

**Testimony before the Committee on Energy and Commerce
U.S. House of Representatives
David L. Lakey, M.D., Commissioner
Texas Department of State Health Services
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Introduction

Good morning, my name is David Lakey, Commissioner of the Texas Department of State Health Services. I am a pediatric and adult infectious disease physician, and have served as commissioner for approximately three years. During my tenure as commissioner, I have led the Texas public health response to multiple events including Hurricanes Dolly, Gustav and Ike.

History has taught us that pandemics occur periodically. However, the timing and severity of the next one was unknown. The last pandemic was 40 years ago. Federal and state governments have planned and exercised for an influenza pandemic for many years.

The 2009 pandemic is significantly different from the high severity “bird flu” pandemic for which our nation had been preparing. Because this pandemic began on our continent instead of overseas, we had a shorter time to initiate response efforts. We had to define the illness and the severity as we responded. The

fortunate news throughout this event is that, although this virus spreads easily, its severity is at the lower end of the scale.

Adjusting Vaccine Distribution Strategies

Because of these differences, our state and the nation as a whole had to rapidly flex plans to match the situation. The ability to adjust plans is a critical component to any successful response. For this pandemic, this included modifying plans to distribute the new H1N1 vaccine.

Previous pandemic plans, due to the anticipated high level of severity, had focused on mass vaccination clinics. However, mass vaccination clinics have specific challenges. These challenges include: insufficient supplies for the anticipated demand, long lines, the inability to vaccinate all who show up to be vaccinated, exposure of high risk individuals, and logistical issues, such as record-keeping and pre-registration to receive the vaccine. Mass vaccination is resource intensive and may divert health care resources away from taking care of patients.

School-based clinics are a means to vaccinate the masses.

Challenges with these clinics include obtaining informed consent

and the difficulty targeting the highest priority patients when vaccine is scarce.

In light of our real world experience with this pandemic, Texas and many other states decided to adjust these plans and strategies.

We decided to use the private sector and public providers as much as possible to provide the vaccine directly to their usual patients. This includes the use of pharmacies as vaccination locations. This method allows providers to pre-identify their priority populations, thus allowing individuals to obtain the H1N1 vaccine the same way they obtain their usual health care and seasonal flu shot. This method allows a more targeted approach in reaching priority populations.

Different states are using alternative strategies based on their experience, public health structure, resources and capabilities. Some states, like California, are utilizing larger vaccination clinics, while others, like Texas and Massachusetts, are relying heavily on the private sector to distribute vaccines.

To accommodate the delivery of vaccine to health care providers across Texas, we developed a new tool to allow providers to register efficiently to be part of this strategy and to pre-identify the number of individuals they intend to serve in each priority population. This web-based application is linked to our primary flu information source, www.TexasFlu.org.

Currently, ~12,600 health care providers in Texas have registered to receive the vaccine, and, of these, vaccine has been apportioned to more than 7,000.

To complement the registration process and to address concerns and questions from health care providers and the public about the many facets of the H1N1 pandemic, our department has contracted with Texas 2-1-1, a program that serves as the single point of coordination for statewide health and human services information and referral in Texas.

Supply

The amount of vaccine available to all states is obviously much less than was predicted. Thus, states have had to further adjust their plans to help ensure the most vulnerable are protected.

Texas continues to order the state's full allocation of the H1N1 vaccine as quickly as possible, with more than 3 million doses ordered and 3.3 million doses allocated as of November 13.

Note, however, that this amount of vaccine was originally predicted to be available to Texas by mid-October.

Because of this limited supply, states have to target populations based on risk and type of vaccine that is available. This will gradually expand to additional groups as the supply and the type of vaccine available increases.

For example, only the nasal spray type of the vaccine was available to Texas initially. The nasal form of the vaccine cannot be used with pregnant women or individuals with chronic conditions. For this reason, we had to focus our distribution on providers that cared for young children 2-4 years of age with no underlying health conditions and the health care providers without high risk conditions that serve that population.

As additional vaccine has become available, we have been able to reach other groups. We are now able to vaccinate pregnant women, people who live with or provide care for infants younger

than 6 months, children 6 months – 4 years of age, high risk children 5 - 18 years of age, and health care and emergency medical services personnel with direct patient contact including EMS. We have just begun allocating vaccine for high risk adults. However, we have not received the necessary volume of vaccine to reach the population of healthy children.

Distributing vaccine to the providers

Once the FDA approves and releases vaccine lots, that vaccine becomes available for distribution to the states. Almost daily, CDC informs states the amount and type of vaccine that is available to be ordered. We then determine where this vaccine should be shipped and confirm that the providers still want the vaccine.

It is a challenge to match the current priority groups with the providers that serve these populations in a way that considers the vaccine types and also ensures good geographic distribution. This can be a complicated and tedious process.

Texas apportions available vaccine to health care providers serving the highest priority population. We recently adjusted

our plan by allocating 20 percent of all vaccine to local health departments to fill identified gaps found at the local level.

Once Texas places an order, McKesson, the national distributor, ships large vaccine orders directly to providers and bulk vaccine to GIV, Texas' contracted third party distributor. This contractor assists the state in getting vaccine to smaller providers across the state.

Challenges

I would like to finish by mentioning several of the challenges we in state public health face as part of this pandemic that began only seven months ago.

- a. During this time, we as a nation have identified and characterized this disease, isolated the virus, figured out how to best grow it in the lab, converted vaccine manufacturing plants over to H1N1 production, performed clinical trials, and developed new vaccine allocation and distribution systems. This is an incredible amount of work over this short time period.
- b. All of this work was accomplished in light of significant reductions to public health resources across the nation

- and the loss of the public health workforce in the economic downturn. We estimate that over the last year 15,000 public health jobs have been lost nationally.
- c. Despite our success, there is a national perception that we are falling short, partly because we set expectations too high about the amount of vaccine that would be available initially.
- The national supply hasn't been adequate to meet the public demand that was created.
- d. Additionally, we created the perception that vaccine would be available to all priority groups immediately. These priority groups account for over half of the U.S. population.
- Because of the supply limitations, states have had to narrow these groups and focus on those most severely impacted by the disease.
- e. There is also confusion about when vaccines are allocated, ordered, shipped and the steps that go into getting vaccine to the people that need it. Some of the misperceptions relate to differences in how states manage vaccine distribution. These misperceptions have led to false impressions that either states are not being allocated

their entire allotment, or that states are not ordering their allotment timely. Both impressions are false.

- f. There is a challenge in developing tools to link individuals seeking vaccine with those providers that have it. This is complicated by the limited supply.
- Various tools have been developed, including web-based systems.
 - The challenge is that most of the providers we are using are being shipped a limited number of doses based on their priority populations. They do not have sufficient supplies to expand out of these groups. Publicizing all these provider names on a web-based system could cause another misperception that vaccine would be available to the general population at these sites. This would quickly overburden these health care providers. The result is that these providers may not participate the next time we call for their assistance.
 - In Texas, we have attempted to address this challenge by:
 1. Using 2-1-1 to link individuals to providers.

2. Providing vaccine to local health providers to serve as a safety net if their usual provider does not have vaccine.

- We are in the process of implementing a flu locator now that vaccine is becoming more available across provider groups. This locator will target public health care providers and larger providers, such as pharmacies.
- g. We have a challenge with the intermittent nature in which pandemic and disaster preparedness has been funded in the past.
- We appreciate the federal government's response to the 2009 H1N1 pandemic and the help Texas and the other states have received, including the Public Health Emergency Response (PHER) funding and the provision of vaccines.
 - However, previous one-time pandemic planning funding did not allow us to sustain the resources needed for a response like we are currently undertaking.
 - This will not be the last pandemic to be seen in our lifetime.

- To continue to be better prepared for public health threats and to protect our individual states and the nation, it will take a continuous and sustained investment.

Finally, we appreciate the commitment of the CDC, the Office of the Assistant Secretary for Preparedness and Response, and other federal agencies that have worked closely with state and local public health. We are in continuous contact and talk on the phone multiple times a week working to find solutions to these difficult issues. Our ultimate goal is to protect the health, safety and well-being of our citizens.

Thank you.