

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**
	Other critical government personnel		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 3



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)

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

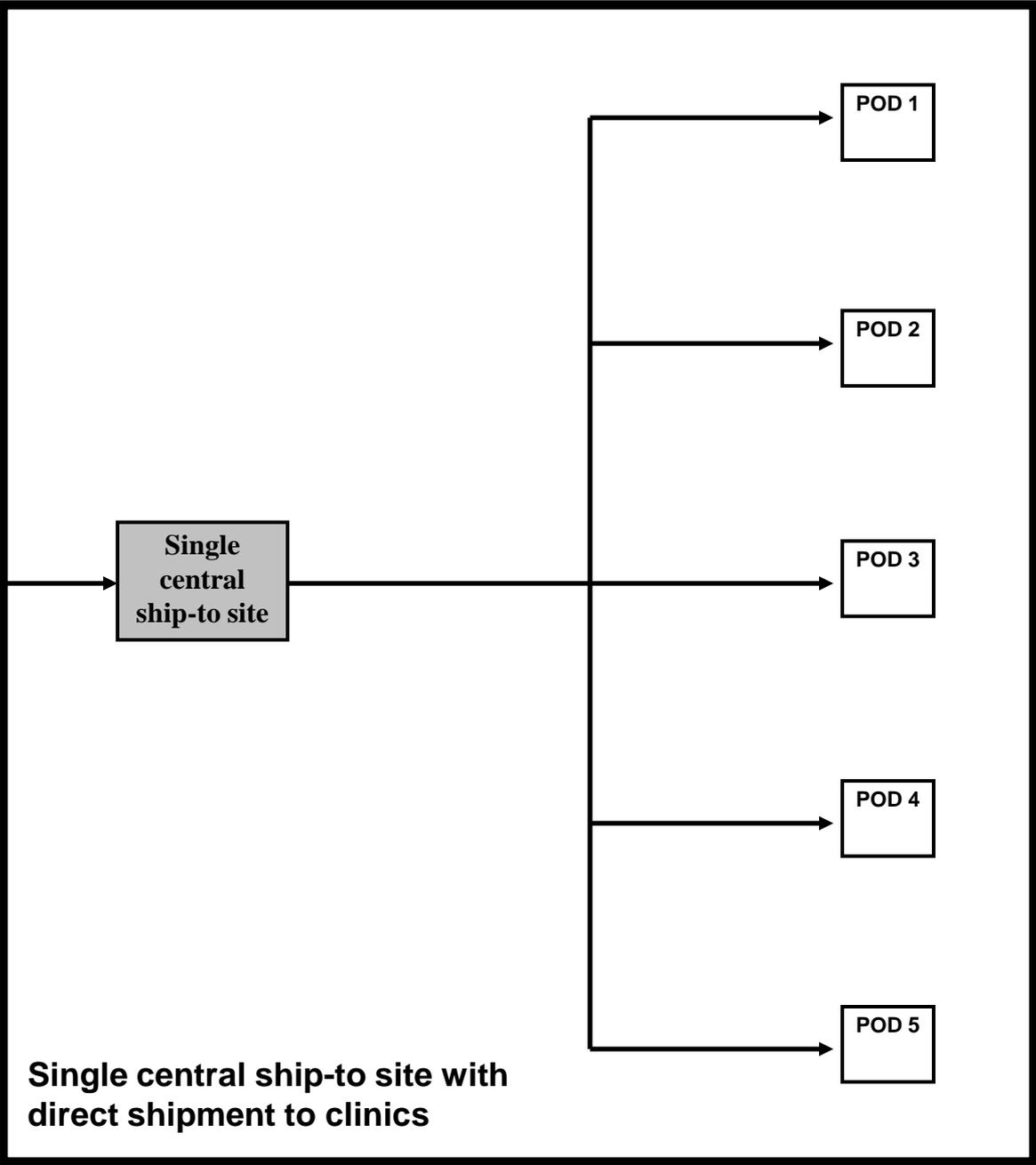
POD 2

POD 3

POD 4

POD 5

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



**Vaccine, adjuvant,
needles and syringes**

**Single
central
ship-to site**

**Regional/local
sub-ship-to
site #1**

**Regional/local
Sub-ship-to
site #2**

POD 1

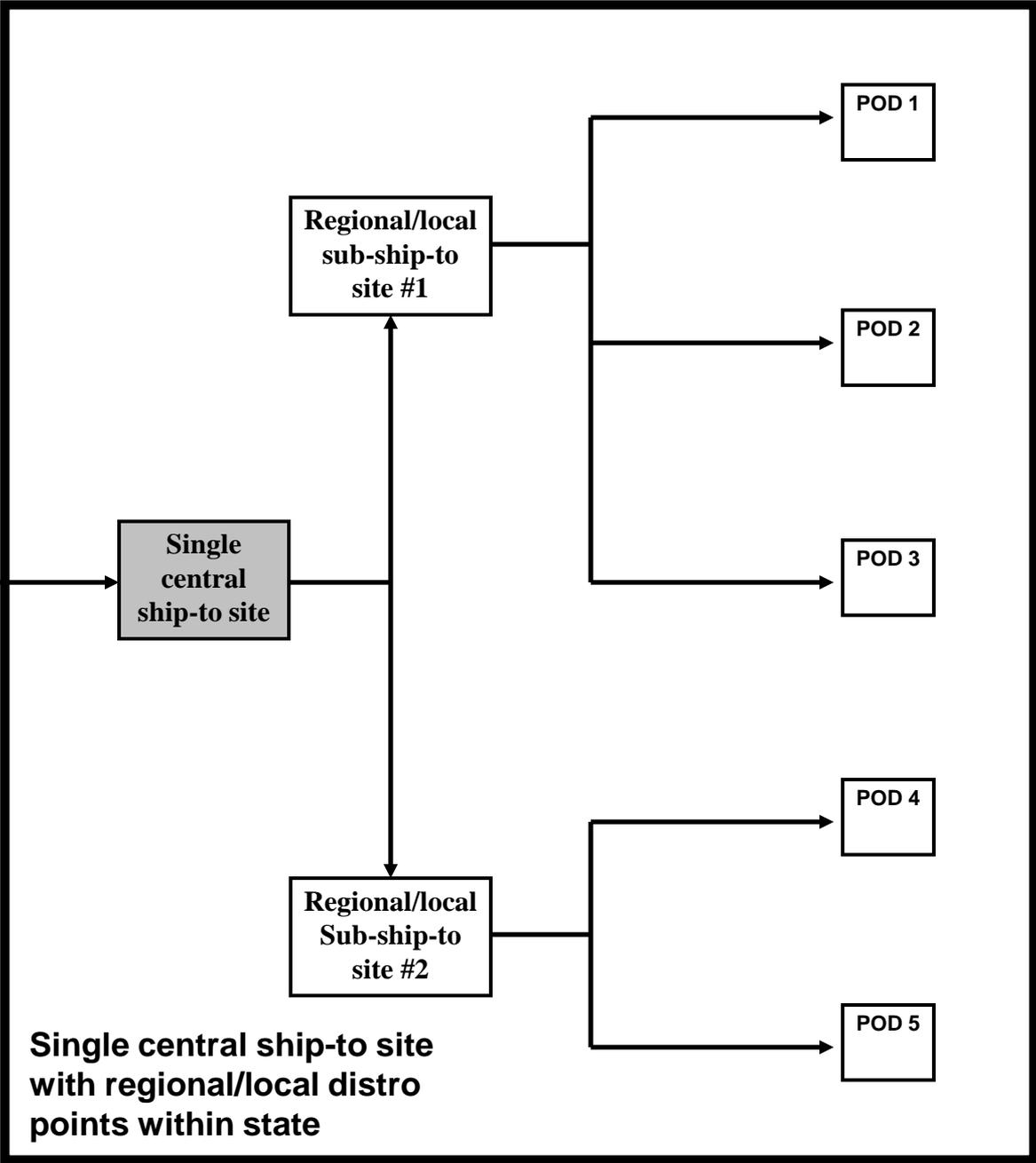
POD 2

POD 3

POD 4

POD 5

**Single central ship-to site
with regional/local distro
points within state**



**Vaccine, adjuvant,
needles and syringes**

**Ship-to site
#1**

POD 1

POD 2

**Ship-to site
#2**

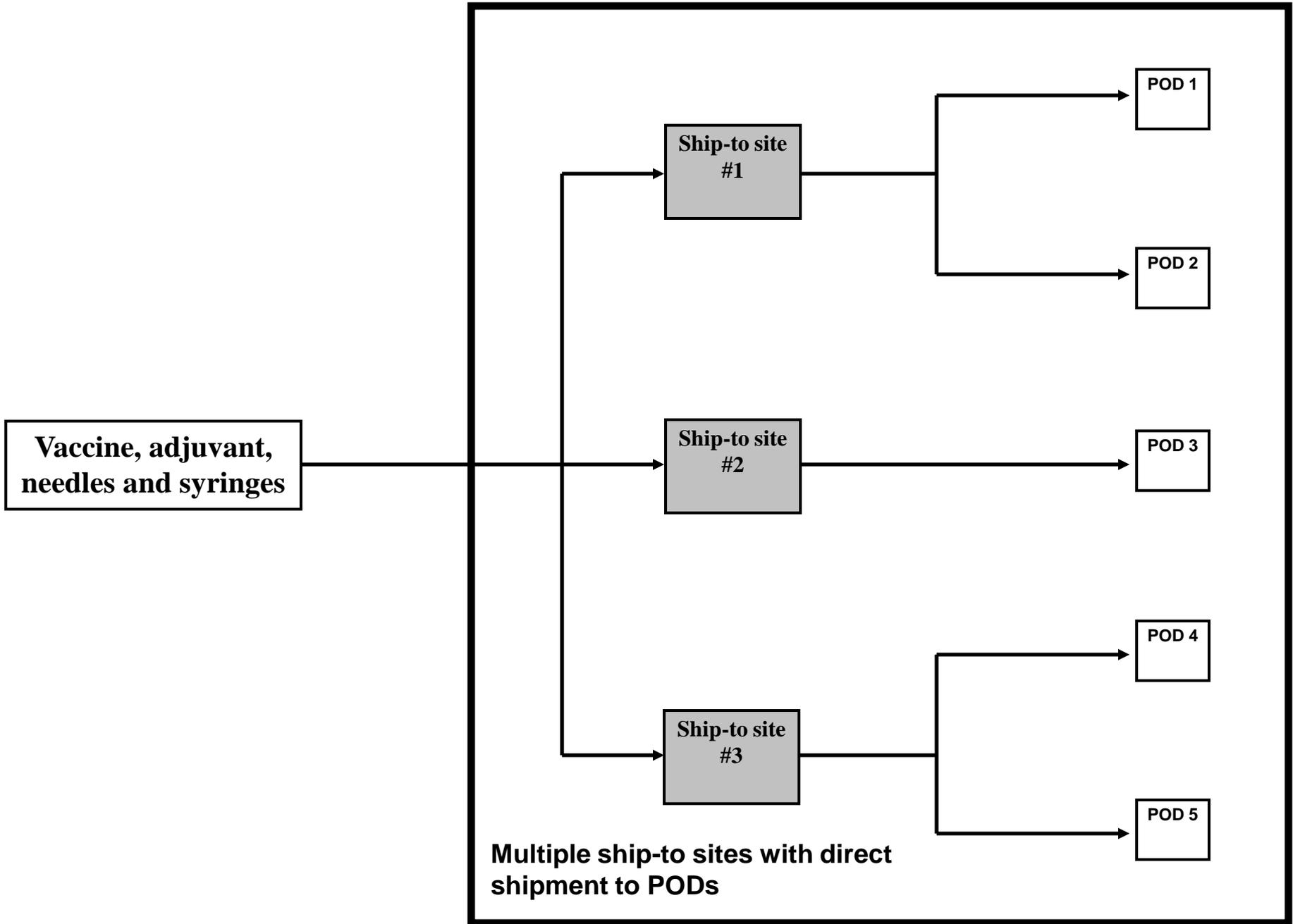
POD 3

**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**

