; (E) Workforce, Capacity, and Infrastructure; (F) Federal/State/Local Coordination; and (G) Communications. These categories were further refined into subcategories to assist in organizing the data. The subcategories are identified at the beginning of topic area in Section III, “*Environmental Scan Data.*”

## Limitations

Some limitations should be noted with the environmental scan. First, the review included only a relatively limited number of documents. Many of the documents that were reviewed, however, were evaluations/reviews conducted or sponsored by governmental agencies like CDC and the U.S. Department of Health and Human Services (HHS) or by organizations representing public health partner organizations like ASTHO. These sources were considered to be the most relevant in identifying information for the H1N1 Policy Barriers Project. Next, a number of the reviews were conducted during the initial phases of the outbreak in spring and summer 2009. The issues and problems identified earlier in the response may have been addressed or made obsolete as response efforts evolved. Finally, some of the sources addressing pandemic influenza preparedness generally were researched or drafted prior to the advent of the H1N1 outbreak, but released during the course of the event. The sources provided insight into the perceived status of various aspects of the public health system’s general preparedness for pandemic influenza.

## II. Overview of Environmental Scan Data

The environmental scan was conducted to create a baseline of issues that state health agencies and the public health system encountered as the H1N1 outbreak and response progressed. The IPRs, AARs and other assessments identified many logistical, operational and administrative issues—especially during the early months of the outbreak—but also addressed policy questions. Where logistical, operational and administrative issues arose, some of these were the result of either direct or indirect policy/legal decisions. The reports and reviews by non-governmental organizations and some federal government organizations (e.g., Congressional Research Service, Government Accountability Office) tended to focus more on long-term issues contributing to pandemic preparedness (e.g., health care surge, public health infrastructure). The issues identified in the environmental scan are consistent with the issues/themes raised in the other elements of the ASTHO H1N1 Policy Barriers Project (survey, state meeting reports, and Advisory Panel meeting).

The following summaries provide a brief overview of the issues/topics identified in the environmental scan. Again, **much of the data used in the environmental scan came from sources developed as the**

**H1N1 outbreak was ongoing; the below summaries should be reviewed with this in mind.** The detailed scan data is contained in Section III, “*Environmental Scan Data.*”

## **ICS, Command and Control, and Authority**

### *Emergency Declarations*

More clarification was needed about the implications of the various types of federal emergency declarations. Inconsistent wording of federal emergency declarations caused confusion. Issues were also identified regarding federal Stafford Act applicability and its provisions, as well as state emergency declarations. There was a need to examine alternative state legal and policy approaches to expanding authority and improving response during public health emergencies. Clearer messaging was needed regarding emergency authorities and community mitigation measures.

### *Statutory and Regulatory Waivers*

States needed to share information about their approaches to statutory/regulatory waivers. More work was needed in identifying all state laws/policies that should be waived during a response. Timelier issuance and standard formatting was needed for Medicaid waivers issued by the Center for Medicare and Medicaid Services (CMS). There was a need to better identify the parameters and implications of Emergency Medical Treatment and Active Labor Act (EMTALA) waivers.

### *PREP Act*

A number of issues were identified regarding the Public Readiness and Emergency Preparedness Act (PREP Act): clarifying the relationship between PREP Act and state liability protections; clarifying the language and scope of PREP Act immunities; clarifying the extent of PREP Act liability coverage and scope of remedies available; better defining adverse incidents under the PREP Act; examining the interplay between the PREP Act and emergency use authorizations (EUAs); and reviewing PREP Act liability coverage for private points of dispensing (PODs).

### *Community Mitigation Measures Generally*

The following issues were identified regarding community mitigation measures: questions about implementing community mitigation measures; the need for guidance to public health agencies for high-risk and vulnerable populations; the need to refine messaging around community mitigation measures; and tracking implemented community mitigation measures.

### *School Dismissal and Closure*

The officials/agencies that had the authority to close schools should be clearly identified. State and localities needed clear recommendations on closing schools, as well as refined messaging regarding school closure. There needed to be reporting and tracking of school closures. Efforts should have been made to identify and plan for the consequences of school closure decisions. Overall, more resources were needed to assist schools in preparedness planning activities.

### *Travel Restrictions/Quarantine and Isolation*

There was a need to identify practical barriers and solutions for implementing quarantine and isolation. Legal authorities to close borders should be reviewed.

### *Other Issues*

Two other issues were identified. First, the needs of and issues surrounding undocumented persons should have been considered. Second, consumer protection and price gouging issues were a concern.

## **Surveillance, Epidemiology, and Laboratory Services**

### *Surveillance Data Collection and Analysis*

A number of issues arose on the following topics: information sharing between epidemiologists and laboratorians; data collection issues; surveillance guidance; and strategies and surveillance system needs.

### *Reporting of Estimated Cases, Deaths and Hospitalizations*

States expressed concerns about the following issues: guidance on reporting cases; case reporting and privacy; and messaging about cases, deaths, hospitalizations.

### *Laboratory and Epidemiologic Services*

States noted that demands on public health laboratories needed to be better managed during the outbreak. Concerns were also expressed about the varying capacities for global surveillance. There were also long-term needs identified in addressing surveillance, epidemiology, and laboratory research and development requirements.

## **Medical Care and Medical Countermeasures**

### *Medical Countermeasures Generally<sup>1</sup>*

States identified concerns over planning and decision making for allocating countermeasures. Additional guidance was needed regarding the appropriate use of countermeasures. Regarding the Strategic National Stockpile (SNS), it was noted that CDC needed to review and revise its guidances and policies. States also raised issues and questions about the distribution and delivery of SNS assets; ownership and use of SNS assets after distribution; local distribution of countermeasures; and tracking the use of SNS assets. Additional planning and exercising was needed regarding the deployment of SNS assets.

States identified a number of issues related to inventory management and the supply chain for countermeasures, including: supply chain visibility and status; data about inventory/supply chain; redirection of assets; and inventory storage and security issues. There was a need for guidance and funding for disposing of countermeasures.

Regarding the administration of countermeasures, states identified issues/questions in the following areas: administering countermeasures to federal employees; access to countermeasures by special and vulnerable populations; and questions about fees for dispensing assets from stockpiles.

### *Antivirals*

States acknowledged that investments in pandemic planning and stockpiling antiviral medications paid off. Questions and concerns were raised about: antiviral formulation options; compounding antivirals; and the need to clarify antivirals policy guidance.

Several issues were identified regarding antiviral stockpiles, inventory management and supply chain matters, including: supplies, distribution, delivery and use of SNS antivirals; private stockpiles; supply chain visibility; and antiviral extension and relabeling.

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<sup>1</sup> This section refers to medical countermeasures generally, which may include antivirals, personal protective equipment (PPE) and vaccines, in addition to other measures. Issues specifically related to antivirals, PPE or vaccines are also addressed in separate sections of the summary.

Regarding administering antivirals, a number of issues were raised, including: questions about the legal requirements for administering antivirals; antivirals messaging; clinical and pharmacy guidelines on administering antivirals; access to antivirals by special and vulnerable populations; and the use of antivirals for post-exposure prophylaxis. Antivirals payment and coverage issues were also cited. The need for tracing antiviral resistance, efficacy and harm was also identified.

#### *Personal Protective Equipment (PPE)*

Questions and concerns about the use of N95 respirators by health care personnel during the treatment of suspected/confirmed H1N1 cases dominated discussions about PPE. Issues regarding N95s included: general concerns about guidance; conflicts between CDC, National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA) mask guidances; potential fines for non-compliance with OSHA requirements; and allocation of N95 masks. Several supply issues were noted regarding N95 masks, including: specification of mask types in the SNS stockpile; and determining if a shortage of masks existed. States also identified issues related to PPE messaging and clinical site guidance.

#### *Emergency Use Authorizations*

A number of issues related to emergency use authorizations (EUAs) were identified: specifying EUA requirements and timing; EUA messaging; content and format of EUA patient information sheets; extension of EUA antivirals; and termination of EUAs.

#### *Medical Equipment Caches and Tracking*

Several issues related to medical equipment caches and tracking of these assets were identified. It was noted that states' progress in tracking medical equipment must continue. Questions were raised about the U.S. Department of Health and Human Services (HHS) HAvBED program. More generally, concerns and needs were identified regarding medical response capacity and financing health care system preparedness.

#### *Alternate Care Sites*

Concerns and ongoing needs were identified regarding alternate care site planning.

#### *Standards of Care*

Several issues were cited regarding standards of care during emergency events, including: alternate standards of care messaging; addressing alternate/crisis standards of care; and general concerns about alternate standards of care.

#### *EMTALA*

Concerns and questions were raised regarding Emergency Medical Treatment and Active Labor Act (EMTALA) screening issues.

#### *Medical Care and Medical Countermeasures Communication*

A number of issues were identified related to communications about medical care and countermeasures, such as: communications to/from CDC, other federal agencies and organizations; communication mechanisms/frequency and messaging; communications with the health care community; and communications with other partners.

## National Vaccination Campaign

### *Vaccine Identification, Formulation and Manufacture*

Comments and concerns were raised about the methods of vaccine production and the timing of vaccine development and availability.

### *Vaccine Allocation and Prioritization Approaches*

A number of issues were identified related to vaccine allocation and prioritization, including: equitable allocation of small quantities of vaccines; Advisory Committee on Immunization Practices (ACIP) recommendations and special populations; allocation of vaccine from the federal government; allocation of vaccine from state/local governments; the timing of vaccine availability; conflicting/changing messaging; and vaccine reallocation.

### *Vaccine Distribution and Delivery*

It was noted that plans for rapid distribution and administration of vaccinations must be refined. Other issues were cited regarding the distribution and delivery of H1N1 vaccine, including: vaccine shipping information and conditions; questions about the quality/necessity of ancillary supplies sent with vaccines; guidance on using remaining H1N1 vaccine; and vaccine disposal issues.

### *Administering Vaccines*

States raised a variety of issues related the authority to administer vaccine. Strategies to increase the number of vaccinators included: licensing modifications to allow a range of health professions to vaccinate; qualifying school nurses as public health employees to administer vaccines and report immunizations; and lowering patient age for vaccination. Other issues included questions about consent to vaccinate; authority to restrict vaccination recipients; the use of school vaccination clinics. Sources addressing vaccine payment and reimbursement issues acknowledged that payment systems for vaccine administration must be improved, and that state insurance laws do not mandate coverage of vaccines during declared public health emergencies.

### *Vaccine Tracking, Coverage, Recall and Adverse Events Reporting*

Issues related to using immunization registries to track vaccinations were identified. A number of issues were raised regarding vaccine coverage, including: vaccine uptake and coverage rates; coverage among health care workers; uptake and coverage data/monitoring; and using school immunization data. It was also noted that vaccine tracking systems must be enhanced to monitor for adverse reactions. Additionally, the different reporting requirements of the multiple federal vaccine injury compensation funds should be clarified.

### *Vaccination Communications*

It was noted that vaccination outreach activities must include special efforts to encourage young adults, minorities, and other at-risk individuals get vaccinated.

### *Vaccination Other Issues*

Other issues related to vaccine and vaccinations identified were: international vaccination efforts; and vaccine research and development needs.

## **Workforce, Capacity and Infrastructure**

### *Flexing/Surging Public Health Capacity*

Many agreed that public health departments do not have enough resources to adequately respond to emergencies given their current capacity. It was specifically noted that: public health workforce capacity is strained; public health legal capacity must be enhanced; and national public health partner organizations and associations may not have the depth of staffing to maintain a prolonged response.

### *Health Care/Medical Surge*

It was noted that health care systems can be easily overwhelmed in an emergency. Suggestions generated included using partnerships with health care to prepare for medical surge, and exercising and documenting lessons through after-action reports. Overall, it was noted that there is a need for sustained funding to improve hospital and trauma center preparedness and response.

### *Volunteers Surge*

Several concerns were noted about the ability to use volunteers, including recruiting volunteers, volunteer registration, and the protection of volunteer public health workers from tort liability.

### *Workforce Mandates*

Questions were raised about the legal authority to mandate vaccination for health care workers.

### *Worker Protection, Employment and Insurance*

A number of issues were raised regarding worker protection, employment, and insurance during the H1N1 outbreak. These included: employer privacy/disclosure obligations; employment protections for workers who get sick; coverage under sick leave and health care policies for isolation/quarantine; and financing catastrophic emergency care.

### *Community Recovery/Resiliency*

It was suggested that state and local communities must consider community recovery and resilience capacity as part of their pandemic and emergency planning activities.

### *Workforce, Capacity, and Infrastructure Other Issues*

A number of needs and suggestions were identified regarding: funding and modernizing core public health capacities; and strengthening and maintaining the public health workforce.

## **Federal/State/Local Coordination**

### *Intergovernmental Coordination and Activities*

A variety of issues were identified related to governmental coordination. States noted that interagency collaboration, coordination and clarity associated with decision making needs improvement. There was a need to create a “common operating picture” as a means to more effectively share standardized data and information between the different levels of government. Specifically, federal, state, and local health departments should share lessons, innovations, and resources. There should be improved information flow between federal and state/local public health attorneys. Relationships with state/federal public health counsel need to be expanded to include relationships with legal counsel in additional federal agencies. State/federal public health attorneys need to expand their communication and education efforts with legal counsel to local public health agencies. Finally, coordination with national public health partner organizations is an important part of the public health system’s emergency response efforts.

### *Categorical Grants and Cooperative Agreements*

Regarding categorical grant and cooperative agreement flexibility, it was repeatedly noted that states needed flexibility in using funding during pandemic/emergency response situations. This included addressing the restrictions on the use of Public Health Emergency Response (PHER) funds.

### *Public Health Funding Needs*

It was noted that public health preparedness funding from state and federal sources must be increased and sustained.

### *Stakeholder Engagement and Interaction*

Regarding stakeholder interactions overall, states' sought to determine how best to maintain, enhance, or create partnerships that may benefit response to seasonal and pandemic influenza.

Interactions with the health care sector were seen as needing improvement. States felt that communication between the public health system and health providers was not well coordinated. It was also noted that public health officials and their lawyers need to develop and maintain communication with legal counsel to hospitals, health systems, and other traditional stakeholders, as well as with nontraditional organizations that assisted the H1N1 response. It was also suggested that federal and state authorities partner to provide training and technical assistance to states and localities on key issues related to medical surge and alternate standards of care.

### *Special and Vulnerable Populations*

Additional guidance was needed to assist state and local public health authorities in protecting high risk individuals. Especially identified were the uninsured, the underinsured, and undocumented workers as populations that need extra consideration in planning as access to health care for these groups is a barrier to their protection. Given the genesis of H1N1 in Mexico, it was recommended that outreach be conducted to vulnerable migrant populations from Mexico in the U.S.

### *Pandemic Planning, Exercising and Implementation*

It was noted that pandemic planning, exercises and implementation activities must continue at all levels of government. Specifically identified were the need to complete work and updates on the U.S. National Strategy for Pandemic Influenza and Plan and implementation of the Pandemic and All-Hazards Preparedness Act (PAHPA).

## **Communication**

### *Messaging Coordination, Media Relations, and Ad Campaigns*

States noted that coordinating messaging was and remains a challenge for the H1N1 response. The need for improved intergovernmental coordination and a communications chain of command were significant issues raised by the states. States also noted that the World Health Organization's pandemic alert phases caused confusion with the media and the public.

### *Public Outreach*

Providing clear information to the public was seen as essential for allaying fears and building trust during the H1N1 outbreak. It was suggested that health agencies should develop and disseminate forceful public health messages about ways to practice good hygiene and understand influenza symptoms and remedies.

### *Communications with Stakeholders*

States found that improvements were needed in communications with health care providers and with special/vulnerable populations.

### III. Environmental Scan Data

Section III contains the detailed composite data culled from the sources reviewed for the environmental scan. It is important to note that while many aspects and nuances of the issues are addressed in the data presented, the compiled information may not reflect every element of an issue as experienced by a specific state or may not have been experienced by every state in the same way. The goal was to present the range of issues identified in the reviewed documents. The recommendations recorded in this document do not necessarily represent the views and recommendations of ASTHO or the final recommendations of the H1N1 Policy Barriers Project.

The data in the subsequent sections is quoted directly from the original source materials, which sources are numerically referenced at the end of the scan document.

The issues are presented in the following categories, which were used throughout the ASTHO H1N1 Policy Barriers Project: (A) ICS, Command and Control, and Authority; (B) Surveillance, Epidemiology, and Laboratory Services; (C) Medical Care and Countermeasures; (D) National Vaccination Campaign; (E) Workforce, Capacity, and Infrastructure; (F) Federal/State/Local Coordination; and (G) Communications. These categories were further refined into subcategories, which are identified at the beginning of each topic area, to assist in organizing the data.

Each issue entry is presented in the following format:

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<b><i>Issue:</i></b>	<b>A statement of the issue(s) identified.</b> Description of the issue and its various impacts on the H1N1 response.  The information is quoted directly from the original source material (i.e., IPR, AAR, etc.).
<b><i>Issue Type:</i></b>	Characterization as a policy issue or a legal issue (i.e., a policy issue that has legal implications). Where both elements apply, both are listed.
<b><i>Recommendations Identified:</i></b>	Listing of the various recommendations suggested by the reviewed sources.  The information is quoted directly from the original source material (i.e., IPR, AAR, etc.).

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## III.A ICS, Command and Control, and Authority

Please see the introduction to Section III on page 13 for general information about the data contained in this subsection.

### ICS, Command and Control, and Authority Section Contents

A.1	H1N1 Response Command
A.2	Emergency Declarations
A.3	Statutory and Regulatory Waivers
A.4	Liability and Compensation
	A.4.1    PREP Act Issues
	A.4.2    Liability and Compensation Other Issues
A.5	ICS, Command and Control, and Authority Guidance and Standards
A.6	Non-Pharmaceutical Interventions (NPI)
	A.6.1    Community Mitigation Measures - General
	A.6.2    School Dismissal and Closure
	A.6.3    Travel Restrictions and Border Closing
	A.6.4    Quarantine and Isolation
A.7	ICS, Command and Control, and Authority Communications
A.8	ICS, Command and Control, and Authority Other Issues

### Summary of Issues

#### A.1 H1N1 Response Command

- None identified

#### A.2 Emergency Declarations

- Need to clarify the implications of the various types of federal emergency declarations.
- Inconsistent wording of federal emergency declarations can cause confusion.
- Stafford Act applicability and provisions.
- State emergency declarations.
- Need to examine alternative state legal and policy approaches to expanding authority and improving response during public health emergencies.

#### A.3 Statutory and Regulatory Waivers

- Need to share information about states' approaches to statutory/regulatory waivers.
- Need to examine alternative state legal and policy approaches to expanding authority and improving response during public health emergencies.
- Identify all state laws/policies that should be waived during a response.
- Need for timely issuance and standard format for Medicaid waivers by CMS.
- Identify the parameters and implications of EMTALA waivers.

#### A.4 **Liability and Compensation**

##### A.4.1 ***PREP Act Issues***

- Relationship between PREP Act and state liability protections.
- Clarify the language and scope of PREP Act immunities.
- Extent of PREP Act liability coverage and scope of remedies available.
- Adverse incidents under the PREP Act.
- Examine the interplay between the PREP Act and EUAs.
- PREP Act liability coverage for private PODs.

##### A.4.2 ***Liability and Compensation Other Issues***

- None identified

#### A.5 **ICS, Command and Control, and Authority Guidance and Standards**

- Effect of CDC guidance.
- General recommendations for CDC guidance.

#### A.6 **Non-Pharmaceutical Interventions (NPI)**

##### A.6.1 ***Community Mitigation Measures – General***

- Implementing community mitigation measures.
- Guidance to public health agencies for high-risk and vulnerable populations.
- Need to refine messaging around community mitigation measures.
- Tracking community mitigation measures.

##### A.6.2 ***School Dismissal and Closure***

- Clearly identify what officials/agencies have the authority to close schools.
- Need clear recommendations on implementing school closures.
- Need to refine messaging regarding school closure.
- Reporting and tracking school closures.
- Need to identify and plan for the consequences of school closure decisions.
- Resources are needed to assist schools in preparedness planning activities.

##### A.6.3 ***Travel Restrictions and Border Closing***

- Authority to close borders.

##### A.6.4 ***Quarantine and Isolation***

- Identify practical barriers and solutions for implementing quarantine and isolation.

#### A.7 **ICS, Command and Control, and Authority Communications**

- Clearer messaging is needed regarding emergency authorities and community mitigation measures.

#### A.8 **ICS, Command and Control, and Authority Other Issues**

- Undocumented persons.
- Consumer protection/price gouging issues.

## Issues Detail

### A.1 H1N1 Response Command

*Issues:* None identified

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### A.2 Emergency Declarations

*Issue:* **Federal Emergency Declarations — Need to clarify the implications of the various types of federal emergency declarations.**

- “Need to clarify the implications of alternative types of federal emergency declarations. The President issued an emergency declaration for H1N1 under the National Emergency Act as opposed to the Stafford Act. Clarification is needed as to the differences between the two types of emergencies, as well as how these declarations differ from the Secretary of HHS’s determination of a public health emergency. Of particular concern is what resources flow from the various declarations.” [6]
- “Difference between determination of a public health emergency by the Secretary of Health and Human Services and a Presidential declaration of emergency under the Stafford Act or under the National Emergencies Act; implications of each.”[8]

*Issue Type:* Legal

*Recommendations Identified:*

- “Develop and disseminate to state and local public health agencies a fact sheet that compares the implications of alternative federal emergency declarations, especially for the availability of financial and other resources they trigger. Disseminate previously developed FEMA matrix.” [6]

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*Issue:* **Federal Emergency Declarations — Inconsistent wording of federal emergency declarations can cause confusion.**

- “Need to resolve conflicting interpretations of the missing reference to “EMTALA” in the President’s Declaration of National Emergency on October 24, 2009, pursuant to the National Emergencies Act. The President’s declaration of emergency addressed Section 1135 waivers and named these programs as eligible for waivers: Medicare, Medicaid, the Children’s Health Insurance Program (CHIP) and the Health Insurance Portability and Accountability Act (ACT). EMTALA was not named in the declaration, although it was specifically named in the Secretary’s 1135 waiver granting CMS the authority to waive EMTALA penalties where indicated. It therefore is unclear whether states may request EMTALA waivers under Presidential emergency declarations. (There is speculation that EMTALA intentionally was excluded from the President’s declaration because of problems associated with the declaration of emergency that followed Hurricane Katrina in 2005.)” [6]
- “Social Security Act 1135 waivers addressed in the Presidential Declaration under the National Emergencies Act; waiver of EMTALA requirements not specifically stated within the Declaration, although other specific programs eligible for 1135 waivers were named: Medicare, Medicaid, State Children’s Health Insurance Program (CHIP) and Health Insurance Portability and Accountability Act (HIPAA).” [8]

*Issue Type:* Legal

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*Recommendations Identified:* • “Request official, written resolution of this issue.” [6]

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**Issue:** **Federal Emergency Declarations — Stafford Act applicability and provisions.**

- “The lack of a Stafford Act declaration hindered the coordination of NIMS structure.” [9]
- “Emergency declarations under the Stafford Act in the event of an outbreak of infectious disease are not unprecedented. In 2000, the detection of West Nile virus in New York and New Jersey was used as the basis of an emergency declaration under the Stafford Act. However, there may be uncertainty regarding whether a flu pandemic, or any outbreak of infectious disease, would be eligible for major disaster assistance under the Stafford Act.” [13]
- “The authority of the President to declare a major disaster under the Stafford Act in response to a flu pandemic may be subject to some debate and likely depends upon whether a flu pandemic would qualify as a “natural catastrophe” under the Stafford Act. FEMA has historically excluded biological incidents from major disaster declarations under the Stafford Act, but extensive policy under the Bush administration appeared to consider biological incidents, or at least flu pandemics, to be eligible for major disaster assistance.” [13]

*Issue Type:* Legal, Policy

*Recommendations Identified:* None identified

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**Issue:** **State emergency declarations.**

- “Differences in state emergency declarations create inconsistencies in authorities.” [4]
- “Need for state public health emergency declarations; wording of these.” [8]

*Issue Type:* Legal

*Recommendations Identified:* None identified

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**Issue:** **Need to examine alternative state legal and policy approaches to expanding authority and improving response during public health emergencies.**

- “States have taken a variety of approaches to expanding public health authority and improving response—such as authorizing certain professions to vaccinate, overcoming procurement or hiring obstacles, handling school vaccination programs, and maintaining privacy of health information—during public health emergencies. Many state and local public health agencies would benefit from understanding these approaches’ pros and cons but information about them is not readily available.” [6]

*Issue Type:* Legal, Policy

*Recommendations Identified:* • “PHLP [CDC Public Health Law Program] should consider compiling practical information on states’ alternative approaches, disseminating it in user-friendly forms, and creating a structured menu state and local public health emergency preparedness officials and legal counsel may use in strengthening their emergency legal preparedness.” [6]

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### A.3 Statutory and Regulatory Waivers

<b>Issue:</b>	<b>Need to share information about states' approaches to statutory/regulatory waivers.</b> <ul style="list-style-type: none"><li>• “What approaches are states taking to waiving statutory and regulatory requirements during response to public health emergencies? States’ approaches vary according to their unique laws and approaches to managing emergency responses. States’ laws vary in the scope and conditions of waivers; some actually authorize the executive branch to make new legal authority during defined, emergency-related conditions. Some states hinge waivers on declarations of emergency or on findings that local jurisdictions are overwhelmed. Some states have inventoried statutory/regulatory requirements for potential waiver. Some states prohibit waiver of judicially made law. Some states require waiver of certain regulations (e.g., professional licensure) to be effected by the oversight agency while others allow ICS officials to do that. Some require action by the Governor. Note that statutory and regulatory waivers raise separation of powers questions. Sharing information about these varying approaches may provide insight to other states.” [7]</li><li>• “Various approaches of states to waiving laws or regulations during a public health emergency.” [8]</li></ul>
<b>Issue Type:</b>	Legal
<b>Recommendations Identified:</b>	<ul style="list-style-type: none"><li>• “Test these issues in the context of public health emergency exercises. Share information about states’ approaches through the [CDC] Public Health Legal Counsel Listserv.” [7]</li></ul>

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<b>Issue:</b>	<b>Need to examine alternative state legal and policy approaches to expanding authority and improving response during public health emergencies.</b> <ul style="list-style-type: none"><li>• “States have taken a variety of approaches to expanding public health authority and improving response—such as authorizing certain professions to vaccinate, overcoming procurement or hiring obstacles, handling school vaccination programs, and maintaining privacy of health information—during public health emergencies. Many state and local public health agencies would benefit from understanding these approaches’ pros and cons but information about them is not readily available.” [6]</li></ul>
<b>Issue Type:</b>	Legal, Policy
<b>Recommendations Identified:</b>	<ul style="list-style-type: none"><li>• “PHLP should consider compiling practical information on states’ alternative approaches, disseminating it in user-friendly forms, and creating a structured menu state and local public health emergency preparedness officials and legal counsel may use in strengthening their emergency legal preparedness.” [6]</li></ul>

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<b>Issue:</b>	<b>Identifying all state laws/policies that should be waived during a response.</b> <ul style="list-style-type: none"><li>• “State/local laws or policies preventing the recruitment, hiring, or retention of the public health professionals necessary to respond to H1N1 (ex. Merit system, furloughs, hiring freezes, posting requirements, contractor v. FTE, etc.).” [8]</li><li>• “State/local procurement laws or policies hindering respond to H1N1 (ex. Competitive bidding).” [8]</li></ul>
<b>Issue Type:</b>	Legal, Policy
<b>Recommendations Identified:</b>	None identified

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- Issue:** **Need for timely issuance and standard format for Medicaid waivers by CMS.**
- “*Is CMS prepared to issue Medicaid waivers on a timely basis during public health emergencies?* Based on its experience in seeking approval for Medicaid reimbursement for services provided under altered standards of care (required due to emergency conditions) from its regional HHS/CMS office, one state suggested that all regional HHS/CMS offices develop pre-drafted orders authorizing such waivers.” [7]

**Issue Type:** Legal

- Recommendations Identified:**
- “Request CMS institute procedures to issue emergency-related waivers rapidly and consistently across HHS regions. Share waivers that have already been drafted as possible templates.” [7]
  - “Sample form/format of 1135 waivers for submission to Centers for Medicare & Medicaid Services (CMS).” [8]
  - “CMS process for approving waivers and enforcement.” [8]

- 
- Issue:** **Identify the parameters and implications of EMTALA waivers.**
- “What are the parameters of EMTALA waivers? It has been reported that an EMTALA waiver only waives federal sanctions for violators and does not bar state lawsuits. [State] would shield hospitals from liability under state law by drafting waivers to provide immunity for hospitals that comply with an executive order authorizing them to cease admissions and transfer patients without a medical screening exam. Since a Secretary’s EMTALA waiver is good for only 72 hours (but may be renewed), is there danger that the waiver could expire before the need for it ends? (Reportedly, objections to the successive EMTALA waivers during the Katrina response may discourage successive waivers in the future.)” [7]
  - “Parameters of waivers of EMTALA sanctions.” [8]
  - “Concern that hospitals had to be out of compliance before requesting the 1135 waiver; risk of not being granted the waiver.” [8]

**Issue Type:** Legal

- Recommendations Identified:**
- “Determine if EMTALA waivers bar state lawsuits and whether the U.S. Department of Health and Human Services has adopted a policy not to renew EMTALA waivers.” [7]
  - “Obtain permission and, if granted, disseminate the [State] waiver to state and local public health legal counsel.” [7]

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## A.4 Liability and Compensation

### A.4.1 PREP Act

- Issue:** **Relationship between PREP Act and state liability protections.**
- “*What is the relationship between PREP Act liability protection and state liability protection?* The PREP Act does not require states to declare emergencies in order to qualify for liability protection but it does require that states adhere to state laws regarding dispensing, storage, distribution, etc. If states were to not strictly comply with their own laws, they might lose PREP Act coverage. However, a state could waive or loosen its own

laws pursuant to an emergency declaration issued in accordance with its adopted emergency response plans. Thus a state whose own emergency response plan requires such a declaration will have to issue one in order not to lose PREP Act coverage. Separately, a state may want to issue a declaration to trigger its own liability or immunity protections or to activate its own liability protection for health care workers providing mass care – that is, workers acting beyond the scope of the PREP Act which is limited to provision of antivirals and other countermeasures. States may want to declare an emergency to protect healthcare organizations from liability for rationing. Finally, states may need to declare emergencies to implement rationing of materiel and care.” [7]

*Issue Type:* Legal

*Recommendations Identified:*

- “State public health attorneys should be familiar with the PREP Act and its implications for their state’s emergency declarations. In addition, they should be familiar with the implications of their state’s emergency declarations for liability protection, rationing, and other emergency response functions. Any and all conditions for full PREP Act liability and compensation coverage should be clearly stated, so state and local health agencies can take the necessary actions to remain within the PREP Act’s coverage.” [7]

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*Issue:* **Clarify the language and scope of PREP Act immunities.**

- “PREP Act declaration wording suggests that liability extends to federal contracts, etc. and activities authorized in response to a public health emergency; requirement of both elements would limit liability to only federal programs and not extend to state programs.” [8]
- “PREP Act coverage requires that the countermeasures be voluntary; would coverage still be extended should a state mandate that all healthcare workers, for example, be vaccinated.” [8]
- “Definition of “Qualified Persons” under the PREP Act, extent of coverage.” [8]
- “Need to clarify PREP Act language regarding the applicability of immunity of covered countermeasures. The language contained in the PREP Act declaration under “I. Covered Countermeasures” states that immunity “shall only be in effect with respect to: 1) Present or future Federal contracts, cooperative agreements... and 2) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer...” (emphasis added.). The connector “and” appears to require that both elements be present. State attorneys expressed concern about availability of coverage only in circumstances where both elements exist. Federal attorneys suggest that the “and” should be read as an “or” and was originally intended to cover a broad range of actions, including relevant state or local activities, absent willful misconduct. (For example, some antivirals were purchased with state money at federal encouragement. Later the state antivirals were shelved and stored with SNS assets so that it would be difficult to track which antiviral a given injured patient had received. Construing the PREP Act declaration to require both elements, liability coverage would extend to the SNS asset but not the state asset; but construing the PREP Act declaration to require only one or the other element, both federal and state assets would be covered.) States are still concerned that a court may not come to this interpretation in a lawsuit, absent written guidance.” [6]

*Issue Type:* Legal

*Recommendations Identified:*

- “Either publish guidance/comments stating that the “and” is meant to be read as an “or” or amend the PREP Act declaration to state “or.” [6]

**Issue:**

**Extent of PREP Act liability coverage and scope of remedies available.**

- “Need to clarify the difference between the extent of PREP Act liability coverage and the actions for which compensation available is under the Countermeasure Injury Compensation Program. The PREP Act protects a relatively wide spectrum of workers from liability for a variety of potential injuries caused by vaccine and by vaccine manufacture, distribution, absent willful misconduct. In contrast, the Countermeasure Injury Compensation Program covers only administration or use of a given countermeasure. It was proposed that there would be a list of types of measures covered, but one has not been released thus far. For injuries where the PREP Act offers liability protection but the Countermeasure Injury Compensation Program (CICP) does not provide coverage, what remedy, if any, is available to the injured person? Some particular injuries described include adverse reactions to the countermeasure, needle pricks of healthcare workers, warehouse slip and falls, or vehicle accidents en route to clinics.” [6]
- “Whether PREP Act coverage extends when withholding a countermeasure, due to limited resources.” [8]
- “Types of injuries for which liability protection is extended under the PREP Act v. types of injuries compensated from the Countermeasure Injury Compensation Fund; remedies for persons injured in types not compensated by the Countermeasure Injury Compensation Fund.” [8]
- “Details regarding the Countermeasure Injury Compensation Fund; differences between this fund and other injury compensation funds such as dates/deadlines, reporting requirements, etc.” [8]
- “If Congress appropriates money for the new “Covered Countermeasures Process Fund,” victims could, in lieu of suing, accept payment under the new fund. Compensation under this fund would be in the same amount as in prescribed by section 264, 265, and 266 of the Public Service Health Act for persons injured as a result of the administration of certain countermeasures against smallpox. These three sections provide, respectively, medical benefits, compensation for lost employment income, and death benefits, but do not provide damages for pain and suffering.” [13]

**Issue Type:**

Legal

**Recommendations Identified:**

- “Develop a fact sheet comparing PREP Act liability coverage to CICP compensation and including specification of injuries covered by the CICP. For injuries not covered, determine what remedy, if any, the injured person might be able to pursue.” [6]

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**Issue:**

**Adverse incidents under the PREP Act.**

- “What level of reporting of adverse incidents is sufficient to trigger PREP Act liability protection? The trigger level of reporting has not been explained. Concerns were raised that failure to comply in full with the adverse incidents reporting or any other conditions specified in an EUA could prevent full PREP Act coverage for (a) tort liability protections and (b) compensation for adverse reactions to countermeasures. State/local health departments want to ensure they report the appropriate information to the appropriate agencies to ensure full PREP Act coverage.” [7]
- “Level of information required when reporting of adverse events sufficient to trigger liability protection/full PREP act coverage.” [8]

**Issue Type:**

Legal

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*Recommendations Identified:* • “Explain compliance requirements for full PREP Act coverage, issue guidance to clarify procedures related to reporting of adverse incidents, and identify all actions necessary for state/local health departments to assure PREP Act coverage.” [7]

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*Issue:* **Examine the interplay between the PREP Act and EUAs.**

- “Interplay between Public Readiness and Emergency Preparation (PREP) Act (which authorizes the Secretary of Health and Human Services to issue a declaration that provides immunity from tort liability for claims of loss relating to the administration or use of countermeasures to diseases, threats and conditions determined to constitute a present, or credible risk of a future public health emergency) and Emergency Use Authorizations (EUAs) (which the Commissioner of the Food and Drug Administration (FDA) may issue, once a public health emergency has been determined by the Secretary of Health and Human Services, or other type of emergency has been appropriately declared as described in the Project BioShield Act, for use of an unapproved drug, device, or biological product, or for an unapproved use of an approved drug, device, or biological product, assuming other statutory requirements have been met).” [8]

*Issue Type:* Legal

*Recommendations Identified:* None identified

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*Issue:* **PREP Act liability coverage for private PODs.**

- “How can private PODs be better assured of PREP Act liability coverage? State/local health departments and the private firms and other organizations that manage private PODs want to be certain of PREP Act coverage. Model language is needed for inclusion in contracts, MOUs/MOAs, or other relevant documents.” [7]
- Assurance of liability protection for private Points of Distribution (PODs).” [8]

*Issue Type:* Legal

*Recommendations Identified:* • “Review existing documents relating to PREP Act coverage, e.g., 2009 [State] legislation. Draft model contract language or a template/checklist. Examine alternative methods such as use of volunteer indemnification. Related: Compile questions that arise re private PODs, e.g., may they charge administrative fees to patients; are their workers covered by PREP Act/other liability protections?” [7]

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#### A.4.2 Liability and Compensation Other Issues

*Issue:* None identified

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### A.5 ICS, Command and Control, and Authority Guidance and Standards

*Issue:* **Effect of CDC guidance.**

- “Is CDC guidance a mandate? State and local public health agencies are at times

concerned that CDC guidance on a particular point has been perceived as mandating action by state/local agencies or as establishing authoritative standards of care, thereby creating potential legal liability.” [7]

*Issue Type:* Policy, Legal

*Recommendations Identified:*

- “Except in instances where CDC intends to mandate action, CDC guidance documents should state explicitly that compliance with the guidance is voluntary.” [7]

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***Issue:* General recommendations for CDC guidance.**

*Issue Type:* Policy

*Recommendations Identified:*

- “Subject matter expert (SME) review of draft guidance. CDC should include state and local subject matter experts (SME) in review of draft guidance prior to its release. Identify/provide SME guidance review support to CDC.” [4]
- “Look at adding language regarding public health actions causing “no harm: to individuals/society.”[4]
- “Provide policy tools that are flexible rather than prescriptive.” [4]
- “Re-think alignment of public health recommendations at individual/family level. What are the barriers, obstacles, and agendas; what is the right level of public health intervention?” [4]

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## A.6 Non-Pharmaceutical Interventions (NPI)

### A.6.1 Community Mitigation Measures - General

***Issue:* Implementing community mitigation measures.**

- “Ambiguity in federal laws and guidance and how they are applied in emergencies creates confusion.” [4]
- “Mitigation policies are based on an already changed antiviral policy.” [4]
- “Schools are going to open before the vaccine is available to fully protect students. The following tasks must also be completed:
  - Identify strategies and interventions and develop standardized curricula (e.g., hand hygiene, etc.) for schools to implement.
  - Define public health role in shaping intervention actions and messaging.
    - This could include sending letters home with kids to their parents from a health official with recommendations and explanations.
  - Provide granularity regarding triggers and appropriate responses.
  - Develop broad guidelines specific to prophylactic use of antivirals.
  - Provide goals and strategies in terms people understand regarding the school closure decisions (why or why not close?). Consider the need to:
    - Define roles and responsibilities needed to keep schools open
    - Align incentives to keep schools open
    - Partner to remove obstacles (e.g., Federal funds for nutrition programs not awarded when schools close)
    - Provide tool-kit of recommendations from previous/ongoing studies of

schools closed.”[4]

- “Local health department structures and reporting requirements/processes vary by state. The local health department structures and reporting requirements vary from state to state and impact how community mitigation strategies are implemented, reported, and supported. Federal agencies do not have clear visibility and understanding of the differences.” [4]

*Issue Type:* Policy, Legal

- Recommendations Identified:*
- “Sharing of decision making processes regarding implementing community mitigation interventions would be helpful for other communities/states.” [4]
  - “Provide an easy tool that identifies state health department structure and reporting.” [4]

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***Issue:* Guidance to public health agencies for high-risk and vulnerable populations.**

- “CDC should provide guidance to assist state and local public health authorities in protecting high risk individuals. The first wave of this pandemic has shown that people with underlying medical conditions are at greater risk of death from H1N1. Plans and messaging for how best to protect these populations are needed for future waves. In addition to those with underlying conditions, the group highlighted the uninsured, the underinsured, and undocumented workers as populations that need extra consideration in planning. Access to health care for these groups is a barrier to their protection.” [4]
- “The public health community role in addressing at-risk populations needs to be further explored/defined.” [4]
- “Reaching IV drug users and other vulnerable populations with NPI is a problem.” [3]
- “Protection against deportation of undocumented persons seeking preventive care or treatment for A (H1N1).” [8]

*Issue Type:* Policy

- Recommendations Identified:*
- “Identify action recommendations for special populations (e.g., prisons, jails, juvenile homes, other types of residential facilities).” [4]

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***Issue:* Need to refine messaging around community mitigation measures.**

- “How to message in the situation if all family members are vaccinated and one gets sick, it is not advised that the other family members come visit them in the hospital.” [3]
- “Need to create an understanding that appropriate mitigation strategies will vary from community to community based on local infection rates.” [4]
- “It is important to have social distancing in faith-based communities, congregations, etc. What has been the reception of the public health messaging on community mitigation in the faith based communities? They have been pretty receptive in [STATE] and since most of them have some connection to health care, there has not been much push back and they agreed with the messaging.” [3]
- “Physicians who saw a lot of cases told parents it was “just the flu.” Messages need to move away from saying that Novel H1N1 Influenza is just like seasonal flu because there are many ways in which this virus is different from seasonal flu. The public cannot understand why there would be different interventions for H1N1 if they are told that it is the same as seasonal flu.” [4]
- “People who have been exposed need reassurances about their risk of illness and the purpose of prophylactic medication if prescribed.” [4]

- “Sick leave and policies for limiting mass gatherings were also problematic. There were numerous media reports of people with influenza-like illness continuing to go to work because they had no sick leave and feared losing their jobs, and some parents sent sick children to school because they could not stay home to care for them. In addition, while they were not instituted during the outbreak, it became clear to officials how difficult it would be to carry out plans to limit mass gatherings or cancel major events if that became necessary. In areas of Mexico, there were serious economic ramifications when officials recommended people avoid shopping and public events.” [23]

*Issue Type:* Policy

*Recommendations Identified:* None identified

***Issue:* Tracking community mitigation measures.**

- “Mitigation strategy tracking requirements need to be identified (e.g., closures, absenteeism).” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

## A.6.2 School Dismissal and Closure

***Issue:* Clearly identify what officials/agencies have the authority to close schools.**

- “School closures raise legal issues. The main question is who has the legal authority to institute a school closure. A CDC-requested study of state legal authorities to close schools found that school closure is legally possible in most jurisdictions during both routine and emergency situations. The study also indicated that state authority for closure may be vested at various levels of government and in different departments, generally the state or local education agencies or state or local departments of health. However, if there is a state or local declaration of emergency, the authority to close schools shifts to the state emergency management agencies in most jurisdictions. These varying laws may create legal controversies over who has the authority to make the school closure decision. In addition, there could be legal challenges to whatever school closure decision is made, particularly if the duration of a school closing is lengthy. Issues may also arise regarding whether school employees will be paid for the time the schools are closed.” [13]

*Issue Type:* Legal

*Recommendations Identified:* None identified

***Issue:* Implementing school closure — Need clear recommendations on closing schools.**

- “Clear recommendations are needed on school closure procedures.” [4]
- “There were mixed recommendations for when to close schools. The public found it confusing that schools closed for H1N1, while there are similar numbers of cases of seasonal flu each year and schools are not closed. For those schools that decided/needed to close, the length of time they should close was unclear.” [4]

- “Schools will open this fall before there is vaccine to protect students and contingency plans and guidance are needed.” [4]
- “Good data on triggers was not available for implementing community mitigation measures. Current framework may not be effective.” [4]
- “Differences between Federal mitigation guidance/recommendations and local decision making were not clearly understood.” [4]
- “Officials could use assistance in communicating or explaining reasons for implementing or not implementing mitigation efforts.” [4]
- “Some leaders are concerned about legal liabilities surrounding decisions made (e.g., closing or not closing schools).” [4]
- “It would have been helpful to have options/alternatives to provide to states (maybe a model) versus taking extreme action by shutting down schools.” [4]

*Issue Type:* Policy, Legal

- Recommendations Identified:*
- “*School closure guidance needs to be reviewed and refined. There is a need to develop appropriate guidance to assist in both the community decision process and marketing strategies that:*
    - Identify the issues to consider.
    - Recommend who should be involved in the discussions.
    - Provide strong rationale why to keep schools open – “safe schools guidance”.
    - Provide recommendations for decision making if closures are indicated.” [4]
  - “*States and localities should follow CDC guidance for school and day care closures: Communities around the country should follow the federal guidance on school closures and find the balance between limiting the spread of disease and causing social disruption by closing schools.*” [21]

- Issue:* **Need to refine messaging regarding school closure.**
- “Messages need to include reasoning for closing schools and not closing schools (e.g., the best place for well children is at school; the best place for sick children is at home). Some jurisdictions received pressure from the public for not closing schools, yet it was difficult to articulate the justification for doing so.” [4]
  - “Vaccine availability and school opening may not coincide; need to explore how to best advise public health and school officials how to communicate issues to parents and students.” [4]
  - “There is a need to provide effective messages to:
    - “Fix” message on seasonal flu versus H1N1 to highlight the differences and why the two need to be treated differently.
    - Explain why and why not (e.g., some schools close, some do not).
    - Provide recommendations and explanations to parents of school aged students regarding closure decisions.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

<b>Issue:</b>	<p><b>Reporting and tracking school closures.</b></p> <ul style="list-style-type: none"> <li>• “School closure reporting varies from state to state causing labor intensive, ad hoc information gathering. Provide recommendations for school closure dismissal system that honors the reporting protocols between local and state while also getting CDC the information needed.” [4]</li> <li>• “CDC is developing a system whereby schools would report closures directly to CDC, and participants expressed concern over this school dismissal reporting procedure proposal.” [4]</li> </ul>
<b>Issue Type:</b>	Policy
<b>Recommendations Identified:</b>	<ul style="list-style-type: none"> <li>• “Survey states on current school closure reporting requirements/needs and state contacts.” [4]</li> </ul>

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<b>Issue:</b>	<p><b>Need to identify and plan for the consequences of school closure decisions.</b></p> <ul style="list-style-type: none"> <li>• “Maintenance of public benefits during school dismissal (e.g., federal school meals program).” [8]</li> <li>• “Consequences of school closings: state/local health officials were not prepared to assist families and assist schools.” [4]</li> <li>• “It was not well communicated where students should/should not be when schools closed.” [4]</li> <li>• “Closing schools had a large affect on poorer areas, which caused issues such as work-related challenges for parents and nutrition for children.” [4]</li> <li>• “School closings have major ramifications for students, parents, and employers. In areas where schools were closed due to H1N1, parents had to scramble to find alternative child care arrangements, which were complicated by the guidance that children home from school should stay separated. Many parents had to face taking sick leave from work to stay home to care for their children even if they were not ill, or taking days off without pay if they did not have sick leave. Many families also rely on the school meal programs and before and after school care, which were also not available when schools were closed. In the event that another outbreak occurs or the H1N1 returns in the fall and schools may have to close in more places and for longer durations, these complications would become an even bigger concern. This is especially problematic for jurisdictions that require a minimum number of days attended to graduate.” [23]</li> </ul>
<b>Issue Type:</b>	Policy
<b>Recommendations Identified:</b>	<ul style="list-style-type: none"> <li>• “Work with partners to review all policies creating obstacles (e.g., school funding, meals issues). Consider: <ul style="list-style-type: none"> <li>▪ Developing alternative solutions to deliver nutrition in a different way when schools close.</li> <li>▪ Seeking federal funds to continue even if schools are closed during a public health crisis.” [4]</li> </ul> </li> </ul>

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<b>Issue:</b>	<p><b>Resources are needed to assist schools in preparedness planning activities.</b></p> <ul style="list-style-type: none"> <li>• “Schools do not have funds/resources to address planning/preparedness.” [4]</li> <li>• “There is a need to develop a national strategy and look for funding to assist schools in developing school-based preparedness plans in conjunction with public health planning.” [4]</li> <li>• “Closer coordination/collaboration is needed between public health and other partners for</li> </ul>
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- planning and issue identification/resolution (vertical and horizontal integration).” [4]
- “School pandemic influenza planning is neither consistent nor exercised.” [4]

*Issue Type:* Policy

*Recommendations Identified:* • “CDC should work with HHS and the Department of Education on Readiness and Emergency Management for School (REMS) grants to help keep schools involved in public health preparedness and response.” [1]

### A.6.3 Travel Restrictions and Border Closing

*Issue:* **Authority to close borders.**

- “The most drastic measure discussed so far is “to close the borders.” Presumably, this would entail a blanket bar on all aliens and citizens seeking entry into the United States regardless of their health. There appear to be no laws specifically authorizing an executive agency to take such action. However, Congress could presumably enact a law to do so, at least with regard to aliens, because the Supreme Court has long recognized “the power to expel or exclude aliens as a fundamental sovereign attribute that is largely immune from judicial control. However, United States citizens cannot be barred from entering the United States. Thus, if Congress were to theoretically “close the borders,” it could do so only by excluding aliens.” [13]
- “In the absence of an act of Congress, it may be possible for the President to “close the borders” to aliens by Executive Order. However, this course of action appears to be fraught with legal and practical challenges, which would likely result in extensive litigation. Because Congress has not given the President authority to conduct blanket closings of borders, it would appear that the President could do so only if the exclusion power is one where he has concurrent authority with Congress. Although this exclusion power is characterized as a power “exercised by the Government’s political departments largely immune from judicial control,” the President appears to have rarely exercised any authority within this realm outside of the authority expressly delegated by an act of Congress. Considering the rather extensive inadmissibility regime codified within the Immigration and Nationality Act, it would appear unlikely that the President can exercise this power without express congressional authorization.” [13]

*Issue Type:* Legal

*Recommendations Identified:* None identified

### A.6.4 Quarantine and Isolation

*Issue:* **Identify practical barriers and solutions for implementing quarantine and isolation.**

- “Pay more attention to issues surrounding voluntary isolation/quarantine to understand inhibitors (financial concerns, care providers, child care).” [4]
- “There are many competing factors contributing to decisions to continue to work even when sick. Some may be related to leave and teleworking policies that may not support staying home.” [4]
- “Polling states on good practices to reduce transmission by recommending leave from work/school when ill (highlight leave policies, teleworking).” [4]

- “Identify how long contacts should be isolated.” [4]
- “There is a lack of practical guidance regarding isolation and quarantine.
  - It is unethical to advise household contacts to stay home with ill individuals without providing antivirals to contacts—this is articulated in the community mitigation guidance document. How should contacts be advised to remain at home and still have access to antivirals?
  - There were differing recommendations for siblings of sick children – should they stay home from school, too? If not, should they be placed on antivirals?” [4]
- “Concern regarding antiquated federal and state quarantine and isolation laws; ensuring due process rights of individuals subject to quarantine or isolation orders under older laws.” [8]

*Issue Type:* Policy, Legal

- Recommendations Identified:*
- “Review issues and revise/provide guidance on isolation and quarantine.” [4]
  - “Identify leave/teleworking policies that support workers staying home when ill by surveying states on leave/teleworking policy issues.” [4]

## A.7 ICS, Command and Control, and Authority Communication

*Issue:* **Clearer messaging is needed regarding emergency authorities and community mitigation measures.**

- “There are many ideas on how we should communicate on the federal and state level, but we need to look at effective messaging for populations that may not have access to the communication types that are widely used i.e. websites.” [3]
- “One of the most important lessons learned is that effective messaging is necessary.” [3]
- “Early and ongoing communication is necessary to reduce social stigmatization of groups and individuals and agricultural products.” [4]
- “States should look at creative ways that effective messaging is being done on the local level.” [3]
- “There is a need for clear, consistent messaging to help with response efforts.” [4]
- “Determine what to say/recommend to exposed people.” [4]
- “Clearly state public health role in protecting population.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

## A.8 ICS, Command and Control, and Authority Other Issues

*Issue:* **Undocumented persons.**

- “Are there legal protections against deportation of undocumented persons seeking preventive care or treatment for H1N1? The fear of deportation by Immigration and Customs Enforcement (ICE) may deter illegal aliens from reporting disease and seeking health care. It also may deter parents who are illegal aliens from allowing their school children to be vaccinated, especially if the children’s information is retained in a register

or other records.” [7]

*Issue Type:* Legal, Policy

*Recommendations Identified:* • “Seek clarification about ICE policy.” [7]

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*Issue:* **Consumer protection/price gouging issues.**

- “Attempts to sell fraudulent Tamiflu and other countermeasures.” [8]
- “State laws to address price gouging of vaccinations such as seasonal influenza, antivirals, or medical supplies such as protective eyewear or N95 masks.” [8]
- “Use of general consumer protection laws to address price gouging.” [8]

*Issue Type:* Legal, Policy

*Recommendations Identified:* None identified

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## III.B Surveillance, Epidemiology, and Laboratory Services

Please see the introduction to Section III on page 13 for general information about the data contained in this subsection.

### Surveillance, Epidemiology, and Laboratory Services Section Contents

- B.1 Surveillance Data Collection and Analysis
- B.2 Reporting of Estimated Cases, Deaths and Hospitalizations
- B.3 Laboratory Services - General
- B.4 Epidemiology - General
- B.5 Surveillance, Epidemiology, and Laboratory Services Communications
- B.6 Surveillance, Epidemiology, and Laboratory Services Other Issues

### Summary of Issues

- B.1 Surveillance Data Collection and Analysis**
  - Information sharing between epidemiologists and laboratorians.
  - Data collection issues.
  - Surveillance guidance and strategies.
  - Surveillance system needs.
- B.2 Reporting of Estimated Cases, Deaths and Hospitalizations**
  - Guidance on reporting cases.
  - Case reporting and privacy.
  - Messaging about cases, deaths, hospitalizations.
- B.3 Laboratory Services – General**
  - Demands on public health laboratories need to be better managed.
- B.4 Epidemiology – General**
  - None identified
- B.5 Surveillance, Epidemiology, and Laboratory Services Communications**
  - None identified
- B.6 Surveillance, Epidemiology, and Laboratory Services Other Issues**
  - Global surveillance.
  - Surveillance, epidemiology, and laboratory research and development needs.

## Issues Detail

### B.1 Surveillance Data Collection and Analysis

- Aiding Factors:*
- “The Advisory Committee on Immunization Practices (ACIP) data-based recommendations were called a great success.” [1]
- 

- Issue:*                   **Information sharing between epidemiologists and laboratorians.**
- “Epidemiologists and laboratorians need to better communicate testing priorities.” [4]
  - “Necessary resources are not in place for collecting epidemiological data.” [4]
  - “Gate keepers and roles need to be determined for prioritization.” [4]
  - “There are problems at the local and state levels determining what information and how much can be given out and/or shared with the public.” [4]

*Issue Type:*           Policy

*Recommendations Identified:*   None identified

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- Issue:*                   **Data collection issues.**
- “Many people lauded the work of surveillance and laboratory systems, but expressed concerns about comparability of data at the national level in the case of the former and capacity of systems when facing more complex and resource demanding challenges, in the case of the latter.” [1]
  - “From increasing funding, staffing and BRFSS sample size to improving laboratory capacity to identify and report more respiratory viruses, it was clear to participants that the U.S. surveillance and laboratory infrastructure performed well but needs sustained funding and support, especially if future outbreaks and pandemics are more severe.” [1]
  - “Collection and reporting of individual case data is neither sustainable nor necessary for an effective long-term response.
    - Exceptions include targeted populations of interest, such as pediatric deaths, pregnant women, and health care workers.
    - Methods of displaying and representing population data should be developed and employed routinely to shift public and media expectation away from individual case-based data.” [4]
  - “The need for everyday data to build models.” [1]
  - “Data are needed in a more timely fashion.” [4]
  - “Current data sources are not sufficient.” [4]
  - “Better electronic reporting systems are needed.” [4]
  - “There is not a national consistent way of reporting when sharing data/information between local, state and federal jurisdictions.” [4]
  - “A plan to examine other nations’ surveillance systems and epidemiologic methodologies to see what they have developed.” [1]
  - “The challenge of not knowing what was happening in the Southern Hemisphere in real-time.” [1]
  - “Better animal monitoring and surveillance data, including swine.” [1]

- “It is important to note that about 75% of the diseases that have emerged over the past decade have originated from animals. As a result, effective responses to the growing threat of infectious diseases require a multidisciplinary approach that brings together stakeholders from a variety of sectors, including agricultural and animal health.” [14]

*Issue Type:* Policy

*Recommendations Identified:*

- “Consolidate and standardize surveillance data display and sharing to improve situational awareness for all state and local public health decision-makers. This again reinforces the need for, and importance of, a common operating picture for state and local health agencies.” [1]
- “Increase interoperability of electronic systems, such as school absenteeism data.” [1]
- “Consider adding additional respiratory infection data on FluView.” [1]
- “Secure sufficient and sustained funding in order to strengthen a national data system for epidemiology and surveillance activities, which are critical sources of information for public health decision making.” [1]
- “Secure resources to adequately fund BRFSS as a valuable data source.” [1]
- “One state health official suggested having the flexibility to hire more sexually transmitted infection (STI) investigators, who could be cross-trained and easily shift assignments and assist in pandemic response.” [1]
- “*The surveillance recommendations in the President’s Council of Advisors on Science and Technology (PCAST) report should be fully-funded and implemented.* Disease surveillance systems in the United States have been out-of-date for decades. Having rapidly available data that is easily accessible is essential to allow experts to track the course and severity of the disease, determine who is most at risk when, identify when additional antivirals or equipment are needed in a particular community, detect adverse reactions to the vaccine, or learn if the disease is becoming resistant to antivirals. HHS officials have been working hard to improve systems so they can monitor the spread of H1N1, and the PCAST report identifies specific ways to continue to upgrade H1N1 surveillance systems and capabilities to link systems among hospitals, health departments, and other health providers, to compile real-time data. Enough resources should be devoted to ensuring these recommendations are carried out as swiftly as possible, and officials should find ways to leverage these capabilities and lessons to modernize all U.S. disease surveillance systems.” [21]

*Issue:*

**Surveillance guidance and strategies.**

- “H1N1 surveillance requirements for the fall need to be defined.” [4]
- “Need to determine if the surveillance goals for the fall will be similar to seasonal influenza, i.e., identifying where, when, among whom and how severe disease is occurring.” [4]
- “The surveillance needs, guidelines and requirements need to be outlined over the summer in order to be implemented by September 2009.” [4]
- “Local, state and federal partners need to come together to determine what specific information needs to be shared cross-jurisdictionally, and what epidemiologic system needs are anticipated.” [4]
- “Passing information to the right people at the right time was/is a challenge.” [4]
- “A better process of passing data/information needs to be implemented.” [4]
- “Better guidelines are needed for determining/identifying who is at risk or the “at risk” groups.” [4]
- “Target testing to address public health needs should be refined.” [4]
- “Roles and responsibilities are not clear for each sector (i.e. local, state and federal).” [4]

- “The role of private testing for private providers is not clear.” [4]
- “Dissemination of information between local, state and federal levels is not consistent.” [4]
- “Better internal communication is needed.” [4]
- “Syndromic surveillance information proved useful. For instance, many jurisdictions used school absenteeism data to help enhance their understanding of influenza and support local decisions. Participants expressed an interest in both extending those partnerships (including through the Readiness and Emergency Management for Schools [REMS] grant through the U.S. Department of Education) and determining whether absenteeism data can be used or compared on a broader scale.” [1]
- “Strengthen surveillance and laboratory capacity needed for public health decision-making, including spending time determining whether and how to reduce variability among surveillance systems to provide a clearer national picture.” [1]
- “Recognize the importance of collecting and packaging data in a useful way to numerous audiences with differing needs, particularly the media.” [1]
- “Better guidance on when a change in percentage of ILI due to influenza triggers a change in clinical practice and how rapid test figures into this process.” [1]
- “Communication of changes to the case definition has not been in a way that highlights the changes. State and local public health staffs spend valuable time identifying what specific modifications have been made when the updated case definition is issued from the CDC.” [4]

*Issue Type:* Policy

*Recommendations Identified:*

- “*Surveillance priorities need to be clarified.* Top priorities for surveillance are determining the severity of illness and the risk factors for infection since these data drive decision-making. There should be movement toward greater nationwide consistency in the reporting of data. Use of sentinel providers is an option for more timely, less labor intensive surveillance. Surveillance for antiviral resistance should also be prioritized.” [4]
- “To develop a surveillance strategy that incorporates the following surveillance principles:
  1. Severity index (disease surveillance)
  2. How to target virus surveillance resources (laboratory surveillance)
  3. Ensure good strain surveillance (laboratory surveillance)
  4. Understand risk groups in a dynamic fashion (disease surveillance)
  5. Base plans for Novel H1N1 on the current seasonal flu systems (both surveillance groups)
  6. National consistency of reporting (both surveillance groups)
  7. Timeliness (both surveillance groups)
  8. Integrate alternate data sources (disease surveillance)
  9. Plans on whether or not to use case counting (laboratory surveillance)
  10. Leverage and enhance electronic reporting systems (disease surveillance).” [4]
- “Develop a standard “play book” on effective school absenteeism monitoring and interpretation.” [1]
- “Provide better guidance on when the change in the percentage of ILI due to flu triggers a change in clinical practice, and how rapid tests contribute to/influence this assessment.” [1]
- “Secure adequate funding to sustain disease surveillance and laboratory program services made possible through the CDC Public Health Emergency Response (PHER) cooperative agreement (Phases I and II) which is scheduled to terminate on July 30, 2010.” [1]

**Issue:**

**Surveillance system needs.**

- “Who will monitor and/or control the surveillance system needs to be determined.” [4]
- “Goals need to be determined and set as to how the surveillance system will be used.” [4]
- “A less labor intensive surveillance system needs to be established.” [4]
- “The need to balance the tension between the immediacy of the situation versus granularity of information.” [1]
- “How best to refine surveillance systems to detect and capture the occurrences of considerable variability in disease, both geographically (e.g. neighborhood/community outbreaks) and within population groups (e.g. race/ethnicity).” [1]
- “Use of the current surveillance system as a diagnostic system caused issues.” [4]
- “There needs to be separation between the surveillance system and diagnostic system.” [4]
- “The top priorities for surveillance are determining severity of illness and risk factors for infection.
  - Severity of illness drives decision-making.
  - There should be movement toward greater nationwide consistency in the reporting of data.
  - Use of sentinel providers is an option for more timely, less labor intensive surveillance.
  - Surveillance for antiviral resistance should also be prioritized.” [4]
- “Systems and protocols should build on and improve upon those for seasonal influenza response.
  - However, alternate data sources and health information technology, such as syndromic surveillance, Google, and electronic health records systems, should be leveraged for better situational awareness.” [4]
- “The current system does not capture or determine the severity of illness in real time.” [4]
- “Illness severity was not easily determined or characterized.” [4]

**Issue Type:**

**Policy**

**Recommendations Identified:**

- “Seasonal influenza surveillance systems and sources should be modified and enhanced to support pandemic operations at the federal, state and local levels.” [4]
- “Revise surveillance systems to capture more specific data on at-risk and vulnerable populations.” [1]
- “Obtaining more locally oriented and granular disease surveillance data (as compared to statewide or national) to better target public health response and services, given local variability of influenza outbreaks.” [1]
- “Re-examine ILINet for the purpose of creating greater standardization and consistency among states as it pertains to definition interpretation (e.g. “widespread, “regional”, etc) and reporting.” [1]
- “Conduct an evaluation of epidemiologic and surveillance systems used during the H1N1 response to determine what worked well and what could be improved. As part of this process, determine what data elements were necessary and useful and cull out those which were not for the purpose of streamlining and simplifying data acquisition and analysis.” [1]
- “A more integrated approach to federal biosurveillance programs is needed that is based on a clearly defined mission, goals, and priorities. This approach should include a scientific analysis of what information is needed to manage various health emergencies, interoperability among various surveillance systems, and a process for continuous improvement of the systems through rigorous evaluation of events and exercises.” [29]
- “The federal and state governments should harness the momentum toward universal health information technology to improve digital linkages between public health agencies and

- hospitals so as to improve public health access to the key clinical data.” [29]
- “The federal government should invest in increasing the surge capacity of clinical and public health laboratories and in the development and dissemination of rapid diagnostic tests.” [29]
  - “The HPP should continue to promote the development of healthcare coalitions for a variety of reasons, one of which is to provide a mechanism to collect critical information from hospitals and other healthcare facilities. The HPP, along with CMS and the CDC, should continue to promote digital linkages between hospitals and health departments.” [29]

## B.2 Reporting Estimated Cases, Deaths and Hospitalizations

<i>Issue:</i>	<p><b>Guidance on reporting cases.</b></p> <ul style="list-style-type: none"> <li>• “Clearly identify reporting requirements. Collection and reporting of individual case data is neither sustainable nor necessary for an effective long-term response. Exceptions include targeted populations of interest, such as pediatric deaths, pregnant women, and health care workers. Methods of displaying and representing population data should be developed and employed routinely to shift public and media expectation away from individual case-based data.” [4]</li> <li>• “There are problems with daily reporting vs. weekly reporting.” [4]</li> <li>• “The use of case count information is not uniform across states.” [4]</li> <li>• “Need to determine if case counting should be used.” [4]</li> <li>• “Case-based reporting is not practical or sustainable.” [4]</li> </ul>
<i>Issue Type:</i>	Policy
<i>Recommendations Identified:</i>	<ul style="list-style-type: none"> <li>• “To develop a collection and reporting Standard Operating Procedure (SOP) for disease surveillance that is sustainable during a long term response. The guidance must include exceptions for targeted populations of interest, such as pediatric deaths, pregnant women, and health care workers.” [4]</li> </ul>

<i>Issue:</i>	<p><b>Case reporting and privacy.</b></p> <ul style="list-style-type: none"> <li>• “Are existing legal requirements adequate to prevent inadvertent disclosure of patients’ identity, including disclosure via CDC publications such as the Morbidity and Mortality Weekly Report (MMWR)? A recent MMWR article reportedly contained epidemiologic information enabling inferential identification of an H1N1 patient. States would like clarification of privacy protection laws application to CDC in such cases. (Note: a) Some states’ laws explicitly allow their health agencies to disclose identifiable information to local health agencies and to CDC; b) One state recently enacted authority to disclose disease information to local health agencies in other states.)” [7]</li> <li>• “Level of identifiers reported to media to inform public of risk balanced against individual right to privacy.” [8]</li> <li>• “Prevention of disclosure of identifiable patient information.” [8]</li> <li>• “Disclosure of information through channels outside of public health (ex. Coroner’s office).” [8]</li> <li>• “Disclosure of names of schools or school districts with students with confirmed A (H1N1) cases to inform other parents of risk.” [8]</li> <li>• “Implication of Family Educational Rights and Privacy Act (FERPA) for schools’ ability to report information to immunization registries and public health agencies.” [8]</li> </ul>
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*Issue Type:* Policy, Legal

*Recommendations Identified:*

- “Communicate CDC’s relevant legal authorities and policies to state and local public health counsel.” [7]

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*Issue:* **Messaging about cases, deaths, hospitalizations.**

- “Use of data in media communications was a complicated issue.” [1]
- “A need for enhanced explanation of CDC case, hospitalization, and death estimates to the public.” [1]
- “Having the ability to preview of CDC’s media messages so states could be ready for media questions, when feasible.” [1]
- “A single streamlined source of case information did not exist.” [4]
- “In some instances, the federal government got ahead of states/locals when reporting state/local cases before families and community had been notified.” [4]
- “Recognize the importance of collecting and packaging data in a useful way to numerous audiences with differing needs, particularly the media.” [1]

*Issue Type:* Policy

*Recommendations Identified:*

- None identified

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### B.3 Laboratory Services General

*Issue:* **Demands on public health laboratories need to be better managed.**

- “Diagnostic needs and surveillance needs should be balanced, with public health laboratories focusing on surveillance needs. However, public health laboratories still need to monitor which strains are circulating in the environment and any virological changes in strains.” [4]
- “Laboratories are overwhelmed with private sector testing and do not have the capacity to handle all of the samples.” [4]
- “Better clinical guidelines and clinician education on which patients to test will reduce the testing burden on laboratories and target testing to public health needs.” [4]
- “Communication and cooperation with private laboratories will be critical to a comprehensive understanding of the outbreak and a successful response.” [4]
- “Improved communication between epidemiologists and laboratorians around testing priorities is needed.” [4]
- “More regional type laboratories would be helpful in communicating information but may be hard to stand up by this fall.” [4]
- “There is a need to improve communication to suspect cases regarding the longer timeline to receive lab results, and why it takes longer.” [4]
- “There is a need for better guidance to physicians on how to use the rapid diagnostic tests, and which decisions should be made based on a negative test.” [4]

*Issue Type:* Policy

- Recommendations Identified:*
- “To provide guidance to clinical and public health laboratories on diagnostic testing and virus studies.” [4]
  - “Consider making CDC laboratory test kits available to at least a subset of trusted private partners to increase laboratory surge capacity and overall sentinel surveillance capacity.” [1]
  - “Secure sufficient and sustained funding to improve lab capacity to ensure more timely lab results and the ability to maintain a high level of testing, if necessary; this is especially critical in the territories.” [1]
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#### B.4 Epidemiology - General

*Issue:* None identified

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#### B.5 Surveillance, Epidemiology, and Laboratory Services Communications

*Issue:* None identified

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#### B.6. Surveillance, Epidemiology, and Laboratory Services Other Issues

- Issue:* **Global surveillance.**
- “Some observers are concerned that the lack of confirmed cases of H1N1 human cases to date in any African country is more an indication of the poor condition of laboratory and surveillance systems in Africa rather than a lack of H1N1 transmission. Although there is consensus that laboratory and disease surveillance capacity is weak in most African countries, CDC, USAID, and other international health experts have been working to improve those systems.” [14]
  - “Efforts are underway to improve the surveillance and detection of pandemic-related threats, but targeting assistance to countries at the greatest risk has been based on incomplete information, particularly from developing countries.” [17, 20]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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*Issue:* **Surveillance, epidemiology, and laboratory research and development needs.**

*Issue Type:* Policy

- Recommendations Identified:*
- “*Modernize disease surveillance systems.* Every health department and health agency should be part of a 21st century surveillance system that meets national standards and is interoperable between jurisdictions and agencies to ensure rapid information sharing. Surveillance systems should be able to detect and help manage response to infectious disease outbreaks or a bioterrorist attack. Plans should ensure adequate laboratory
-

surveillance of influenza and other infectious diseases, as well as testing for pathogens such as E. Coli, Methicillin-resistant Staphylococcus aureus (MRSA), and extensively drug-resistant Tuberculosis (XDR-TB).” [22]

- “*Modernize an obsolete food safety system.* Congress should enact strong food safety modernization legislation that would give FDA increased authority and tools to prevent foodborne illness. Bills currently before Congress include provisions that would allow FDA to require food plants to identify potential hazards and take steps to mitigate them, trace foodborne outbreaks, increase inspection of facilities, and recall tainted foods.” [22]
  - “*Public health should be a central part of the design and implementation of health information technology systems.* Current health information technology is concentrated on electronic health records (EHRs), which are used to improve patient care and efficiency. As the use of EHRs grows, public health officials’ need for near real-time data on disease surveillance should be factored into their design and implementation. Public health officials can use data from EHRs to monitor the health of the population and the demand for care, making them invaluable tools to help detect and mitigate public health emergencies. In order to encourage the development of EHRs that also benefit public health, the Office of the National Coordinator for Health Information Technology (ONC) is releasing proposed meaningful use criteria that will define how new health IT systems developed with funds from the 2009 American Recovery and Reinvestment Act (ARRA) function.” [22]
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## III.C Medical Care and Medical Countermeasures

Please see the introduction to Section III on page 13 for general information about the data contained in this subsection.

### Medical Care and Medical Countermeasures Section Contents

- C.1 Medical Countermeasures (MCM) General
  - C.1.1 Identification, Formulation and Manufacture of MCM
  - C.1.2 MCM Allocation Approaches and Guidance
  - C.1.3 MCM Stockpiles, Inventory Management and Supply Chain
    - C.1.3.a MCM Stockpiles
    - C.1.3.b MCM Inventory Management and Supply Chain
  - C.1.4 MCM Destruction and Disposal
  - C.1.5 MCM Distribution
    - C.1.5.a MCM Distribution from Stockpiles
    - C.1.5.b Distributed MCM Inventory Management and Supply Chain
  - C.1.6 Administering MCM
    - C.1.6.a Authority to Administer MCM
    - C.1.6.b MCM Administration Sites/Practices
    - C.1.6.c MCM Payment/Reimbursement
  - C.1.7 MCM Tracking/Recall
  - C.1.8 MCM Adverse Events Reporting
  - C.1.9 MCM Coverage Determination and Reporting
- C.2 Antivirals
  - C.2.1 Identification, Formulation and Manufacture of Antivirals
  - C.2.2 Antivirals Allocation Approaches and Guidance
  - C.2.3 Antivirals Stockpiles, Inventory Management and Supply Chain
    - C.2.3.a Antivirals Stockpiles
    - C.2.3.b Antivirals Inventory Management and Supply Chain
  - C.2.4 Antivirals Destruction and Disposal
  - C.2.5 Antivirals Distribution
    - C.2.5.a Distribution of Antivirals from Stockpiles
    - C.2.5.b Distributed Antivirals Inventory Management and Supply Chain
  - C.2.6 Administering Antivirals
    - C.2.6.a Authority to Administer Antivirals
    - C.2.6.b Antivirals Administration Sites/Practices
    - C.2.6.c Antivirals Payment/Reimbursement
  - C.2.7 Antivirals Tracking/Recall
  - C.2.8 Antivirals Adverse Events Reporting
  - C.2.9 Antivirals Coverage Determination/Reporting
- C.3 Personal Protective Equipment (PPE) and Infection Control Measures (ICM)
  - C.3.1 Identification, Formulation and Manufacture of PPE/ICM
  - C.3.2 PPE/ICM Allocation Approaches and Guidance
  - C.3.3 PPE/ICM Stockpiles, Inventory Management and Supply Chain
    - C.3.3.a PPE/ICM Stockpiles
    - C.3.3.b PPE/ICM Inventory Management and Supply Chain
  - C.3.4 PPE/ICM Destruction and Disposal
  - C.3.5 PPE/ICM Distribution
    - C.3.5.a PPE/ICM Distribution from Stockpiles
    - C.3.5.b Distributed PPE/ICM Inventory Management and Supply Chain
  - C.3.6 Administering PPE/ICM
    - C.3.6.a Authority to Administer PPE/ICM
    - C.3.6.b PPE/ICM Administration Sites/Practices
    - C.3.6.c PPE/ICM Payment/Reimbursement
  - C.3.7 PPE/ICM Tracking/Recall
  - C.3.8 PPE/ICM Adverse Events Reporting
  - C.3.9 PPE/ICM Coverage Determination/Reporting
- C.4 Emergency Use Authorizations
- C.5 Medical Equipment Caches and Tracking
- C.6 Alternate Care Sites
- C.7 Standards of Care
- C.8 EMTALA Issues
- C.9 Medical Care and Medical Countermeasures Communication
- C.10 Medical Care and Medical Countermeasures Other Issues

## **Summary of Issues**

### **C.1 Medical Countermeasures (MCM) General**

#### **C.1.1 *Identification, Formulation and Manufacture of MCM***

- None identified

#### **C.1.2 *MCM Allocation Approaches and Guidance***

- MCM allocation planning.
- Guidance issues.

#### **C.1.3 *MCM Stockpiles, Inventory Management and Supply Chain***

##### **C.1.3.a *MCM Stockpiles***

- SNS – Need to review/revise guidance and policies.
- SNS – Planning and exercising needs.
- Ventilator supply issues.

##### **C.1.3.b *MCM Inventory Management and Supply Chain***

- Supply chain visibility and status.
- Data about inventory/supply chain.
- Redirection of assets.
- Inventory storage and security issues.

#### **C.1.4 *MCM Destruction and Disposal***

- Guidance and funding needed for disposing of countermeasures.

#### **C.1.5 *MCM Distribution***

##### **C.1.5.a *MCM Distribution from Stockpiles***

- SNS – Information about distribution and delivery of SNS assets.
- Ownership and use of SNS assets after distribution.
- Local distribution of countermeasures.

##### **C.1.5.b *Distributed MCM Inventory Management and Supply Chain***

- Commercial supply chain visibility.
- Countermeasure Response and Administration (CRA) System.

#### **C.1.6 *Administering MCM***

##### **C.1.6.a *Authority to Administer MCM***

- None identified

##### **C.1.6.b *MCM Administration Sites/Practices***

- Administering MCMs to federal employees.
- Access to MCMs by special and vulnerable populations.
- MCMs administered at clinical sites.

##### **C.1.6.c *MCM Payment/Reimbursement***

- Fess for dispensing assets from stockpiles.

- C.1.7 ***MCM Tracking/Recall***
  - Tracking use of SNS assets.
- C.1.8 ***MCM Adverse Events Reporting***
  - None identified
- C.1.9 ***MCM Coverage Determination and Reporting***
  - None identified
- C.2 **Antivirals**
  - C.2.1 ***Identification, Formulation and Manufacture of Antivirals***
    - Investments in pandemic planning and stockpiling antiviral medications paid off.
    - Antivirals formulation options.
    - Compounding antivirals.
  - C.2.2 ***Antivirals Allocation Approaches and Guidance***
    - Need to clarify antivirals policy guidance.
  - C.2.3 ***Antivirals Stockpiles, Inventory Management and Supply Chain***
    - C.2.3.a ***Antivirals Stockpiles***
      - Supplies and use of SNS antivirals.
      - Private stockpiles.
    - C.2.3.b ***Antivirals Inventory Management and Supply Chain***
      - Antivirals extension and relabeling.
  - C.2.4 ***Antivirals Destruction and Disposal***
    - None identified
  - C.2.5 ***Antivirals Distribution***
    - C.2.5.a ***Distribution of Antivirals from Stockpiles***
      - Distribution and delivery of SNS assets.
    - C.2.5.b ***Distributed Antivirals Inventory Management and Supply Chain***
      - Supply chain visibility.
  - C.2.6 ***Administering Antivirals***
    - C.2.6.a ***Authority to Administer Antivirals***
      - Legal requirements for administering antivirals.
    - C.2.6.b ***Antivirals Administration Sites/Practices***
      - Antivirals messaging.
      - Clinical guidelines on administering antivirals.
      - Pharmacy guidelines.
      - Access to antivirals by special and vulnerable populations.
      - Post-exposure prophylaxis.
    - C.2.6.c ***Antivirals Payment/Reimbursement***
      - Antivirals payment and coverage issues.

- C.2.7 ***Antivirals Tracking/Recall***
  - None identified
- C.2.8 ***Antivirals Adverse Events Reporting***
  - Antivirals resistance tracking.
  - Tracking efficacy and harm of antivirals.
- C.2.9 ***Antivirals Coverage Determination/Reporting***
  - None identified
- C.3 **Personal Protective Equipment (PPE) and Infection Control Measures (ICM)**
  - C.3.1 ***Identification, Formulation and Manufacture of PPE/ICM***
    - None identified
  - C.3.2 ***PPE/ICM Allocation Approaches and Guidance***
    - Mask guidance general concerns.
    - CDC vs. NIOSH and OSHA mask guidance.
    - Potential fines for non-compliance with OSHA requirements.
    - PPE allocation principles.
    - Allocation of N-95 masks.
  - C.3.3 ***PPE/ICM Stockpiles, Inventory Management and Supply Chain***
    - C.3.3.a ***PPE/ICM Stockpiles***
      - SNS – Specification of mask types in stockpile.
    - C.3.3.b ***PPE/ICM Inventory Management and Supply Chain***
      - Determining if a shortage of PPE exists.
  - C.3.4 ***PPE/ICM Destruction and Disposal***
    - None identified
  - C.3.5 ***PPE/ICM Distribution***
    - C.3.5.a ***PPE/ICM Distribution from Stockpiles***
      - None identified
    - C.3.5.b ***Distributed PPE/ICM Inventory Management and Supply Chain***
      - None identified
  - C.3.6 ***Administering PPE/ICM***
    - C.3.6.a ***Authority to Administer PPE/ICM***
      - None identified
    - C.3.6.b ***PPE/ICM Administration Sites/Practices***
      - PPE messaging.
      - PPE clinical guidance.
    - C.3.6.c ***PPE/ICM Payment/Reimbursement***
      - None identified

- C.3.7 ***PPE/ICM Tracking/Recall***
  - None identified
- C.3.8 ***PPE/ICM Adverse Events Reporting***
  - None identified
- C.3.9 ***PPE/ICM Coverage Determination/Reporting***
  - None identified
- C.4 **Emergency Use Authorizations**
  - EUA requirements and timing.
  - EUA messaging.
  - Content and format of EUA patient information sheets.
  - Extension of EUA antivirals.
  - EUA termination.
- C.5 **Medical Equipment Caches and Tracking**
  - Tracking of medical equipment.
  - HAvBED reporting.
  - Medical capacity concerns.
  - Financing health care system preparedness.
- C.6 **Alternate Care Sites**
  - Alternate care site planning.
  - Alternate care site concerns.
- C.7 **Standards of Care**
  - Alternative standards of care messaging.
  - Alternate/crisis standards of care must be addressed.
  - Altered standards of care concerns.
- C.8 **EMTALA Issues**
  - EMTALA screening issues.
- C.9 **Medical Care and Medical Countermeasures Communication**
  - Communications general observations.
  - Communications to/from CDC, other feds and organizations.
  - Communication mechanisms/frequency and messaging.
  - Communications with the health care community.
  - Communications with other partners.
- C.10 **Medical Care and Medical Countermeasures Other Issues**
  - Identify and collect best practices.
  - Policy and funding issues.

- Medical countermeasures research and development needs.

## **Issues Detail**

### C.1 Medical Countermeasures (MCMs) - General

#### C.1.1 Identification, Formulation and Manufacture of MCMs

*Issue:* None identified

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#### C.1.2 MCM Allocation Approaches and Guidance

**Issue**

**MCM allocation planning.**

- “Clarification of who is to provide assets, including vaccines, to federal workers, contractors and their families.
  - Identify the federal facility workers and contractors within a jurisdiction.
  - Federal agencies should reach out to states/locals to identify themselves.
  - Clarify who will be administering assets (i.e., vaccines when received by feds and who will administer them?).
  - Ensure that assets are used following recommended clinical guidelines.” [4]
- “Identify priority groups for critical infrastructure.” [4]
- “Clarify/identify federal agencies in states and determine:
  - Who has good Continuity of Operations Plans?
  - Who has assets available/who needs them?
  - Who needs additional assistance/education?” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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**Issue:**

**Guidance issues.**

- “There is a lack of clear guidance on the appropriate use of countermeasures.” [4]
- “At the start of the event, it was unknown how severe the situation actually was. As a result, the messaging to providers was based on the more severe situation that was anticipated.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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### C.1.3 MCM Stockpiles, Inventory Management and Supply Chain

#### C.1.3.a MCM Stockpiles

- Issue:** SNS – Need to review/revise guidance and policies.
- “Guidance about when to use the stockpile is important.” [4]
  - “It was decided that DSNS would release the stockpile very early to be in place in case disease ended up being severe.” [4]
  - “DSNS assumed that the stockpile would be immediately used because of anticipated severity. When that didn’t happen, guidance made it clear to only use as a “last resort.” ” [4]
  - “More guidance was needed on how to work with HHS/REC Program in the request process.” [9]
  - “A county health officer raised what she described as an ethical and equity issue. Her jurisdiction planned SNS distribution based on a duty to safeguard a cache of supplies to serve the needs of the uninsured and undocumented. Those needs did not arise as anticipated, leaving the jurisdiction with a full warehouse, and prompting her to ask IPR participants, “Now what?” ” [1]
  - “Prescriptions written need to correspond with surveillance, and supply when requests are made.” [9]
  - “*Lack of clear guidance regarding triggers for the states to release the stockpile.* There is confusion about what events trigger the release/use of the stockpile. Stockpile should be used under emergency situations only, but the definition of “emergency” may vary from state to state. It is also necessary to identify who is responsible for distributing the stockpile, and to whom.” [4]

**Issue Type:** Policy

- Recommendations Identified:**
- “Survey to determine what states currently consider their triggers. From this survey, perhaps best practices can be used to develop recommendations.” [4]
  - “Stakeholders will develop triggers for releasing stockpile assets.” [4]
  - “Establish a protocol and process to guide the review and determination of states’ requests to CDC to draw down medical countermeasures from the SNS, balancing the needs of the states to adequately protect the public, including forward community placement of medical countermeasures when warranted, with CDC’s stewardship responsibility to prudently manage limited assets.” [1]
  - “Provide thorough and timely guidance on distribution planning assumptions and on all hazards SNS planning to assist in responding to any event.” [9]
  - “Scalable operational plans at the federal level.” [9]
  - “Scalable SNS state plans integrated into larger medical countermeasure plans.” [9]
  - “Funding priorities should be more aligned with planning requirements.” [9]
  - “Engaging large private sector partners would be helpful.” [9]

- 
- Issue:** SNS – Planning and exercising needs.
- “The 2009-2010 H1N1 response tested the federal, state and local SNS programs’ ability to deliver materiel and medical countermeasures in an unprecedented manner. Planning assumptions based upon a scenario which anticipated an H5N1 virus coming to the United States through Asia had to be totally redeveloped. Plans that had focused on worst case

scenarios must now be considered from a less severe perspective with the potential to “ramp up.” Jurisdictions will need to exercise plans that are redeveloped from these lessons learned. Despite the challenges encountered in this response, the system delivered the materiel and guidance that it was designed to deliver and demonstrated the resilience necessary to benefit future responses to pandemic influenza and other threats.” [9]

*Issue Type:* Policy

- Recommendations Identified:*
- “States need to conduct flexible scalable exercises, based on scenarios that are less than worst case scenarios. This would identify issues that only occur when there is a lack of urgency.” [9]
  - “CDC should provide distribution planning assumptions.” [9]
  - “All hazards SNS plans would assist in responding to any event (FYI, CA now calls it medical countermeasure planning, not SNS.)” [9]
  - “Make SNS scalable and integrated into larger medical countermeasure plans.” [9]
  - “Scalable operational plan at the federal level.” [9]
  - “Planning, not the plan itself is critical.” [9]
  - “Adjust the Technical Assistance Review (TAR); make it capability based.” [9]
  - “Funding requirements should be more aligned with planning requirements.” [9]
  - “Guidance on engaging large private sector partners would be helpful.” [9]

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*Issue:* **Ventilator Supply Issues**

- “Survey states to identify what types of ventilators are needed for future SNS acquisition decisions and to guide state procurement actions.” [1]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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### *C.1.3.b MCM Inventory Management and Supply Chain*

*Issue:* **Supply chain visibility and status.**

- “There is confusion over who manages the supply chain issue. There should be a single point of contact with authority to monitor all supply (public/private), and can provide adequate information without breaching proprietary information.” [4]
- “There is a lack of visibility of state, local, private and federal stockpile assets.” [4]
- “Guidance and implementation must be feasible and support what is actually in the supply chain.” [4]
- “DSNS has been trying to keep the other federal agencies “back” from asking the states about their supply chain. But they do need information, even if it’s just aggregate information to report back. During an event, they need to know what a reasonable frequency is. Likely, daily will be too much, but weekly will likely be necessary.” [4]
- “If there is no visibility and accountability of supply, critical decisions cannot be made regarding supply.” [4]
- “DSNS will be drafting a situational report with the following information included:
  - Current inventory levels

- Burn rates if possible
  - What to do in the event of shortages.” [4]
- “The flow of supply chain information from states back to federal government is not clear. Need adequate information from states to assist federal government in making policy and supply chain decisions.” [4]
- “There was a lack of visibility of stockpile, state, local and commercial/private assets. There is a need for supply chain visibility for the following reasons:
  - Accountability of resources so federal government knows what is available and if they need to reconsider policy issues and/or look to resupply.
  - Need to know when there is a shortage (first, “shortage” must be defined).
  - States/locals need to know what brands are in the stockpile so they know how to train/fit-test, and what to expect.” [4] [1]
- “Information needs to move up the chain and trainings on SNS have to be given to all stakeholders.” [9]
- “Having an executive summary for an SNS plan and moving the request procedure to a web-based system seems like a logical next step. Also, it would helpful if the requesting process was part of the inventory management system.” [9]
- “It is important that any type of medical countermeasure goes through the established system to avoid problems for the states.” [9]

*Issue Type:* Policy

- Recommendations Identified:*
- “Create or tap into existing systems to improve “line of sight” situational awareness in order to possess more robust and real time information on how states are using medical countermeasures, including decision triggers, and how they are addressing special needs or circumstances (e.g. providing medical countermeasures to the uninsured).” [1]
  - “Develop aggregate report from state survey that will address issues (Are they dispensing? Are there spot/regional/state shortages? What is a shortage?).” [4]

*Issue:* **Data about inventory/supply chain.**

- “DSNS is in the process of developing a web-based dashboard that would make supply chain information highly visible. The allocation process will also be posted.” [4]
- “RITS was not intuitive and was therefore not very feasible to use for inventory management.” [9]
- “It was suggested that the Dashboard be available to state.” [9]
- “There is a need for pre-populated data from the stockpile managed inventory.” [9]
- “There is a need for a better inventory list of products that are being received.” [9]

*Issue Type:* Policy

- Recommendations Identified:*
- “Make better use of hospital data and apply meaningful use criteria to further integrate data streams to obtain and fuse real time information on medical countermeasure use and disease burden. Consider initiating electronic medical records (EMR) pilot projects involving state and local health departments.” [1]
  - “Dashboard development through DSNS to assist in providing visibility of antivirals and PPE.” [4]

<b>Issue:</b>	<b>Redirection of assets.</b>
	<ul style="list-style-type: none"> <li>• “Many have unused items still in warehouses; some would like permission to redirect those supplies for non-H1N1 activities.” [1]</li> <li>• “Use of SNS assets nearing expiration for indigent patients.” [8]</li> </ul>
<i>Issue Type:</i>	Policy
<i>Recommendations Identified:</i>	<ul style="list-style-type: none"> <li>• “Allow states to redirect unused H1N1 response supplies for other legitimate public health activities.” [1]</li> </ul>

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<b>Issue:</b>	<b>Inventory storage and security issues.</b>
	<ul style="list-style-type: none"> <li>• “Long term storage has issues related to leases and use of PHER funds. There are also issues related to disposal and removal of product.” [9]</li> <li>• “States need to reevaluate scalable security requirements.” [9]</li> <li>• “One RSS site for one emergency may not work for another emergency so different RSS sites need to developed in states (short-term vs. long-term).” [9]</li> <li>• “Long-term storage sites will be expensive and need to comply with many federal regulations so this needs to be addressed moving forward.” [9]</li> </ul>
<i>Issue Type:</i>	Policy, Legal
<i>Recommendations Identified:</i>	None identified

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#### C.1.4 MCM Destruction and Disposal

<b>Issue:</b>	<b>Guidance and funding needed for disposing of countermeasures.</b>
	<ul style="list-style-type: none"> <li>• “Many jurisdictions requested guidance and even financial assistance for the disposal of some countermeasures (including ancillary supplies associated with vaccine distribution).” [1]</li> <li>• “Another critical discussion issue was the disposal of the medical countermeasures when they have expired or are no longer needed. Many of the state SNS coordinators in attendance indicated that they were seeking increased information and flexibility with their SNS supplies. Many jurisdictions requested guidance and financial assistance for the disposal of some countermeasures (including ancillary supplies associated with vaccine distribution).” [9]</li> <li>• “Funding is an issue when considering disposal options, and is also a crucial issue in warehousing and storage of other supplies. Many states do not have the space or funds to store supplies or for expenses related to security of stored assets.” [9]</li> <li>• “CDC is developing guidance on the relabeling of assets with expiration dates extended by FDA.” [4]</li> </ul>
<i>Issue Type:</i>	Policy, Legal
<i>Recommendations Identified:</i>	None identified

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## C.1.5 MCM Distribution

### C.1.5.a MCM Distributed from Stockpiles

**Issue:**

**SNS – Information about distribution and delivery of SNS assets.**

- “Information from CDC to states was not clear regarding the delivery of SNS assets. Some states had communication issues, and were unaware of what they were receiving and when. There is a need for better situational awareness of delivery timelines and content.” [4]
- “More inventory transparency was needed – states did not know what specific items they were receiving, and in some cases had to check the shipment themselves before redistribution. For example, whether the RSS was receiving 50 gloves or 50 pairs of gloves, etc.” [9]
- “Logistically – the trucks delivering SNS need to have detailed packing slips, and receivers should be aware of what they are receiving and when.” [4]
- “Local jurisdictions were aware of and prepared for state plans to distribute countermeasures.” [9]
- “Everyone indicated that the SNS response went smoothly in the spring, and challenges have begun now, with long-term storage issues.” [9]
- “Work needs to be done to determine a better ability to track dispensing of assets (burn rates, rather than patient level) and adopt a format for tracking data before an event.” [9]
- “There was a lack of quality control on shipments and validations of arrival of shipments.” [9]
- “Communication of the contents of FedEx shipments was often unclear.” [9]
- “Mistakes that were made were somewhat to be expected given the volume of trucks leaving the warehouse.” [9]
- “The tracking and estimates of arrivals were very weak.” [9]
- “States would like to have a direct role in tracking arrivals of shipments. This would allow drivers to contact state EOCs to provide ETAs. Likewise, states able to directly contact truck drivers would allow for better estimates of arrivals.” [9]
- “Two separate operations were taking place; a pharmaceutical and non-pharmaceutical response, which often led to confusion and a lack of clarity about what products were coming from whom.” [9]
- “States often wanted more detail than CDC was able to provide.” [9]
- “SNS release caused transportation, storage and other logistical issues.”
  - CDC/Division of SNS (DSNS) is developing a dashboard to capture information on the availability and use of antivirals and PPE by August 1, 2009. The dashboard will include aggregate reporting on supplies and shortages. This will improve visibility of the supply chain from the manufacturer to the dispensing site.
  - ASTHO will deploy a survey in July to capture information on already distributed SNS assets. Information gathered will include whether a state has dispensed any assets and, if so, how much of the supply remains, who they distributed assets to, and what triggered the decision to begin dispensing.
  - CDC is developing guidance on the relabeling of assets with expiration dates extended by FDA.” [4]

**Issue Type:** Policy

*Recommendations Identified:*

- “To establish consistent information to be distributed to states receiving stockpile, DSNS will ensure packing slips are included with the shipment and that all deliveries are tracked.” [4]
- “CDC should create a portal with advance shipping notices, barcodes, and delivery time. It was also mentioned that during the response, states sought increased information and flexibility with SNS supplies, such as delivering to multiples sites within a city.” [1]

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*Issue:*

**Data needs regarding the status of distributed stockpile assets.**

- “After the pro-rata supply was distributed to the states, the federal government lost visibility of the distributed assets.” [4]
- “Jurisdictions expressed a desire for more state specific inventory data rather than national aggregate data to make informed decisions about allocations of materiel. DSNS noted that businesses have a need to keep their information private to remain viable. Therefore, when dealing with distributors, DSNS recommended adopting their business model instead of trying to change it.” [9]
- “To address some of the issues regarding data management, CDC/DSNS senior leadership representatives previewed the development of an all-hazards information portal with advance shipping notices, barcodes, and delivery times that will alleviate many of the logistic, inventory management, and data collection concerns that became apparent during the H1N1 response.” [9]
- “Need to agree upon simple and minimal basic data elements that are needed by CDC from all states for requests of more assets, and a consistent mechanism(s) for supplying the states.” [9]
- “Information requirements need to be defined in advance.” [9]
- “Standard formats for data collection are needed since states and federal partners wanted information in different formats, making it difficult to effectively collect and report the data.” [9]
- “Hospitals and clinics were resistant to computer entered data (firewalls, resistance to passwords), so many states used fax machine to send information.” [9]
- “Private partners were not willing to enter their data into another system, either state or federal. There is a need for these private partners to be able to dump their data into a system. This will help establish a baseline of materiel available.” [9]
- “All levels of Public Health were unable to get a real-time data snapshot of inventory or usage.” [9]
- “It was difficult for both CDC and the states to get data from the local level.” [9]
- “The resistance level to compliance with data requests went up as the number of requests increased during the response.” [9]
- “Some states found out that their scannable forms did not work and that the barcode system was not conducive to rapid response.” [9]

*Issue Type:*

Policy

*Recommendations Identified:*

- “Conduct a survey of state health agencies to determine supply and supply equity (and determine what their current “triggers” are).” [4]
- “Implement an SNS call line with basic information on products to assist state and local officials given the range of product manufacturers and product types and models.” [1]
- “Create a process to barcode SNS assets so states can integrate with their existing warehousing systems.” [1]

- Issue:** **Ownership and use of SNS assets after distribution.**
- “States have questions regarding ownership of SNS assets once they have been distributed. Do MOUs developed for activation of push-packs also apply to later distribution of push-pack assets? If not, do new MOUs need to be developed to cover late distribution? Do state/local health departments own the assets or does the federal government? May states use assets as they wish, including sharing with other states?
    - Push-pack MOUs state that unused product remains federal property but the Division of Strategic National Stockpile (DSNS) has stated it is state property to be used as the states decide. It is unclear if the original push-pack MOUs govern later distribution since they were developed originally only to apply to initial push-pack asset distribution.” [7]
  - “Applicability of prior Memorandums of Understanding (MOUs) to later distribution of Strategic National Stockpile (SNS) assets.” [8]
  - “Drafting of new MOUs regarding SNS assets.”[8]
  - “States’ use of SNS assets; ability to share assets with other states.” [8]

*Issue Type:* Legal

*Recommendations Identified:* • “Determine the scope of application of the original push-pack MOUs. If needed, draft amendments to the push-pack MOUs or develop new, generic template MOUs.” [7]

- Issue:** **Local distribution of countermeasures.**
- “Improve local pandemic influenza vaccine and antiviral drug distribution and dispensing preparedness. CDC, in coordination with States, could improve pandemic influenza vaccine and antiviral drug distribution and dispensing preparedness at the local level.” [12]
  - “Drafting sample “Point Of Distribution” (POD) agreements for SNS assets.” [8]

*Issue Type:* Policy, Legal

*Recommendations Identified:*

- “Determine why localities appear to be in the early stages of planning for pandemic influenza vaccine and antiviral drug distribution and dispensing, and provide assistance to improve their preparedness.” [12]
- “Prioritize the planning areas where States should focus any carryover or future pandemic influenza funding to quickly improve local preparedness to distribute and dispense vaccines and antiviral drugs.” [12]
- “Place special emphasis on ensuring localities develop actionable vaccine and antiviral drug distribution and dispensing plans. Specifically, plans should identify the organizations or individuals responsible for carrying out specific actions and the sources that would be necessary to staff distribution and dispensing positions and should be supported by valid, detailed formal agreements with partnering agencies.” [12]
- “HHS recommends that States and localities collaborate with community partners to develop and exercise their pandemic influenza plans.” [12]

### **C.1.5.b Distributed MCM Inventory Management and Supply Chain**

- Issue:** **Commercial supply chain visibility.**
- “There still needs to be a two way dialog between public health and manufacturers so it is

understood when there is a shortage (still need to define “shortage”).” [4]

- “When should assets be moved out of private sector to meet needs?” [4]
- “It is necessary to know what is in the commercial supply. There are proprietary issues associated with this but it is very important information to know locally and at the federal level. FDA does have visibility but is not allowed to release this information.” [4]
- “State SNS coordinators also stated that they needed more information on the supply chain to make decisions about whether to release their own supply. After the HDMA presentation, there was a request to have continuing education on the supply chain (webinars, etc.) available to a wider audience.” [9]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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***Issue:* Countermeasure Response and Administration (CRA) System.**

- “CRA is adding module, but some states do not use.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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## C.1.6 Administering MCM

### C.1.6.a Authority to Administer MCM

*Issue:* None identified

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### C.1.6.b MCM Administration Sites/Practices

***Issue:* Administering MCMs to federal employees.**

- “There is a need to identify federal employees within a state and clarify how countermeasures will be provided to this population. Federal agencies need to reach out to states and locals to ensure they are accounted for in medical countermeasure plans. State and local health agencies will work with federal agencies to clarify the number of federal workers, contractors, and family members to be covered by federal Continuity of Operations Plans (COOP) versus those covered as part of the general population of the jurisdiction. They will also clarify who will be responsible for administering assets as well as ensure that assets are used according to recommended clinical guidelines.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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**Issue:** Access to MCMs by special and vulnerable populations.

- “Public health agencies will explore policies to address equity of access to medical countermeasures by the uninsured and underinsured.” [4]

**Issue Type:** Policy

**Recommendations Identified:** None identified

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**Issue:** MCMs administered at clinical sites.

- “Refine medical surge capacity.” [4]
- “There is a need to better define clinical severe disease to assist physicians with treatment.” [4]
- “Define what information needs to be proactively collected including the clinical treatment piece and estimated burn rate and costs.” [4]

**Issue Type:** Policy

**Recommendations Identified:** None identified

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#### C.1.6.c MCM Payment/Reimbursement

**Issue:** Fess for dispensing assets from stockpiles.

- “May states allow dispensers (or prescribers who also dispense) to charge a small fee when dispensing antivirals or other SNS assets? Other programs such as Vaccine for Children Program allow for dispensers to charge a small fee (~\$14) covering the costs of dispensing. A similar charge might help to facilitate mass dispensing for H1N1 vaccine or antivirals. If this is allowed, and the doctor was both a prescriber and dispenser, would charging a fee run afoul of the Stark Act?” [7]
- “Ability to charge fee for dispensing antivirals and other SNS assets.” [8]

**Issue Type:** Legal, Policy

**Recommendations Identified:**

- “Clarify whether states can allow dispensers to charge a small fee covering costs of dispensing vaccine or antivirals. Clarify whether the Stark Act might be violated if a doctor were to charge this fee while acting as both prescriber and dispenser.” [7]

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#### C.1.7 MCM Tracking/Recall

**Issue:** Tracking use of SNS assets.

- “Must SNS assets be tracked to the patient level? Is specific tracking information needed or is that up to the states? It is unclear whether SNS assets must be tracked to the patient level. States are currently tracking assets to varying degrees. Options/proposals for tracking could include a) tracking vaccinated children through existing immunization registries; b) tracking immunized adults in order to know who has received a first dose if two doses are recommended (some states track antivirals this way); c) tracking of health

- care workers, including volunteer emergency workers, who receive immunization.” [7]
- “Level of tracking of SNS assets required; information required for tracking.” [8]
- “There should be a way to track to see if stockpile was distributed in an equitable way.” [4]

*Issue Type:* Legal, Policy

*Recommendations Identified:*

- “CDC should clarify whether states are required to track SNS assets to the patient level. States will then be able to move forward with selecting the appropriate tracking option for their state.” [7]

### C.1.8 MCM Adverse Events Reporting

*Issue:* None identified

### C.1.9 MCM Coverage Determination and Reporting

*Issue:* None identified

## C.2 Antivirals

*Aiding Factors:* **Investments in pandemic planning and stockpiling antiviral medications paid off.**

- “Federal, state, and local efforts to develop and exercise pandemic response plans over the last several years enabled public health officials to react to the outbreak effectively and keep the public informed. Investments in antiviral stockpiles and enhanced vaccine manufacturing capacity also proved to be prudent.” [23]

### C.2.1 Identification, Formulation and Manufacture of Antivirals

*Issue:* **Antivirals formulation options.**

- “A major emerging issue for many states was the scarcity of medical countermeasures for pediatrics. Additionally, pediatric countermeasures are very expensive to produce, are not manufactured quickly, and cannot be shelf-life extended.” [9]
- “Policy on inventory procurement and holdings for all formulations – states did not know that SNS was purchasing Tamiflu liquid – caused inventory “re-dos” for pediatric formulations.” [9]

*Issue Type:* Policy

*Recommendations Identified:*

- “Make intravenous zanamivir available as a countermeasure.” [1]

- Issue:** **Compounding antivirals.**
- “Compounding at the pharmacy was a real eye-opener. Everything is so streamlined, but it took extra staffing to make sure we had it covered.” [5]
  - “It was hard for some people to find a pharmacy that was doing the compounding.” [5]
  - “Reimbursement was also an issue. Some CMS policies don’t cover compounding.” [5]
  - “There was confusion on the amounts needed. The system would read “100” as “tabs” not “mL.” Things had to be adjusted. It’s hard to get people to focus on an issue if it’s not seen as an immediate problem.” [5]
  - “Only one type of syrup was mentioned in an FDA release, but there was a shortage of that particular one. There was confusion over whether others could be used.” [5]

*Issue Type:* Policy

*Recommendations Identified:* • “Simplify methods for suspending and compounding pediatric suspensions of oseltamivir and other relevant medical countermeasures.” [1]

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## C.2.2 Antivirals Allocation Approaches and Guidance

- Issue:** **Need to clarify antivirals policy guidance.**
- “Policy guidance is confusing, and it must be cleared up.” [4]
  - “Clinical guidance regarding use of antivirals is unclear.
    - Clinical algorithms.
    - Treatment vs. prophylaxis.
    - Post exposure vs. general population prophylaxis.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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## C.2.3 Antivirals Stockpiles, Inventory Management and Supply Chain

### C.2.3.a Antivirals Stockpiles

- Issue:** **Supplies and use of SNS antivirals.**
- “CDC has recommended that antiviral medications be used only for people with severe cases of H1N1 or for people with underlying health conditions. Many states have purchased their full share of antiviral medications, however 13 states have purchased less than half their share of federally-subsidized antiviral medications for use during a pandemic outbreak.” [21]
  - “Many people wanted to use the antivirals as prophylaxis, and did not realize that the SNS assets could not cover everyone to use them in that manner and had to be reserved for treatment.” [9]
  - “What the criteria are for when to draw down from reserves? For instance, when you make a request, when should CDC honor it? Some states make a decision when they have a shortage, while others push out all of the supply if it is needed since there are always more antivirals currently in production.” [3]

- “Regarding a study of product rotations, this is a good idea for the CDC but it should not be a requirement for states and that CDC should look into how to rotate product out and back in.” [3]

*Issue Type:* Policy

- Recommendations Identified:*
- “States should purchase enough antiviral medications to care for at-risk patients in the immediate term. States that have not purchased significant shares of their allotment of antiviral should at least take action to purchase enough to be able to care for at-risk patients or patients with severe cases of H1N1. It is unclear how severe the H1N1 virus will prove to be with high-risk populations this fall and it will likely re-emerge in a third wave, so states should be prepared by having enough medications to protect their citizens if needed.” [21]
  - “Over the long-term, antiviral purchasing policies should be updated to make purchasing antiviral, vaccines, and equipment for the SNS a federal responsibility. Until that happens, states should take action to ensure they have enough medications to protect their citizens.” [21]

**Issue:** Private stockpiles.

- “If there is a scarcity of antivirals, should private sector stockpiles be encouraged? This may deplete assets that the government could purchase.” [4]
- “Don’t forget the principle of shared responsibility. It cannot be completely up to the federal government and state/local governments to protect their citizens. Organizations/industry/employers/individuals must also take responsibility.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

### C.2.3.b Antivirals Inventory Management and Supply Chain

**Issue** Antivirals extension and relabeling.

- “Expiring supply of some antivirals can be relabeled according to FDA regulations and procedures. CDC is currently working this issue and will send out an RFI to all relabelers to assist states in identifying available, qualified relabelers.” [4]
- “Guidance is needed regarding expiring supply of antivirals. To ensure that viable supply is not wasted, it is necessary to establish a process to relabel products whose shelf life has been extended.” [4]

*Issue Type:* Legal, Policy

- Recommendations Identified:*
- “Provide guidance on relabeling “extended” supply.” [4]
  - “Establish a policy to extend the expiration dates of soon-to-expire or expired antivirals to maximize beneficial use potential without compromising safety or efficacy.” [1]

## C.2.4 Antivirals Destruction and Disposal

*Issue:* None identified

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## C.2.5 Antivirals Distribution

### C.2.5.a *Distribution of Antivirals from Stockpiles*

*Issue:* **Distribution and delivery of SNS assets.**

- “Pharmacies were effective at distributing. There were issues of different plans; we need cross-state border plans that are consistent.” [5]

*Issue Type:* Policy, Legal

*Recommendations Identified:*

- “Create a portal that sends advance shipping notices with more details on shipping.” [1]
- “Allow SNS shipments to be delivered to multiple warehouses within a jurisdiction.” [1]

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### C.2.5.b *Distributed Antivirals Inventory Management and Supply Chain*

*Issue:* **Supply chain visibility.**

- “Participants described the CDC/DSNS Dashboard as an improvement in supply chain visibility over what was experienced in the spring; the main criticism being a strong desire to have more granular, local information. This data would have aided local decision-making because national-level supply information had limited planning utility.” [1]

*Issue Type:* Policy

*Recommendations Identified:*

- “To the fullest extent possible, transition the SNS Dashboard to show local-level data, including pharmacy data.” [1]

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## C.2.6 Administering Antivirals

### C.2.6.a *Authority to Administer Antivirals*

*Issue:* **Legal requirements for administering antivirals.**

- “Need to address waiver of state laws or regulations for dispensing of antivirals.” [8]

*Issue Type:* Legal

*Recommendations Identified:* Non identified

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## C.2.6 b Antivirals Administration Sites/Practices

- Issue:** **Antivirals messaging.**
- “There were all kinds of messages on empirical treatment, testing, etc. Messaging needs to be consistent.” [5]
  - “Messaging around oseltamivir was a “pain point” for insurance. If this had been worse, those would have been drugs of choice. We took on a strategy of conservation, but the messaging from CDC gave the public the impression “I want my Tamiflu.” It puts a strain on the system if we’re not consistent; the guidance was inconsistent.” [5]

**Issue Type:** Policy

**Recommendations Identified:** None identified

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- Issue:** **Clinical guidelines on administering antivirals.**
- “CDC will develop a pocket card of clinical algorithms to assist clinicians in antiviral prescribing. While antivirals distributed from the Strategic National Stockpile (SNS) are intended for treatment, additional guidance will clarify the appropriate use of antivirals for treatment versus prophylactic purposes as well as general population prophylaxis versus post-exposure prophylaxis.” [4]
  - “Clinical algorithms for clinicians would be really helpful to ensure that antivirals are not being prescribed to people who do not really need them so not to encourage antiviral resistance.” [4]
  - “HHS is revisiting policy of post-exposure prophylaxis.” [4]
  - “Clear antiviral guidelines will help ensure appropriate prescribing by clinicians and use for the intended population.” [4]
  - “The guidance for H1N1 was different than the guidance from last winter (when planning for a severe pandemic).” [4]
  - “Policy guidance regarding use of antivirals was unclear. It would be helpful if clinicians were provided a tool to assist with the guidelines regarding the prescription of antivirals. Issues still need to be addressed such as: N95 vs. surgical masks; treatment vs. post-exposure prophylaxis; and post-exposure prophylaxis vs. general population prophylaxis.” [4]

**Issue Type:** Policy

- Recommendations Identified:**
- “Development of a pocket card containing clinical algorithms for clinicians.” [4]
  - “Review antiviral treatment recommendations/ guidelines.” [4]
- 

- Issue:** **Pharmacy guidelines.**
- “Remember to include pharmacists in discussions so they know what they should and should not be dispensing (even with a prescription). This can assist in stopping some of the inappropriately distributed scripts.” [4]

**Issue Type:** Policy

*Recommendations Identified:* None identified

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**Issue:** **Access to antivirals by special and vulnerable populations.**

- “Equity of antiviral access needs to be assessed. Under and un-insured individuals will lack access to antivirals if the primary mode of distribution is private.” [4]
- “There is a pressure to lump those at most need for vaccine and prophylaxis together – these are different issues.” [4]
- “Uninsured and underinsured have issues with access to antivirals. This causes distinct equity issues for those who may need antivirals but do not have insurance or cannot afford treatment.” [4]

*Issue Type:* Policy

*Recommendations Identified:* • “Explore policy issues to address equity of access.” [4]

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**Issue:** **Post-exposure prophylaxis.**

- “What are the implications for opening up stockpile antiviral use for post exposure prophylaxis versus using strictly for treatment purposes? There will not be enough supply for those who really need it. Although the guidance says for treatment only, at some point, if the disease is severe enough, maybe it will be appropriate for post-exposure prophylaxis.” [4]
- “Main issues for antiviral policy guidelines include:
  - Treatment vs. Prophylaxis
  - Post-exposure Prophylaxis vs. general population prophylaxis.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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### **C.2.6.c Antivirals Payment/Reimbursement**

**Issue:** **Antivirals payment and coverage issues.**

- “One SHA has relationships with providers and wanted to make sure all persons were covered regardless of insurance coverage and this system has worked well.” [3]
- “In [State] the current Medicaid amount (\$3.70) covered those who are uninsured and their Pharmacy Board decided that antivirals can be sent to other places without a wholesaler’s license, as long as providers have some kind of tracking system in place to know where it is going.” [3]
- “Medicare/Medicaid reimbursement was also an issue. Some CMS policies don’t cover compounding.” [5]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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## C.2.7 Antivirals Tracking/Recall

*Issue:* None identified

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## C.2.8 Antivirals Adverse Events Reporting

*Issue:* **Antivirals resistance tracking.**

- “A question was raised on whether antiviral resistance tracking is robust enough, an issue the group felt warranted high priority attention in the next 90 days.” [1]

*Issue Type:* Policy

*Recommendations Identified:* • “Determine if the current system for tracking antiviral resistance is sufficiently robust.” [1]

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*Issue:* **Tracking efficacy and harm of antivirals.**

- “Antiviral drugs have never been used on this scale before so it is important that someone is tracking the efficacy and the harm of them so that in the future it can be seen what system works for those who are getting the benefit of taking the drugs. There ought to be crucial clinical information that can come out of this so it is important that states make sure someone is looking at this. This is something to ask CDC about.” [3]
- “Participants raised concerns about the availability and amount of data on peramivir use, requesting greater visibility at the local level on its use and clinical impact.” [1]

*Issue Type:* Policy

*Recommendations Identified:* • “Work with major academic centers on clinical trial enrollment protocols for critically ill patients to achieve a uniform study standard in the review of medical countermeasures safety and efficacy.” [1]

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## C.2.9 Antivirals Coverage Determination/Reporting

*Issue:* None identified

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## C.3 Personal Protective Equipment (PPE) and Infection Control Measures (ICM)

### C.3.1 Identification, Formulation and Manufacture PPE/ICMs

*Issue:* None identified

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### C.3.2 PPE/ICM Allocation Approaches and Guidance

**Issue:**

**Mask guidance general concerns.**

- “CDC’s fall N-95 respirator guidance was also described as an improvement over what was in place in the spring. A participant suggested that CDC re-examine the guidance to see if measures should be expanded or scaled back, especially in light of now having a H1N1 vaccine and known disease severity.” [1]
- “CDC’s Guidance on surgical N-95 respirator masks is highly dependent on assumptions, including how many people will use the N-95 masks and what are the attack rates of those who use them. The use of the N-95 masks should be determined on a facility-to-facility basis.” [3]
- “The divergence of guidance had a negative effect – things became unclear and confusing. The new workgroup to be convened will address these issues and make a determination of what the guidance will be.” [4]
- “Some jurisdictions created their own guidances which conflicted with/amended CDC guidelines (e.g., for N-95 respirators).” [4]
- “The need to revisit the policy on fit-testing and medical clearance requirements for N-95 respirators was also raised. CDC announced that they are in the process of standing up a workgroup to draft a new/revised guidance.” [1]
- “Need to consider guidance practicality – does it need to include N95 fit testing, which is both labor and cost intensive.” [4]
- “N95 issues – availability, science behind it, guidance on use, fit testing (e.g., not enough workforce to fit test in rural areas).” [9]

**Issue Type:**

Policy

**Recommendations Identified:**

- “An existing workgroup is working on developing guidance by September 1, 2009, for the use of PPE, both interim and long-term. This guidance will resolve existing conflicts in recommendations from OSHA and CDC regarding the use of N95 respirators versus surgical masks, address the challenges of fit testing, and consider the PPE needs of professions beyond health care workers.” [4]
- “Reexamine the N-95 respirator guidance to be more practical without compromising worker safety.” [1]
- “Standardization of sizing or a design that does not require fit testing.” [9]
- “National policies about fit testing.” [9]
- “Guidance on inventory and use – an inventory list of what is in SNS is helpful, but does not meet all needs to resolve the issue.” [9]
- “Definition of “shortage,” and its use as a trigger.” [9]
- “Timing issues, size of package, arrival ETAs.” [9]
- “Logistics policies (e.g., “shipped from” labels were still on some boxes after they had been delivered).” [9]

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**Issue:**

**CDC vs. NIOSH and OSHA mask guidance.**

- “There was a lack of clear guidance regarding PPE. The guidance regarding use of PPE from OSHA and CDC was clear, but not compatible, and practical obstacles to implementing CDC guidance arose in many settings. This was discussed numerous times but no resolution was made. Better alignment between CDC and OSHA would reduce both confusion and legal risk for state and local health systems.” [4]
- “At the start of the outbreak, CDC issued precautionary guidance for what could be a very

severe disease (due to news from Mexico). This included screening of individuals, tracing contacts, and monitoring respiratory illness suspected to be influenza A H1N1. The National Institute of Occupational Safety and Health (NIOSH) and OSHA wanted to ensure protection of health care workers. CDC kept in mind that they may have to convene a larger group of experts to put together better science-based recommendations if NIOSH/OSHA decided to lessen their recommendations. This appeared that it might become an intergovernmental issue with stakeholders, because the cost/benefit of PPE would spark extensive discussion.” [4]

- “Some states chose to suggest droplet vs. aerosol guidance/precautions which caused legal issues with OSHA.” [4]
- “Relationship of Occupational Safety and Health Administration (OSHA) requirements to Centers for Disease Control and Prevention (CDC) guidance.” [8]
- “OSHA requirement of fit testing of N95 masks, timing/minimal resources.” [8]
- “Look at a bundled approach, PPE alone will not be sufficient to stop the pandemic from escalating. Must consider PPE/antivirals, Community Mitigation, and Environmental/Engineering controls.” [4]

*Issue Type:* Policy, Legal

*Recommendations Identified:*

- “The short-term action items centered on the N95 issue, including creating a list of activities N95 respirators should be reserved for, defining criteria for states to determine and declare a N95 shortage, and planning and estimating N95 respirators needed considering different priorities/situations.” [3]
- “An existing workgroup is working on developing guidance by September 1, 2009, for the use of PPE, both interim and long-term. This guidance will resolve existing conflicts in recommendations from OSHA and CDC regarding the use of N95 respirators versus surgical masks, address the challenges of fit testing, and consider the PPE needs of professions beyond health care workers.” [4]
- “Develop guidance through the CDC workgroup – both interim and long-term. Realize that this will likely take a long time, but set an aggressive target date for completion to stress the importance of this guidance.” [4]
- “Health care personnel should follow the guidance from HHS and OSHA on the best way to protect health care personnel. Given there is likely going to be a shortage of N-95 respirator masks in many communities, officials should clearly communicate guidance to health facilities on the best way to allocate personal protective equipment and reduce the need for respirators among health care workers.” [21]

*Issue:*

**Potential fines for non-compliance with OSHA requirements.**

- “Need to clarify whether the Occupational Safety and Health Administration (OSHA) will penalize hospitals and other institutions that follow their states’ worker protection recommendations if those recommendations conflict with National Institute for Occupational Safety and Health (NIOSH, a unit of CDC) recommendations or with other federal guidance for worker safety.” [6,7]
- “OSHA often closely relies on NIOSH recommendations for workplace safety standards. However, it appears that sometimes OSHA does not release a timely “compliance directive” stating whether it will adopt NIOSH recommendations for a particular instance. For instance, OSHA ruled a hospital was in violation for not using N95 masks as recommended by NIOSH, even though the hospital was in compliance with guidance from the state and local health departments. OSHA compliance directives on N95 masks were issued in November 2009, several months after that violation. There is also concern that lack of compliance with NIOHS recommendations, even when not officially adopted by

OSHA, may give grounds for private litigation if a worker or patient is injured, especially if the institution has received an OSHA violation notice.” [6,7]

*Issue Type:* Legal, Policy

*Recommendations Identified:*

- “Clarify the relationship between NIOSH recommendations and OSHA safety requirements. Post CDC definitions of “guidance,” “recommendation,” and “requirement” on website. Clarify interaction between federal law/guidance and state regulations. Clarify guidance for worker safety practices if official recommendations cannot be met (e.g., if the supply of N95 masks is inadequate).” [6,7]

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***Issue:* PPE allocation principles.**

- “It is challenging to change recommendations and guidance if they are not consistent. Additionally, a shortage should not dictate changing recommendations for proper use of PPE.” [4]
- “Guidance must consider alternate standards of care for PPE; should not plan to not have enough respirators, but contingency plans should be made if this is the case. Always have to try to get more if there is a shortage, even if alternate plans exist.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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***Issue:* Allocation of N-95 masks.**

- “N95s are also needed for all hazards and so you never want to deplete the whole cache. Also, political ramifications and relationships with other entities that use N95s must be taken into account. Police and fire departments as well as organizations such as OSHA and SHEA should be consulted.” [3]
- “Need to examine the private vs. public supply of PPE.” [4]
- “There is not enough supply to cover health care workers, and this is a real issue.” [4]
- “Occupational health world needs to be involved so they are on the same page with public health.” [4]
- “There has been a dedicated focus on health care workers, but this needs to be expanded to other professions that will likely be at risk.” [4]
- “For non-health care workers, there may not be enough exposure to warrant a respirator, and workers who will be directly dealing with sick people should be protected. Additionally, sick health care workers should not go to work.” [4]
- “How to encourage responders to continue showing up for work if they are not being provided proper protection? It is the duty of employers to ensure their workers are protected.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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### C.3.3 PPE/ICM Stockpiles, Inventory Management and Supply Chain

#### C.3.3.a PPE/ICM Stockpiles

**Issue:** SNS – Specification of mask types in stockpile.

- “In the spring, 25 million N-95 respirator masks were deployed from the SNS to states, but this inventory was never restocked, reportedly due to lack of dedicated funding. The current stockpile of 79.7 million N-95s is considered to be severely lacking according to a number of experts and now because of high demand, the product is on back order.” [21]
- “There is a lack of knowledge by states/locals over what brands of PPE are in the stockpile. This causes issues with training and fit testing.” [4]
- “DSNS: Respiratory Protection Devices (RPD) in stockpile are 3M, Kimberly Clark, Moldex. Stockpile product was procured 4 years ago to protect health care workers.” [4]
- “Some of the model facilities have fit with the 1860 mask while the SNS has been sending out the Kimberly Clark masks.” [4]

**Issue Type:** Policy

**Recommendations Identified:** • “Replenish and update equipment in the SNS.” [21]

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#### C.3.3.b PPE/ICM Inventory Management and Supply Chain

**Issue:** Determining if a shortage of PPE exists.

- “How to define a shortage? Having to go into the state cache means you have a shortage. The number for this will be a best guess estimate and that will be the guideline, but criteria are needed to determine what the definition of a shortage is. The consensus in one state was that the definition doesn’t include what the CDC has in supply or what states have, but rather is when they have to dip into the state stockpile. So, if a facility/industry cannot buy what they are required to buy and their orders cannot be filled, there is a shortage and a need to dip into the state stockpile. States do not want to use state cache for minor incidents.” [3]
- “[States] debated whether four weeks is sufficient time for states to determine if they will have a shortage of N-95 masks. An assessment of how many masks are in the state and national stockpile before setting a timeline for when a state should or can declare a mask shortage. Also, it is difficult for a [state] to determine whether a hospital is experiencing a shortage. The hospital is the end user with real-time data; thus, the hospital should be the entity to make this determination. If four weeks is the timeframe chosen, then it must be further clarified; for example, declare a shortage by four weeks or before four weeks.” [3]
- “The [states] recognized that the definition of the term “shortage” should be clarified. For instance, should the term be defined as the hospital’s ability to acquire masks, rather than what is in the hospital’s possession at the time? Also, would declaring a “shortage” trigger other actions? If so, what would they be? Lastly, will the entity (CDC versus a state) who declares a shortage determine the outcome? In addition to standardizing the definition of shortage, there should be enough masks to use during fit-testing, as well as enough trained mask fit-testers to support the effort.” [3]

**Issue Type:** Policy

*Recommendations Identified:* • “Need to create standard definition/conditions for determining if a shortage exists.” [3]

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### C.3.4 PPE/ICM Destruction and Disposal

*Issue:* None identified

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### C.3.5 PPE/ICM Distribution

#### C.3.5.a *PPE/ICM Distribution from Stockpiles*

*Issue:* None identified

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#### C.3.5.b *Distributed PPE/ICM Inventory Management and Supply Chain*

*Issue:* None identified

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### C.3.6 Administering PPE/ICM

#### C.3.6.a *Authority to Administer PPE/ICM*

*Issue:* None identified

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#### C.3.6.b *PPE/ICM Administration Sites/Practices*

*Issue:* **PPE messaging.**

- “Have to be sure to educate the public and providers that PPE will not necessarily prevent disease.” [4]
- “There must be a unified message. Consider what the message is, the mode it is being released, and ensure it is consistent across the board (other languages too).” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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#### C.3.6.c *Payment/Reimbursement for PPE/ICM*

*Issue:* None identified

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### C.3.7 PPE/ICM Tracking/Recall

*Issue:* None identified

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### C.3.8 PPE/ICM Adverse Events Reporting

*Issue:* None identified

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### C.3.9 PPE Coverage Determination/Reporting

*Issue:* None identified

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## C.4 Emergency Use Authorizations

- Aiding Factors:*
- “Antiviral deployment, particularly under the emergency use authorization (EUA) for intravenous peramivir, was widely described as having worked well.” [1]
  - “This response represented the first time EUAs were authorized, and they occurred quickly. The EUA Web site was considered a useful resource by the meeting participants.” [9]
- 

- Issue:* **EUA requirements and timing**
- “CDC and FDA will meet by August 1, 2009, to discuss the timely posting of EUAs and rapid responses to questions from the states regarding EUAs.” [4]
  - “EUA issues included the need to have EUA’s posted in a timely manner.” [4]
  - “Legal issues regarding EUA are still unclear. Need to communicate with FDA to assist with resolution of EUA issues. There is a need for timely posting of EUA and timely response to questions regarding EUA.” [4]
  - “Whether Tamiflu EUA requires state declaration of public health emergency before distribution of countermeasures.” [8]
  - “The fact that there were no pre-existing EUAs to refer to (e.g., Cipro and Doxy) presented a challenge.” [9]
  - “Differences between EUA and Shelf Life Extension Program (SLEP) were confusing.” [9]

*Issue Type:* Policy, Legal

- Recommendations Identified:*
- “Public health law meeting will address these issues, and FDA will need to be involved.” [4]
  - “Extend the EUA for peramivir.” [1]
-

- Issue:** **EUA messaging.**
- “Communication about why the EUA was in place and what the EUAs did for the states would have been helpful.” [9]
  - “There was a need for national level public messaging in lay terms to explain the “whats” and “whys” to the EUAs.” [9]
  - “Information to the public and to professionals needs to be different – separate communication is necessary.” [9]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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- Issue:** **Content and format of EUA patient information sheets.**
- “*Do patient information sheets adequately address EUAs?* Information sheets currently provided to patients do not explain that the antiviral has not completed the standard FDA drug approval; they don’t explain the liability protections provided by the PREP Act; nor do they inform patients how to file for compensation for adverse effects. As a result, patients may give consent without full disclosure, raising a potential issue about whether the consent was an informed one.” [7]
  - “*May patient information sheets required by EUAs be translated into other languages? Should federal or state agencies perform the translation?* The language of the EUAs seems to suggest that translating the patient information sheet into another language might be a violation because “changes” to the patient information sheet are prohibited. However, the Civil Rights Act of 1964 requires that the federal government and any programs receiving federal funds (including state governments) must provide information in languages commonly spoken in the community. Further, the Department of Justice has a statement on serving persons with limited English proficiency and H1N1 planning to ensure “language access” which can be found at [http://www.usdoj.gov/crt/h1n1\\_response.php](http://www.usdoj.gov/crt/h1n1_response.php). It has been suggested that as long as the translation is consistent with the EUA it will not be considered a “change” and will not be prohibited. If patient information sheets can indeed be translated, it would be cost efficient and provide greater accuracy if the translation could be done at the federal level for more common languages rather than having each state translate the same information for the same languages and potentially reaching different translations.” [7]
  - “Adequacy of patient information sheets in addressing EUAs.” [8]
  - “Translation of patient information sheets into other languages constituting change.” [8]
  - “Translation into other languages should be done in advance.” [9]

*Issue Type:* Legal, Policy

*Recommendations Identified:*

- “Revise information sheets to provide additional information to patients.” [7]
- “Clarify that translation of EUAs are not prohibited as changes. Recommend that patient information sheets be translated into the more common languages by the federal government rather than by states.” [7]

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<b>Issue:</b>	<p><b>Extension of EUA antivirals.</b></p> <ul style="list-style-type: none"> <li>• “Does extension of EUA antivirals’ shelf life require relabeling? The Food and Drug Administration (FDA) appears to require relabeling of expired antivirals but CDC Division of Strategic National Stockpile (DSNS) appears not to.” [7]</li> <li>• “Extension of shelf life of antivirals, relabeling requirements.” [8]</li> </ul>
<b>Issue Type:</b>	Legal
<b>Recommendations Identified:</b>	<ul style="list-style-type: none"> <li>• “CDC and FDA should clarify the federal policy and should adopt a single, consistent policy. Current and any new policies should be posted as rapidly as possible.” [7]</li> <li>• “Note – CDC DSNS issued the following statement on July 16: The FDA’s Emergency Use Authorization (EUA) has been amended to include dispensing of the Tamiflu for oral suspension with the original expiry date of June 30, 2009. Under the EUA, the shelf-life extended (new expiry 5/31/2011) Tamiflu for oral suspension may be now be dispensed and does not require relabeling. In lieu of relabeling, the provider dispensing Tamiflu for oral suspension must provide a copy of the Patient/Parent Fact Sheet (attached and posted on the CDC website). Please note that the fact sheet does refer the patient/parent to a FDA website to validate, by lot number, the new expiry date of the product. The FDA is currently working on the website and they anticipate that the information will be posted early next week. Fact sheets are available at <a href="http://www.cdc.gov/h1n1flu/eua/tamiflu.htm">http://www.cdc.gov/h1n1flu/eua/tamiflu.htm</a> EUA Letter of Authorization is available at <a href="http://www.cdc.gov/h1n1flu/eua/pdf/fda_letter_tamiflu.pdf">http://www.cdc.gov/h1n1flu/eua/pdf/fda_letter_tamiflu.pdf</a>.” [7]</li> </ul>

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<b>Issue:</b>	<p><b>EUA termination.</b></p> <ul style="list-style-type: none"> <li>• “The EUA termination date was defined as one year unless otherwise stated. However, when that year began was unclear.” [9]</li> <li>• “Guidance on the termination of EUAs is still needed. What will be covered in this guidance, which is currently under development, is unclear. Can an EUA be extended beyond June 23, 2010, the termination of the declaration of public health emergency.” [9]</li> <li>• “Guidance on the disposal of products after the EUA terminates is also needed. This is currently under discussion and CDC will ask for state and local input through ASTHO and NACCHO.” [9]</li> </ul>
<b>Issue Type:</b>	Legal, Policy
<b>Recommendations Identified:</b>	None identified

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## C.5 Medical Equipment Caches and Tracking

<b>Issue:</b>	<p><b>Tracking of medical equipment.</b></p> <ul style="list-style-type: none"> <li>• “All of the selected localities had acquired limited medical equipment for a pandemic, but only three of the five States had electronic systems to track beds and equipment. All 10 localities had acquired limited caches of medical equipment; however, many experienced difficulties with managing this equipment. In addition, only three of the five States had implemented electronic systems to track available hospital beds and medical equipment during an emergency.” [11]</li> </ul>
<b>Issue Type:</b>	Policy

*Recommendations Identified:* • “ASPR should continue to emphasize the importance of managing medical equipment currently being stockpiled for a public health emergency, such as a pandemic.” [11]

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*Issue:* **HAvBED reporting.**

- “A number of these issues were raised with ASPR at the Fifth Annual ASTHO Directors of Public Health Preparedness (DPHP) meeting in September 2009. The approach taken by ASPR in setting HAvBED up and then telling Directors of Public Health Preparedness about it after the fact was challenging at best, and for many states the new requirements do not fit into what is already set up.” [3]
- “Mechanisms that were already in place in the states to track med surge in geographic areas and the HAvBED system are not consistent with how this data is collected.” [3]
- “The HAvBED working group, formed by ASTHO, sent a letter and consensus documents, which they created in response to the new HAvBED data elements and CONOPS, to [HHS]. The work group created the recommendations on the HAvBED data elements and the CONOPS document, which contains both general comments as well as suggested revisions.” [3]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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*Issue:* **Medical capacity concerns.**

- “We reported that state officials raised several concerns related to their ability to increase hospital capacity, including maintaining adequate staffing levels during mass casualty events, a problem that was more acute in rural communities. While 19 of 20 states we surveyed reported that they could increase numbers of hospital beds in a mass casualty event, some state officials were concerned about staffing these beds because of current shortages in medical professionals, including nurses and physicians. Some state officials reported that their states faced problems in increasing hospital capacity because many of their rural areas had no hospital or small numbers of medical providers. For example, officials from a largely rural state reported that in many of the state’s medically underserved areas hospitals currently have vacant beds because they cannot hire medical professionals to staff them.” [15]
- “Further actions are needed to address the capacity to respond to and recover from an influenza pandemic, which will require additional capacity in patient treatment space, and the acquisition and distribution of medical and other critical supplies, such as antivirals and vaccines.” [17, 20]

*Issue Type:* Policy

*Recommendations Identified:* • “Hospitals and health care providers must have clear and practiced plans in place to respond to emergencies or a major influx of patients. Planning must include how to provide continued care for daily emergencies and chronic care during emergencies, separating infectious patients from others in intake and emergency departments, and discouraging the “worried well” from overcrowding emergency rooms.” [21]

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**Issue:**

**Financing health care system preparedness.**

- “Health care system preparedness requires significant investments in infrastructure, staff, and supplies. When funding declines -- whether at the federal, state, or local level -- the immediate impact on health care system preparedness may not be evident. After all, in the United States we are fortunate that catastrophic health emergencies are rare events. However, funding cuts in the Hospital Preparedness Program (HPP) have severely curtailed preparedness activities across the nation.” [22]
- “In a public health emergency, health care systems and workers will be on the front lines, but as a nation we have not equipped them with the resources and training they need. The federal government should provide increased and sustained funding for health care system preparedness activities -- whether through the existing HPP or through a new funding mechanism.” [22]

**Issue Type:**

Policy

**Recommendations Identified:**

- “Fully fund the Hospital Preparedness Program. The HPP focuses on improving the clinical response to a large-scale health emergency, which includes both developing surge capacity and continuity of operations planning. On average, hospitals receive about \$80,000 per year, but some receive as little as \$10,000 per year. In FY 2009, the HPP was funded at \$393 million. In the short-term, this crucial program should be funded at \$588 million, which is the FY 2004 level adjusted for inflation. ASPR is in the process of realigning the HPP funding with the states’ fiscal year (July/June). ASPR also should consider transitioning the HPP one-year grant to a multi-year grant which would enable states, health care coalitions, and hospitals more time to implement their activities and to monitor and evaluate their effectiveness.” [22]
- “Expand the hospital preparedness program to include the ambulatory care system. As we have seen over the course of the H1N1 pandemic, ambulatory care centers and doctors’ offices have been overwhelmed by the surge in patients seeking care. Presently, there is no system in place to help build capacity among these providers. Congress should reexamine the PAHPA legislation and consider directing ASPR to expand the existing HPP grants beyond hospitals to include both ambulatory care clinics and private practitioners.” [22]
- “Develop a long-term solution to funding hospital preparedness. In the long-term, the administration and Congress should examine ways to build hospital preparedness into the federal health care financing system, by providing, for example, enhanced reimbursement rates under Medicare to those facilities that are willing to expand and maintain their emergency response capacity. This would remove the funding of hospital preparedness from the unpredictability of the annual appropriations cycle.” [22]

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## C.6 Alternate Care Sites

**Issue:**

**Alternate care site planning.**

- “Most of the selected localities were in the early stages of planning for alternate care sites.” [11]
- “Alternate care sites are preselected facilities, such as schools or convention centers, that have been identified for potential use during emergencies to help alleviate overcrowding in hospitals.” [11]
- “Nine localities had either identified or were in the process of identifying alternate care sites to be used in a pandemic; however, few had signed formal agreements.” [11]
- “None of the localities that were planning to use alternate care sites had plans that included the scope of care and how these sites would be managed, staffed, and supplied.” [11]

*Issue Type:* Policy

*Recommendations Identified:*

- “ASPR should continue to emphasize the importance of planning for alternate care sites for use during a pandemic.” [11]

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*Issue:* **Alternate care site concerns.**

- “Some state officials reported that it was difficult to identify appropriate fixed facilities for alternate care sites. Officials from two states reported that some small, rural communities had few facilities that would be large enough to house an alternate care site.” [15]
- “Officials from some states also reported that some of the facilities that could be used as alternate care sites had already been allocated for other emergency uses, such as emergency shelters.” [15]
- “Some state officials also reported concerns about reimbursement for medical services provided at alternate care sites, which are not accredited health care facilities, and concerns regarding how certain federal laws and regulations that relate to medical care would apply during a mass casualty event for care provided at alternative care sites.” [15]

*Issue Type:* Policy, Legal

*Recommendations Identified:*

- “Despite the clear need for alternate care sites following a mass casualty event, there are several barriers to their successful roll-outs. To address these barriers, TFAH recommends the following measures:
  - Increase local, state, and regional planning with clear delineation of responsibilities and authority;
  - Foster public-private partnerships among health care practitioners;
  - Employ operational drills to test the deployment of mobile units and the creation of alternative care sites; and,
  - Address licensing and liability concerns for health care workers, behavioral health professionals, and volunteers and liability concerns for non-health care volunteers; and third-party entities that play host to alternative care sites.” [22]
- “In addition, emergency planners will need to obtain, stockpile, and store supplies, equipment and medicines for use in the alternative care sites.” [22]
- “*Regional coordination of health care facilities, including alternative care sites, with public health and emergency management.* Hospitals, state and local health departments, and emergency management agencies should continue to build and strengthen regional consortiums to organize and plan for public health emergencies. Such regional collaboration can lead to more efficient use of resources among hospitals and health departments, including personnel, and facilitate the sharing of promising practices. This coordination should include all federal resources active in the region, including VA and DOD facilities. (Regional efforts could be within a locality or across county and/or state lines depending on the size of the communities involved.)” [22, 21]

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## C.7. Standards of Care

*Issue:* **Alternative standards of care messaging.**

- “Careful messaging is needed regarding ASC.” [3]
- “Should talk about alternate standards of care as the standards of care in a disaster situation.” [3]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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- Issue:* Alternate/crisis standards of care must be addressed.**
- “The term “Altered (or Crisis) Standard of Care” is most commonly understood as a change in the duty that a physician or other medical professional owes to the person being cared for as a consequence of unusual circumstances relating to the delivery of care. This duty historically has been discussed only within the context of the application of the duty owed by a physician or other medical professional to a specific person. Within a public health context, a legal issue arises with regard to the duty owed to a large number of persons in need of care, particularly during a public health emergency.” [6]
  - “Questions of how to equitably and consistently determine division of scarce resources (space, staff, and supplies) during an emergency, as well as how to limit liability for decisions made regarding scarce resources during an emergency, have led states to consider development of protocols. With development of protocols, states must consider whether they can adequately address these questions when resources vary widely across the state (rural v. urban), or when it is unknown where an outbreak will hit first or hit hardest.” [6]
  - “States should ensure that protocols, if developed, clearly state when they can be activated or whether requests are required first, as well as whether only some of the protocols can be activated rather than the entirety.” [6]
  - “Most of the selected localities had not identified guidelines for altering triage, admission, and patient care; many cited liability concerns. During a pandemic, health care professionals may need to alter how they provide medical care by allocating scarce resources in a manner that saves the greatest number of lives. Nine localities had not identified guidelines for altering triage, admission, and patient care during a pandemic. Seven of these localities noted that providers in their localities were concerned that they would be legally at risk if they were to alter their standards for triage, admission, or patient care, and all nine reported that they wanted additional State or Federal guidance.” [11]
  - “It we do not have altered standards of care capacity, hard decisions have to be made, so it is important that we have them. One state was over 38% of capacity, which is considered the breaking point so how do we quantify where we are now. We are already in a alternate standards of care situation and asked how states are reporting this surge.” [3]
  - “Necessity of term “Crisis” or “Altered” Standards of Care for medical professionals during a public health emergency.”[8]
  - “Criteria under which these standards of care might be considered.” [8]
  - “Legal authority for standards of care, if necessary.” [8]

*Issue Type:* Legal, Policy

- Recommendations Identified:*
- “States should consider whether to develop protocols for division of scarce resources. PHLP might consider compiling protocols from states that have already drafted them to compare/contrast the breadth, depth, and content of the protocols. States should also consider methods to educate the public on surge capacity and what they can expect during an emergency.” [6]
  - “ASPR should emphasize the importance of identifying and adopting guidelines for altering triage, admission, and patient care during a pandemic.” [11]
-

**Issue:**

**Altered standards of care concerns.**

- “Some state officials reported that they had not begun work on altered standards of care guidelines, or had not completed drafting guidelines, because of the difficulty of addressing the medical, ethical, and legal issues involved.” [15]
- “For example, in 2005 HHS estimated that in a severe influenza pandemic almost 10 million people would require hospitalization, which would exceed the current capacity of U.S. hospitals and necessitate difficult choices regarding rationing of resources. HHS also estimated that almost 1.5 million of these people would require care in an intensive care unit and about 740,000 people would require mechanical ventilation. Even with additional stockpiles of ventilators, there would likely not be a sufficient supply to meet the need.” [15]
- “Since some patients could not be put on ventilators, and others would be removed from ventilators, standards of care would have to be altered and providers would need to determine which patients would receive them.” [15]
- “In addition, some state officials reported that medical volunteers are concerned about liability issues in a mass casualty event. Specifically, state officials reported that hospitals and medical providers might be reluctant to provide care during a mass casualty event, when resources would be scarce and not all patients would be able to receive care consistent with established standards.” [15]
- “According to these officials, these providers could be subject to liability if decisions they made about altering standards of care resulted in negative outcomes. For example, allowing staff to work outside the scope of their practice, such as allowing nurses to diagnose and write medical orders, could place these individuals at risk of liability.” [15]

**Issue Type:**

Policy, Legal

**Recommendations Identified:**

- “*Need federal leadership in crisis standards of care planning and development.* States currently are responsible for planning and developing crisis standards of care, but progress on this front is quite varied, with some states much further along than others. Inconsistencies in standards of care among states could undermine the public’s trust and make it harder for them to accept crisis standards of care.” [22, 21]
- “To eliminate this potential barrier, the federal government should play a much more active role in the planning and development of crisis standards of care, considering it has experience making prioritization decisions in a public health emergency. For example, federal agencies issued the H1N1 flu vaccine prioritization, so they should be able to offer more specifics for crisis standards of care planning and development. The federal government should take steps to address the legal issues associated with shifting to a different paradigm of providing health care when the need for care overwhelms available resources (i.e., staff, supplies, space) during catastrophic public health emergencies.” [22, 21]

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## C.8 EMTALA Issues

**Issue:**

**EMTALA screening issues.**

- “*What constitutes “adequate” or “minimal” screening “adequate screening” under EMTALA?* Adequate screening has not been clearly defined.” [7]
- “Definition of “adequate” or “minimal” screening under Emergency Medical Treatment and Active Labor Act (EMTALA) which generally requires that hospitals accepting Medicare payments provide patients coming to the emergency department medical screening and stabilizing treatment for emergency medical conditions without

regard to citizenship, legal status, or ability to pay.” [8]

*Issue Type:* Legal

*Recommendations Identified:* • “Determine what constitutes “adequate screening” during public health emergencies.” [7]

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## C.9 Medical Care and Countermeasures Communications

*Aiding Factors:* • “There was always someone available at CDC to answer questions when the states called.” [9]

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*Issue:* **Communications general observations.**

- “Communication could have been better in the fall when the process was often unclear. This could have been helped by sharing the CDC Operational Plan, or by giving clearer instructions about who to contact. It was sometimes unclear as to who was in charge. Contradictions in guidance given between project officers, particularly when transitions were occurring between project officers.” [9]
- “States did not know about shift changes or operational periods at CDC. CDC in turn did not know the shifts and schedules of the states. There was a different sense of urgency between the states.” [9]
- “Some states would have liked more communication to have been conducted via email.” [9]
- “Some states would have liked access to CDC’s WebEOC.” [9]
- “There were changes in amount and quality of communication from spring to fall. In the fall States often did not know what materiel was coming and when it would arrive until very close to its arrival. States were left with little lead time to plan for the receipt.” [9]
- “There is often a lack of coordination of messages from federal agencies, and contradictory direction.” [9]
- “Coordination of multiple federal calls needs to occur.” [9]
- “Immunization and SNS programs staff need to have more frequent communication.” [9]
- “There was inconsistency about to whom information from CDC was sent, which sometimes went to the SNS coordinator and sometimes to epidemiologists.” [9]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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*Issue:* **Communications to/from CDC, other feds and organizations.**

- “Communications occurred by: email, fax, webinars, HAN notices, and conference calls.” [9]
- “Information was primarily received from CDC/DSNS, but also from HHS/REC and Trust for America’s Health.” [9]
- “It would have been helpful if the federal government had provided communication to national unions who had concerns about receiving assets.” [9]
- “In some cases there remains a disconnect between the HPP and SNS programs, as ASPR

and CDC requirements often differ. Some jurisdictions are trying to remedy this by combining them into the same program.” [9]

- “While noting that CDC cannot lobby, it was suggested that there should be a “legal preparedness workgroup” which would provide recommendations on legal issues instead of each jurisdiction advocating for certain changes individually.” [9]
- “Clarification should have been provided on whether DoD or the VA system would receive their own antivirals.” [9]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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**Issue:** **Communication mechanisms/frequency and messaging.**

- “One jurisdiction had (prior to H1N1) developed a secure website where information could be posted for local public health partners.” [9]
- “Messages from the State Health Officials were channeled to various partners.” [9]
- “Some jurisdictions began using social media such as Facebook and Twitter to communicate messages about H1N1 to the public, coordinated through their PIO, which received positive feedback.” [9]
- “Communication had occurred between some partners, especially during planning stages, but during the response it was much more frequent – weekly or in some cases, daily.” [9]
- “In some cases states provided their own guidelines based on availability of the asset (for example the pediatric oral suspension).” [9]
- “Guidance was provided to the recipients of the assets, which included information on the EUA, factsheets, recommendations based on CDC guidelines, and answers to various questions concerning security or other issues. Training with hospitals was also conducted in some areas.” [9]
- “Asset recipients in some cases were required to sign a contract requiring them to adhere to stated requirements, including data reporting.” [9]
- “Some local jurisdictions have held ESF-8 county level summits, which has helped tie together all partners and improve communication.” [9]
- “Regular regional meetings to test the consistency of public messaging across the region.” [9]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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**Issue:** **Communications with the health care community.**

- “There was a major challenge with the medical community who did not always endorse the vaccine.” [9]
- “Often the POC at a hospital did not relay information to the rest of the facility.” [9]
- “Guidances from CDC were relayed to healthcare providers and other stakeholders as they came.” [9]
- “Peer to peer communication needed to be provided to the medical community, as they were not always receptive to communication from public health.” [9]

- “Healthcare and pharmacy needed to be provided pre-emergency education on EUAs, liability protection, SNS, etc., that could be reinforced during an event.” [9]

*Issue Type:* Policy

*Recommendations Identified:* None identified

**Issues:** **Communications with other partners.**

- “New partners were engaged, including: educators, the Board of Healing Arts, emergency coordinating officers of all agencies within the state and county level emergency managers.” [9]
- “New partners were the federally qualified health centers, which required some education/training on both sides to work with them.” [9]
- “Some of the recommendations as related to school closure or community mitigation were confusing.”[9]
- “There were multiple barriers in reaching the POC at schools – not getting them on the phone, having to go through multiple layers of staff to reach them during school hours, etc.” [9]

*Issue Type:* Policy

*Recommendations Identified:* None identified

## C.10 Medical Care and Medical Countermeasures Other Issues

**Issue:** **Identify and collect best practices.**

- “October 2009, an HHS official reported that the agency was designing a Web portal to serve as a clearinghouse on preparedness and response, with an emphasis on the allocation of scarce medical resources, in part as a result of GAO’s recommendation. In January 2010, an HHS official reported that efforts to design and develop the Web portal were continuing.” [15]

*Issue Type:*

*Recommendations Identified:* • “CDC, ASTHO, and NACCHO should collect best practices and lessons learned regarding SNS distribution. This would include assessing what has been reported as considerable variability in state and local interfaces as it pertains to plans, practices, and communications on state to local distribution and use of antivirals and other medical countermeasures.” [1]

**Issue:** **Policy and funding issues.**

- “Address the FFY11 budget, which has no money for state and local pandemic flu preparedness, which must be continued.” [1]
- “There is a need for better coordinated situational awareness and information management across federal cross agency/state/local/associations including more transparency of activities.” [4]

- “Situation Report (SITREP) issue: how to better streamline and prioritize information during the event?” [4]

*Issue Type:* Policy

- Recommendations Identified:*
- “Provide flexibility with existing funds and time to spend current funds.” [1]
  - “As part of the more formal after-action report, reexamine the scope and parameters governing the public health use of antivirals and reaffirm or redefine the complementary yet distinct role of the public health and medical/health care sectors regarding medical countermeasures management and use.” [1]

**Issue:** **Medical countermeasures research and development needs.**

*Issue Type:* Policy, Legal

- Recommendations Identified:*
- “Clarify requirements and deliverables under Project BioShield contracts. ASPR should coordinate with NIH, FDA and CDC to ensure future BioShield requests for proposals and procurement contracts for new countermeasures have clearly articulated requirements, expectations, and deliverables.” [22]
  - “Bolster domestic production capacity for countermeasures, including vaccines, and personal protective equipment (PPEs). As we have seen during the course of the H1N1 flu pandemic, the United States has limited production capacity for manufacturing flu vaccines and personal protective equipment, such as N95 respirator masks. These shortages have led to confusion, and in some cases fear and panic among the U.S. population. The U.S. government, working through BARDA or other federal agencies, should direct more money to growing domestic production capacity for pandemic countermeasures.” [22]
  - “Expand the Shelf Life Extension Program. Congress should extend the Shelf Life Extension Program (or establish a new, parallel, SLEP-like program within FDA) to include states’ and locals’ antiviral and antibiotic medications. Currently, state and local stockpiles could have shorter shelf lives even though the nation is depending on state and local stockpiles to meet national goals.” [22]

## III.D National Vaccination Campaign

Please see the introduction to Section III on page 13 for general information about the data contained in this subsection.

### National Vaccination Campaign Section Contents

- D.1 Identification, Formulation and Manufacture
- D.2 Allocation Approaches
- D.3 Stockpiles and Inventory Management
  - D.3.1 Stockpiles
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- D.4 Distribution and Delivery
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  - D.5.3 Payment/Reimbursement
- D.6 Vaccine Tracking/Recall
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- D.8 Coverage Determination/Reporting
- D.9 Liability and Compensation
- D.10 Vaccination Guidance/Policies
- D.11 Vaccination Communications
- D.12 Vaccination Other Issues

### Summary of Issues

#### D.1 Identification, Formulation and Manufacture

- Methods of vaccine production.
- Timing of vaccine development and availability.

#### D.2 Allocation Approaches

- Equitable allocation of small quantities of vaccines.
- Allocation from the federal government.
- Allocation from state/local governments.
- Timing of vaccine availability; conflicting/changing messaging.
- Vaccine reallocation.

#### D.3 Stockpiles and Inventory Management

##### D.3.1 *Stockpiles*

- None identified

- D.3.2 ***Inventory Management***
  - None identified
- D.3.3 ***Destruction and Disposal***
  - Vaccine disposal issues.
- D.4 **Distribution and Delivery**
  - D.4.1 ***Distribution and Delivery Issues – General***
    - Refine plans for rapid distribution and administration of vaccinations.
    - Vaccine shipping information and conditions.
    - Ancillary supplies were not properly targeted.
  - D.4.2 ***Distribution of Vaccines from Stockpiles***
    - Need guidance on using remaining H1N1 vaccine.
- D.5 **Administering Vaccines**
  - D.5.1 ***Authority to Administer***
    - Lowering patient age for vaccination.
    - Consent to vaccinate.
    - Authority to restrict vaccination recipients.
    - Licensing modifications to allow a range of health professions to vaccinate.
    - Qualify school nurses as public health employees to administer vaccines and report immunizations.
  - D.5.2 ***Administration Sites/Practices***
    - School vaccine clinic issues.
    - Vaccination administration/uptake generally.
  - D.5.3 ***Payment/Reimbursement***
    - Payment systems for vaccine administration must be improved.
    - State insurance laws do not mandate the coverage of vaccines during declared public health emergencies.
- D.6 **Vaccine Tracking/Recall**
  - Using immunization registries.
- D.7 **Adverse Events Reporting**
  - Vaccine tracking systems must be enhanced to monitor for adverse reactions.
- D.8 **Coverage Determination/Reporting**
  - Work to increase uptake and coverage rates.
  - Coverage among healthcare workers.
  - Uptake and coverage data/monitoring.
  - Using school immunization data.

## D.9 **Liability and Compensation**

- Need to clarify the different reporting requirements of the multiple federal vaccine injury compensation funds.

## D.10 **Vaccination Guidance/Policies**

- ACIP recommendations and special populations.

## D.11 **Vaccination Communications**

- Vaccination outreach activities.

## D.12 **Vaccination Other Issues**

- International vaccination efforts.
- Vaccine research and development needs.

# **Issues Detail**

## D.1 **Identification, Formulation and Manufacture**

- Aiding Factors:*
- “The licensure process for the 2009 H1N1 influenza vaccine and the safety monitoring systems reflect a commitment on the part of regulatory agencies and the public health community to ensuring that the 2009 mass immunization campaign emphasizes vaccine safety. Given that the 2009 H1N1 vaccine is manufactured in the same manner as seasonal influenza vaccines, it seems reasonable to base an assessment of its safety on the long-standing and consistent safety profile of seasonal influenza vaccines. Beyond that, the large number of ongoing clinical trials and the number of surveillance systems currently employed to monitor adverse events will provide continual data on safety and will continue to inform public policy as the immunization campaign continues.” [28]

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*Issue:*

**Methods of vaccine production.**

- “New technologies for vaccine production are not yet FDA-approved. Use of technologies that might be perceived as “experimental” could undermine public confidence in a pandemic vaccine.” [24]
- “There has been some debate about whether the United States could have used emergency authorities held by the FDA to permit different vaccine technologies to be used during this pandemic campaign so as to speed production and/or increase the amount of vaccine available.” [24]
- “Given the very high level of skepticism in the U.S. (and around the world) about vaccines in general and some of the concerns about the pandemic vaccine in particular, it has been critical for federal officials to reassure the public that this is the very same vaccine manufacturing process that hundreds of millions of Americans have taken safely to protect themselves against seasonal flu. Clinical trials for this pandemic vaccine were thorough and efficient, providing additional reassurance to the American people. Approval of cell-based vaccines against a novel influenza virus, when not currently approved for the seasonal virus, would have been considered experimental by many Americans. There may have been a misperception that the vaccine had not gone through the usual rigorous FDA approval process. This would have complicated efforts to encourage all Americans, especially those at highest risk, to receive a vaccination against the H1N1 virus.” [24]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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**Issue**                    **Timing of vaccine development and availability.**

- “It is expected that FDA will streamline process so vaccine is available before fall.” [4]
- “Manufacturers may have vaccine available, but streamline FDA clinical trials to be sure vaccine will be available for use. Lab tests should be included as well.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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## D.2 Allocation Approaches

**Issue:**                    **Equitable allocation of small quantities of vaccines.**

- “One of the challenges identified is that the vaccine is coming in small quantities. The process of equitably allocating the small quantities of vaccine is complicated. There was discussion about differentiating H1N1 and seasonal flu vaccine distribution messages. There was also discussion around any best practices for allocating these small doses.” [3]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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**Issue:**                    **Allocation from the federal government.**

- “The policy decision that the federal government should be the central purchaser and distributor of vaccine was wise from public health and ethical standpoints.” [24]
  - “Centralization has permitted the federal government to control the flow of the limited supply. Every state is receiving vaccine on a per capita basis, rather than based on private ordering, state budgets, population demographics, or political decision-making. An influenza outbreak does not acknowledge or respect state borders, and no American should be less protected based on where he/she lives.” [24]
  - “If the federal government had depended on a private distribution system, as the previous Administration had suggested, we likely would have seen a repeat of the 2004-2005 seasonal flu vaccine shortage scenario -- wherein some providers would have sufficient vaccine, while others would have little or none, depending entirely on which vaccine manufacturer had been contracted with to supply vaccine.” [24]
  - “Although all states are temporarily experiencing shortages, all states are suffering shortfalls equally.” [24]
  - “The situation is not always as clear on the local level, where distribution within states appears uneven in some cases.” [24]
  - “This is not to say that there have not been glitches in this new, untested, centralized system. But as best TFAH can determine, federal health officials have moved as rapidly as possible to address the problems.” [24]
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*Issue Type:* Policy

*Recommendations Identified:* None identified

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**Issue**

**Allocation from state/local governments.**

- “Public confusion may well have been exacerbated by the fact that each state and locality has determined how to distribute its supply once received from the federal government.” [24]
- “While all jurisdictions have kept to the general prioritization of certain populations, they have often acted differently in terms of which individuals within the prioritized grouping would get vaccine first. This may well have been due to how supply was ordered by the states and/or distributed within the states. For example, some localities have prioritized health care workers, some have prioritized the vaccination of children, and still others have made pregnant women a top priority.” [24]
- “Population demographics differ from state-to-state, so it is sensible to allow some flexibility between locales (for example, if the pandemic had targeted seniors, Arizona and Florida may have very different distribution plans than other states). However, the wide variation in distribution methodologies has created a fair amount of confusion among the public.” [24]
- “Although each health department based their plans on a larger supply of vaccines, HHS may want to revisit this issue and consider some standardization in future emergencies since it is not unreasonable for the American people to expect some level of consistency in approach. Otherwise, they may think that the target population hierarchies articulated by the federal government are not science-based.” [24]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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**Issue:**

**Timing of vaccine availability; conflicting/changing messaging.**

- “States are struggling with messages to the public that vaccine is available, and yet only small amounts are reaching the states - it makes it look like the federal and state entities are not coordinated in their messages. Federal government is creating high expectations in the public when states have limited supply for target groups.” [3]
- “Recently, the federal government has been pushing for states to put vaccine delivery information on their dedicated flu Web sites. Considering the challenge of effective messaging, the federal government is overshooting when they want this information on state Web sites. While it is appreciated that the messaging of vaccine roll-out is coming out, there should be a slow build up of messaging to the public.” [3]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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**Issue:** **Vaccine reallocation.**

- “Reallocation of vaccine to alleviate temporary shortages under FDA regulations, definition of “emergency medical reasons.”” [8]

**Issue Type:** Legal, Policy

**Recommendations Identified:** None identified

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## D.3 Stockpiles and Inventory Management

### D.3.1 Stockpiles

**Issue:** None identified

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### D.3.2 Inventory Management

**Issue:** None identified

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### D.3.3 Destruction and Disposal

**Issue:** **Vaccine disposal issues.**

- “A demobilization plan that thoroughly addresses the many logistical and financial issues around disposal of vaccine was a high priority for many participants.” [1]
- “Managing vaccine uptake and disposal in the next 90 days was a key concern.” [1]
- “Disposal of excess H1N1 vaccine either after expiration or after.” [8]
- “A key to the disposal issue is the characterization of the vaccine as either medical or hazardous waste as each has separate disposal requirements. States would prefer materiel be classified as medical waste because the cost associated with disposal will be less than if it is deemed “hazardous waste.” Further recommendations from the state representatives included consistent labeling across states; medical or hazardous waste; use Public Health Emergency Response (PHER) carry forward funds to store or centralize vaccine that will not expire; using PHER funds to recollect vaccine.” [9]
- “The government supplied vaccines and materials for free; the administration fee providers collect was meant to cover disposal costs. The other added benefit is that this program bumped revenue overall for pharmacies.” [5]

**Issue Type:** Policy

**Recommendations Identified:**

- “Create a plan for the safe and reasonable disposal of expired vaccine and identify a funding source to cover the attendant costs, especially if this will take place after July 30th when PHER funds are due to terminate.” [1]

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## D.4 Distribution and Delivery

### D.4.1 Distribution and Delivery Issues - General

- Issue:** **Refine plans for rapid distribution and administration of vaccinations.**
- “H1N1 will present the first mass vaccination effort to be conducted in a short time frame in modern U.S. history. States and localities should continue to revise plans for the most effective ways to provide vaccinations once they are available. Federal, state, and local officials need to identify if additional resources are needed to pay for administration of vaccines, especially if third party payers do not provide adequate coverage for the insured.” [21]
  - “Participants saw a looming need to determine how vaccine would be distributed next flu season and how to preserve partnerships through that transition.” [1]
  - “Use of “public safety exceptions” to public health information requests in some states to address the concern that releasing names and locations of influenza A (H1N1) vaccine providers might burden individual providers and jeopardize safety of doctors and patients.” [8]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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- Issue:** **Vaccine shipping information and conditions.**
- “Discussion focused on vaccine allocation and the differences between when the allocation is shipped versus when it is ordered, and having state-specific data shared with the media. There are concerns about public interpretation of the different numbers and creating unrealistic expectations.” [3]
  - “Examine and, if warranted, develop a plan for corrective action to address reported temperature control issues resulting in the freezing of the vaccine while in transit due to cold climatic conditions encountered.” [1]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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- Issue:** **Ancillary supplies were not properly targeted.**
- “Ancillary supplies were procured and made available as a hedge against shortages or supply chain interruptions. However, a number of areas of concern were expressed included the fact that providers were not familiar with the types and brands of needles and syringes that were provided and/or these supplies were considered substandard; as a result, they were not used. There was also confusion about the intended use of the syringes and large-bore needles that were included in the ancillary supply kits for mixing of vaccine with adjuvant since non-adjuvanted vaccines were used. Additionally, sharps containers were generally not needed or were not useful. CDC should provide more oversight to procurement of ancillary supplies and should vet the products before shipping them.” [1]

*Issue Type:* Policy

*Recommendations Identified:* • “Examine the quality of ancillary supplies provided for the H1N1 vaccination campaign based on complaints from the field generated during the current response.” [1]

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## D.4.2 Distribution of Vaccines from Stockpiles

**Issue**                      **Need guidance on using remaining H1N1 vaccine.**

*Issue Type:*              Policy

*Recommendations Identified:* • “Establish guidance on the benefits and most appropriate course of action regarding maintaining state-based stockpiles of residual H1N1 vaccine for possible future use.” [1]

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## D.5 Administering Vaccines

**Aiding Factors:**        • “Public health built and/or expanded wide-ranging partnerships to immunize people, including with pharmacies; physicians; clinics; hospitals; medical and professional associations; schools; colleges and universities; Medical Reserve Corps (MRCs); community and faith-based organizations (CFBOs); tribes; and others. Much of the discussion during this session addressed such partnerships and how to maintain momentum through the transition to seasonal influenza.” [1]

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### D.5.1 Authority to Administer

**Issue:**                      **Lowering patient age for vaccination.**

- “Assess the impact of the varying patient age requirements and limitations to the authority to administer influenza vaccines among states. Assess the related impacts in states that issued emergency orders lowering the allowable age for the express purpose of increasing vaccination coverage in order to inform future decisions and possible reform and national harmonization of this public safety requirement.” [1]

*Issue Type:*              Policy

*Recommendations Identified:*      None identified

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**Issue:**                      **Consent to vaccinate.**

- “Problems were encountered in the accurate completion and submission of the consent forms for school children around LAIV administration (e.g. known medical contraindications not declared).” [1]

*Issue Type:*              Policy

*Recommendations Identified:*      None identified

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**Issue:** **Authority to restrict vaccination recipients.**

- “Ability of town-run clinics to restrict A (H1N1) vaccination to residents of the town.” [8]

**Issue Type:** Policy

**Recommendations Identified:** None identified

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**Issue:** **Licensing modifications to allow a range of health professions to vaccinate.**

- “Do states’ licensing requirements need to be modified to authorize additional professions to administer vaccines during a mass vaccination campaign? States are taking diverse approaches to authorizing nonmedical professions to administer vaccinations.” [7]
- “Plans should be reviewed and possibly revised in consideration of pharmacists serving in a greater capacity as first-tier vaccinators in future planning efforts.” [1]
- “State modification of licensing requirements to allow additional professions to administer vaccines during surge, such as pharmacists, dentists, veterinarians, EMTs, etc.” [8]

**Issue Type:** Legal, policy

**Recommendations Identified:** “Further explore this issue and share approaches on Public Health Legal Counsel Listserv.” [7]

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**Issue:** **Qualify school nurses as public health employees to administer vaccines and report immunizations.**

- “How can school nurses be encouraged to administer immunizations and report on immunizations? Assuming FERPA issues regarding immunizations administered by school employees being part of education records have been addressed, having MOUs in place to qualify school nurses as public health agency employees potentially could alleviate their liability concerns and authorize them to report immunizations.” [8]
- “Use of school nurses and facilities to administer vaccination, encouragement of school nurses to administer vaccines and report on immunizations.” [8]

**Issue Type:** Legal, Policy

**Recommendations Identified:** • “CDC and U.S. Department of Education could determine whether this option would be allowable both under FERPA and under federal laws addressing liability. If allowable, request U.S. Department of Education issue guidance.” [8]

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## D.5.2 Administration Sites/Practices

**Issue:** **School vaccine clinic issues.**

- “Common concerns about school vaccine clinics centered on how to increase vaccine uptake, particularly LAIV, and how to overcome administrative hurdles such as staffing, consent forms, and managing second doses. Among the biggest successes were school clinics and the vaccination of pregnant women. Use of poison control centers in the response for such things as medical errors reporting was described as successful.” [1]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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***Issue:* Vaccination administration/uptake generally.**

- “The discussion highlighted a number of anecdotes that had common characteristics such as, leveraging non-public health resources such as vaccinators through a variety of means including PHER funds; bringing pharmacies into partnership with public health; using the pandemic to strengthen existing systems such as provider registries; training people who could reach communities generally not receptive to governmental public health; and communicating effectively and early with partners.” [1]
- “There is a need to develop/refine mass vaccination plans and seek partner assistance in planning (schools, public health).” [4]
- “Improving vaccine uptake through administrative and outreach strategies
  - Further reducing barriers such as vaccine administration co-payment/fees.
  - Identifying and using effective, contemporary, and trusted outreach and messaging approaches to improve coverage rates among high school and college age groups.” [1]
- “Create a revised national, scenario-based plan for the next 90 days. This plan should also include subcomponents such as a communications and outreach plan to increase the public’s understanding of the availability, importance and safety of H1N1 vaccination; and an operations plan.” [1]
- “Capitalize on partnerships created with physicians, pharmacies, and retailers to advance seasonal flu activities.” [1]
- “Increase efforts to educate providers and the public on the necessity for and safety of the H1N1 vaccination, both injectable and LAIV.” [1]

*Issue Type:* Policy

- Recommendations Identified:*
- “Develop a more formal and detailed transition plan for the upcoming 2010/2011 influenza season building upon the experiences and successes from the H1N1 pandemic response, including:
    - increased epidemiological and laboratory disease surveillance;
    - increased production and availability of season vaccine;
    - communications and outreach strategies;
    - funding levels and sources necessary to sustain requisite public health services; and
    - consideration for the expanded role of school located vaccination services to more effectively reach children as target populations as well as their families.” [1]
  - “Expand ongoing efforts to identify, summarize, and share lessons learned and useful vaccination practices for future application.” [1]
  - “*Vaccination campaigns must continue past the fall to prepare for a potential third wave outbreak.* The fact that the H1N1 vaccine will likely not be available to the entire population in October and that the virus is proving to be mild so far could mean that efforts are not made to try to encourage the entire population to get vaccinations. It is likely, however, that a third wave outbreak of H1N1 will occur, and it could become more virulent. Federal, state, and local health departments should make plans to encourage all Americans to get vaccinated even past the height of the fall and winter outbreak, in case
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there is a third wave H1N1 outbreak and to help people build immunity for potential future related flu strains.” [21]

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### D.5.3 Payment/Reimbursement

- Issue:** **Payment systems for vaccine administration must be improved.**
- “As PHER funding phases out, third party payers will be needed to help continue vaccination services and vaccine uptake.” [1]
  - “Reduce/remove barriers such as vaccine administration co-payment and administration fees, which were clearly identified as conditions impeding vaccine uptake of and coverage rates of at-risk populations.” [1]
  - “Further reduce/remove barriers such as vaccine administration co-payment and administration fees.” [1]
  - “Revamp and simplify business processes to allow more efficient third party billing to insurers to recover allowable costs for the administration of the vaccine.” [1]
  - “Healthcare providers’ ability to bill \$.01 for A (H1N1) vaccination to avoid technology/system issues.” [8]
  - “While the federal government will pay for the purchase and distribution of vaccines, payment for the administration of vaccines will be the responsibility of insurance providers, state or local health officials, or in some cases, it possibly will become an out-of-pocket cost for individuals. Clear policies and effective systems must be established as quickly as possible to ensure that health departments, health care providers, clinics, pharmacies, and other organizations who will be administering the vaccines to individuals will receive compensation.” [21]

**Issue Type:** Policy, Legal

- Recommendations Identified:**
- “Medicare and Medicaid should ensure their policies cover the administration of H1N1 vaccines and out-of-network care for H1N1 related illnesses and to allow providers to bulk bill for the administration of vaccines to their beneficiaries through roster billing.” [21]
  - “DOL should communicate with ERISA-governed health benefit plans offered by private employers to encourage them to waive co-pay requirements for vaccines and out-of-network restrictions and to provide information to state and local health departments to help with their vaccination campaigns in communities.” [21]
  - “OPM and DOD should work with their contractors to waive co-pay requirements for vaccines and out-of-network restrictions and to provide information to state and health departments to help with their vaccination campaigns in communities.” [21]
  - “The Treasury Department and IRS should remind nonprofit hospitals that immunizations are a key community benefit, and the importance of meeting community benefit standards as part of retaining tax-free status. They should encourage nonprofit hospitals to be an active part of vaccination campaigns in communities, making their facilities and staff available to work with state and local health departments.” [21]

- 
- Issue:** **State insurance laws do not mandate the coverage of vaccines during declared public health emergencies.**
- “No state insurance laws address coverage and payment of vaccines and their administration during periods of declared public health emergencies. Although 32 states and the District of Columbia (Table 1) do maintain some level of pediatric immunization mandate, the mandates are, as our previous research has shown, so weak as to leave all

states without mandatory coverage of routine immunizations for children under 18. Furthermore, because immunization mandates relate to routine immunization, an insurer would be acting lawfully in our view were it to refuse to pay the administration fee for a vaccine that was administered as a result of a public health emergency, which by definition is not routine.” [25]

*Issue Type:* Legal

*Recommendations Identified:*

- “State insurance laws should mandate the coverage of vaccines during declared public health emergencies. States should enact an insurance coverage mandate that requires insurers operating in both the individual and group health insurance markets to cover and pay for vaccine administration fees during periods of declared public health emergencies, when the vaccines themselves have been distributed on a nationwide basis. The benefit of an insurance mandate is that it would utilize standard insurance claims payment methods for assuring payment to participating providers. Insurers could trigger their claims payment system once a public health emergency is declared, allowing providers, whether in- or out-of-network, to submit vaccine administration claims on members’ behalf, using specially designed claims forms.” [22]

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## D.6 Vaccine Tracking/Recall

*Issue:* **Using immunization registries.**

- “Increase the functionality and interoperability of electronic immunization registries to track and monitor vaccinations.” [1]
- “Focus on communication messages around seasonal flu vaccine to ensure all 114 million doses are used and using the immunization registries to understand and track demographics of who is being vaccinated.” [3]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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## D.7 Adverse Events Reporting

*Issue:* **Vaccine tracking systems must be enhanced to monitor for adverse reactions.**

- “A better system is needed to track when vaccinations are administered. This is crucial for determining if anyone is having adverse effects related to the vaccine.” [21]
- “Enhance vaccination and adverse events reporting mechanisms through the Veterans’ Administration system.” [1]
- “Reporting of adverse incidents related to H1N1 vaccination.” [8]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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## D.8 Coverage Determination/Reporting

- Issue:** **Work to increase uptake and coverage rates.**
- “Redouble efforts to overcome opportunities missed to be more effective in achieving higher coverage rates of high school and college-aged individuals to include identifying and using effective, contemporary, and trusted outreach and messaging strategies and approaches.” [1]
  - “Increasing vaccination coverage rates, including an emphasis on key messages such as:
    - People remain at risk because the virus is still circulating.
    - The elderly and people with chronic underlying medical conditions are under-immunized.
    - The vaccine is safe, readily available, and easy to administer and receive.
    - Children under 10 years old who received one vaccination must receive their second dose.” [1]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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- Issue:** **Coverage among healthcare workers.**
- “A concerted effort should be made to improve vaccine acceptance among healthcare providers to increase vaccine coverage rates of healthcare workers. Education should also work to expand their knowledge and comfort base to more effectively advise patients on the medical appropriateness and relative safety of H1N1 vaccine, both injectable and LAIV.” [1]
  - “Potential partnerships with large HMOs should be explored to capitalize on their approach and track record in positively influencing physician beliefs and behaviors.” [1]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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- Issue:** **Uptake and coverage data/monitoring.**
- “There were limited vaccine uptake and coverage data to guide local public health efforts.” [1]
  - “Monitoring for vaccine coverage is being done through the BRFSS (Behavioral Risk Factor Surveillance Survey - state level estimates of coverage). Forty-nine out of 50 states are using the BRFSS, which gives us a measure of ILI and state by state breakouts, and should provide the most robust data on coverage in pregnant women and healthcare workers. Other coverage monitoring systems used are SDI which provides office claims data and the RAND internet survey which looks at healthcare personnel. In addition there is the National 2009 H1N1 Flu Survey and the Harvard Opinion Poll which can track vaccine uptake and help determine potential demand.” [3]
  - “Monitoring doses administered was problematic; a better system is needed for tracking including obtaining more robust and useful data from private sector providers.” [1]
  - “Continue efforts to increase vaccination coverage rates.” [1]

*Issue Type:* Policy  
*Recommendations Identified:* None identified

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***Issue:*** **Using school immunization data.**

- “Does FERPA limit schools’ ability to provide information to immunization registries and public health agencies? Some school districts believe that FERPA prohibits them from disclosing identifiable information to public health agencies for surveillance and control of serious communicable diseases. What options are available to utilize schools for vaccination and not violate FERPA? If school nurses vaccinate as agents of the state/local public health agency under an MOUs, would nurses be able to report? Would FERPA still be violated if the nurses received their standard school salary or carried out the vaccination duties during regular school hours? Clarification is needed from the Department of Education, as well as an update to the FERPA guidance, advising whether schools may report necessary information to immunization registries and public health agencies based on the health and safety emergency exception to FERPA.” [7]

*Issue Type:* Legal

*Recommendations Identified:*

- “Issue new or clarify 2007 existing guidance (found at <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/guidance/pan-flu-guidance.pdf>) allowing provision of communicable disease and immunization information to be reported to immunization registries and public health agencies.” [7]
- “Consider an amendment to 34 CFR Section 99.36(b) to expressly mention that nothing in FERPA prevents release of information to public health officials in an emergency.” [7]
- “Share analyses of states’ FERPA-public health issues by [State] and other states.” [7]
- “State and local public health legal counsel may review the FERPA Q&A document on the U.S. Department of Education website: <http://www.ed.gov/admins/lead/safety/emergencyplan/pandemic/guidance/flu-faqs.pdf>.” [7]

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## D.9 Liability and Compensation

***Issue:*** **Need to clarify the different reporting requirements of the multiple federal vaccine injury compensation funds.**

- “The multiple federal vaccine injury compensation funds (such as the National Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program) have different reporting and deadline requirements. These differences may cause confusion for persons charged with reporting, such as vaccinators, when an injury occurs.” [6]

*Issue Type:* Legal

*Recommendations Identified:*

- “Develop and disseminate a fact sheet that clearly distinguishes and compares key reporting provisions of the different vaccine programs. Ensure that this information clarifies what will be covered once H1N1 is part of a trivalent vaccine as this change might be an additional source of confusion.” [6]

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## D.10 Vaccination Guidance/Policies

**Issue:**

**ACIP recommendations and special populations.**

- “A variety of issues arose with at-risk and minority and ethnic populations that required focused response. For example, Washington State is working through sovereignty issues that were raised at least partly as a result of the ACIP recommendations being at odds with the role of elders in the tribal community; challenges to the ACIP recommendations out of reluctance of some providers to say no to patients not in the priority group but wanting to be vaccinated, especially the elderly; lack of trust and concerns about vaccine safety in many communities, including African-Americans in Baltimore; and fears about vaccine (safety and porcine products) in Minnesota’s Somali community.” [1]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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## D.11 Vaccination Communications

**Issue:**

**Vaccination outreach activities.**

- “*Special efforts must be made to reach out to encourage young adults, minorities, and other at-risk groups to get vaccinated:* Health departments must intensify efforts to encourage high-risk individuals to get H1N1 vaccinations. Young adults, pregnant women, and minorities, in particular, traditionally have low flu vaccination rates and often do not know where or how to get vaccinations. In addition, a significant percentage of young adults do not have health insurance, which could deter them from going to get vaccinations. Outreach to minority populations must reflect culturally-competent communications and be delivered by respected, trusted, and culturally-competent messengers.” [21]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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## D.12 Vaccination Other Issues

**Issue:**

**International vaccination efforts.**

- “In addition to questions of access, others raise concern about the capacity of poorer countries to effectively administer mass vaccination and treatment campaigns. WHO reported that it would not conduct mass H1N1 vaccination campaigns should a vaccine be developed. Instead, the organization expects that national authorities will undertake such efforts. Some argue that countries that are already incapable of administering routine vaccines will be unlikely to successfully undertake such an effort.” [14]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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**Issue:** Vaccine research and development needs.

**Issue Type:** Policy

- Recommendations Identified:**
- *“Enhance research and development of vaccines and public health technologies.* Basic technology and tools of public health must be modernized to adequately protect the American people. This includes research and development of vaccines and improved chemical laboratory testing capabilities. Collaboration with the private sector as envisioned under BARDA and Project BioShield will be essential.” [22]
  - *“Continue to assess new influenza vaccine technologies.* The U.S. Food and Drug Administration (FDA) should move forward in assessing new technologies that are already in use in influenza vaccines in other countries -- including use of adjuvants and cell-based vaccines. If data from other countries do not meet FDA’s standards, FDA should work closely with industry and the National Institutes of Health (NIH) to collect the data needed for decision making.” [22]
  - *“Clarify requirements and deliverables under Project BioShield contracts.* ASPR should coordinate with NIH, FDA and CDC to ensure future BioShield requests for proposals and procurement contracts for new countermeasures have clearly articulated requirements, expectations, and deliverables.” [22]
  - *“Bolster domestic production capacity for countermeasures, including vaccines, and personal protective equipment (PPEs).* As we have seen during the course of the H1N1 flu pandemic, the United States has limited production capacity for manufacturing flu vaccines and personal protective equipment, such as N95 respirator masks. These shortages have led to confusion, and in some cases fear and panic among the U.S. population. The U.S. government, working through BARDA or other federal agencies, should direct more money to growing domestic production capacity for pandemic countermeasures.” [22]
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## III.E Workforce, Capacity, and Infrastructure

Please see the introduction to Section III on page 13 for general information about the data contained in this subsection.

### Workforce, Capacity and Infrastructure Section Contents

- E.1 Flexing Existing Staff
- E.2 Surge Capacity
  - E.2.1 Public Health Surge
  - E.2.2 Health Care/Medical Surge
  - E.2.3 Volunteers Surge
- E.3 Workforce Mandates
- E.4 Worker Protection, Employment and Insurance
- E.5 Community Recovery/Resiliency
- E.6 Workforce, Capacity, and Infrastructure Other Issues

### Summary of Issues

#### E.1 Flexing Existing Staff

Public health departments did not have enough resources to adequately respond to emergencies.

#### E.2 Surge Capacity

##### E.2.1 *Public Health Surge*

- Public health workforce capacity is strained.
- Organizations and associations may not have the depth of staffing to maintain a prolonged response.
- Enhance public health legal capacity.

##### E.2.2 *Health Care/Medical Surge*

- Health care systems can be overwhelmed in an emergency.
- Partnerships with health care to prepare for medical surge.
- There is a need for sustained funding to improve hospital and trauma center preparedness and response.
- Exercising and documenting lessons through after-action reports.

##### E.2.3 *Volunteers Surge*

- Protection of volunteer public health workers from tort liability.
- Recruiting volunteers and volunteer registration concerns.

#### E.3 Workforce Mandates

- Mandatory vaccination of health care workers.

#### E.4 **Worker Protection, Employment and Insurance**

- Employer privacy/disclosure obligations.
- Employment protections.
- Coverage under sick leave and health care policies.
- Financing catastrophic emergency care.

#### E.5 **Community Recovery/Resiliency**

- State/local communities must consider community recovery/resilience capacity as part of their pandemic/emergency planning.

#### E.6 **Workforce, Capacity, and Infrastructure Other Issues**

- Fund and modernize core public health capacities.
- Strengthen and maintain the public health workforce.

### **Issues Detail**

#### E.1 **Flexing Existing Staff**

**Issue:** Public health departments did not have enough resources to adequately respond to emergencies.

- “Federal, state, and local health departments are stretched too thin to adequately respond to emergencies after decades of underfunding the public health infrastructure. Capacity to track, investigate, and contain cases of H1N1 has been hampered due to lack of resources. For instance, CDC and state laboratory testing was days to more than a week behind the on-the-ground reality. Also, the country must make a sustained commitment to pandemic preparedness by providing consistent federal funding for stockpiling medicines and medical supplies, training, and planning activities. However, there have been no state and local pandemic preparedness funds appropriated since fiscal year (FY) 2006. If the current outbreak had been more severe, state and local health departments likely would have been even more overwhelmed.” [23]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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#### E.2 **Surge Capacity**

##### E.2.1 **Public Health Surge**

**Issue:** Public health workforce capacity is strained.

*Issue Type:* Policy

*Recommendations Identified:* • “The public health workforce is seriously strained, and budget cuts are resulting in additional layoffs. Federal, state, and local governments must take action to recruit, train,

and retain the next generation of public health professionals in public health. Despite tough economic times, it is important to sustain the public health workforces to protect America's health." [23]

- "Public and private health care organizations should develop means to boost staff during a public health emergency, through the use of incentives for current staff, the development of crisis standards of care to allow for changes in staffing ratios and administrative work requirements for staff, and the use of volunteers or nontraditional staff, such as emergency medical technicians and medical and nursing students." [22]
- "The surge workforce should be recruited in advance in order to ensure licensing and accreditation issues are resolved before an emergency strikes." [22]

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**Issue:** **Organizations and associations may not have the depth of staffing to maintain a prolonged response.**

- "National public health partner organizations experienced staffing and funding constraints during the H1N1 response. The national public health associations positioned themselves as the points of contact for information and situational awareness, largely due to the use of the Incident Command System (ICS) structure that many activated." [2]

**Issue Type:** Policy

- Recommendations Identified:**
- "Create/identify processes for dealing with maximized resources and staff at national partner organizations during a response." [2]
  - "National public health partner organizations should collaborate to hold strategic discussions with funders on issues related to allocation of resources in response to an event." [2]

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**Issue:** **Enhance public health legal capacity.**

**Issue Type:** Legal, Policy

- Recommendations Identified:**
- "Improve the existing system of surveillance for emergent legal issues that may impede emergency response." [6]
  - "Improve the existing communications network among legal counsel to state, local, and federal public health agencies to accelerate resolution of emergent legal issues." [6]
  - "Engage state/local counsel in emergency planning. Legal counsel to public health agencies can make important contributions to the development of public health emergency plans—in addition to their critical role as problem solvers during the response phase—and should participate in their development." [6]
  - "Assure common situational awareness of legal issues. Public health emergency response managers and legal counsel may have different understandings of the implications of emergent legal issues. Potential confusion can be minimized by improved real-time, program-counsel communication during the response phase." [6]
  - "Strengthen legal preparedness to address all-hazards public health emergencies. Public health agencies should periodically assess their legal capacity to implement effective response to public health emergencies and make needed improvements. [CDC] PHLP provides a portfolio of tools for this purpose on its website (<http://www.cdc.gov/phlp>)." [6]

## E.2.2 Health Care/Medical Surge

- Aiding Factors:*
- “CMS responded well to ASPR, CDC, and HHS, put out tremendous communications and has done a good job.” [3]
- 

*Issue:* **Health care systems can be overwhelmed in an emergency.**

- “Even with a mild outbreak, the health care delivery system was overwhelmed. Even this relatively mild outbreak proved to be a low-level “stress test” on the health system. It revealed significant problems and lack of preparedness particularly for out-patient settings where there was inadequate personal protective equipment and a limited understanding of infection control measures. At many hospitals, the “worried well” overwhelmed emergency departments. Also, concerns about health care costs were a deterrent for many in seeking early medical attention, especially among the uninsured and underinsured. A further deterrent to seeking prompt medical care was fear among undocumented immigrants that making contact with health authorities could result in deportation.” [23]
- “Impact on doctors’ resources of workers needing validation to return to work or to prove absences; students needing validation to return to school or to prove absences.” [8]

*Issue Type:* Policy

- Recommendations Identified:*
- “The ability for health providers to manage a massive influx of patients during an emergency remains a major challenge for emergency public health preparedness. The federal government must take a lead in providing guidelines to states on surge capacity planning.” [23]
- 

*Issue:* **Partnerships with health care to prepare for medical surge.**

- “All of the selected localities had established partnerships to prepare for a medical surge; however, the degree to which coordination occurred varied. As of late summer 2008, all 10 localities had developed committees to help plan for a pandemic, as well as health care coalitions to coordinate the efforts of health care facilities. In addition, all localities had started to include hospitals in their emergency response planning. Although these partnerships helped to prepare for a medical surge, the degree to which coordination occurred varied among the 10 localities.” [11]

*Issue Type:* Policy

- Recommendations Identified:*
- “ASPR should continue to emphasize the importance of coordination and involving a wide array of stakeholders in medical surge and pandemic planning.” [11]
  - “Facilitate the sharing of information and emerging practices among States and localities. ASPR, in collaboration with CDC, should collect information on emerging practices from States and localities, as well as experts in the field, to further improve medical surge preparedness. ASPR should employ a variety of strategies to facilitate the sharing of this information and emerging practices among States and localities.” [11]
- 

*Issue:* **There is a need for sustained funding to improve hospital and trauma center preparedness and response.**

- “There is a need for sustained funding for hospital preparedness and trauma centers. The Institute of Medicine has documented that emergency departments are in trouble.” [3]
  - “The challenge is in the emergency rooms, i.e., funds are needed for replacement of ER
-

equipment and other materials.” [3]

*Issue Type:* Policy

*Recommendations Identified:*

- “Evaluate ways to identify needs and funding requirements for ongoing medical surge capacity in the states.” [4]
- “Review the use of limited resources and address issues relating to the “health of the health care system”.” [4]

---

*Issue:* **Exercising and documenting lessons through after-action reports.**

- “All of the selected localities conducted medical surge exercises; however, none consistently documented the lessons learned. Localities conducted between one and seven medical surge exercises over a 2-year period. Most of these exercises were discussion-based, rather than operations-based. Although localities are encouraged to document lessons learned during exercises through the creation of after-action reports and improvement plans, none consistently completed these documents for their exercises. In addition, the existing documentation that we reviewed showed that localities needed to make improvements within the five medical surge components.” [11]

*Issue Type:* Policy, Legal

*Recommendations Identified:*

- “Ensure that States and localities consistently document the lessons learned from preparedness exercises that address medical surge. Given the importance of exercises in strengthening preparedness, ASPR, in collaboration with CDC, should ensure that States and localities consistently document the lessons learned from all medical surge exercises that require documentation.” [11]

---

### E.2.3 Volunteers Surge

*Issue:* **Protection of volunteer public health workers from tort liability.** [8]

*Issue Type:* Legal

*Recommendations Identified:*

- “Address the issue of legal protections for medical professionals and volunteers who respond to public health emergencies, such as an influenza pandemic. ASPR should consider working with States to develop appropriate legal protections for medical professionals and volunteers who respond to public health emergencies and who may need to alter standards of care. ASPR should also consider the feasibility of Federal legislation in this area.” [11]
- “*State liability protections for volunteer health professionals:*
  - Liability concerns are a growing challenge to emergency preparedness officials. Volunteers and private entities have expressed reluctance to participate in response and recovery efforts for fear that their actions may make them liable. State legislatures should adopt the UEVHPA, which has been approved by both the National Conference of Commissioners on Uniform State Laws and the American Bar Association, or enact similar legislation that extends liability protection to volunteer health professionals in a public health emergency.
  - Congress should amend the Public Health Service Act to provide Federal Tort Claims Act protection to qualified ESAR-VHP participants when they are activated by the federal government in response to a public health emergency. The federal Public Health Security and Bioterrorism Preparedness and Response

Act of 2002 authorized the ESAR-VHP to help states develop registry systems for the timely identification, verification and use of volunteer health professionals during public health emergencies.<sup>171</sup> In 2006, PAHPA required the federal Secretary of Health and Human Services to link the state systems into a single national network of systems. The state systems continue to be maintained by the individual states, with guidance from the federal government. Despite ongoing efforts to build this national network, the liability issues that can arise from activating the ESAR-VHP remain an area of concern.” [22]

- “*State entity emergency liability protection.* State legislatures should consider extending Good Samaritan liability protections to those non-health care volunteers and business and non-profit entities that provide emergency assistance.” [22]
- “*Surge Workforce and volunteer protections:* Hospitals, health care providers, and public health departments should redouble efforts to recruit additional medically-trained staff for times of emergency. This includes creating incentive systems for employees to work overtime and to find trained volunteers who can be screened and would be ready and reachable during times of emergency. Issues of liability protection must also be addressed. Many volunteers and private entities have expressed reluctance to participate in emergency health response efforts due to concerns about liability. A number of states have passed legislation to protect volunteer health professionals. The federal government could also take measures to extend liability protections if Congress amended the Public Health Service Act to provide Federal Tort Claims Act protection to qualified health professionals when they are activated during emergencies, and Congress could also consider a minimum protection to address liability issues for businesses and non-profit organizations who work with government officials responding to emergencies.” [21]

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**Issue:**

**Recruiting volunteers and volunteer registration concerns.**

- “A patchwork of federal and state laws generally operates to protect volunteers, which may include VHPs, and there are also laws that trigger liability protection specifically for VHPs. Whether a VHP is protected from civil liability depends on a number of factors, including under whose control the VHP operates and whether or not a state of emergency has been declared. It is important to note that liability protections shield volunteers from all civil liability for negligent conduct, i.e., a failure to take adequate care that results in injuries or losses to others. Civil liability for conduct that is more egregious than mere negligence, such as willful, or grossly negligent conduct, is generally not protected.” [13]
- “Fewer than half of the selected localities had started to recruit medical volunteers, and none of the five States had implemented an electronic system to manage them. Four localities had started to recruit, register, and train medical volunteers. All four, however, had concerns about using volunteers. In addition, none of the five States had fully implemented an electronic system for managing medical volunteers. States were required by ASPR to have electronic systems to register medical volunteers and verify credentials by August 2009.” [11]
- “*Electronic medical volunteer registry concerns.* We reported that some states reported that medical volunteers might be reluctant to join a state electronic medical volunteer registry if it is used to create a national medical volunteer registry. PAHPA requires ASPR to use the state-based registries to create a national database. According to state officials, some volunteers do not want to be part of a national database because they are concerned that they might be required to provide services outside their own state. Officials from one state reported that since PAHPA was enacted, recruiting of medical volunteers was more difficult and that the federal government should clarify whether national deployment is a possibility. ASPR officials said that they would not deploy medical volunteers nationally without working through the states.” [15]
- “Additionally, some states expressed concerns about coordination among programs that recruit medical volunteers for emergency response. Officials from one state reported that

federal volunteer registration requirements for the Medical Reserve Corps (MRC) and the electronic medical volunteer registry programs had not been coordinated, resulting in duplication of effort for volunteers. Officials from a second state reported that a volunteer for one program that recruits medical volunteers is often a potential volunteer for another such program, which could result in volunteers being double-counted. This may cause staffing problems in the event of an emergency when more than one volunteer program is activated.” [15]

*Issue Type:* Legal, Policy

*Recommendations Identified:* • “ASPR should continue to emphasize the importance of recruiting, registering, and training medical volunteers for use in a pandemic.” [11]

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### E.3 Workforce Mandates

*Issue:* **Mandatory vaccination of health care workers.**

- “*May state governments compel vaccination of healthcare workers?* Some healthcare workers object to being vaccinated.” [7]
- “*May employers render them unfit for work or impose other limits and restrictions?*” [7]
- “*What are State mandates v. guidelines for healthcare worker vaccination.*” [8]

*Issue Type:* Legal, Policy

*Recommendations Identified:* • “Raise this issue during CDC-sponsored H1N1 teleconferences and communicate the resolution/guidance through the Public Health Legal Counsel Listserv.” [7]

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### E.4 Worker Protection, Employment and Insurance

*Issue:* **Employer privacy/disclosure obligations.**

- “*May employers legally divulge the nature of a worker’s illness?* Employers want to protect employees’ privacy but also may wish to advise well employees they may have been exposed to illness by a sick co-worker. Are employers prohibited from divulging that information? Conversely, are employers liable if they do not inform well employees of potential risk? (Note that the relevant laws may vary between healthcare and non-healthcare employers and between public and private employers.)” [7]

*Issue Type:* Legal

*Recommendations Identified:* • “Will distribute the [STATE] law regarding ill healthcare workers. Workgroup members will contribute additional information. This information will be shared via the Public Health Legal Counsel Listserv.” [7]

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*Issue:* **Employment protections.**

- “*How can employees who are absent from work (e.g., because of illness or quarantine) be protected from losing their jobs and income?* Workers who fear losing their jobs and income may come to work even though ill and thus expose others to disease. Note, unemployment compensation programs do not address problems related to short-term illnesses because eligibility is limited to people who are actively seeking employment.” [7]

- “At least six states, recognizing the lack of statutory protection for employees in a situation where isolation or quarantine may be necessary, have enacted legislation that explicitly prohibits the termination of an employee who is subject to isolation or quarantine. In Delaware, Iowa, Kansas, Maryland, Minnesota, and New Mexico, an employer is prohibited from terminating an employee who is under an order of isolation or quarantine, or has been directed to enter isolation or quarantine. Under Minnesota law, an employee who has been terminated or otherwise penalized for being in isolation or quarantine may bring a civil action for reinstatement or for the recovery of lost wages or benefits.” [13]
- “Two additional states have enacted legislation that addresses the treatment of employees who are subject to quarantine or isolation. Under New Jersey law, an affected employee must be reinstated following the quarantine or isolation. Under Maine law, an employer is required to grant leave to an employee who is subject to quarantine or isolation. The leave granted by the employer may be paid or unpaid.” [13]

*Issue Type:* Legal, Policy

- Recommendations Identified:*
- “Consider seeking revisions to federal and state unemployment compensation law, such as authorizing payment of unemployment compensation during a declared public health emergency so that workers will be more likely to remain home and reduce the risk of transmission of the disease.” [7]
  - “Review other potentially relevant laws, such as the Family Medical Leave Act, for possible revisions that would encourage employees to comply with isolation, quarantine or social distancing measures.” [7]

*Issue:* **Coverage under sick leave and health care policies.**

- “Do sick leave policies cover persons who have been exposed to or are quarantined for a communicable disease? People in quarantine are not yet sick but must be absent from the workplace. They may not be eligible for sick leave status under their employers’ sick leave policies.” [7]
- “Protection of workers from job loss or loss of income due to illness, exposure, caring for an ill family member, or caring for children due to school dismissal, in order to encourage workers not to attend work when ill or exposed and risk exposing others.” [8]
- “Coverage of workers by sick leave policies for exposure or quarantine where the worker has no known symptoms.” [8]
- “A public health emergency will create financial hardships for individuals and the health care system. Because compliance with recommendations to seek immediate care and/or self-isolate or quarantine may be critical to containing the spread of influenza or a terrorist-introduced organism, TFAH believes the federal government should take steps to assure that lack of health insurance or sick leave do not prevent compliance with public health recommendations.” [22]

*Issue Type:* Policy, Legal

- Recommendations Identified:*
- “Review options for issuance of guidance for employers regarding quarantine and sick leave policies as well as other options that may be available (such as administrative leave) to reduce the potential spread of the disease through the worksite.” [7]
  - “Establish minimum paid sick leave standards. The H1N1 flu pandemic has once again validated public health officials’ concerns that employees who lack paid sick leave will show up for work when they are sick and infect coworkers and/or customers. Congress should enact legislation that would require employers to offer paid sick leave, which also

could be used by employees to care for sick children or other family members. Proposed legislation that seeks to address this need includes the Healthy Families Act, sponsored by Rep. Rosa DeLauro (D-CT) and Sen. Christopher Dodd (D-CT). This legislation would require employers with 15 or more employees to offer up to seven days of job-guaranteed paid sick leave each year, to be used to deal with individual medical needs or to care for sick family members.” [22]

- “*Set up emergency sick leave policies and procedures.* The federal government should clarify whether the Department of Labor’s Disaster. Unemployment Assistance Program as currently established would cover workers without sick leave who self-quarantine in the event of a pandemic flu.” [21, 22]

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**Issue:** **Financing catastrophic emergency care.**

- “Even if health reform succeeds, it will be several years before near-universal coverage is achieved. In the meantime, a public health emergency will create financial hardships for individuals and the health care system. Because compliance with recommendations to seek immediate care and/or self-isolate or quarantine may be critical to containing the spread of influenza or a terrorist-introduced organism, TFAH believes the federal government should take steps to assure that lack of health insurance does not prevent compliance with public health recommendations.” [22]

**Issue Type:** Policy

**Recommendations Identified:**

- “*Establish an emergency health benefit.* Congress should establish a short-term emergency health benefit, which would allow hospitals and health care centers to keep functioning during a prolonged public health emergency, while ensuring care to uninsured and underinsured individuals affected by the crisis. Legislation currently under consideration in Congress, the Public Health Emergency Response Act (PHERA), would help ensure that victims of catastrophic public health emergencies have meaningful and immediate access to medically necessary health care services.” [21, 22]
- “*HHS and DHS should institute a policy that no one who contracts H1N1 should be denied care:* HHS and DHS should issue a joint statement outlining a policy that undocumented individuals who receive care for H1N1 will not be subject to enforcement action in order to ensure that people who are sick will seek care, which helps prevent the spread of the disease and also limits emergency room visits by patients who delay seeking care until they are severely sick.” [21]
- “*Caring for the uninsured and underinsured:* A “State of Emergency” health benefit should be created to ensure that all Americans will be cared for during emergencies. Providing care is not only important for the individual patient, but since individuals are contagious, it also helps limit the spread of disease to others. However, if universal health insurance coverage is not achieved, the federal government should act now to create emergency health coverage and reimbursement. The Public Health Emergency Response Act (PHERA) is an example of legislation that would address this concern.” [23]

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## E.5 Community Recovery/Resiliency

**Issue:** **State/local communities must consider community recovery/resilience capacity as part of their pandemic/emergency planning.**

- “HSPD-21 identifies community resilience as one of “the four most critical components of public health and medical preparedness,” along with mass casualty care, mass distribution, and biosurveillance. The U.S. government defines “community resiliency” as the ability of a community to cope and recover from a disaster or public health emergency. A CDC-

funded study states that in order “for a community to be resilient, its members must put into practice early and effective actions, so that they can respond to adversity in a healthy manner.” Taking this into account, preparedness plans need to consider the diverse needs of the U.S. population, in particular, “at-risk,” “special needs,” and “vulnerable” populations. Only by effectively reaching out to all segments of the U.S. population can the country appropriately be prepared to survive and overcome crises.” [22]

*Issue Type:* Policy

*Recommendations Identified:*

- *“Guard against complacency.* One of the biggest challenges facing public health emergency preparedness is complacency. Federal, state, local, tribal, and territorial governments must maintain a sense of urgency regarding preparedness. Officials should communicate the importance of preparedness to the public while not resorting to scare tactics. Engagement with media is the key to building a heightened sense of awareness around the issues of emergency preparedness, especially at the community level.” [22]
- *“Engage communities in planning.* Federal, state, local, tribal, and territorial governments must engage communities in local emergency and pandemic planning. Too often emergency planners just look to their grantees and ignore other key stakeholders, such as volunteer organizations, religious institutions, and schools and universities. Planners must proactively approach these diverse groups and bring them to the table.” [22]
- *“Develop a community education campaign promoting vaccination for H1N1 and all other influenza vaccines, and all vaccines in general.* The U.S. Centers for Disease Control and Prevention (CDC), working with other federal, state, and local partners, should develop an education campaign to assure the American people about the safety and effectiveness of the H1N1 (and all other) influenza vaccines and all vaccines in general. It is important to remind Americans that even with the delays in vaccine availability, they should get vaccinated as soon as they can. It is not clear that the pandemic has peaked, and even if it has, many who might still get sick are still at risk and could be protected by a vaccine. Moreover, historically there is always the danger of a third pandemic wave, which may or may not be more severe than the previous two waves. So being vaccinated now will give critical protection for those who have not become ill during the initial waves. Vaccine hesitancy during the H1N1 vaccination campaign has highlighted the need for ongoing education and outreach to Americans, including underserved populations, about the importance and safety of regular inoculations.” [22]
- *“Focus on disease prevention and health promotion.* Americans cannot be prepared if they are unhealthy, yet chronic disease rates are spiraling out of control in this nation. More than two-thirds of American adults are overweight or obese. One in four has heart disease; and one in three has high blood pressure. Twenty-four million Americans have type 2 diabetes and another 54 million are pre-diabetic. These underlying health conditions pose a challenge when residents are asked to evacuate due to a public health emergency. And we have seen during the H1N1 pandemic that those with chronic conditions are more at risk for complications. Persons dependent on prescription drugs also face challenges when asked to shelter-in-place as they may run out of their medicines. The 2009 American Recovery and Reinvestment Act (ARRA) included \$650 million for community-based interventions, which can be used to bolster resiliency. In addition, the health reform legislation before Congress includes a dedicated funding stream for core public health functions, including prevention of chronic disease.” [22]
- *“Communicating effectively with at-risk individuals.* Federal, state, local, tribal, and territorial officials must design culturally competent risk communication campaigns that use respected, trusted, and culturally competent messengers. Current research and best-practices regarding emergency preparedness communication strategies for at-risk populations should direct the creation and dissemination of these messages.” [22]
- *“Children are not small adults and pandemic and all-hazards preparedness plans must consider the unique needs of children.* Children are inherently vulnerable as they depend

upon adults for food, shelter, supervision and guidance. As such, their needs should be taken into account in all public health emergency and pandemic preparedness efforts. Because disease susceptibility, outcome, and transmission will likely differ for children when compared to adults, recommendations for child social distancing during a pandemic will likely differ from social distancing recommendations for adults. Evacuation and reunification planning should reflect the fact that children are often separated from their parents for much of the day. These plans should also take into account children with special needs. Child advocates, such as teachers and pediatricians, should be consulted as plans are made. Preparedness plans should be clearly communicated to parents, schools, and daycare facilities.” [22]

- “*The president and Congress should carefully consider the recommendations from the National Commission on Children and Disasters, which are due out in 2010.* The National Commission on Children and Disasters, a bi-partisan panel appointed by the president and Congressional leaders, is tasked with examining and assessing the needs of children independently, and in relation to the preparation, response and recovery from all emergencies, hazards and disasters. Following its two-year investigation, the Commission will issue a final report, complete with findings and recommendations, to the president and Congress. These recommendations should be acted upon with utmost urgency.” [22]

## E.6 Workforce, Capacity, Infrastructure Other Issues

**Issue:** Fund and modernize core public health capacities.

**Issue Type:** Policy

- Recommendations Identified:**
- “*A fully-funded and reliable funding stream is needed to support public health preparedness:* Public health infrastructure has been underfunded for decades, according to assessments from CDC, IOM, and other experts. Federal funding for core state public health preparedness was cut 25 percent between FY 2005 and 2009. It is important that states have a reliable, dedicated, and sustained level of funding that is adequate to meet core capabilities and to continue to keep pace with new technologies that can help them better meet the needs of communities. Congress should assure a robust, reliable funding stream through health reform legislation for all core public health activities.” [21]
  - “*A mechanism should be created to ensure that vaccines, medications, and equipment in the SNS are replenished and upgraded as needed:* Right now, there is no systematic way to ensure that new supplies are purchased to replace used items so the country will be prepared for the next emergency. After the H1N1 outbreak, it will also be essential that the SNS and states replenish the supply of antiviral medications to prepare for the potential threat of future outbreaks.” [21]
  - “*All U.S. disease surveillance systems must be modernized:* The nation’s disease surveillance and health tracking systems are severely out-of-date and do not provide real-time or easily accessible data. The upgrades to surveillance during the H1N1 should be used to leverage upgrading the rest of U.S. disease surveillance capabilities. The nationwide implementation of health information technology systems through the American Recovery and Reinvestment Act and health reform proposals must take into account the need for public health data accessibility.” [21]
  - “*Additional core public health infrastructure capabilities must be modernized:* There is no system in place to ensure that the basic public health systems and equipment keep pace with advances in science and technology. There needs to be a systematic way to ensure that the technology and equipment that support core functions, like laboratory testing and communications, are routinely updated.” [21]
  - “*Pandemic plans must be continually revised:* As the emergence of H1N1 demonstrated, new strains of flu can emerge quickly and rapidly. In addition, experts are still concerned

that the H5N1 “bird” flu could potentially become a human pandemic. It is essential that the National Strategy for Pandemic Influenza and state plans be continually revised. Plans should particularly be updated to incorporate the lessons learned during the H1N1 outbreak and response.” [21]

- “*Adequate funding must be provided for on-the-ground response.* Right now, state and local health departments do not currently have enough resources to respond to a severe outbreak.
  - Congress should assure a reliable funding stream for all core public health activities as part of health reform -- both to prevent and address the on-going public health responsibilities of state and local government and to ensure back up capacity is available to respond to a major public health emergency
  - The federal government should update as needed, fully fund, and promptly carry out the President’s National Strategy for Pandemic Influenza Implementation Plan.” [23]

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**Issue:** **Strengthen and maintain the public health workforce.**

- “*The capacity of the public health workforce must be strengthened and maintained.* The growing workforce shortage in the health care and public health fields threatens U.S. emergency preparedness. America’s response will be severely limited, unless the workforce challenges the public health system faces are addressed. PAPHA contained two key provisions related to workforce development, whose implementation TFAH supports. But much more remains to be done to address the public health workforce crisis. Current health reform legislation before Congress includes a variety of provisions to strengthen and support the U.S. public workforce.” [22]

**Issue Type:** Policy

**Recommendations Identified:**

- “*Fund and implement PAHPA workforce provisions.* Congress should appropriate and allocate the necessary funds to implement the HHS workforce demonstration project. This student loan repayment project is intended for individuals who: 1) are eligible for the National Health Service Corps loan repayment program and 2) also agree to serve in a state health department that provides service to a significant number of health professional shortage areas or has areas that are at risk of a public health emergency. Congress should also appropriate and allocate monies necessary to execute the second PAHPA workforce provision, which allocates grants to states to assist in operating state loan repayment programs.” [22]
- “*Establish a public health workforce loan repayment program.* To attract the next generation of public health workers, the federal government should establish a public health workforce loan repayment program. Health reform legislation currently under consideration in Congress includes a provision to establish a public health workforce loan repayment program to eliminate critical public health workforce shortages in federal, state, local and tribal public health agencies. In FY 2010, \$195 million is authorized to be appropriated for this program, and such sums are necessary for FY 2011-2015.” [22]
- “*Enact and fund comprehensive public health workforce scholarship initiatives.* More needs to be done to recruit, train, and retain a qualified public health workforce. The current health reform bills under consideration in Congress include provisions that would establish a public health workforce training and enhancement program consisting of awarding grants and contracts for public health training programs and fellowships and traineeships for students who participate in these programs and who plan to specialize or work in the field of public health.”[22]
- “*Bolster the state and local public health workforce.* The federal government should provide federal matching funds to state and local governments to invest in recruitment, retention, training, and retraining for public health workers. Legislation currently before

Congress would establish a competitive health workforce development grant program to enable state partnerships to complete comprehensive planning and to carry out activities leading to coherent and comprehensive health care workforce development strategies at the State and local levels. The proposed legislation authorizes \$8 million for planning grants and \$150 million for implementation grants for FY 2010 and such sums for each subsequent year.” [22]

- *“Strengthen the U.S. Public Health Service Commissioned Corps.* Congress should strengthen the U.S. Public Health Service Commissioned Corps by increasing the number of active duty personnel, creating a “Ready Reserve Corps” to train and respond to public health emergencies, and establishing a dedicated funding stream for all Corps activities under the management and fiscal control of the Surgeon General. The health reform legislation under consideration in Congress includes provisions that would both 1) eliminate the cap on Commissioned Corps, which is currently set at 2,800, and 2) establish a Ready Reserve Corps to participate in training exercises, be available and ready for involuntary calls to active duty during national emergencies and public health crises, be available for deployment and for backfilling positions left vacant during deployment of active duty Corps members, and be available for service in isolated, vulnerable and medically underserved communities.”[22]
  - *“Recruit the next generation of public health workers.* Congress and the Administration should develop programs to expose and recruit high school students into health careers, with a focus on careers in public health. The health reform bill before Congress includes such language for the creation of a Youth Public Health Program.” [22]
  - *“Support public health systems research on workforce needs and capacity.* The U.S. government should support the establishment of a high-level commission or advisory body to study the workforce needs of the 21st century public health system. Health reform legislation before Congress would establish a commission to disseminate information on: current and projected health care workforce supply and demand, healthcare workforce education and training capacity, retention practices for health care professionals, and recommendations on the development of a fiscally sustainable integrated workforce.” [22]
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## III.F Federal/State/Local Coordination

Please see the introduction to Section III on page 13 for general information about the data contained in this subsection.

### Federal/State/Local Coordination Section Contents

- F.1 Intergovernmental Coordination and Activities
  - F.1.1 Governmental Coordination and Common Operating Picture/Platform
  - F.1.2 National Public Health Organizations
  - F.1.3 Technical Assistance
  - F.1.4 Pandemic Planning, Exercising and Implementation
- F.2 Categorical Grants and Cooperative Agreements
  - F.2.1 Categorical Grant/Cooperative Agreement Flexibility
  - F.2.2 Public Health Funding Needs
- F.3 Stakeholder Engagement and Interaction
  - F.3.1 Health Care Sector
  - F.3.2 Special and Vulnerable Populations
  - F.3.3 Stakeholder Engagement General
- F.4 Federal/State/Local Coordination Communication
- F.5 Federal/State/Local Coordination Other

## Summary of Issues

### F.1 Intergovernmental Coordination and Activities

#### F.1.1 *Governmental Coordination and Common Operating Picture/Platform*

- Interagency collaboration, coordination and clarity associated with decision making needs improvement.
- Create a “common operating picture” as a means to more effectively share standardized data and information between the different levels of government
- Federal, state, and local health departments should share lessons, innovations, and resources.
- International coordination was more complicated than expected.
- Improve information flow between federal and state/local public health attorneys.
- Need to expand relationships with legal counsel in additional federal agencies.
- Need to expand communication with, and education for, legal counsel to local public health agencies.

#### F.1.2 *National Public Health Organizations*

- Coordination with national public health partner organizations.

#### F.1.3 *Technical Assistance*

- Federal technical assistance capacity.

**F.1.4 *Pandemic Planning, Exercising and Implementation***

- Pandemic planning, exercises and implementation activities must continue at all levels of government.
- National Strategy for Pandemic Influenza and Plan.
- Pandemic and All-Hazards Preparedness Act (PAHPA) implementation.

**F.2 *Categorical Grants and Cooperative Agreements***

**F.2.1 *Categorical Grant/Cooperative Agreement Flexibility***

- States need flexibility in using funding during pandemic/emergency response situations.
- Use of PHER funds.

**F.2.2 *Public Health Funding Needs***

- Public health preparedness funding must be increased and sustained at the state and federal levels.

**F.3 *Stakeholder Engagement and Interaction***

**F.3.1 *Health Care Sector***

- Communication between the public health system and health providers was not well coordinated.
- Provide training and technical assistance to States and localities on key issues related to medical surge and alternate standards of care.
- Need to develop and maintain communication with legal counsel to hospitals, health systems, and other traditional stakeholders, as well as with nontraditional organizations that assisted the H1N1 response.

**F.3.2 *Special and Vulnerable Populations***

- Vulnerable migrant populations.

**F.3.3 *Stakeholder Engagement General***

- Determine how to maintain, enhance, or create partnerships that may benefit response to seasonal and pandemic influenza.

**F.4 *Federal/State/Local Coordination Communication***

- None identified

**F.5 *Federal/State/Local Coordination Other***

- None identified

## Issues Detail

### F.1 Intergovernmental Coordination and Activities

#### F.1.1 Governmental Coordination and Common Operating Picture/Platform

**Aiding Factors:** “Local and state participants expressed gratitude for CDC’s coordination of response, and affirmed the value of CDC’s frequent conference calls to share timely information and to clarify key information and help keep public health on the same page. Several people also noted examples where technical assistance from federal employees was extremely useful on the ground.” [1]

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**Issue:** **Interagency collaboration, coordination and clarity associated with decision making needs improvement.**

- “Problems encountered with the Food and Drug Administration (FDA) EUA process resulted in a delay in information sharing with state and local health departments.” [4]
- “Information flow could be improved through more streamlined messaging and greater predictability in the release of information.” [4]
- “Information management was challenging with multiple Situation Reports emanating from multiple sources.” [4]
- “The U.S. Stages and Pandemic Severity Index were sources of confusion and distraction as they garner much attention, but had marginal application and utility in the scenario.” [4]
- “Resolution must be achieved regarding the dichotomy of standards and positions between the CDC and the Occupational Safety and Health Administration (OSHA) regarding the use of N95 respirators.” [4]
- “The plethora of conference calls was at times overwhelming.” [4]
- “Better coordination is needed between state public health and homeland security/emergency management.” [4]
- “A better balance is needed of CDC providing useful (voluntary) guidance without being overly prescriptive to states where it may appear as a requirement. States must retain autonomy but benefit from sound guidance as a means to achieve greater consistency among jurisdictions.” [4]

**Issue Type:** Policy

**Recommendations Identified:** None identified

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**Issue:** **Create a “common operating picture” as a means to more effectively share standardized data and information between the different levels of government.** [1]

- “One county official described a tension between state and federal guidelines, especially when locals were feeling a push to expand vaccination groups on the ground and states had not expanded its groups.” [1]
- “While a number of jurisdictions spoke very positively about the level of coordination, collaboration and inclusion that existed between state and local health in their states, several other local officials were critical of their state health agencies’ handling of the response as it pertained to coordinating and communicating with local health officials.” [1]
- “Develop a strategy and a standardized and synchronized approach for local and state

- after-action reviews and improvement planning.” [1]
- “The number of conference calls became daunting.” [4]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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***Issue:* Federal, state, and local health departments should share lessons, innovations, and resources.**

- “Better systems should be developed for real-time sharing of approaches and innovations across different states, communities, and jurisdictions. In addition, neighboring communities should share and coordinate to the extent possible plans for policies for providing care and information, and if necessary, resources.” [21]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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***Issue:* International coordination was more complicated than expected.**

- “Despite advice from the WHO, some countries chose to close their borders to Mexican citizens or banned pork products from the United States and Mexico. These measures were not based on either science or reasonable public health practices and caused unnecessary economic losses. Once a flu virus is circulating throughout the population, containment strategies, like travel restrictions, generally will not work, given that it is possible to infect others before a person develops flu-like symptoms. Also, the effectiveness of some mitigation strategies implemented (face masks in Mexico) were overstated.” [23]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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***Issue:* Improve information flow between federal and state/local public health attorneys.**

- “How can exchange of information between federal and state/local public health attorneys be improved? State/local legal counsel can better support their agencies’ H1N1 preparedness with more rapid access to updated information about federal legal and policy guidance, as well as with immediate dissemination of federal declarations triggering the operation of federal law or any document changing the requirements for compliance with federal laws, rules or other mandates. Declarations should include reference to earlier, relevant declarations to clarify their relationship. Further, when declarations incorporate prior declarations, often these prior declarations are not readily accessible.” [7]

*Issue Type:* Legal, Policy

*Recommendations Identified:* • “Hold periodic and as-needed teleconferences for updates on federal legal and policy guidance (including issued declarations, changes in federal compliance requirements, etc.) and to facilitate mutual discussion of legal issues.” [7]

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- “Disseminate relevant PREP Act or Public Health Emergency declarations, EUAs, and other federal declarations triggering the operation of federal law or any document changing the requirements for compliance with federal laws, rules or other mandates as soon as they are issued. Disseminate other resources such as “Q&A” materials as rapidly as possible.” [7]
- “Recommend that declarations that incorporate prior declarations include the prior declaration as an attachment or link to the prior declaration when posted.” [7]

**Issue:** **Need to expand relationships with legal counsel in additional federal agencies.**

- “State and local public health agencies sometimes pose legal questions that fall under the domain of HHS agencies other than CDC, such as FDA and CMS, or under the domain of agencies in other departments, such as DHS/FEMA. They need ways to communicate effectively with such agencies during public health emergencies.” [6]

**Issue Type:** Legal, Policy

**Recommendations Identified:** • “[CDC’s] PHLP and CDC’s Office of General Counsel should establish permanent mechanisms for state and local public health counsel to communicate rapidly with counsel to those additional federal agencies.” [6]

**Issue:** **Need to expand communication with, and education for, legal counsel to local public health agencies.**

- “Communication between state and federal attorneys has improved greatly with PHLP facilitation; however, communication channels with legal counsel at the local level are not as well developed. Some local level legal counsel are faced with unique challenges, such as not being focused/specialized in public health law, being on retainer and only contacted as needed rather than more frequent involvement, more frequent turnover, and not receiving as much communication from state or federal public health agencies or counsel.” [6]

**Issue Type:** Legal, Policy

**Recommendations Identified:** • “[CDC] PHLP should consider developing additional ways to facilitate communication among legal counsel to local public health agencies. PHLP should consider developing/disseminating materials on public health emergency law related issues for use by local public health agencies and their counsel.” [6]

## F.1.2 National Public Health Partner Organizations

**Issue:** **Coordination with national public health partner organizations.**

- “CDC recognized the role of the public health partner organizations in an event.” [2]
- “Create and launch a Public Health Recognition Program to honor the many who worked so tirelessly on the H1N1 response including governmental and non –governmental volunteers.” [1]
- “A regularly scheduled check-in among ASTHO, its affiliates, and partner organizations to share information during the response would further improve the response.” [2]
- “The need to streamline and maintain consistent messaging among the national public health partner organizations.” [2]
- “Share information among the national public health partner associations on a regular

basis.” [2]

- “National public health partner organizations must work together to provide federal partners with state and local situational awareness, including communicating needs and identifying areas of collaboration and guidance prior to an event.” [2]
- “Coordination efforts also include the staff at national public health partner organizations such as (list is not exhaustive):
  - The Association of Immunization Managers (AIM)
  - The Association of Public Health Laboratories (APHL)
  - The Association of State and Territorial Directors of Nursing (ASTDN)
  - The Association of State and Territorial Health Officials (ASTHO)
  - The Council of State and Territorial Epidemiologists (CSTE)
  - The National Association of City and County Health Officials (NACCHO)
  - The National Association of State EMS Officials (NASEMSO)
  - The National Public Health Information Coalition (NPHIC)” [2]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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### F.1.3 Technical Assistance

***Issue:* Federal technical assistance capacity.**

- “Federal agencies have provided considerable guidance and pandemic-related information to state and local governments, but could augment their efforts with additional information on school closures, state border closures, and other topics.” [17, 20]
- “Concerns were also voiced about CDC’s Procurement and Grants Office’s (PGO) inability to keep up with the volume of administrative responsibilities on CDC’s end such as processing award notices, redirection requests, etc.” [1]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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### F.1.4 Pandemic Planning, Exercising and Implementation

***Issue:* Pandemic planning, exercises and implementation activities must continue at all levels of government.**

- “Pandemic planning and exercising has occurred at the federal, state, and local government levels, but important planning gaps remain at all levels of government.” [17, 20]
- “At the federal level, agency planning to maintain essential operations and services while protecting their employees in the event of a pandemic is uneven.” [17]
- “Leadership roles and responsibilities for an influenza pandemic need to be clarified, tested, and exercised, and existing coordination mechanisms, such as critical infrastructure coordinating councils, could be better utilized to address challenges in coordination between the federal, state, and local governments and the private sector in preparing for a

pandemic.” [17, 20]

- “Agency progress in pandemic planning is uneven. Although all of the 24 CFO Act agencies reported being engaged in planning for pandemic influenza to some degree, several agencies reported that they were still developing their pandemic plans and their measures to protect their workforce.” [18, 19]
- “The three case study agencies also showed differences in the degree to which their individual facilities had operational pandemic plans. BOP’s correctional workers had only recently been required to develop pandemic plans for their correctional facilities. [BOP’s responses indicated coordination with state and local pandemic planning mechanisms.] Treasury’s FMS had pandemic plans for its four regional centers and had stockpiled personal protective equipment. By contrast, air traffic control management facilities, where air traffic controllers work, had not yet developed facility pandemic plans or incorporated pandemic plans into their all-hazards contingency plans.” [18, 19]
- “*Response plans must be adaptable and science driven.* For years, pandemic flu planning focused on the potential threat of the H5N1 (bird) flu that has been circulating in Asia for the past 10 years. In addition, much of the planning anticipated that there would be a six week lead time between the time a novel flu strain was detected before it reached the United States. H1N1 showed that a new flu strain can emerge quickly or go undetected for a period of time and rapidly spread throughout the world. As the epidemic unfolded, new knowledge required government officials to reassess guidance offered to the public and the medical community. For example, as it became clearer that H1N1 was circulating widely in communities and largely causing mild cases, the U.S. Centers for Disease Control and Prevention (CDC) officials lifted their recommendations on school closures to match the changing circumstances. Different communities faced different situations, such as the extent of the spread of the virus into a community, which resulted in the need for different policies in different places.” [23]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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***Issue:* National Strategy for Pandemic Influenza and Plan.**

- “The Plan is predicated on a type of pandemic different in severity and origin than the current H1N1 pandemic, but it is serving as the foundation for the response to the outbreak, supplemented by an additional plan tailored specifically to the characteristics of the H1N1 pandemic. Nevertheless, the *National Strategy for Pandemic Influenza and Plan* will still be needed for future events as most of the action items in the Plan were to be completed by May 2009. As recommended in earlier GAO work, but not yet implemented, the Plan should be updated to take into account certain missing elements and lessons learned from the H1N1 pandemic; the update should also address the monitoring and assessment improvements GAO identified in this report.” [16]
- “We found that the Plan does not describe the specific circumstances, such as the type or severity of an outbreak or pandemic, under which the response-related action items would be undertaken. In addition, for response-related action items in which the trigger is not an outbreak or pandemic, the Plan does not describe the types of information that would be needed in order to make a decision to implement the action items.” [16]
- “In an August 2009 report on U.S. preparations for the 2009 H1N1 pandemic, the President’s Council of Advisors on Science and Technology highlighted the need for quantitative triggers and recommended that federal agencies adopt structured frameworks for key decision making by incorporating scenarios and specific trigger points for action.” [16]

- “[T]he White House National Security Staff (NSS) and the responsible federal agencies have not been monitoring or reporting on action items in the Plan intended for state and local governments and other nonfederal entities, even though, in some instances, they have information available that would allow them to do so, such as the interagency assessment of state pandemic plans led by HHS. Given that the Plan states that in a pandemic the primary response will come from states and communities, this information should be in the progress reports, notwithstanding that it may be available in other sources.” [16]
- “Performance monitoring and accountability for pandemic preparedness needs strengthening. For example, the May 2006 National Strategy for Pandemic Influenza Implementation Plan does not establish priorities among its 324 action items and does not provide information on the financial resources needed to implement them.” [17, 20]
- “Greater agency accountability is needed to protect federal workers in the event of a pandemic because there is no mechanism in place to monitor and report on agencies’ progress in developing workforce pandemic plans.” [17]
- “There is no mechanism in place to monitor and report on agencies’ progress in developing workforce pandemic plans. Instead of having the Department of Homeland Security (DHS) monitor agency readiness to continue operations while protecting their employees during an influenza pandemic, as originally envisioned under the National Strategy for Pandemic Influenza Implementation Plan (Implementation Plan), the Homeland Security Council (HSC)<sup>4</sup> requested that agencies certify to the council that they were addressing in their plans the applicable elements of a pandemic checklist without including any provisions to assess the progress agencies were making.” [18, 19]

*Issue Type:* Policy

- Recommendations Identified:*
- “To improve how progress is monitored and completion is assessed under the Plan and in future updates of the Plan, the HSC should instruct the NSS to work with responsible federal agencies to:
    - develop a monitoring and reporting process for action items that are intended for nonfederal entities, such as state and local governments;
    - identify the types of information needed to decide whether to carry out the response-related action items; and
    - develop measures of performance that are more consistent with the descriptions of the action items.” [16]

**Issue**                      **Pandemic and All-Hazards Preparedness Act (PAHPA) implementation.**

- “*Strengthening transparency, accountability and oversight of PAHPA implementation.* The Pandemic and All-Hazards Preparedness Act (PAHPA) gave the federal agencies, namely HHS, a series of deliverables and deadlines to produce and meet. While much progress has been made on the implementation of PAHPA, which is notable in light of personnel and funding constraints, much remains to be done. To ensure HHS fully complies with PAHPA and does so in an open and transparent manner, pursuant to the provisions of the statute, Congress should use its oversight powers to ensure full implementation and execution of PAHPA.” [22]

*Issue Type:* Policy

- Recommendations Identified:*
- “*Publish regular progress reports on the implementation of PAHPA.* HHS should regularly provide publicly available updates on the progress made on benchmarks and deliverables under the PAHPA statute. The first and only progress report was released in November 2007.” [22]

- “Continue to develop new evidence-based benchmarks and objective standards. CDC’s Division of State and Local Readiness’ Outcome Monitoring and Evaluation Branch is working closely with PHEP program and evaluation specialists to develop a new set of performance based metrics to measure organizational readiness and response to public health emergencies. As of November 2009, CDC had introduced new, evidence-based benchmarks for two of the five areas identified for initial performance measure development: Incident Management and Crisis & Emergency Risk Communications (CERC). Work continues on outcome oriented objectives for the remaining three priority areas: Biosurveillance, Countermeasure Distribution, and Community Containment strategies. TFAH applauds this work and encourages CDC and its federal, state, and academic partners to continue to work on developing metrics that focus on outcome results from real-life drills and exercises.” [22]
- “Develop and implement the use of standardized preparedness exercises. CDC, in coordination with other government agencies, state and local health departments, research organizations, and universities, should develop and implement the use of standardized public health preparedness exercises. The exercises should include a thorough evaluation and after-action report that is made publicly available. Any weaknesses or gaps identified in the evaluation should be addressed within a specific amount of time.” [22]
- “Incorporate lessons learned into future planning, in particular through assessment of this year’s response to the H1N1 pandemic. The federal government, working with state and local officials, should ensure that all public health authorities conduct a systematic evaluation of the response to H1N1. Lessons learned from these after-action assessments should be incorporated into pandemic and all-hazards preparedness planning.” [22]
- “Collect performance data; assess the results; and, annually release the findings publicly on a state-by-state basis. As required by PAHPA, HHS is in the process of developing a standardized reporting form for all states and hospital grantees. The use of this form will allow HHS to rate the performance of the grantees and to assure the proper expenditure of funds. Data from this form and other evaluations of states’ emergency preparedness should be reported yearly on a state-by-state basis. This allows Americans to appropriately assess their states’ progress and document how states have used taxpayer-supported preparedness funds.” [22]
- “Continuous revision and strengthening of preparedness plans. Federal and state agencies need to keep preparedness plans updated to account for changes in the environment and advancements in scientific knowledge. This includes updating the National Strategy on Pandemic Influenza and all state pandemic plans to reflect the lessons learned in H1N1.” [22]

## F.2 Categorical Grants and Cooperative Agreements

### F.2.1 Categorical Grant/Cooperative Agreement Flexibility

**Issue:**

**States need flexibility in using funding during pandemic/emergency response situations.**

- “Flexibility in funding was a key topic of discussion. A cap on epidemiology and laboratory funding (in PHER) was described as “artificial.” One official noted that part of allowing counties to appropriately respond to H1N1 is to support day-to-day activities. It was also suggested that a scenario-based planning approach be pursued where the cooperative agreement funds and budgets can be matched up to the plan(s).” [1]
- “This discussion also led to a request that CDC simplify reporting requirements to reduce the burden on staff already engaged in response and normal duties.” [1]
- “Key points were the importance of extending the timeframe to allow state and local public health to spend down their funds, allowing flexibility in use of such funds, and re-

tooling the mechanisms used to fund emergency response in the future.” [1]

*Issue Type:* Policy

- Recommendations Identified:*
- “Provide state and local public health with greater administrative flexibility for a fuller range of program activities and, in anticipation of future funding, be forward leaning in crafting a more simple and timely administrative process to award funds and monitor and evaluate performance.” [1]
  - “The federal government should lift restrictions to allow states to reassign employees supported by federal funds to be able to help with the H1N1 response: Federal waivers should be granted to release federal categorically funded program staff to assist with response at the discretion of local health officials.” [21]
- 

*Issue:* **Use of PHER funds.**

- “States also voiced their dissatisfaction with what they felt was a change in policy “mid-stream” regarding the ability to rely on carry-forward funds to sustain some level of operations beyond July 30th from PHER Phases I and II to be better positioned for approaching flu season. Many participants expressed mixed feelings about whether to apply for PHER IV funds.” [1]

*Issue Type:* Policy

- Recommendations Identified:*
- “Identify ways to maintain necessary funding levels for state and local health agencies to sustain program services and infrastructure beyond July 30, 2010 including the ability to carry-forward funds made available through the four funding phases of the Public Health Emergency Response emergency H1N1 supplemental appropriations.” [1]
- 

## F.2.2 Public Health Preparedness Funding

*Issue:* **Public health preparedness funding must be increased and sustained at the state and federal levels.**

- “Public health preparedness requires a well-trained public health workforce, a sustained effort at research and development, the building and maintenance of stockpiles of countermeasures, and hospital surge capacity. Yet federal funding for public health emergency preparedness declined by 27 percent between FY 2005 and FY 2009. It’s not surprising then, that federal, state, and local public health agencies were forced to scramble in the spring of 2009 when the H1N1 flu virus first emerged in the United States.” [22]
- “The federal government should provide increased and stable funding for preparedness activities to state and local health departments. It is a shared responsibility between the federal government and the states. State-generated revenues invested in public health should, therefore, increase as well. As demonstrated in this report, federal funding has fluctuated – limiting the ability of states to build the kind of response capacity that is needed to prepare for everything from a pandemic to a natural disaster to a terrorist attack. The variation in critical state investment in public health also reflects a significant variation in geographic capacity.” [22]

*Issue Type:* Policy

- Recommendations Identified:*
- “Fully fund and stabilize funding for state public health emergency preparedness
-

*activities.* FY 2009 funding for programs dedicated to bioterrorism and public health emergency preparedness capabilities, specifically programs intended to support upgrading state and local capabilities, was \$746 million. The PHEP Cooperative Agreement should be funded at \$1.02 billion, which is the FY 2005 level adjusted for inflation. These funds are used to develop core boots-on-the-ground support for disaster response and any reduction in funding leaves the country at unnecessary levels of risk. Inconsistencies in funding from year to year means that states cannot predict how much money they will receive and this affects their ability to hire and train staff, expand capacity, and implement new programs. A stable funding stream for public health preparedness could also reduce the need for emergency supplemental dollars.” [22]

- “*Pandemic influenza funding.* Any after-action reports completed by federal, state, and local public health authorities on their response to the H1N1 pandemic, should include an assessment of how the emergency supplemental funding was used. This should be the basis to determine how much funding is needed to maintain pandemic preparedness.” [22]
- “*Increase funding for BARDA.* In FY 2009, BARDA received \$275 million, which is nowhere near the amount needed for advanced research and development of medical countermeasures. Congress should appropriate \$1.7 billion for biological countermeasures and diagnostics, and make the funds available over multiple years in the Public Health and Social Services Emergency Fund (PHSSEF) for BARDA’s Advanced Research and Development Fund.” [22]
- “*Funding should be appropriated for the replenishment and maintenance of federal and state stockpiles, as many parts of the stockpiles are set to expire in the coming years.* Funding should also be provided to restore those supplies deployed in response to the H1N1 pandemic. HHS Secretary Kathleen Sebelius should give the president and Congress, a professional judgment budget that includes the cost of replenishing and maintaining stockpiles. Funding to buy new medical countermeasures may require a new Act of Congress as the 2004 Project BioShield does not allow for replenishment and maintenance costs.” [22]
- “*Funding should be appropriated for public health systems research, which is needed to develop evidence-based performance standards.* PAHPA required HHS to work in coordination with the research community and evaluation specialists and develop new objectives to measure how well states respond to major public health emergencies. PAHPA specifically required CDC’s Centers for Public Health Preparedness (CPHP) to focus on systems research, but overall CPHP funding was not increased to account for the program. CDC should provide Congress with a professional judgment budget that includes the cost of fully funding the CPHPs and the Preparedness and Emergency Response Research Centers (PERRCs) to carry out their important work on public health workforce preparedness and public health emergency preparedness research and evaluation.” [22]
- “*A fully-funded and reliable funding stream is needed to support public health.* Public health infrastructure has been underfunded for decades, according to assessments from CDC, IOM, and other experts. It is important that states have a reliable, dedicated, and sustained level of funding that is adequate to meet core capacities and to continue to keep pace with new technologies that can help the states better meet their needs of their communities. Congress should assure a robust, reliable funding stream through health reform legislation for all core public health activities.” [22]
- “*Core public health infrastructure capabilities must be modernized.* There is no system in place to ensure that basic public health systems and equipment keep pace with advances in science and technology. There needs to be a systematic way to ensure that the technology and equipment that support core functions, like laboratory testing and communications, are routinely updated.” [22]
- “*To adequately support public health preparedness needs, Congress should:*
  - Complete the funding to implement the National Strategy for Pandemic Influenza.

- Provide resources for state and local health departments to adequately prepare for outbreaks.
- Maintain investments in state and local preparedness efforts through federal grant programs such as the Public Health Emergency Preparedness cooperative agreements, which have been cut 25 percent over the last five years.
- The federal government should modernize and provide sustained support of disease surveillance systems, public health laboratories, communications systems, and other core public health capabilities needed for rapid detection and response to public health threats.” [23]

## F.3 Stakeholder Coordination and Engagement

### F.3.1 Health Care Sector

**Issue:** **Communication between the public health system and health providers was not well coordinated.**

- “During the outbreak, many private medical practitioners reported that they did not receive CDC guidance documents in a timely fashion. Other practitioners noted that CDC guidance lacked clinically relevant information and was difficult to translate into practical instructions.” [23]

*Issue Type:* Policy

*Recommendations Identified:* None identified

**Issue:** **Provide training and technical assistance to States and localities on key issues related to medical surge and alternate standards of care.** [11]

*Issue Type:* Policy, Legal

*Recommendations Identified:*

- “ASPR, in collaboration with CDC, should address specific State and local challenges, such as identifying alternate care sites, managing medical equipment, and identifying guidelines for alternate standards of care.” [11]

**Issue:** **Need to develop and maintain communication with legal counsel to hospitals, health systems, and other traditional stakeholders, as well as with nontraditional organizations that assisted the H1N1 response.**

- “During H1N1, public health officials and their legal counsel have had increased communication with other stakeholders, such as hospitals and health systems. Further, some states and localities developed relationships with uncommon partners, such as churches, for delivery of vaccine.” [6]

*Issue Type:* Policy

*Recommendations Identified:*

- “States should maintain and expand these relationships and connections.” [6]

### F.3.2 Special and Vulnerable Populations

<b>Issue:</b>	<b>Vulnerable migrant populations.</b> <ul style="list-style-type: none"><li>• “Migrant and seasonal farm workers are a population that is highly vulnerable to pandemic flu due to their economic and social marginality and their already impaired health status.” [27]</li><li>• “There are threats to the health and well-being of Latino migrant and seasonal farm workers (MSFWs) in the U.S. in connection with the 2009 H1N1 influenza outbreak. Such threats included stigmatization, limited access to care, and material circumstances interfering with the ability to follow public health guidelines on disease containment.<ul style="list-style-type: none"><li>• Sporadic reports of stigma emerged against a background of anti-immigrant sentiment.</li><li>• Ingrained barriers to care are likely to delay or prevent vaccination against or treatment for 2009 H1N1 influenza among MSFWs.</li><li>• Meager living conditions may inhibit compliance with official guidance on disease containment.” [27]</li></ul></li></ul>
<b>Issue Type:</b>	Policy
<b>Recommendations Identified:</b>	<ul style="list-style-type: none"><li>• “Crop workers and their families could benefit greatly from vaccination. Providers are encouraged to develop culturally and linguistically competent education campaigns and to present ready opportunities for MSFWs to access vaccine, beginning with high priority groups.” [27]</li><li>• “The following recommendations are intended to assist care providers and health officials during this fall and winter’s flu season in vaccinating priority groups among MSFWs, and in reaching the entire population when sufficient vaccine is available.<ul style="list-style-type: none"><li>• Recognize that many MSFWs may fall into one of the high priority groups for H1N1 vaccination.</li><li>• Offer vaccine to MSFWs regardless of their immigration status and even when vaccine supplies are scarce.</li><li>• Be cognizant of the political climate, which may doubly complicate outreach to and have adverse psychosocial effects on MSFWs.</li><li>• Strive to bring vaccines to MSFWs; do not assume they can visit centralized vaccination sites.</li><li>• Provide immunization cards to overcome problems in ensuring continuity of care.</li><li>• Use non-English, low-literacy, and low-numeracy communications in any vaccination campaign.” [27]</li></ul></li></ul>

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### F.3.3 Stakeholder Engagement General

<b>Issue:</b>	<b>Determine how to maintain, enhance, or create partnerships that may benefit response to seasonal and pandemic influenza.</b> <ul style="list-style-type: none"><li>• “Examples include: increasing the role of pharmacists as immunizers; enhancing participation, communication, and buy-in of physicians and other healthcare providers to reach populations not typically vaccinated to improve overall vaccination rates, including within the healthcare sector workforce; cementing gains made in partnerships with schools, including communications on absenteeism data and school-located vaccine clinics; and collaborating with employers to address issues with workplace points of</li></ul>
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dispensing sites (PODs).” [1]

*Issue Type:* Policy

*Recommendations Identified:*

- “Formulate a steering committee to scope and plan for the next 90 days.” [5]
- “Improve recognition and compensation of pharmacists as providers during the flu season.” [5]
- “Analyze those areas that vaccinated the younger ages and see how that went.” [5]
- “Continue to address billing and reporting issues between pharmacy, insurer, and public health sectors.” [5]
- “Reach out to actuaries’ society on modeling and data collection.” [5]
- “Maintain ability to respond (infrastructure and capacity).” [5]
- “Work with the American Medical Association (AMA) and the American Congress of Obstetricians and Gynecologists (ACOG) to encourage OB-GYNs to vaccinate.” [5]

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#### F.4 Federal/State/Local Communications

*Issue:* None identified

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#### F.5 Federal/State/Local Coordination Other Issues

*Issue:* None identified

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## III.G Communication

Please see the introduction to Section III on page 13 for general information about the data contained in this subsection.

### Communication Section Contents

- G.1 Messaging Coordination, Media Relations, and Ad Campaigns
  - G.1.1 Messaging Coordination
  - G.1.2 Media Relations
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- G.2 Public Outreach
- G.3 Communications with Stakeholders
  - G.3.1 General Communication Issues
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  - G.3.3 Health Care Sector
- G.4 Communications to Policy Makers
- G.5 FOIA Requests and Disposition Communication
- G.6 Communications Other Issues

## Summary of Issues

### G.1 Messaging Coordination, Media Relations, and Ad Campaigns

#### G.1.1 *Messaging Coordination*

- Coordinating messaging was and remains a challenge.

#### G.1.2 *Media Relations*

- Communication channels/coordination.
- WHO pandemic alert phases caused confusion.

#### G.1.3 *Ad Campaigns*

- National Influenza Vaccination Week (NIVW).

### G.2 Public Outreach

- Providing clear, straightforward information to the public was essential for allaying fears and building trust.
- Health providers and health departments should develop and disseminate strong public messages about ways to practice good hygiene and understand symptoms and remedies.

### G.3 Communications with Stakeholders

#### G.3.1 *General Communication Issues*

- Review of overall communications performance.

### G.3.2 *Special and Vulnerable Populations*

- Improving communications with vulnerable and special populations.

### G.3.3 *Health Care Sector*

- Improving communications with health care providers.

## G.4 **Communications to Policy Makers**

- None identified

## G.5 **FOIA Requests and Disposition Communication**

- Open records requests.

## G.6 **Communications Other Issues**

- None identified

## **Issues Detail**

### G.1 **Messaging Coordination, Media Relations, and Ad Campaigns**

- Aiding Factors:*
- “Successful strategies in novel H1N1 communications included: helping media personalize the story, particularly when one family member or community member can encourage another to get vaccinated; identifying and preparing a range of messages, then determining the triggers to change messages; using new media and social media; working through outreach partners; and harmonizing big media buys among levels of government to avoid duplication.” [1]
  - “Regarding vulnerable populations, web sites that contain promising practices (key sites are hosted by ASTHO, CDC, CIDRAP, NACCHO and NPHIC) and suggested that the NACCHO survey being used to collect information from sentinel health departments be modified to include a call for promising practices for at-risk populations to augment the above ongoing efforts.” [1]
  - “IPR participants shared a number of strategies they found effective, such as: [1]
    - “Releasing fliers for undocumented migrant farm workers that contained a phone number for information but did not identify it as a government number.” [1]
    - “Working with social workers to reach children with cerebral palsy and other medical conditions.” [1]
    - “Partnering with consulates to translate health information.” [1]
    - “Using sanitarians working with restaurants and food establishments to reach migrant workers and the undocumented who are employed in this service industry.” [1]
    - “Collaborating with people in Community and Faith Based Organizations (CFBOs) and charging them with leading the fight against H1N1.” [1]
    - “Accessing isolated groups such as the visually impaired through organizations such as Lighthouse for the Blind, which uses a radio station with a special transmitter.” [1]
    - “Reaching out to schools and training centers that serve people with developmental disabilities.” [1]
    - “Conveying flu information and vaccines through Women Infants Children (WIC) program sites.” [1]
    - “Setting up line-billing arrangements that allow pharmacies to bill the health department (instead of turning away people who could not pay for vaccine).” [1]

- “Targeting outreach to shelter and street-living populations.” [1]
- “Using radio as an effective medium in general and especially effective in outreach to some racial and ethnic populations.” [1]

### G.1.1 Messaging Coordination

- Issue:** **Coordinating messaging was and remains a challenge.**
- “Harmonizing communications across the local, state and national public health scene during H1N1 response posed a tremendous challenge because of wide variability in local circumstances, the need to present a consistent message to the public, and the persistent challenge of timing national messages to augment instead of undermine local needs.” [1]
  - “Revise procedures and protocols governing state and local calls with CDC to ensure the integrity of the calls are maintained by excluding those not authorized to participate.” [1]
  - “It was not clearly communicated to states why HHS/CDC did not implement United States Government (USG) stages, and just used WHO phases.” [4]
  - “State and local health officials would have liked a more up front, succinct statement regarding the actual severity of the virus.” [4]
  - “Regarding information updates, an issue existed in providing synchronized information: many agencies (federal, state) had their own EOCs and were pushing out information at varied times which were sometimes redundant and dated. When changes in case definitions/guidance emerged, it was difficult to discern these changes. It would be useful to highlight the changes, or provide a summary.” [4]

**Issue Type:** Policy

- Recommendations Identified:**
- “Expanding ongoing efforts to identify, summarize, and share lessons learned and useful practices.” [1]
  - “Reassessing planning thresholds.” [1]
  - “Reviewing and re-calibrating the current pandemic planning guidance, including the pandemic severity index and the definitions of the pandemic stages.” [1]

### G.1.2 Media Relations

- Issue:** **Communication channels/coordination.**
- “Communication chain of command was a hot topic for participants. A number of comments focused on the roll- out of the FluShot Locator and the tensions in coordinating the stand up of a national portal with individual state website portals.” [1]
  - “There was also a consensus that maintaining the usual communication channels fosters clarity for public health partners, but examples were given that this was not always the case, resulting in confusion and some conflict (e.g. the White House and HHS reaching out directly to governors’ without looping in state and local health officials and their public information officers who were then caught off guard), and a lack of clarity on the respective roles of the HHS and CDC communications efforts.” [1]

**Issue Type:** Policy

- Recommendations Identified:**
- “Further delineate and clarify roles of the HHS and CDC Communications operations.” [1]

- “Revise current procedure in order to share embargoed information with state and local health departments in advance of providing it to the media to allow greater lead time to brief leadership and prepare for media contacts.” [1]
- “The development and sharing of messages in languages other than English and Spanish among federal, state, and local public health agencies would further improve the response.” [2]

**Issue:**

**WHO pandemic alert phases caused confusion.**

- “The WHO pandemic alert phase system was not well matched with the realities of the H1N1 outbreak, since most of the planning was built around concerns of a much more severe pandemic outbreak and focused on the geographic spread and transmission patterns, but not the severity of the disease. WHO is currently considering how to revise its pandemic alert phases to address both the geographic spread as well as the severity of the virus.” [23]
- “There is some debate about whether the WHO should maintain its pandemic influenza phase system, which reflects the spread of the virus and transmission patterns, not severity. As of May 2009, H1N1 appears to be slightly more virulent and more contagious than seasonal influenza. Some observers would like WHO to develop an alert system that is based on severity. Supporters of this idea assert that the public might not understand that though an influenza virus could have reached the highest pandemic phase level, widespread death may not occur. Critics of the system, including some European leaders, warn that if WHO raises the pandemic threat level to Phase 6, panic might ensue and considerable economic and social disruptions may occur.” [14]

*Issue Type:* Policy

*Recommendations Identified:* None identified

### G.1.3 Ad Campaigns

**Issue:**

**National Influenza Vaccination Week (NIVW).**

- “The challenges associated with National Influenza Vaccination Week (NIVW) exemplified difficulties in communications. Opinions varied widely as to whether the timing was off and how it might have been handled differently. The holidays affected the timing of NIVW, as did the initial problems associated with vaccine supply. Despite concerns and criticisms about the timing and to what extent local needs should drive such vaccination events, there was widespread support and appreciation for the quality of the communications materials and that the “national tone was spot on.” [1]

*Issue Type:* Policy

*Recommendations Identified:* None identified

## G.2 Public Outreach

- Aiding Factors:**
- “Consistent messaging by state and local jurisdictions, which inspired public confidence.” [2]
- 

**Issue:** **Providing clear, straightforward information to the public was essential for allaying fears and building trust.**

- “Informing the public about what is known about an outbreak, acknowledging that certain information is not yet known, and updating facts as they become available is paramount to help contain the spread of disease and also give people the facts they need to be prepared, not scared. During the outbreak, the President and other leaders around the country served as clear spokespeople, conveying consistent, accurate information about good hand hygiene, cough/sneeze etiquette, and the need for people to stay home if sick. Effective leadership and communication helped dispel rumors and myths -- from allaying concerns about the safety of imported Mexican foodstuffs to reversing the unfair characterization of Spanish speaking people as carriers of the contagion. Public health officials also encountered the need to explain to members of the public that different policies are not necessarily inconsistent, but tailored to local realities.” [23]
- “Other reflections included missed opportunities to have a bigger impact on youth, less than desirable outcomes regarding healthcare worker engagement as champions (“they should lead not lag”), suboptimal acceptance of LAIV, and not having a clear sense as to the vaccination goals for the various target groups and “when do we declare victory.”” [1]

**Issue Type:** Policy

- Recommendations Identified:**
- “Develop a revised communications plan to cover the next 30-90 days describing the importance and ongoing benefits of vaccination.” [1]
  - “Create and share appropriate and culturally sensitive public education materials.” [2]
- 

**Issue:** **Health providers and health departments should develop and disseminate strong public messages about ways to practice good hygiene and understand symptoms and remedies.**

- “Hospitals and health providers should develop a public messaging system to give people information about symptoms and remedies to prevent unnecessary trips to the emergency room and they should have pandemic plans in place to protect employees.” [21]

**Issue Type:** Policy

**Recommendations Identified:** None identified

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## G.3 Communications with Stakeholders

### G.3.1 General Communications Issues

- Issue:** **Review of overall communications performance.**
- “Nearly all state health departments delivered timely, accessible information via their websites to their constituents, covering the requisite range of topics; far fewer local
-

- jurisdictions did so.” [26]
- “Researchers drew three implications for policy from the analysis of websites for early H1N1 risk communication:
    - The variability across local jurisdictions may be the result of lack of consensus about the role of public health departments. Public health departments must work with state and community agencies to clarify and institutionalize their respective roles.
    - Public health departments need to ensure the ability to communicate with limited-English-proficiency populations, suggesting the need for standards dictating when multilingual information is called for.
    - Federal funding for public health emergency preparedness activities has declined in recent years. Coupled with the economic downturn, this reduction has led many public health departments to cut back their staffs and activities. These cuts threaten to erase much of the progress illustrated by the state health department responses to the H1N1 alert. Efforts to maintain these gains will be important in coming years.” [26]

*Issue Type:* Policy

*Recommendations Identified:* None identified

### G.3.2 Special and Vulnerable Populations

*Issue:* **Improving communications with vulnerable and special populations.**

- “Reaching some of the nation’s most vulnerable people through the right channels with the right messages and encouraging them to get immunized has been a major challenge in this pandemic. There was broad agreement that earlier messaging to prevent and mitigate negative perceptions would have been helpful.” [1]
- “Other observations that IPR participants widely supported included: acknowledging there is trust of certain at-risk groups is key, and sharing strategies and tactics is useful.” [1]
- “Reaching at-risk populations does not mean reinventing the wheel. Instead, public health needs to access and use the vast literature about community based public health work.” [1]
- “Other points discussed in brief included:
  - “Just get started; if you need to modify actions later, do it.”
  - Partner before the next emergency.
  - Consider families as a unit of vaccination.
  - Fill communications vacuum.
  - Speak early, speak often, speak truth.
  - Respect the culture.
  - Healthcare workers are a big challenge: “We shouldn't have trouble de-bunking myths to them.” [1]

*Issue Type:* Policy

*Recommendations Identified:*

- “Immediately assess and cement existing partnerships with community organizations most closely aligned with the at-risk and vulnerable populations to better position for future immunization efforts and other emergency response type activities.” [1]
- “Redouble ongoing efforts and consider expanding efforts, such as through the NACCHO

survey for sentinel network of local health departments, to collect useful and promising practices to more effectively reach and serve the needs of at-risk populations.” [1]

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### G.3.1 Health Care Sector

- Issue:** **Improving communications with health care providers.**
- “Identify ways to better inform and engage physicians (e.g. Twitter, blogs, use of medical care product and pharmaceutical sales representatives, etc.)” [1]
  - “Create a targeted communications strategy to reach healthcare workers and at-risk/vulnerable populations.” [1]
  - “Increasing efforts to educate providers and the public on the necessity for and safety of the H1N1 vaccination, both injectable and live attenuated influenza vaccine (LAIV).” [1]

*Issue Type:* Policy

*Recommendations Identified:* None identified

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## G.4 Communications to Policy Makers

- Aiding Factors:**
- “Public health was elevated in the eyes of the public and legislators and trust was established due to the success of the response.” [2]
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## G.5 FOIA Requests and Disposition

- Issue:** **Open records requests.**
- “Responding to public information requests from the media and others under state open public records laws for names and locations of H1N1 vaccine providers.” [8]
  - “Responding to public information requests from the media and others under state open public records laws for locations of recalled vaccine.” [8]

*Issue Type:* Legal, Policy

*Recommendations Identified:* None identified

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## G.6 Communications Other Issues

**Issue:** None identified

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## References

1	Association of State and Territorial Health Officials. <i>National Public Health Response Partners H1N1 In-Progress Review: Summary of Recommendations</i> . (March 2010)
2	Association of State and Territorial Health Officials. "Summary of State and Local H1N1 Hotwash." (August 10, 2009)
3	Association of State and Territorial Health Officials. "Notes from Joint Policy Committees Meeting – Preparedness Policy, Infectious Disease, & e-Health Committees," (October 13, 2009)
4	Centers for Disease Control and Prevention and Association of State and Territorial Health Officials. <i>CDC/ASTHO Novel H1N1 National Rapid Assessment Project: After Action Report &amp; Improvement Plan</i> (June 30 – July 1, 2009)
5	Association of State and Territorial Health Officials. "Pharmacy, Insurer, Public Health In-Progress Review: Conference Call Summary" (February 5, 2010)
6	Centers for Disease Control and Prevention, Public Health Law Program. "Draft After-Action Report: Legal Issues and the H1N1 Influenza Pandemic" (Draft April 21, 2010)
7	Centers for Disease Control and Prevention, Public Health Law Program. "Report from the July 14, 2009, Influenza H1N1 Legal Issues Assessment Workshop" (July 29, 2009)
8	Centers for Disease Control and Prevention, Public Health Law Program. Appendix A to "Draft After-Action Report: Legal Issues and the H1N1 Influenza Pandemic" (Draft April 21, 2010)
9	Association of State and Territorial Health Officials. <i>2010 ASTHO SNS H1N1 Preliminary After Action Workshop Summary Report</i> (Draft April 30, 2010)
10	[unassigned]
11	U.S. Department of Health and Human Services, Office of the Inspector General. <i>State and Local Pandemic Influenza Preparedness: Medical Surge</i> (OEI-02-08-00210) (September 2009)
12	U.S. Department of Health and Human Services, Office of the Inspector General. <i>Local Pandemic Influenza Preparedness: Vaccine And Antiviral Drug Distribution And Dispensing</i> (OEI-04-08-00260) (September 2009)
13	Congressional Research Service. <i>2009 Influenza A (H1N1) Outbreak: Selected Legal Issues</i> (Order Number: R40560b) (May 21, 2009)
14	Congressional Research Service. <i>2009 Influenza A (H1N1) Outbreak: U.S. Responses to Global Human Cases</i> (Order Number: R40588) (May 26, 2009)
15	Government Accountability Office. <i>Emergency Preparedness: State Efforts to Plan for Medical Surge Could Benefit from Shared Guidance for Allocating Scarce Medical Resources</i> (GAO-10-381T) (January 25, 2010)
16	Government Accountability Office. <i>Influenza Pandemic: Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement</i> (GAO-10-73) (November 24, 2009)
17	Government Accountability Office. <i>Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to Be Addressed</i> (July 29, 2009) (GAO-09-909T)

18	Government Accountability Office. <i>Influenza Pandemic: Greater Agency Accountability Needed to Protect Federal Workers in the Event of a Pandemic</i> (June 16, 2009) (GAO-09-783T)
19	Government Accountability Office. <i>Influenza Pandemic: Increased Agency Accountability Could Help Protect Federal Employees Serving the Public in the Event of a Pandemic</i> (June 12, 2009) (GAO-09-404)
20	Government Accountability Office. <i>Influenza Pandemic: Continued Focus on the Nation's Planning and Preparedness Efforts Remains Essential</i> (GAO-09-760T) (June 3, 2009)
21	Trust for America's Health. <i>H1N1 Challenges Ahead</i> (October 2009)
22	Trust for America's Health. <i>Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism</i> (December 2009)
23	Trust for America's Health. <i>Pandemic Flu: Lessons From the Frontlines</i> (June 2009)
24	Trust for America's Health. Testimony of Jeffrey Levi, PhD Executive Director, Trust for America's Health, before the House Committee on Energy & Commerce Joint Hearing on H1N1 Preparedness: An Overview of Vaccine Production and Distribution (November 18, 2009)
25	Sara Rosenbaum, JD, Nancy Lopez, JD MPH, and Ross Margulies, JD/MPH [Cand.], "Analysis of the Extent to Which State Insurance Laws Mandate Coverage and Payment of Vaccines and Vaccine Administration Fees during Periods of Declared Public Health Emergencies," Department of Health Policy, The George Washington University School of Public Health and Health Services (November 2, 2009)
26	Rand Corporation. "Risk Communication in the Early Stages of the H1N1 (Swine Flu) Alert: How Effective Were State and Local Public Health Departments?" Jeanne S. Ringel, Elizabeth Trentacost, Nicole Lurie – Fact sheet based on <i>Health Affairs</i> , Vol. 28, No. 4, 2009, pp. w743-w750.
27	UPMC, Center for Biosecurity (Monica Schoch-Spana, Nidhi Bouri, Ann Norwood and Kunal Rambhia). <i>Preliminary Findings: Study of the Impact of the 2009 H1N1 Influenza Pandemic on Latino Migrant Farm Workers in the U.S.</i> (November 23, 2009)
28	UPMC, Center for Biosecurity (Matthew Watson and Jennifer Nuzzo). Issue Brief, <i>Licensure, Evaluation, and Adverse Event Monitoring of the 2009 H1N1 Influenza Vaccine</i> (November 13, 2009)
29	UPMC, Center for Biosecurity (Eric S. Toner). <i>Creating Situational Awareness: A Systems Approach</i> (June 2009)

## Appendix 1: Bibliography and Summary of Materials Reviewed

### Public Health Partner Meetings, In-progress Reviews, and After-action Summaries

Reference Number	
1	<p>Association of State and Territorial Health Officials. <i>National Public Health Response Partners H1N1 In-Progress Review: Summary of Recommendations</i>. (March 2010)</p> <p>Summary from CDC-sponsored in-progress review held with national partner organizations February 9-10, 2010</p>
2	<p>Association of State and Territorial Health Officials. “Summary of State and Local H1N1 Hotwash.” (August 10, 2009)</p> <p>ASTHO sponsored a facilitated State and Local Principal Responders “Hotwash” among ASTHO, NACCHO and ASTHO affiliates active in the spring H1N1 response on July 20, 2009.</p>
3	<p>Association of State and Territorial Health Officials. “Note of Joint Policy Committees Meeting – Preparedness Policy, Infectious Disease, &amp; e-Health Committees,” (October 13, 2009)</p> <p>Summary of October 2009 joint ASTHO policy committees meeting.</p>
4	<p>Centers for Disease Control and Prevention and Association of State and Territorial Health Officials. <i>CDC/ASTHO Novel H1N1 National Rapid Assessment Project: After Action Report &amp; Improvement Plan</i> (June 30 – July 1, 2009)</p> <p>Workshop summary of a joint CDC/ASTHO meeting to conduct a nationwide rapid assessment of several key operational activities to inform an improvement process for ongoing H1N1 response.</p>
5	<p>Association of State and Territorial Health Officials. “Pharmacy, Insurer, Public Health In-Progress Review: Conference Call Summary” (February 5, 2010)</p> <p>Summary of in-progress review conference call held February 5, 2010, with ASTHO and the National Association of Chain Drug Stores to identify successes and failures of the H1N1 vaccination program.</p>
6	<p>Centers for Disease Control and Prevention, Public Health Law Program. “Draft After-Action Report: Legal Issues and the H1N1 Influenza Pandemic” (Draft April 21, 2010)</p> <p>Summary report from CDC PHLP meeting held February 17, 2010, with state and local public health counsels regarding legal issues/barriers arising during the H1N1 response.</p>
7	<p>Centers for Disease Control and Prevention, Public Health Law Program. “Report from the July 14, 2009, Influenza H1N1 Legal Issues Assessment Workshop” (July 29, 2009)</p> <p>Summary report from CDC PHLP meeting held July 14, 2010, with state and local public health counsels regarding legal issues/barriers arising during the H1N1 response.</p>

8	Centers for Disease Control and Prevention, Public Health Law Program. Appendix A to “Draft After-Action Report: Legal Issues and the H1N1 Influenza Pandemic” (Draft April 21, 2010)  Cumulative list of legal issues/barriers arising during the H1N1 compiled by CDC PHLP from April 2009 to February 2010.
9	Association of State and Territorial Health Officials. <i>2010 ASTHO SNS H1N1 Preliminary After Action Workshop Summary Report</i> (Draft April 30, 2010)  Summary report from CDC-sponsored meeting of state SNS and CRI coordinators on March 23, 2010, to discuss issues arising in the H1N1 response.

## Publications

### Governmental

Reference Number	
11	U.S. Department of Health and Human Services, Office of the Inspector General. <i>State and Local Pandemic Influenza Preparedness: Medical Surge</i> (OEI-02-08-00210) (September 2009)  This study samples of 5 states and 10 localities and presents a snapshot of these states’ and localities’ preparedness for an influenza pandemic as of late summer 2008.
12	U.S. Department of Health and Human Services, Office of the Inspector General. <i>Local Pandemic Influenza Preparedness: Vaccine And Antiviral Drug Distribution And Dispensing</i> (OEI-04-08-00260) (September 2009)  This study focuses on the extent to which selected localities have prepared to distribute and dispense vaccines and antiviral drugs during an influenza pandemic. [Note: study was reviewed for information relevant for state health agencies.]
--	U.S. Department of Health and Human Services, Office of the Inspector General. <i>OIG 2010 Workplan</i> lists the following anticipated reviews in 2010: <ul style="list-style-type: none"> <li>• <i>Agency for Healthcare Research and Quality - Bioterrorism Epidemic Outbreak Response Model</i> - Survey State and local governments to determine the extent to which they are aware of and use the Bioterrorism Epidemic Outbreak Response Model (BERM) and “Community-Based Mass Prophylaxis: A Planning Guide for Public Health Preparedness” (the planning guide). (OEI; 00-00-00000; expected issue date: FY 2010; new start)</li> <li>• <i>Use of Public Health Preparedness and Response for Bioterrorism Program Funds for Employee Compensation</i> - Review States’ use of the Public Health Preparedness and Response for Bioterrorism program funding as it relates to employee compensation. (OAS; W-00-10-57228; various reviews; expected issue date: FY 2010; new start)</li> <li>• <i>Pandemic Influenza Planning</i> - Review HHS’s implementation of high-risk areas of its pandemic influenza plan, including review of appropriate morbidity and mortality rates; supplies of pre-pandemic vaccines, post-pandemic vaccines, and antivirals; reliance on vaccine policies; and vaccine and antiviral distribution. Will also assess the extent to which States are reporting and meeting performance goals. (OAS; W-00-10-57229; expected</li> </ul>

	issue date: FY 2010; new start)
--	<p>United States Government. <i>Assessment of States' Operating Plans to Combat Pandemic Influenza: Report to Homeland Security Council</i> (January 2009) Available at <a href="http://pandemicflu.gov/professional/states/state_assessment.html">http://pandemicflu.gov/professional/states/state_assessment.html</a> (accessed April 26, 2010)</p> <p>This report summarizes the status of States' operating plans with respect to preparedness for, response to, and recovery from an influenza pandemic. This assessment fulfills a requirement established by the Homeland Security Council, Executive Office of the President of the United States, in its <i>National Strategy for Pandemic Influenza: Implementation Plan</i>. [Note: the assessment report was reviewed but not referenced in the environmental scan.]</p>
13	<p>Congressional Research Service. <i>2009 Influenza A (H1N1) Outbreak: Selected Legal Issues</i> (Order Number: R40560b) (May 21, 2009)</p> <p>A review of selected legal issues related to H1N1. [Note: The May 21, 2009 CRS report R40560b updated an earlier version of the <i>Legal Issues</i> report on May 4, 2009 (Order Number: R40560)]</p>
14	<p>Congressional Research Service. <i>2009 Influenza A (H1N1) Outbreak: U.S. Responses to Global Human Cases</i> (Order Number: R40588) (May 26, 2009)</p> <p>A summary of the global outbreak of H1N1 and U.S. contributions to the outbreak abroad.</p>
15	<p>Government Accountability Office. <i>Emergency Preparedness: State Efforts to Plan for Medical Surge Could Benefit from Shared Guidance for Allocating Scarce Medical Resources</i> (GAO-10-381T) (January 25, 2010)</p> <p>Published testimony of Cynthia A. Bascetta, Director, GAO Health Care Section, Before the Subcommittee on Management, Investigations, and Oversight, Committee on Homeland Security, House of Representatives, January 25, 2010. The statement summarizes a June 2008 report, <i>Emergency Preparedness: States Are Planning for Medical Surge, but Could Benefit from Shared Guidance for Allocating Scarce Medical Resources</i> (GAO-08-668) and included some updated information as well.</p>
16	<p>Government Accountability Office. <i>Influenza Pandemic: Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement</i> (GAO-10-73) (November 24, 2009)</p> <p>Report to the Chairman, Committee on Homeland Security, House of Representatives on progress toward implementing the Homeland Security Council's (HSC) May 2006 <i>Implementation Plan for the National Strategy for Pandemic Influenza</i>. The report does not specifically address H1N1 response activities.</p>
17	<p>Government Accountability Office. <i>Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to Be Addressed</i> (GAO-09-909T) (July 29, 2009)</p> <p>Published testimony of Bernice Steinhardt, Director, Strategic Issues, GAO, before the Committee on Homeland Security, House of Representatives July 29, 2009. The statement synthesizes prior GAO work consisting of 13 reports and 4 testimonies related to national preparedness for a possible influenza pandemic.</p>
18	<p>Government Accountability Office. <i>Influenza Pandemic: Greater Agency Accountability Needed to Protect Federal Workers in the Event of a Pandemic</i> (GAO-09-783T) (June 16, 2009)</p> <p>Published testimony of Bernice Steinhardt, Director, Strategic Issues, GAO, before the Subcommittee on Oversight of Government Management, the Federal Workforce, and the District of Columbia, Senate Committee on Homeland Security and Governmental Affairs, June 16, 2009. This testimony addresses pandemic planning by federal agencies.</p>

19	<p>Government Accountability Office. <i>Influenza Pandemic: Increased Agency Accountability Could Help Protect Federal Employees Serving the Public in the Event of a Pandemic</i> (GAO-09-404) (June 12, 2009)</p> <p>The report addresses federal agency planning and preparedness for an influenza pandemic.</p>
20	<p>Government Accountability Office. <i>Influenza Pandemic: Continued Focus on the Nation's Planning and Preparedness Efforts Remains Essential</i> (GAO-09-760T) (June 3, 2009)</p> <p>Testimony of Bernice Steinhardt, Director, Strategic Issues, GAO, before the Ad Hoc Subcommittee on State, Local, and Private Sector Preparedness and Integration, Senate Committee on Homeland Security and Governmental Affairs, June 3, 2009. The statement synthesizes prior GAO work related to national preparedness for a possible influenza pandemic.</p>
--	<p>Government Accountability Office. <i>Influenza Pandemic: Sustaining Focus on the Nation's Planning and Preparedness Efforts</i> (GAO-09-334) (February 26, 2009)</p> <p>This report synthesizes prior GAO work related to national preparedness for a possible influenza pandemic.</p>

### **Nongovernmental Organizations**

Reference Number	
21	<p>Trust for America's Health. <i>H1N1 Challenges Ahead</i> (October 2009)</p> <p>The report examines the nation's capacity to respond to the H1N1 influenza outbreak in terms of medical care capacity, vaccines, antiviral medication, health care, and the special needs of at-risk communities</p>
22	<p>Trust for America's Health. <i>Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism</i> (December 2009)</p> <p>Annual report assessing the level of preparedness in states, evaluating the federal government's role and performance, and offering recommendations for improving emergency preparedness.</p>
23	<p>Trust for America's Health. <i>Pandemic Flu: Lessons From the Frontlines</i> (June 2009)</p> <p>This report reviews early lessons learned from the response to the H1N1 influenza outbreak and identifies ongoing core vulnerabilities in U.S. pandemic flu preparedness.</p>
26	<p>Rand Corporation. "Risk Communication in the Early Stages of the H1N1 (Swine Flu) Alert: How Effective Were State and Local Public Health Departments?" Jeanne S. Ringel, Elizabeth Trentacost, Nicole Lurie – Fact sheet based on <i>Health Affairs</i>, Vol. 28, No. 4, 2009, pp. w743-w750.</p> <p>An assessment of the timeliness, accessibility, and thoroughness of state and local risk communication activities in the early stages of the H1N1 outbreak.</p>
--	<p>Rand Corporation. "A National Agenda for Public Health Systems Research on Emergency Preparedness" by: Joie Acosta, Christopher Nelson, Ellen Burke Beckjord, Shoshana R. Shelton, Erin Murphy, Kristin J. Leuschner, Jeffrey Wasserman (August 2009)</p> <p>This report presents the findings from an expert panel convened to develop a broad public health systems research agenda for emergency preparedness. [Note: This report covers discussions held</p>

	prior to the outbreak of H1N1 and does not specifically address recommendations related to H1N1. However, many of the recommendations are consistent with recommendations made by other sources related to the H1N1 outbreak.]
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### **Academic Research Centers**

Reference Number	
--	UPMC, Center for Biosecurity (Kunal J. Rambhia and Jennifer Nuzzo), Issue Brief, <i>International Progress in Vaccine Development and Distribution</i> (December 17, 2009)  This issue brief provides an overview of the major vaccination efforts around the world, highlighting specific events and controversies that have arisen.
27	UPMC, Center for Biosecurity (Monica Schoch-Spana, Nidhi Bouri, Ann Norwood and Kunal Rambhia). Issue Brief, <i>Preliminary Findings: Study of the Impact of the 2009 H1N1 Influenza Pandemic on Latino Migrant Farm Workers in the U.S.</i> (November 23, 2009)  This research brief presents preliminary study findings on the impact of H1N1 on Latino migrant farm workers and presents recommendations to providers on serving this vulnerable population.
28	UPMC, Center for Biosecurity (Matthew Watson and Jennifer Nuzzo). Issue Brief, <i>Licensure, Evaluation, and Adverse Event Monitoring of the 2009 H1N1 Influenza Vaccine</i> (November 13, 2009)  This report addresses licensure, evaluation, and adverse event monitoring for the H1N1 vaccine.
--	UPMC, Center for Biosecurity (Tara Kirk Sell, Jennifer Nuzzo, Eric Toner). Issue Brief, <i>Where Does H1N1 Influenza Information Come from? An Overview of Influenza Surveillance in the United States</i> (November 2, 2009)  This brief summarizes surveillance data sources for the CDC and explains how this data has been used during the H1N1 outbreak.
29	UPMC, Center for Biosecurity (Eric S. Toner). <i>Creating Situational Awareness: A Systems Approach</i> (June 2009)  This white paper was prepared for the June 10, 2009, workshop on medical surge capacity hosted by the Institute of Medicine Forum on Medical and Public Health Preparedness for Catastrophic Events.
--	UPMC, Center for Biosecurity (Jennifer Nuzzo). Issue Brief, <i>A Closer Look at WHO Pandemic Declaration</i> (June 11, 2009)  The document summarizes the World Health Organization's H1N1 pandemic declarations and recommendations.
--	UPMC, Center for Biosecurity (Ann Norwood, MD, Brooke Courtney, JD, MPH, Eric Toner, MD, and Amesh Adalja, MD). Issue Brief, <i>The Use of Antivirals for 2009 H1N1 Influenza Virus Infection</i> (May, 13, 2009)  The issue brief describes and evaluates CDC guidances on antivirals.

--	UPMC, Center for Biosecurity (Monica Schoch-Spana, PhD, Ann Norwood, MD, Nidhi Bouri, and Kunal Rambhia). Issue Brief, <i>Social Stigma Attached to “Swine Flu”—An FAQ for U.S. Elected Leaders and Health Officials</i> (April 30, 2009)  A FAQ document addressing social stigma issues arising in the H1N1 and suggestions for addressing stigma issues.
--	UPMC, Center for Biosecurity (Brooke Courtney). Issue Brief, <i>FDA Emergency Use Authorizations (EUAs): What Are They and What Do They Mean for the Swine Flu Response?</i> (April, 29, 2009)  A FAQ document describing FDA EUAs.
--	UPMC, Center for Biosecurity (Staff of the Center for Biosecurity). Issue Brief, <i>Can the Current Swine Flu Outbreak Be Contained? In A Word, No</i> (April 29, 2009)  An assessment of the inability of H1N1 to be contained using border closure and travel restrictions.
--	UPMC, Center for Biosecurity (Jennifer Nuzzo). Issue Brief, <i>Border Restrictions: Not an Effective Means of Preventing the Spread of Swine Flu</i> (April 28, 2009)  An issue brief describing why border restrictions are ineffective at preventing the spread of H1N1.

## Articles and Testimony

Reference Number	
25	Sara Rosenbaum, JD, Nancy Lopez, JD MPH, and Ross Margulies, JD/MPH [Cand.], “Analysis of the Extent to Which State Insurance Laws Mandate Coverage and Payment of Vaccines and Vaccine Administration Fees during Periods of Declared Public Health Emergencies,” Department of Health Policy, The George Washington University School of Public Health and Health Services (November 2, 2009)  The article examines whether state insurance laws require health insurers to pay the costs associated with the administration of immunizations during declared public health emergencies.
--	Nancy Lopez, JD, MPH, Ross Margulies, JD/MPH [Cand.], and Sara Rosenbaum, JD. “Analysis of State Medicaid Agency Performance in Relation to Incentivizing the Provision of H1N1 Immunizations to Eligible Populations,” Department of Health Policy, The George Washington University School of Public Health and Health Services (November 22, 2009)  This articles analyzes the extent to which state Medicaid agencies translated CMS Guidance on H1N1 into clear information for participating providers clarifying payment for costs associated with the administration of H1N1 vaccines, especially in states that do not otherwise cover and pay for recommended ACIP immunizations as part of treating adult patients.
--	James G. Hodge Jr., JD, LL.M.; Brooke Courtney, JD, MPH. “Assessing the Legal Standard of Care in Public Health Emergencies,” <i>JAMA</i> . 2010;303(4):361-362.
24	Trust for America’s Health. Testimony of Jeffrey Levi, PhD Executive Director, Trust for America’s Health, before the House Committee on Energy & Commerce Joint Hearing on H1N1 Preparedness: An Overview of Vaccine Production and Distribution (November 18, 2009)

--	Trust for America’s Health. TFAH comments on proposed OPM rule for sick leave during a pandemic (September 2009)
--	Trust for America’s Health. Testimony of Jeffrey Levi, PhD, Executive Director Trust for America’s Health Before the Subcommittee on Federal Workforce, Postal Service and the District of Columbia Committee on Oversight and Government Reform (May 14, 2009)

**Webinars, Presentations and Websites**

Reference Number	
--	Rand Corporation. “The H1N1 Pandemic: Lessons Learned from the Cities Readiness Initiative, Briefing by Christopher Nelson and Edward Chan (September 2009) Available at <a href="http://www.rand.org/multimedia/video/2009/09/14/h1n1_pandemic_lessons_learned.html">http://www.rand.org/multimedia/video/2009/09/14/h1n1_pandemic_lessons_learned.html</a> (last accessed April 28, 2010)

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