

# **Novel Influenza Vaccine Program Planning Activities**

## **National Vaccine Advisory Committee Meeting**

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**



# Previous pan flu vaccine planning assumptions

- **Planned around influenza A H5N1 virus**
- **Focused on Pandemic Severity Index 5 scenario (1918-like)**
- **Potential for significant economic and social disruption**
- **Pre-pandemic influenza vaccine available for 20M critical infrastructure and key resources workers**

# **Previous pan flu vaccine planning assumptions cont.**

- **Priority placed on development and production of a pandemic influenza vaccine**
- **Seasonal influenza vaccine production and vaccination efforts curtailed**
- **Pandemic influenza vaccine available in limited quantities in ~4-5 months**
- **Government-managed public sector vaccination campaign (federal, state and local)**

# Previous pan flu vaccine planning assumptions cont.

- Goal to vaccinate all persons in the U.S. who choose to be vaccinated

## HOWEVER

- Initial limited supply would necessitate prioritization of vaccine

# **Specific objectives of pan flu vaccine prioritization**

- **Protect those who are essential to the pandemic response and provide care for persons who are ill (healthcare workers)**
- **Protect those who maintain essential community services**
- **Protect workers who are at greater risk of infection due to their job (emergency responders)**
- **Protect children**



Category	Target Group	Estimated Number*	Severity of Pandemic		
			Severe	Moderate	Less severe
Homeland and national security	Deployed and mission critical personnel	700,000	Tier 1	Tier 1	Tier 1
	Essential support & sustainment personnel	650,000	Tier 2	Tier 2	Tier 2
	Intelligence services	150,000	Tier 2	Tier 2	Tier 2
	Border protection personnel	100,000	Tier 2	Tier 2	Tier 2
	National Guard personnel	500,000	Tier 2	Tier 2	Tier 2
	Other domestic national security personnel	50,000	Tier 2	Tier 2	Tier 2
	Other active duty & essential support	1,500,000	Tier 3	Tier 3	Not Targeted**
Health care and community support services	Public health personnel	300,000	Tier 1	Tier 1	Tier 1
	Inpatient health care providers	3,200,000	Tier 1	Tier 1	Tier 1
	Outpatient and home health providers	2,500,000	Tier 1	Tier 1	Tier 1
	Health care providers in LTCFs	1,600,000	Tier 1	Tier 1	Tier 1
	Community support & emergency management	600,000	Tier 2	Tier 2	Not Targeted**
	Pharmacists	150,000	Tier 2	Tier 2	Not Targeted**
	Mortuary services personnel	50,000	Tier 2	Tier 2	Not Targeted**
	Other important health care personnel	300,000	Tier 3	Tier 3	Not Targeted**
Critical infrastructure	Emergency services sector personnel (EMS, law enforcement and fire services)	2,000,000	Tier 1	Tier 1	Tier 1
	Mfrs of pandemic vaccine & antivirals	50,000	Tier 1	Tier 1	Tier 1
	Communications/IT, Electricity, Nuclear, Oil & Gas, and Water sector personnel	2,150,000	Tier 2	Tier 2	Not Targeted**
	Financial clearing & settlement personnel		Tier 2	Tier 2	Not Targeted**
	Critical operational & regulatory government personnel		Tier 2	Tier 2	Not Targeted**
	Banking & Finance, Chemical, Food & Agriculture, Pharmaceutical, Postal & Shipping, and Transportation sector personnel	3,400,000	Tier 3	Not Targeted**	Not Targeted**
General population	Pregnant women	3,100,000	Tier 1	Tier 1	Tier 1
	Infants & toddlers 6-35 mo old	10,300,000	Tier 1	Tier 1	Tier 1
	Household contacts of infants < 6 mo	4,300,000	Tier 2	Tier 2	Tier 2
	Children 3-18 yrs with high risk condition	6,500,000	Tier 2	Tier 2	Tier 2
	Children 3-18 yrs without high risk	58,500,000	Tier 3	Tier 3	Tier 3
	Persons 19-64 with high risk condition	36,000,000	Tier 4	Tier 3	Tier 2
	Persons >65 yrs old	38,000,000	Tier 4	Tier 3	Tier 2
	Healthy adults 19-64 yrs old	123,350,000	Tier 5	Tier 4	Tier 4

# U.S. Pan Flu Vaccine Strategic Current & Possible New Goals

- **Vaccines**
  - **Goal #1:** Establish and maintain a dynamic pre-pandemic influenza vaccine stockpile available for 20 M persons (2 doses/person) **or more persons depending on vaccine mfg. capacity & results of dose-sparing adjuvant studies and prime-boost immunization studies:** H5N1 vaccine stockpiles
  - **Goal #2:** Provide pandemic vaccine to all U.S. citizens within 6 months of a pandemic declaration: pandemic vaccine (600 M doses)

***National Strategy for Pandemic Influenza (Nov 2005) and HHS Pandemic Influenza Plan (Nov 2005)***

**<http://www.pandemicflu.gov>**

# **Novel H1N1 vaccination campaign planning**

- **No pandemic declaration yet, but planning must move forward rapidly to prep for fall 2009**
- **Decisions to develop and manufacture a vaccine are independent from the decision to administer**
- **Epidemiologic picture emerging over summer 2009**
- **Necessary to plan for range of pandemic severity scenarios (mild, moderate, severe)**
- **Economic/social disruption may not be extensive**

# **Novel H1N1 vaccination campaign planning cont.**

- **Initial vaccine supply may be larger than previously anticipated (plan for limited, moderate, and larger supply scenarios)**
- **Vaccine priority groups will be evaluated in the context of current epidemiologic data**
- **Seasonal influenza vaccine supply minimally affected by novel H1N1 vaccine development and production**

# **Novel H1N1 vaccination campaign planning cont.**

- **Near simultaneous and overlapping seasonal and novel H1N1 vaccination campaigns is a possibility**
- **More limited, targeted novel H1N1 vaccination campaign may be appropriate**
- **Scenario planning around implementation options necessary**

# Vaccine distribution (current model)

- Vaccine allocated to states pro rata
- Vaccine shipped to state-designated vaccine ship-to sites under the direction of CDC
- Initial demand expected to exceed supply
  - When (demand  $\ggg$  supply): allocation model with weekly shipments to states
  - When (demand  $\geq$  supply or supply  $>$  demand): transition to an ordering model with states placing orders as needed

# Vaccine distribution cont.

- **Manufacturers/distributors ship vaccine to states using established distribution channels**
- **States receive vaccine at pre-designated ship-to sites (870 sites nationwide)**
- **Vaccine distribution monitored via CDC's FluFinder**
- **States able to access FluFinder data for through the CDC secure data network**

**Vaccine, adjuvant,  
needles and syringes**

**Single  
central  
ship-to site**

**POD 1**

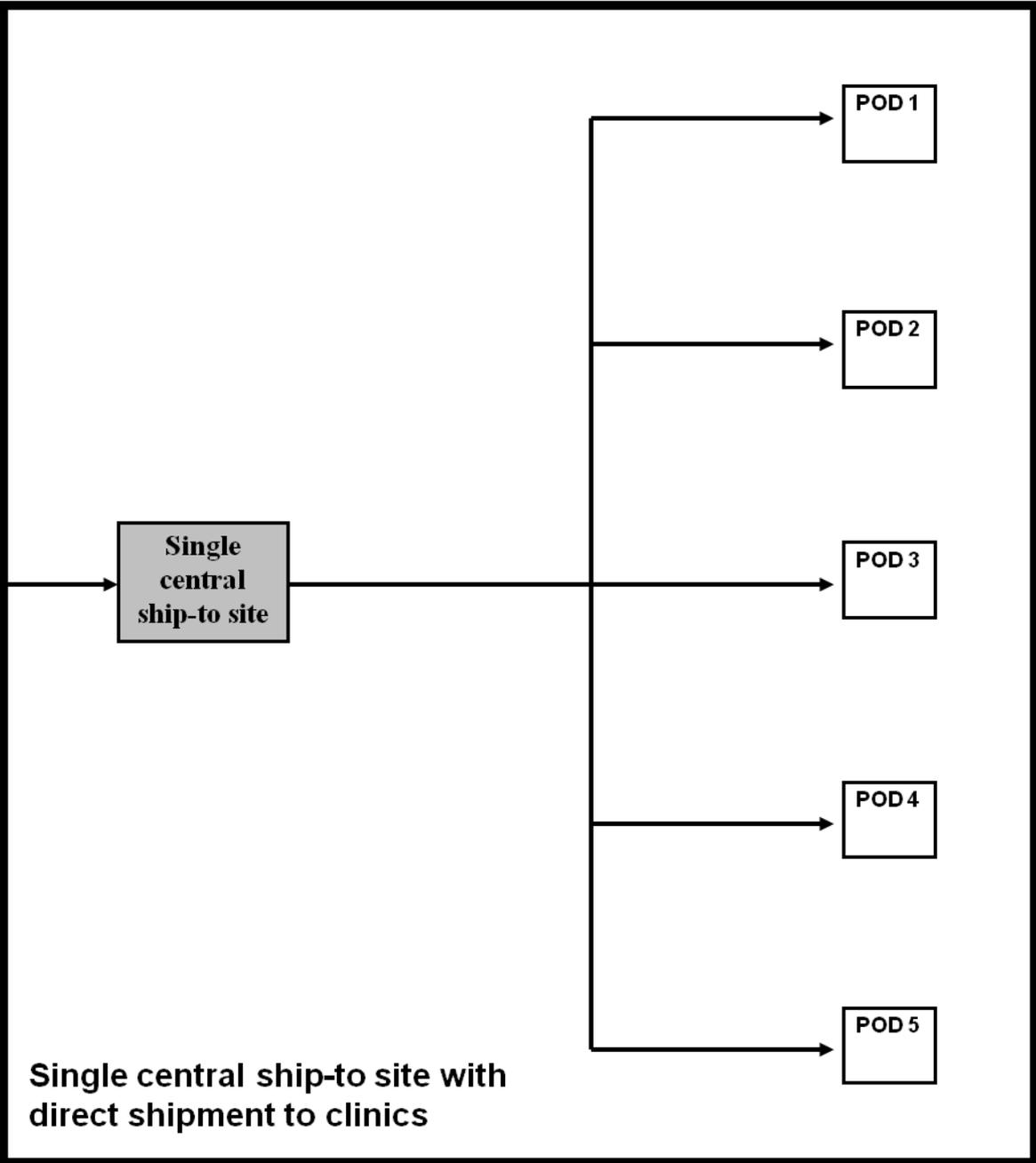
**POD 2**

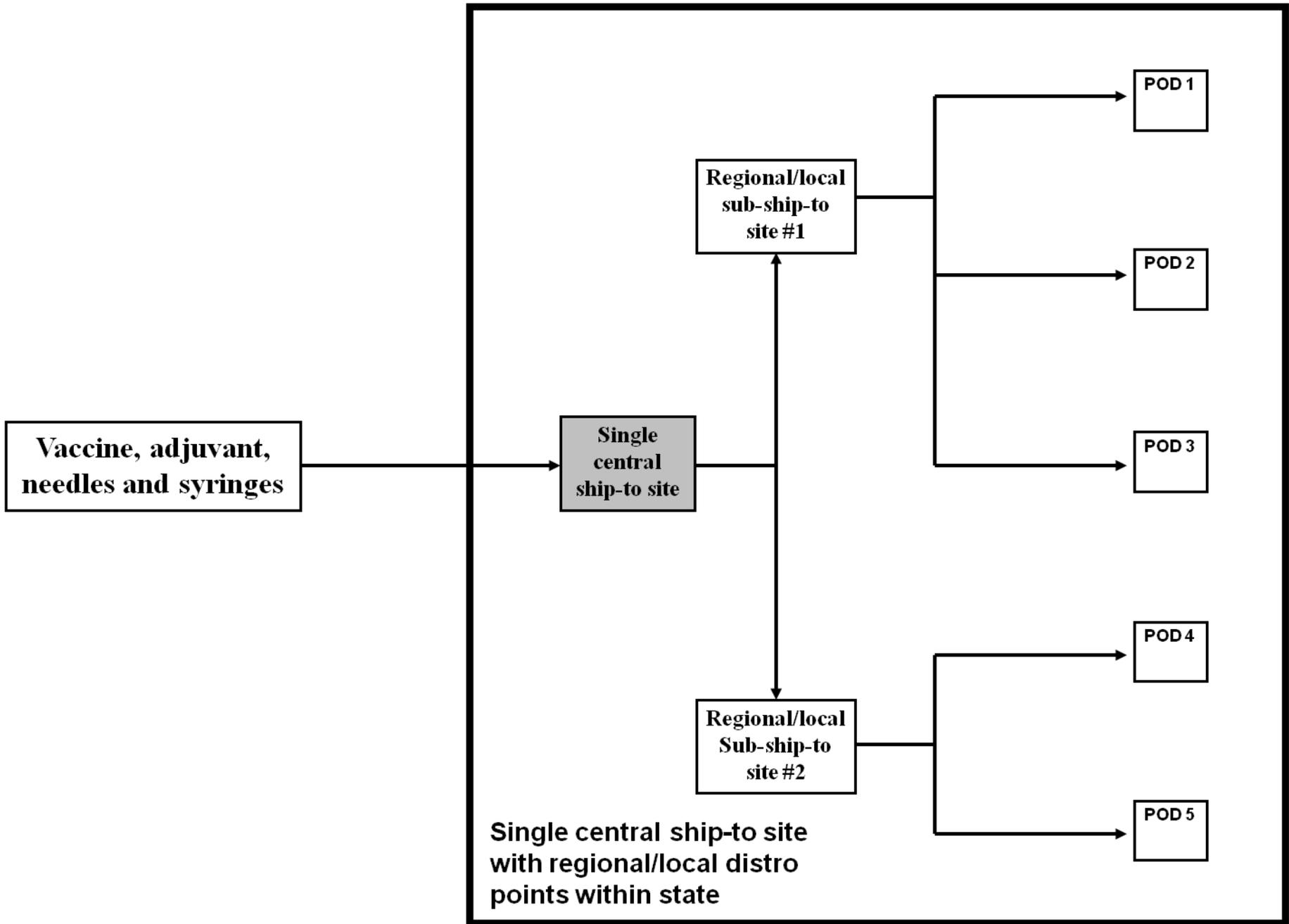
**POD 3**

**POD 4**

**POD 5**

**Single central ship-to site with  
direct shipment to clinics**





**Vaccine, adjuvant,  
needles and syringes**

**Ship-to site  
#1**

**POD 1**

**POD 2**

**Ship-to site  
#2**

**POD 3**

**Ship-to site  
#3**

**POD 4**

**POD 5**

**Multiple ship-to sites with direct  
shipment to PODs**

# **Operations at the state and local levels**

- **State-designated ship-to sites must be capable of**
  - **Receiving, storing, securing and repackaging vaccine**
  - **Allocating vaccine to regional/county distribution points and to vaccination clinics**
  - **Follow-on distribution to distribution points and clinics**
- **Allocation, distribution, and administration within a state will be a state and local function**
- **Security at ship-to sites, in transit to clinics, and at clinics will be a state and local responsibility**

# Operations at the state and local levels cont.

- **Clinic selection should consider local/community needs**
  - **Public sector large-scale vaccination clinics**
  - **School-based clinics**
  - **Healthcare facilities (high concentration of Tier 1 workers)**
  - **Large occupational health clinics in Tier 1 businesses/orgs**
  - **Traditional healthcare settings**
- **Options for vaccinators include**
  - **Health department staff**
  - **Medical staff at facility or under MOA**
  - **Contract mass vaccinators**
  - **Other trained staff and volunteers**

# Monitoring vaccine utilization

- **Early stages of administration: CDC's Countermeasure and Response Administration (CRA) System**
  - Option 1: Existing immunization information system (IIS)
  - Option 2: Aggregate reporting using CRA application
  - Option 3: Individual level reporting using CRA application which then aggregates data
- **When measurable amount of vaccine has been administered: population-based surveys**
  - Existing platforms include NIS and BRFSS

# Challenges at the state and local levels

- **Resources (financial, staffing, equipment, supplies)**
- **Transition from state and local health department-managed depot model for childhood vaccine program to VMBIP model may limit surge distribution capability**
  - **Cold storage capacity**
  - **Transportation to local health departments and clinics**
  - **Vaccine handling expertise and experience in maintaining cold chain during transport and administration**

# **Challenges at the state and local levels cont.**

- **Coordination with critical infrastructure/key resources sector businesses and organizations**
- **Facility and transportation route security**

# Next steps

- **Expanded CDC planning and response process (Vaccine TF with specialty teams to include)**
  - **Implementation team**
  - **Distribution team**
  - **Communications team**
  - **Vaccine Safety team**
- **Engagement with state/local immunization, preparedness and SNS programs via ASTHO/NACCHO planning sessions**
- **Scenario planning around varying degrees of pandemic severity and varying distribution and administration options**