

Being Ready for the Next Pandemic: Expanded Access to Pandemic Vaccines

Coordination Between Public Health and Pharmacies

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The Next Pandemic Will Likely Be Different Than 2009 H1N1

	2009 H1N1	Possible Future Pandemic
Severity	Mild-moderate	High in all ages
Susceptibility	higher in younger groups	All ages
No. of vaccine doses required	One dose; except for <9 years	2 doses for all ages
Use of Adjuvant	Not used	Probable
Demand for vaccination	<i>Mild-moderate</i>	<i>Likely high, if severe and vaccine available early</i>

Planning for Next Influenza Pandemic

□ Planning assumptions:

- Disease may peak <20 weeks from first US case
- Disease could be severe
- 2 vaccine doses separated by 21 days needed for all ages
 - Use of adjuvant is likely, potentially mixed at point of administration
- Demand for vaccination may be extremely high
- 30M vaccines available for distribution each week due to:
 - Improvement in vaccine manufacturing capacity and
 - Use of antigen sparing strategy with adjuvants

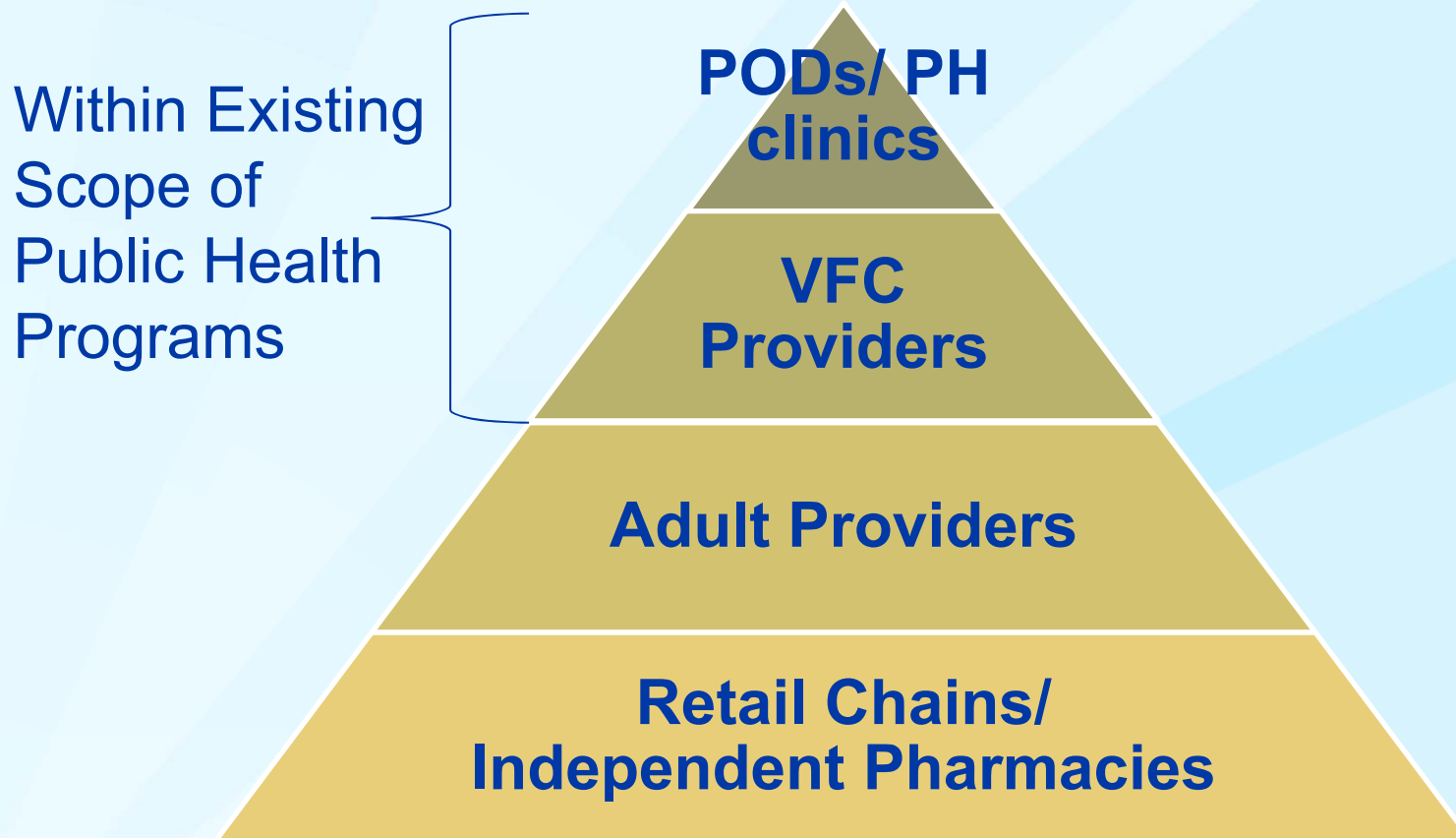
□ Influenza pandemic preparedness goals:

- Vaccinate 80% of jurisdiction population with 2 doses separated by 21 days within 16 weeks
- Be ready to begin vaccinating at maximum capacity as early as possible (vaccine may be available 60 days after notification)

Vaccine Administration Capacity: Past, Present, and Future

- ❑ **2009 H1N1 vaccine administration:**
 - Only ~5 million vaccine doses were administered during peak vaccination week of 2009 H1N1, after ~4 months of planning
- ❑ **Seasonal influenza vaccine administration:**
 - ~12 million influenza vaccines administered during peak week of administration during recent influenza seasons.
- ❑ **In next pandemic, expanding vaccination capacity is needed:**
 - While Vaccines For Children (VFC) program can reach pediatric populations, but also need more effort to rapidly immunize adults across the community
 - PODs alone may not serve this need
 - Need to leverage existing systems and partners to ensure early widespread pandemic vaccine availability

Using a Layered Approach: Leveraging the Strengths of Public Health and Private Sector



Pharmacies as Pandemic Partners

- ❑ **Pharmacists are increasingly important routine vaccinators**
 - ~280,000 vaccinating pharmacists in U.S.
 - 1 in 4 seasonal influenza vaccinations given to adults were administered in a pharmacy or retail setting¹

- ❑ **Pharmacists also offer expanded access to vaccinations during 2009 H1N1 pandemic**
 - Underutilized as H1N1 vaccine was not broadly available in pharmacy settings until after the peak of disease and public demand had waned²

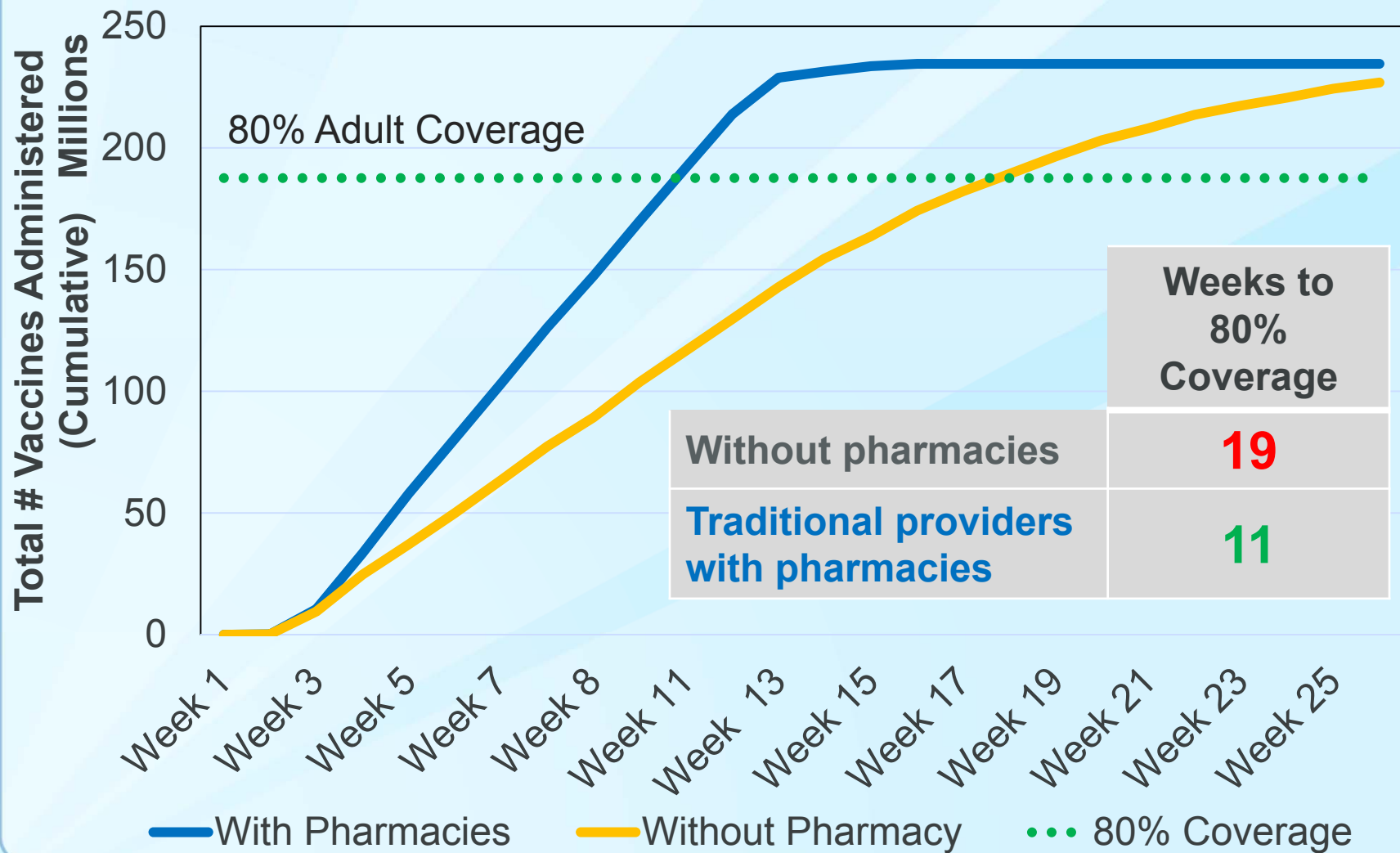
- ❑ **During a severe pandemic, widespread vaccination not beginning until pandemic disease is peaking would have little impact³**
 - Expanded use of pharmacist vaccinators early in a pandemic response represents an important mechanism for rapidly vaccinating the public

¹ FluVaxView, <http://www.cdc.gov/flu/fluview/nifs-estimates-nov2015.htm>

² Koonin et al., *Disaster Medicine and Public Health Preparedness* 2011

³ Biggerstaff et al., *Clinical Infectious Diseases* 2015

Preliminary Illustration of Model Predictions: Weeks to 80% Single Dose Adult Pandemic Vaccination Coverage*



* Schwerzmann, Graitcer et al, submitted for publication

*****Preliminary*****

Logistical Considerations For Pandemic Vaccination Program

- ❑ For pharmacies to be fully leveraged, significant pre-pandemic planning and coordination is needed
- ❑ Vaccine program planning and logistics for pandemic is different than seasonal influenza:
 - During influenza pandemic, federal government works with vaccine manufacturers to develop pandemic vaccine supply for entire U.S.
 - Pandemic influenza vaccine cannot be purchased directly from manufacturers as done by most pharmacies for seasonal influenza vaccines
 - State public health programs are typically given pro-rata allocations and responsible for managing provider orders within jurisdiction
 - Pharmacist and other providers must establish relationship with public health to order pandemic vaccine
 - Pandemic vaccine may require a higher level of tracking than seasonal influenza vaccine
 - Tracking may be important for clinical purposes, especially if multiple doses are required, adjuvant needed to be matched between doses, and persons are vaccinated in various settings

Current State of Coordination Between Public Health and Pharmacies for Pandemic Planning

- ❑ **Most public health programs acknowledge that pharmacists would be valuable pandemic vaccinators**

- ❑ **CDC review of internal state and local planning suggests that significant gaps in coordination remains*:**
 - Many programs still report that, even given a scenario of sufficient pandemic vaccine supply, <10% of state pandemic vaccine would be allocated to pharmacies and retail settings
 - ~1/3 of public health programs report that pharmacies would only be incorporated in later, rather than earlier, in the vaccine campaign
 - Few programs have formal agreements, such as Memorandum of Understanding, with pharmacies in place to improve pre-pandemic vaccine program planning and response

* Unpublished internal CDC data, based on Program Annual Assessment and Pandemic Influenza Readiness Assessment

Improving Pandemic Vaccine Program Coordination

- **Since 2013, CDC partnered with the Association of State and Territorial Health Officials (ASTHO) to determine best practices to improve coordination between public health and pharmacies**
 - Conducted structured interviews and held multiple workshops to obtain input from pharmacy, public health preparedness and immunization leadership
 - National work group formed including public health programs, APhA, NACDS, NASPA, and individual pharmacies

- **National work group developed a template Public Health/ Pharmacy Memorandum of Understanding (MOU) in 2015**
 - Facilitates participation by national/ regional pharmacies by promoting standard approach across states, while allowing for flexibility in implementation given differences between jurisdictions

Pandemic Vaccine Program Template MOU Between Public Health and Pharmacies

- ❑ **Template MOU outlines specific best practices for pandemic influenza vaccine program planning and response processes**
 - <http://www.astho.org/Infectious-Disease/Pandemic-Influenza/MOU-State-Pharmacy-Pandemic-Influenza-Vaccination-Campaign/>
 - <http://www.pharmacist.com/pharmacy-and-public-health-collaboration>
- ❑ **Major topics covered in template include sections on:**
 - Pharmacist processes for participation in state pandemic vaccine ordering system/ plan
 - Pandemic vaccine allocation to pharmacies, proposed criteria
 - Pandemic vaccine distribution, coordination between CDC's contracted distributor and pharmacies' distributor
 - Pandemic vaccination documentation, including use of the immunization information system (IIS), and tracking of distribution to sites
 - Pandemic vaccine payment issues, given cost of pandemic vaccine is covered by federal government
 - Overall coordination for communications and response leadership

Improved Coordination Between Public Health and Pharmacies for Pandemic Vaccine Program Planning: Next Steps

- ❑ **CDC, ASTHO, NACDS, NASPA, and APhA are working with pilot states to implement the template MOU**
 - APhA and NACDS also have separate demonstration projects
- ❑ **ASTHO and partners developing MOU implementation toolkit based on pilot results**
 - Information in the toolkit will include standard processes and timelines, background slides for informational purposes and promotion
 - Toolkit designed for use by states, pharmacies, and pharmacy associations
- ❑ **CDC considering making coordination with pharmacies for pandemic vaccine planning a formalized activity for immunization and preparedness programs**
 - Conducting briefings with state's pharmacy association on logistics of pandemic planning process and coordinating local health efforts

Summary

- ❑ **Pharmacies have potential to significantly expand access to vaccines during the next pandemic**
- ❑ **While public health programs acknowledge potential role of pharmacists during a pandemic, more work is needed to ensure pharmacies incorporated early**
 - Especially given logistical differences between planning for pandemic and conducting seasonal influenza vaccination
- ❑ **Formal agreements, such as Memorandum of Understanding, are important in ensuring efficient coordination for pandemic vaccine response**
 - [ASTHO MOU: http://www.astho.org/Infectious-Disease/Pandemic-Influenza/MOU-State-Pharmacy-Pandemic-Influenza-Vaccination-Campaign/](http://www.astho.org/Infectious-Disease/Pandemic-Influenza/MOU-State-Pharmacy-Pandemic-Influenza-Vaccination-Campaign/)
 - [APhA resources: http://www.pharmacist.com/pharmacy-and-public-health-collaboration](http://www.pharmacist.com/pharmacy-and-public-health-collaboration)
 - Joint letter in support of state-level MOUs with pharmacies (CDC, NACDS, APhA, NASPA, ASTHO)

Joint letter in support of state-level MOUs between pharmacies and state public health: CDC, NACDS, APhA, NASPA, ASTHO



To State Pharmacy Association Executives, State and Territorial Health Officials, and Pharmacy Providers:

As the face of neighborhood healthcare, pharmacies and pharmacists offer convenient and accessible patient-centered services every day and during public health emergencies. In an influenza pandemic, pharmacies will play a critical role in increasing access to pandemic vaccines. Enhanced pre-pandemic coordination between pharmacies and public health programs, particularly in planning for expanding public access and improving timeliness of pandemic vaccine delivery, can significantly improve overall community response efforts during an influenza pandemic.

In the event of an influenza pandemic, state and territorial health agencies would receive an allocation of pandemic influenza vaccine from the Federal government based on their population density. These state and territorial health agencies would be responsible for managing vaccine orders and distribution within



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