

The President's Council of Advisors on Science and Technology

Executive Report

U.S. Preparations for the 2009-H1N1 Influenza

In April 2009, a novel influenza A (H1N1) virus (2009-H1N1) appeared in Mexico, causing pneumonias and 59 deaths in Mexico City alone. The virus soon spread to the United States and to other continents. Within two months, the World Health organization (WHO) declared that the viral outbreak met the criteria of a level 6 pandemic. Although initial concerns of an extremely high fatality rate have receded, the expected resurgence of 2009-H1N1 in the Fall poses a serious health threat to the United States.

Since the initial report of the outbreak, the Federal Government, through various departments, agencies, and offices, has been actively studying the course of events, responding to them, and planning for a resurgence of the pandemic this fall. In late June, President Obama requested that his Council of Advisors on Science and Technology (PCAST) undertake an evaluation of the 2009-H1N1 epidemic and the nation's response to a probable recurrence.

In this Executive Report, PCAST assesses the emerging Federal response to a second wave, identifies critical questions and gaps in this response, and suggests additional opportunities for mitigation. PCAST's observations, conclusions, and recommendations presented here are based on the analysis of its 2009-H1N1 Working Group, consisting of 3 PCAST members and a further 11 non-governmental experts in virology, public health, pediatrics, medicine, epidemiology, immunology, and other relevant scientific fields. The Working Group's deliberations were informed by discussions with government officials and others on various aspects of the 2009-H1N1 pandemic.

2009-H1N1 in Historical Context

Based on the history of influenza pandemics over the past hundred years, PCAST places the current outbreak somewhere between the two extremes that have informed public opinion about influenza. On the one hand, the 2009-H1N1 virus does not thus far seem to show the virulence associated with the devastating pandemic of 1918-19; moreover, medical science now has many potent tools at our disposal to mitigate an influenza pandemic in ways that were not possible ninety years ago. On the other hand, the 2009-H1N1 virus is a serious threat to our nation and the world, unlike the "swine flu" episode in 1976 that led to the vaccination of over 40 million Americans in the absence of any spread of the virus beyond an initial four cases at a single Army base.

The Current Situation and a Plausible Scenario

Indeed, the 2009-H1N1 influenza is already responsible for significant morbidity and mortality world-wide — from its appearance in the spring, its continued circulation in the U.S. this summer, and its spread through many countries in the Southern Hemisphere during their winter season. While the precise impact of the fall resurgence of 2009-H1N1 influenza is impossible to predict, a plausible scenario is that the epidemic could:

- **produce infection of 30–50% of the U.S. population this fall and winter**, with symptoms in approximately 20–40% of the population (60–120 million people), more than half of whom would seek medical attention.
- **lead to as many as 1.8 million U.S. hospital admissions during the epidemic**, with up to 300,000 patients requiring care in intensive care units (ICUs). Importantly, these very ill patients could occupy 50–100 percent of all ICU beds in affected regions of the country at the peak of the epidemic and could place enormous stress on ICU units, which normally operate close to capacity.
- **cause between 30,000 and 90,000 deaths in the United States**, concentrated among children and young adults. In contrast, the 30,000–40,000 annual deaths typically associated with seasonal flu in the United States occur mainly among people over 65. As a result, 2009-H1N1 would lead to many more years of life lost.
- **pose especially high risks for individuals with certain pre-existing conditions**, including pregnant women and patients with neurological disorders or respiratory impairment, diabetes, or severe obesity and possibly for certain populations, such as Native Americans.

There is an important issue with respect to **timing**:

- The fall resurgence may well occur as early as September, with the beginning of the school term, and the peak infection may occur in mid-October.
- But significant availability of the 2009-H1N1 vaccine is currently projected to begin only in mid-October, with several additional weeks required until vaccinated individuals develop protective immunity.
- This potential mismatch in timing could significantly diminish the usefulness of vaccination for mitigating the epidemic and could place many at risk of serious disease.
- PCAST emphasizes that this is a planning scenario, not a prediction. But the scenario illustrates that an H1N1 resurgence could cause serious disruption of social and medical capacities in our country in the coming months. The circumstances underscore the importance of:
 - ✓ ensuring that the nation's complex and distributed healthcare systems are prepared to deal with the potential surge in demand, especially with respect to critical care.
 - ✓ ensuring that all feasible steps are taking to protect the most vulnerable populations.

Preparations for the Pandemic: Observations and Recommendations

Preparation for the predicted fall resurgence has been constrained by time and materials: the virus appeared in late spring and its resurgence is anticipated in early fall, while vaccine production currently requires at least 6 months. On the other hand, the development of preparedness plans was greatly stimulated by the recognition a few years ago of the threat posed by a highly lethal avian influenza; preparations developed for this potential threat facilitated the response to the current, quite different strain of influenza virus.

PCAST is impressed by the efforts underway across our government—including the breadth and depth of thinking, energy being devoted, and awareness of potential pitfalls. The response is probably the best effort ever mounted against a pandemic, reflecting past preparedness efforts and the quality and commitment of the people involved.

Still, PCAST found some aspects of the decision-making and preparation processes that we believe could be improved, even in the short time remaining before the fall. These findings and recommendations are discussed at considerable length in its Working Group report.

Reflecting the rapid pace of response in the Federal Government, some of the suggested actions are already being considered, planned, or initiated by relevant agencies. In these cases, our recommendations are intended to provide support and additional focus to such efforts. Our recommendations fall into seven major categories:

1. Coordination. We suggest that coordination of the decision-makers could be more effectively orchestrated if a single person in the White House were assigned the responsibilities of clarifying decision-making authorities and processes, ascertaining that all important issues are resolved in a timely fashion, and reporting to you about actions to be taken.

2. Scenarios. We believe that preparations could be strengthened if the Federal Government developed and disseminated a few specific planning scenarios that Federal, state, local, and private entities could use to assess their capacities and plans for medical and non-medical interventions.

3. Surveillance. The ability to respond to the epidemic will depend on reliable and timely information about its course at the national, regional, and local level. We believe there are opportunities to make important upgrades to existing national surveillance systems in time for the expected fall resurgence.

4. Response. There are four critical pillars of a mitigation effort: vaccines, anti-viral drugs, medical care, and non-medical interventions that diminish virus spread. In particular, we focus on decisions that could reduce instances of severe disease and death by accelerating the delivery and use of vaccines; developing integrated plans to protect especially vulnerable populations; and ensuring access to intensive care facilities.

5. Barriers. Some legal, social, and financial barriers exist that may reduce compliance with some recommended measures for mitigation and we propose ways that the Federal Government and others could work to overcome such barriers.

6. Communication. Communication plans for relaying to the states, health workers, and the general public the government's recommended actions for mitigation are in some cases inadequate and should be strengthened.

7. Future Preparedness. The current outbreak highlights gaps in our capacity to combat epidemics caused by influenza and other agents. We outline steps that can be taken in the next few years, including improving vaccine production and design, anti-viral drug development, and health surveillance systems.

Action Items

In the report, PCAST makes a number of recommendations about specific aspects of the national preparations. Several are of special importance and warrant consideration for immediate or near-term action. Specifically, PCAST proposes that the President:

i. Designate a senior member of the White House staff, preferably the President's Homeland Security Advisor, to be responsible for **coordination** of all major decision-making about the 2009-H1N1 pandemic.

and that the relevant Federal agencies:

ii. Produce and disseminate several **planning scenarios** and work with Federal, state, local, and private entities to **anticipate potential 'surge' demand** (especially for critical care, e.g., ICUs and respirators) and **develop logistical plans** for such contingencies.

iii. Expand CDC's existing **surveillance systems** to track information about influenza-like illnesses from an integrated network of sites, including data from population sampling, emergency rooms, and hospitals, with emphasis on critical care units.

iv. **Accelerate production** of an initial quantity of **finished vaccine** as early as mid-September, to allow vaccination of up to 40 million people, with emphasis on the most vulnerable age and disease groups, as soon as initial data are available on safety and immunogenicity. This decision would need to be made almost immediately.

v. **Develop focused plans** to identify, reach, and **protect members** of the most **vulnerable groups** and their health care providers in time to make use of the protective methods at the nation's disposal.

vi. Prepare a **communication plan** that would deliver appropriate and effective messages about the range of available medical and non-medical interventions, including especially vaccination, to the public in a timely fashion.

vii. **Organize a multi-agency effort**, under the direction of the National Security Council, to improve the **design and production of influenza vaccines**, so that effective vaccination programs can begin more promptly in the course of future epidemics caused by new strains of influenza virus.x xi

Caveats About the Report

The urgency of an ongoing pandemic, one that is likely to worsen in the next month or two, has compelled PCAST and its Working Group to perform its tasks rapidly. Under these circumstances, some of the information gathered by the Working Group for this report (such as the schedule for availability of vaccines and clinical data on infected individuals) must be viewed as provisional and subject to change.

Given the complexity of the situation and the many activities underway to deal with it, PCAST recognizes that the Working Group could not analyze the problem from every perspective and has doubtless failed to acknowledge all of the useful work that is already being done by members of the Obama Administration. In particular, the report does not rigorously address the measures that might need to be taken in the unlikely event that the pandemic proves to be much more severe than we currently envision.

Next Steps

PCAST hopes that its report and that of its Working Group help guide the urgent work that the Administration has undertaken to mitigate the effects of the 2009-H1N1 pandemic. PCAST and its Working Group are prepared to respond to additional questions that members of the Administration might have in the coming months.