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The HHS Pandemic Plan and Vaccine & Antiviral Drug Targeting

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Pandemic Planning Chronology

- (May 2005 – Pandemic presentation to ACBSA)
- Nov 1, 2005 – President's announcement of National Strategy for Pandemic Influenza
- Nov 2, 2005 – Release of HHS Pandemic Influenza Strategic Plan (www.pandemicflu.gov)
- Dec 10, 2005 – Executive Branch tabletop exercise
- Ongoing – Development of National Strategic plan & Departmental implementation plans

Presentation Outline

- Assumptions on the spread and impacts of a pandemic
- Pandemic vaccine and antiviral strategies
- Next steps in planning

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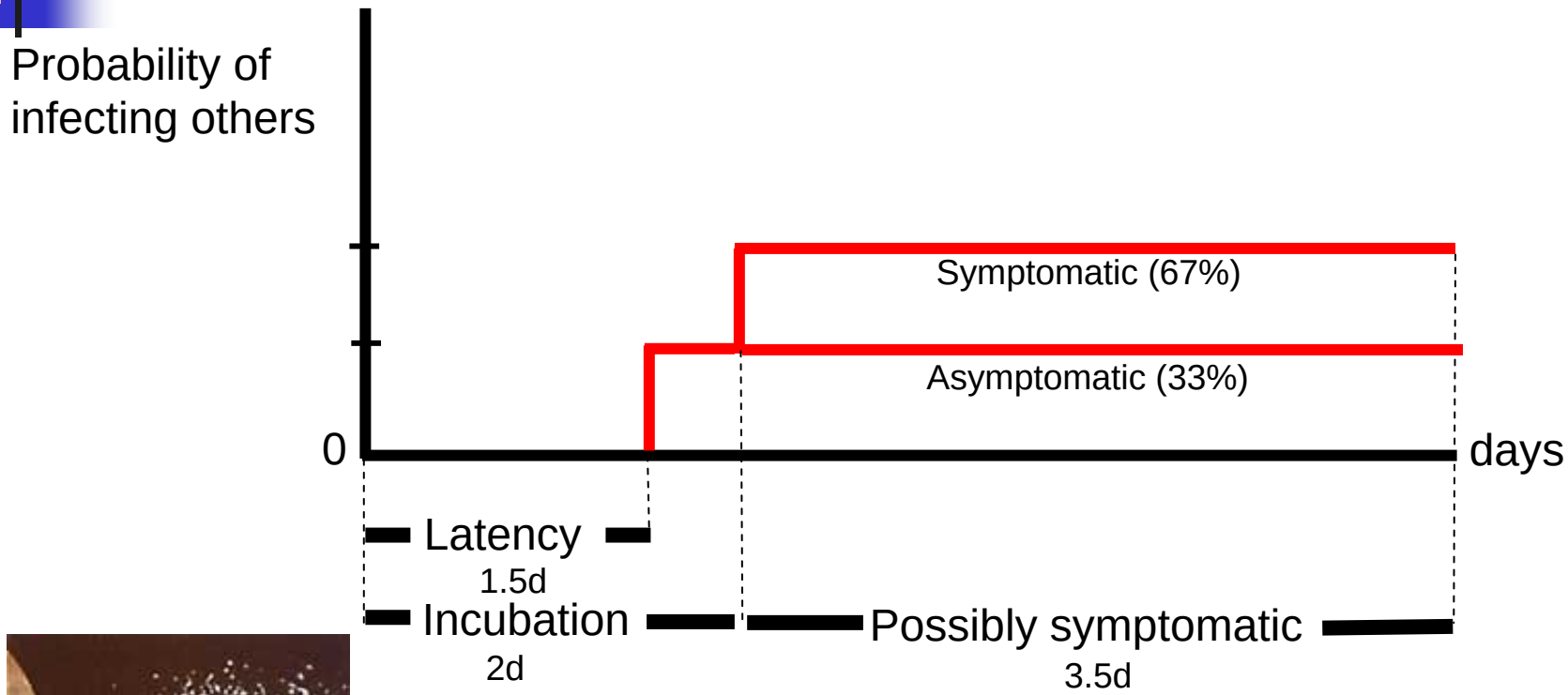
Caveats on Pandemic Planning Assumptions

- Assumptions are based on 20th century pandemics
  - N = 3
  - Each pandemic has been different
  - Impacts of H5N1 infection in Asia are more severe than seen in prior pandemics
- Extrapolations may be incorrect because of changes in medical care and society
  - Lower hospitalization rates
  - Improved medical care and antiviral drugs
  - Increased complexity of networks and global supply chains

Pandemic Planning Assumptions 1: Illness & Transmission

- Illness rate during the first disease wave: ~30%
  - Rates of hospitalization and death vary with virulence of the pandemic virus, not the rate of illness
- Transmission by contact with respiratory secretions
  - Children will have a major role in transmission because of a higher infection rate, more viral shedding, and closer contact with others
- Average period between infection and illness: ~2 days
  - Viral shedding and transmission risk during last ½ day of this period

Natural History of Seasonal Influenza Infection

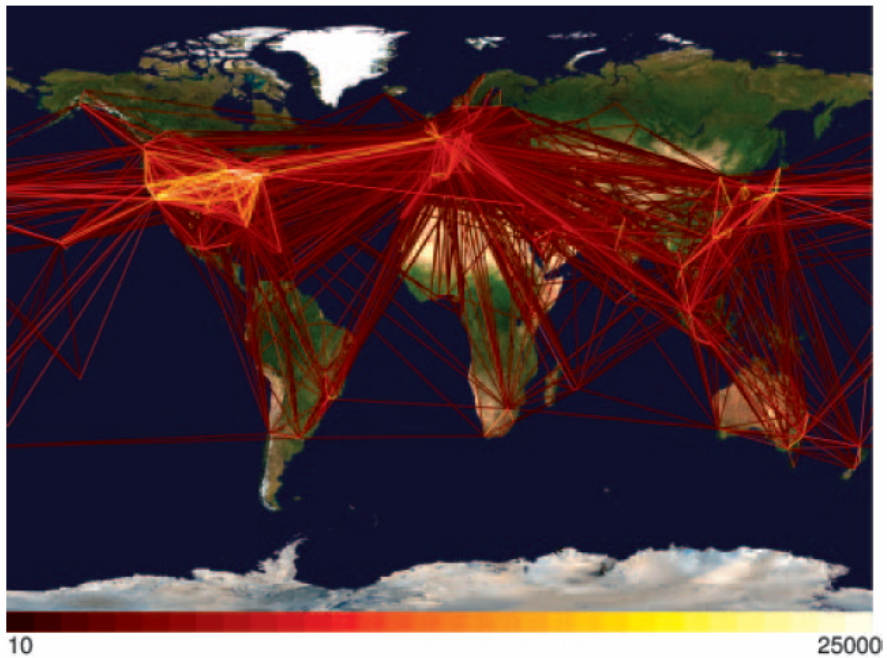


Exposure and infection

Implications of Influenza Natural History

- Disease may be spread by asymptomatically infected persons.

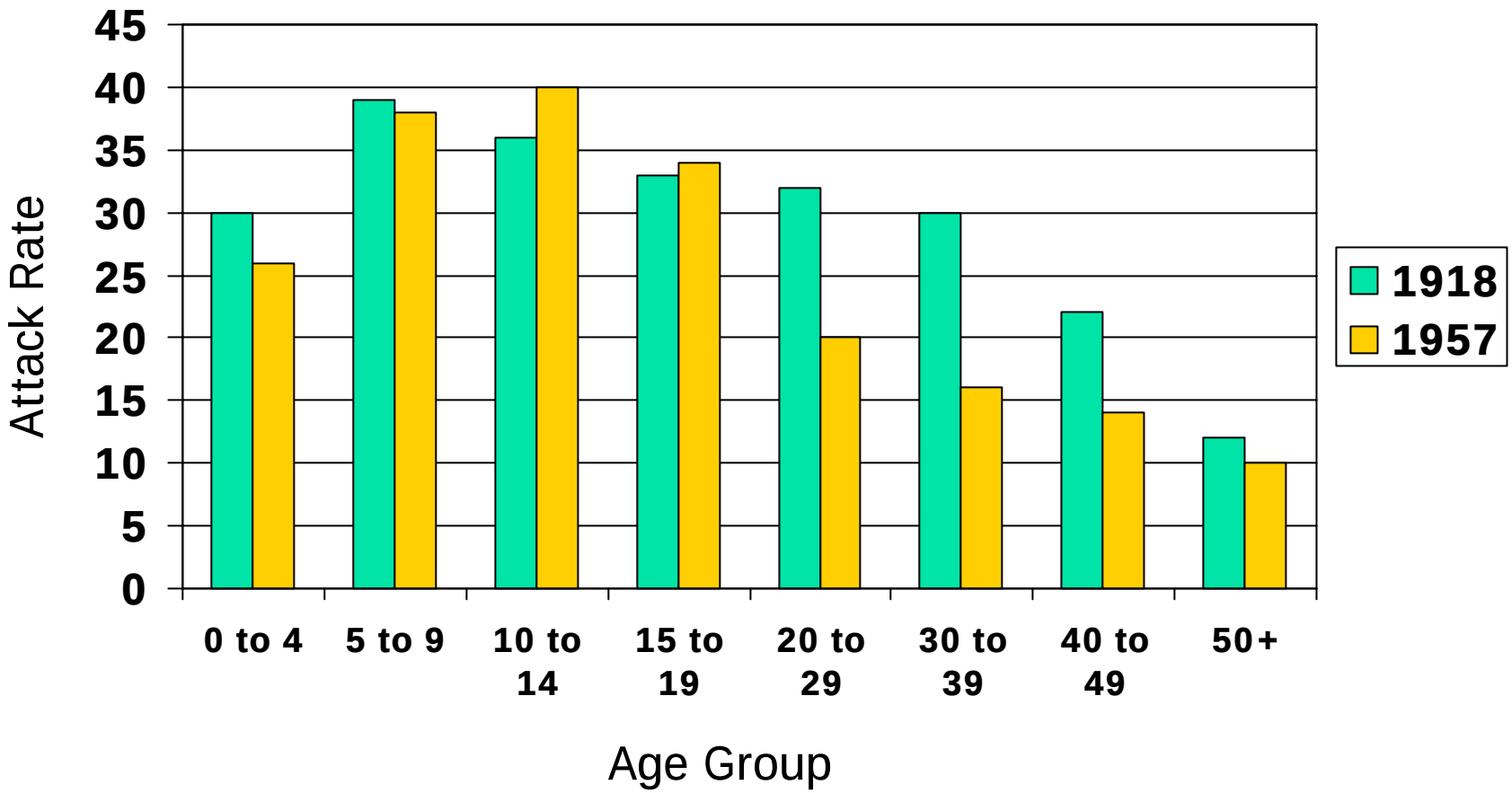
- Given ~2 days from infection until symptoms, most asymptomatic infected people who get on an airplane still will be asymptomatic when they get off.



Pandemic Planning Assumptions 2: Community Impacts & Absenteeism

- Community outbreaks will last 6-8 weeks
- At the outbreak peak, absenteeism may be ~40%
  - Includes absence from illness, caring for ill family members, and fear of becoming infected at the workplace
  - Rates will be lower before and after the peak
  - Absenteeism will differ based on the severity of the pandemic and the occupation
  - Public health measures (e.g., closing schools, snow days) also will affect absenteeism

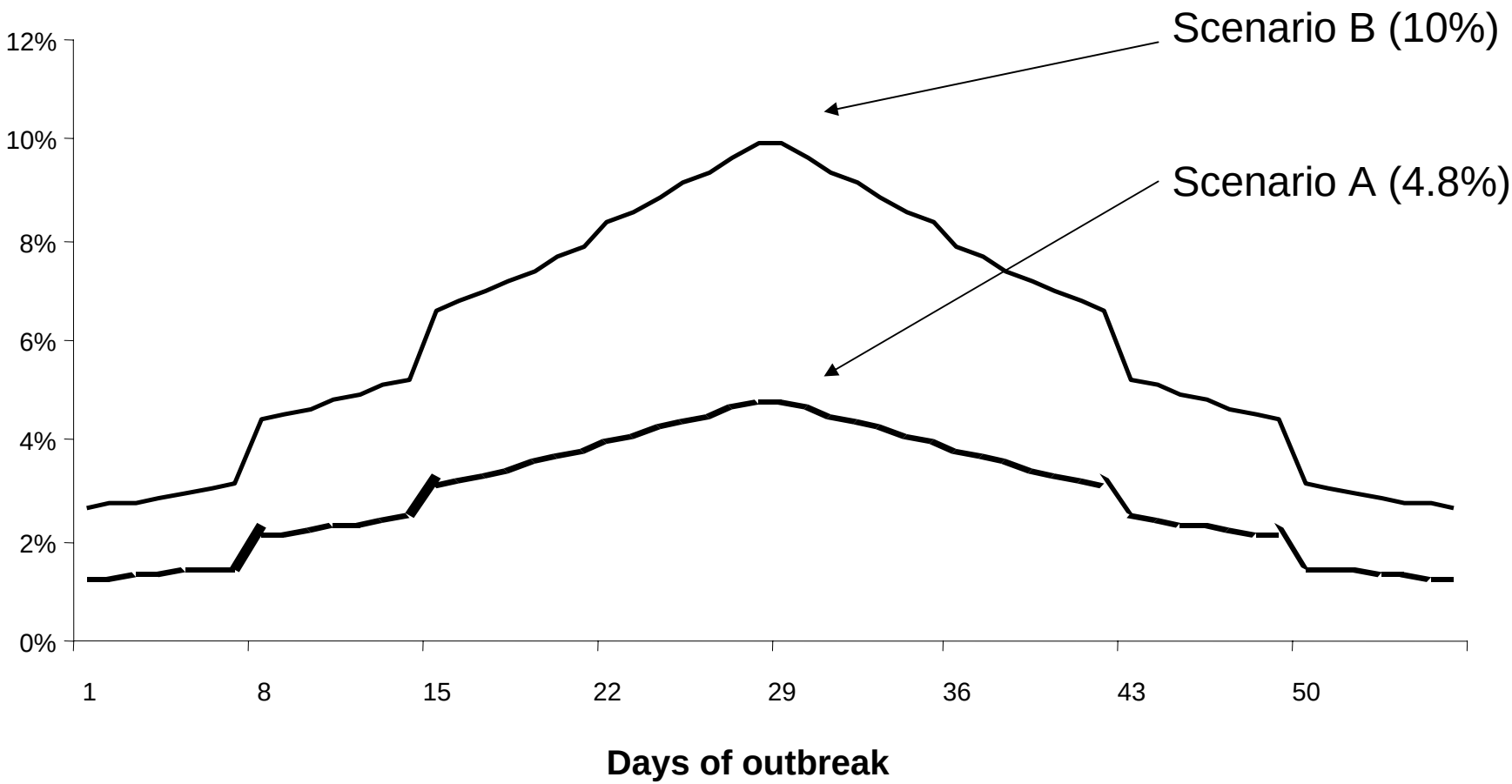
Clinical Influenza Attack Rates, 1918 and 1957



Model of Work Loss During a Pandemic

- Data extrapolated from 1957/68 pandemics
- Includes work loss due to
  - Illness, hospitalization, death
  - Caring for an ill family member
- Low/high estimates applied for days off work per episode

Proportion of Work Days Lost Due to Pandemic Influenza



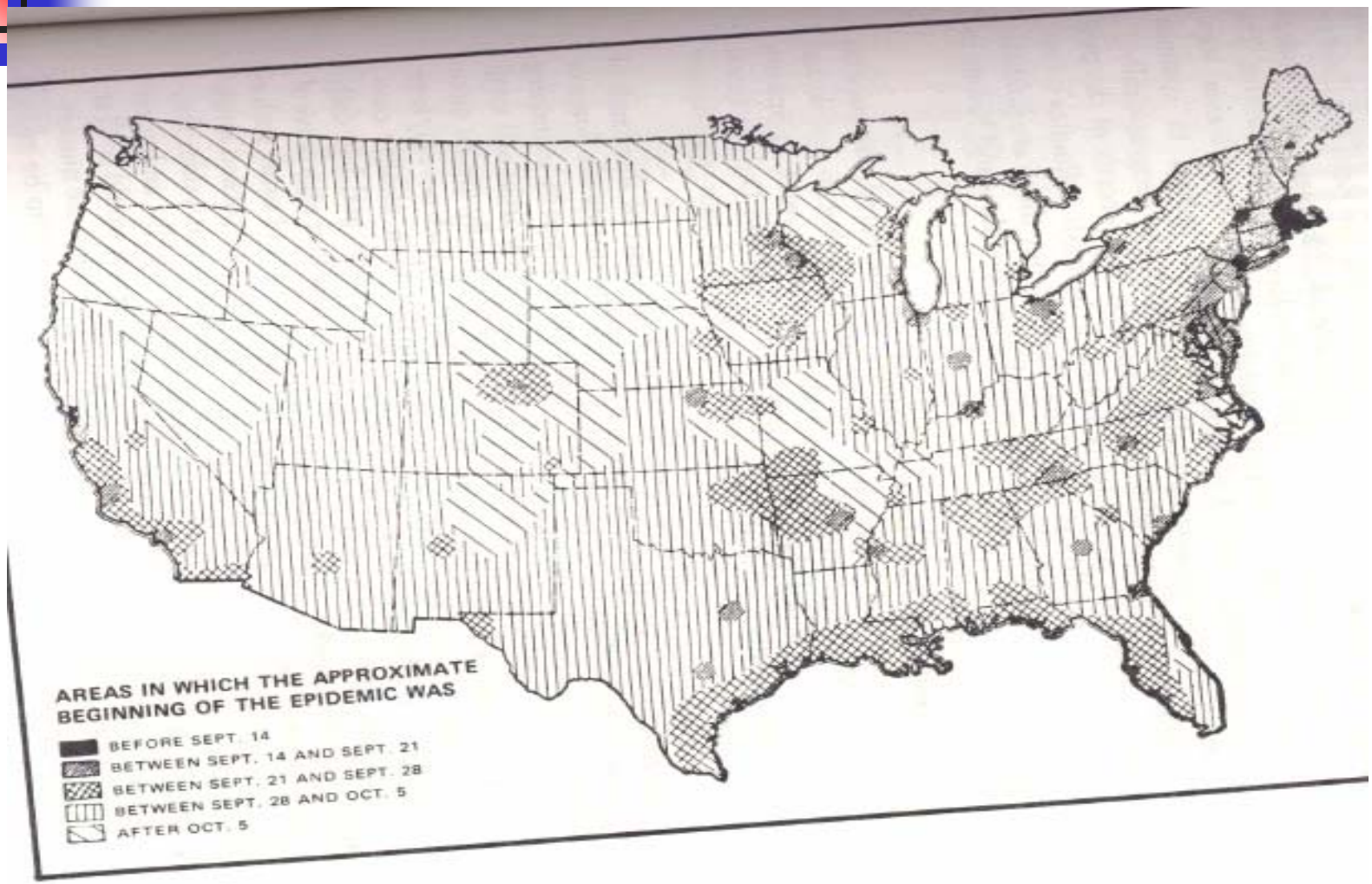
Limitations of Work Loss Model

- Unclear duration of work loss with illness
- Impacts will vary between communities, industries, and worksites
- Estimates are based on less severe pandemics
- Work loss from fear of becoming ill is not included

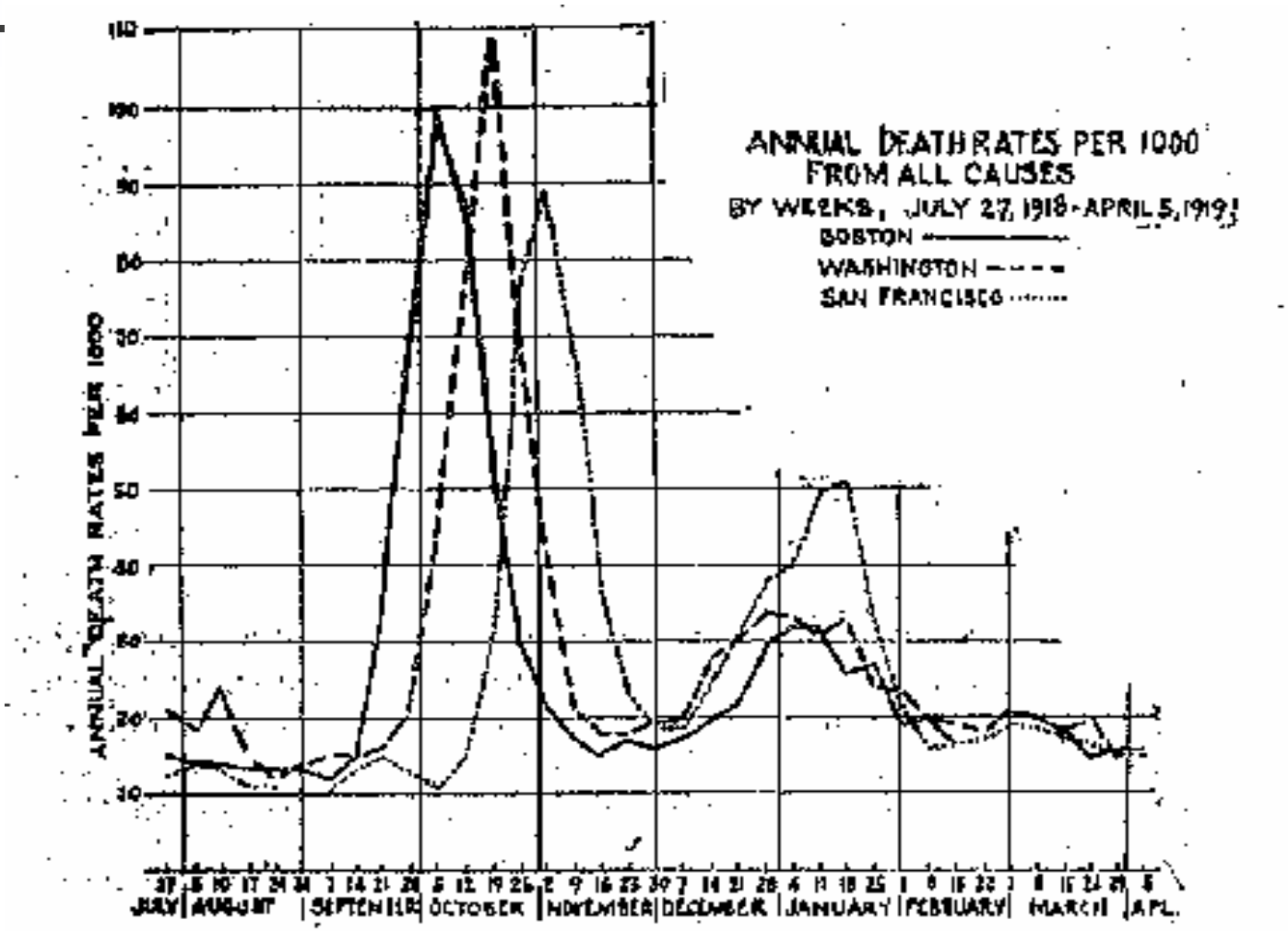
Pandemic Planning Assumptions 3: Seasonality & Disease Spread

- Introduction of disease into the U.S. will be at major travel hubs
- Multiple areas will be affected simultaneously
- Over 1-2 months the entire country will be affected
- Disease waves are likely to occur in the fall, winter, and possibly spring

Pandemic Influenza Spread: Sept. to Oct., 1918



1918-19 Influenza Pandemic: Death Rates in 3 Cities, Fall & Winter Waves



Asian Influenza in the U.S., July 1957

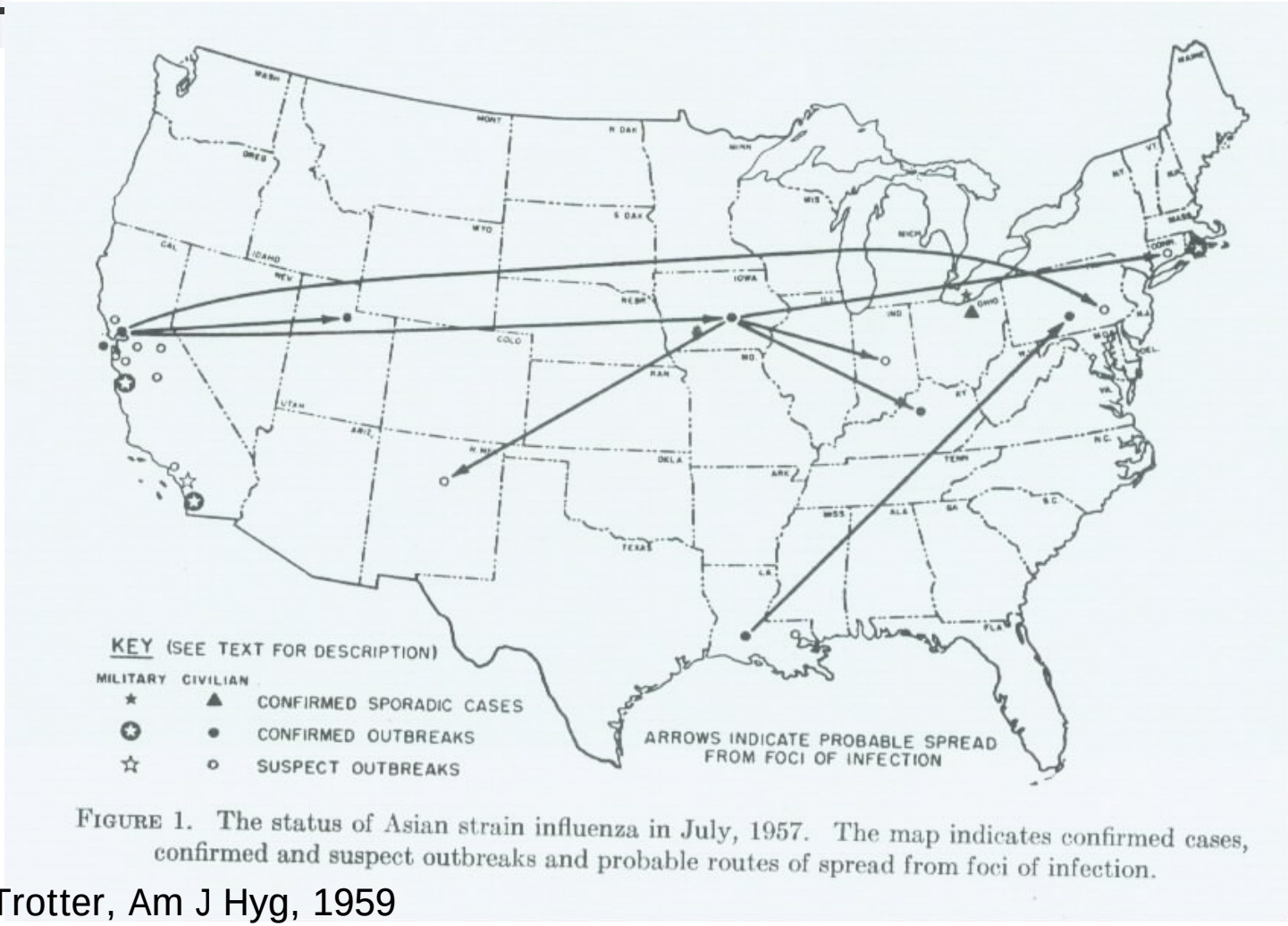


FIGURE 1. The status of Asian strain influenza in July, 1957. The map indicates confirmed cases, confirmed and suspect outbreaks and probable routes of spread from foci of infection.

Ref: Trotter, Am J Hyg, 1959

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Percentage of counties per State reporting Influenza outbreaks, July – October, 1957

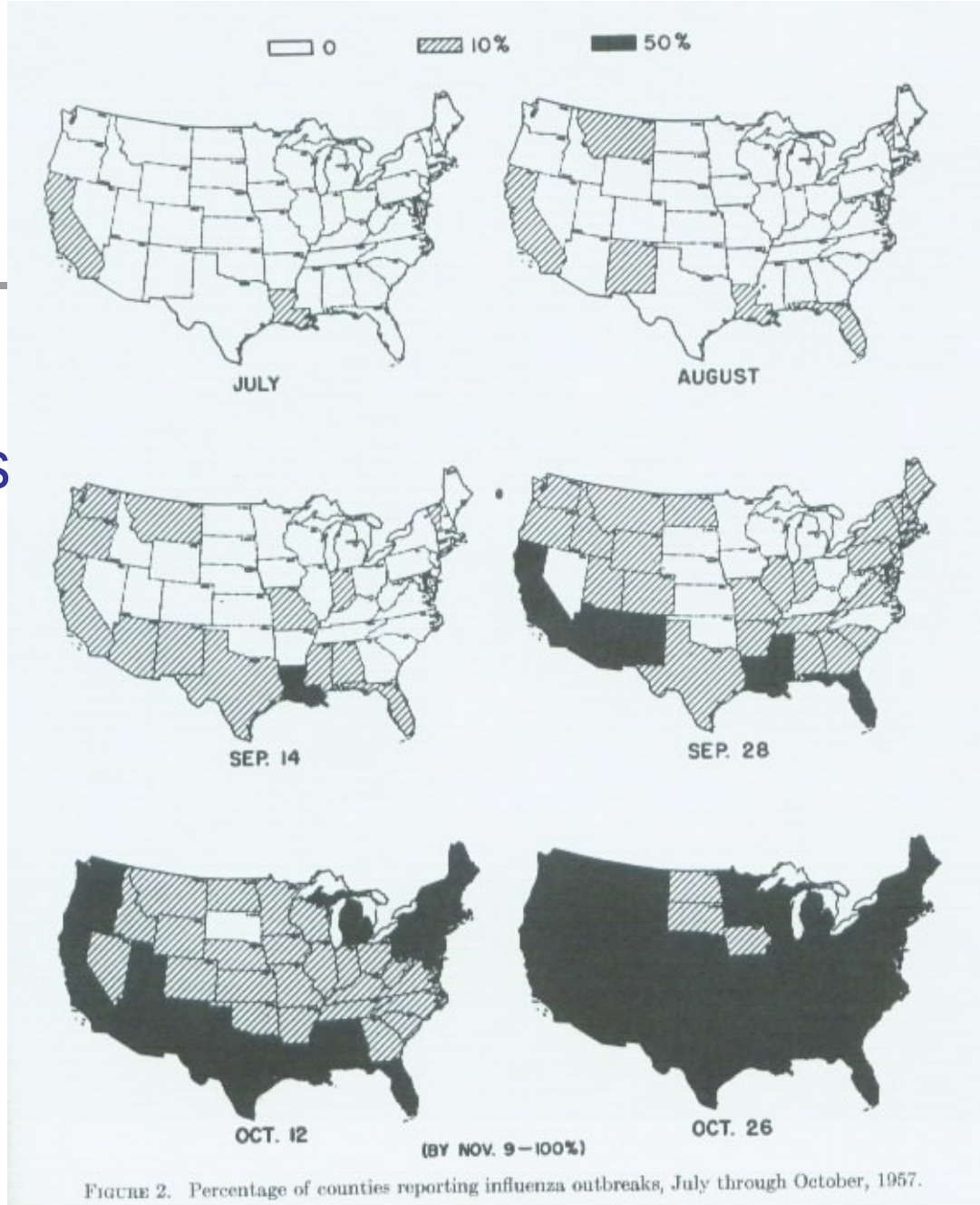


FIGURE 2. Percentage of counties reporting influenza outbreaks, July through October, 1957.

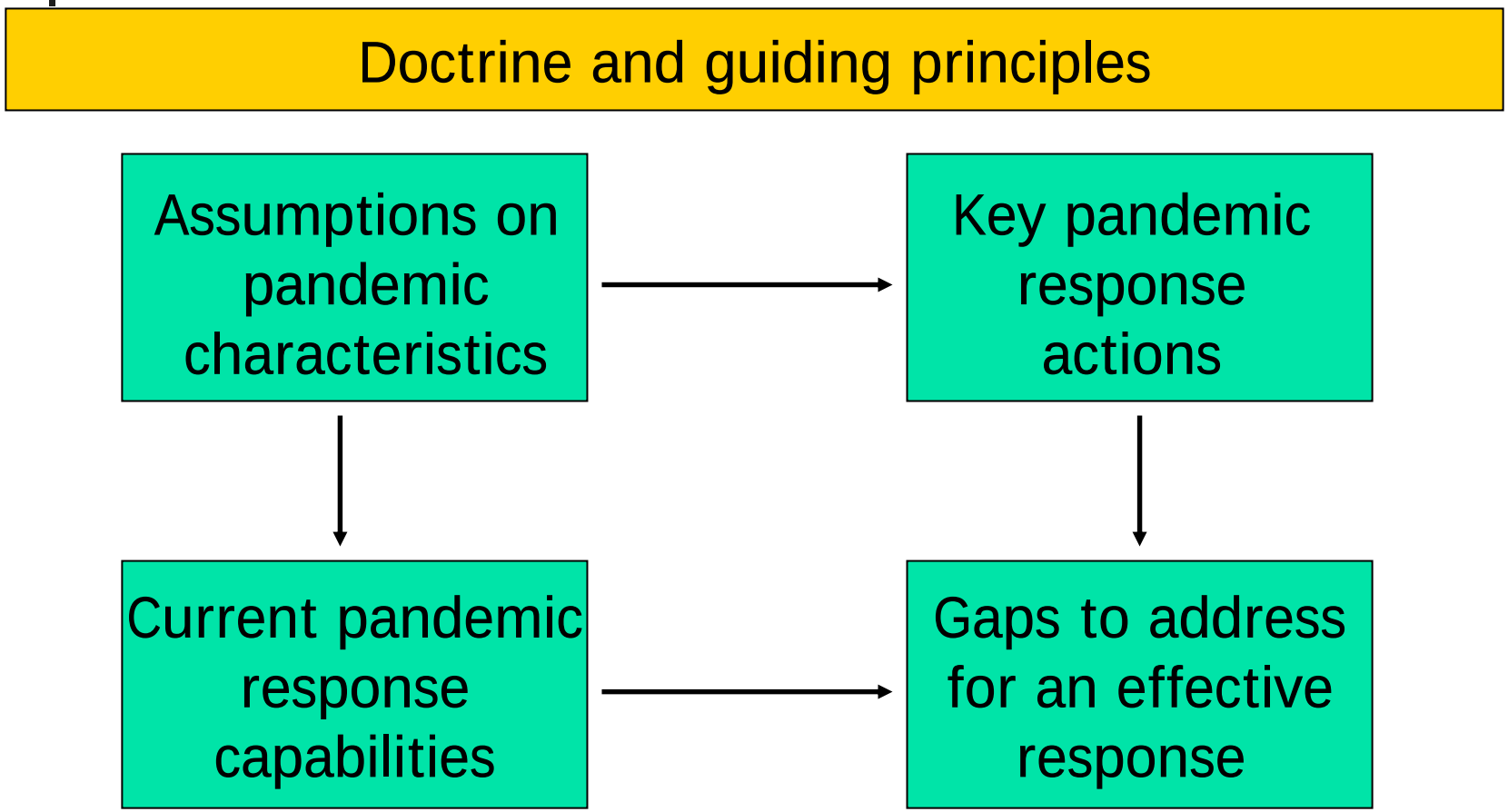
Ref: Trotter, Am J Hyg, 1959

Lessons From the Spread of Prior Pandemics

- Depending on timing and season, community outbreaks may be delayed after first introduction
- There is no consistent pattern of spread
  - Urban areas likely affected first
  - National spread within 1-2 months
- Many areas will have simultaneous outbreaks limiting ability to shift personnel and resources

The HHS Pandemic Plan: Vaccine & Antiviral Drugs

Basis for the HHS Pandemic Influenza Strategic Plan



Pandemic Influenza Vaccine

- Doctrine: sufficient vaccine available for the entire population within 6 months
- Current U.S. based vaccine production capacity
  - 1 U.S. manufacturer
  - 4-6 months for production of first vaccine doses
  - Capacity depends on amount of antigen required per dose and number of doses needed for protection
  - HHS support for cell culture based production but new vaccines and facilities will take ~5 years

U.S.-Based Influenza Vaccine Production Capacity

Estimated U.S.-based vaccine production	**Vaccinated / mo (2 doses)**	
	N	**% Pop**
Current capacity; 2 doses, 90 ug/dose	1.7 M	0.6%
2007 capacity (est); 2 doses, 90 ug/dose	3.3 M	1.1%
Current capacity; 2 doses, 18 ug/dose	8.3 M	2.8%

Pre-Pandemic Vaccine

- HHS strategy to stockpile pre-pandemic vaccine to protect 20 M persons for possible pandemic strains
  - H5N1 stockpile for 5.7 M civilians and 1.8 M military personnel by 2/06
  - Production limited to period between annual campaigns

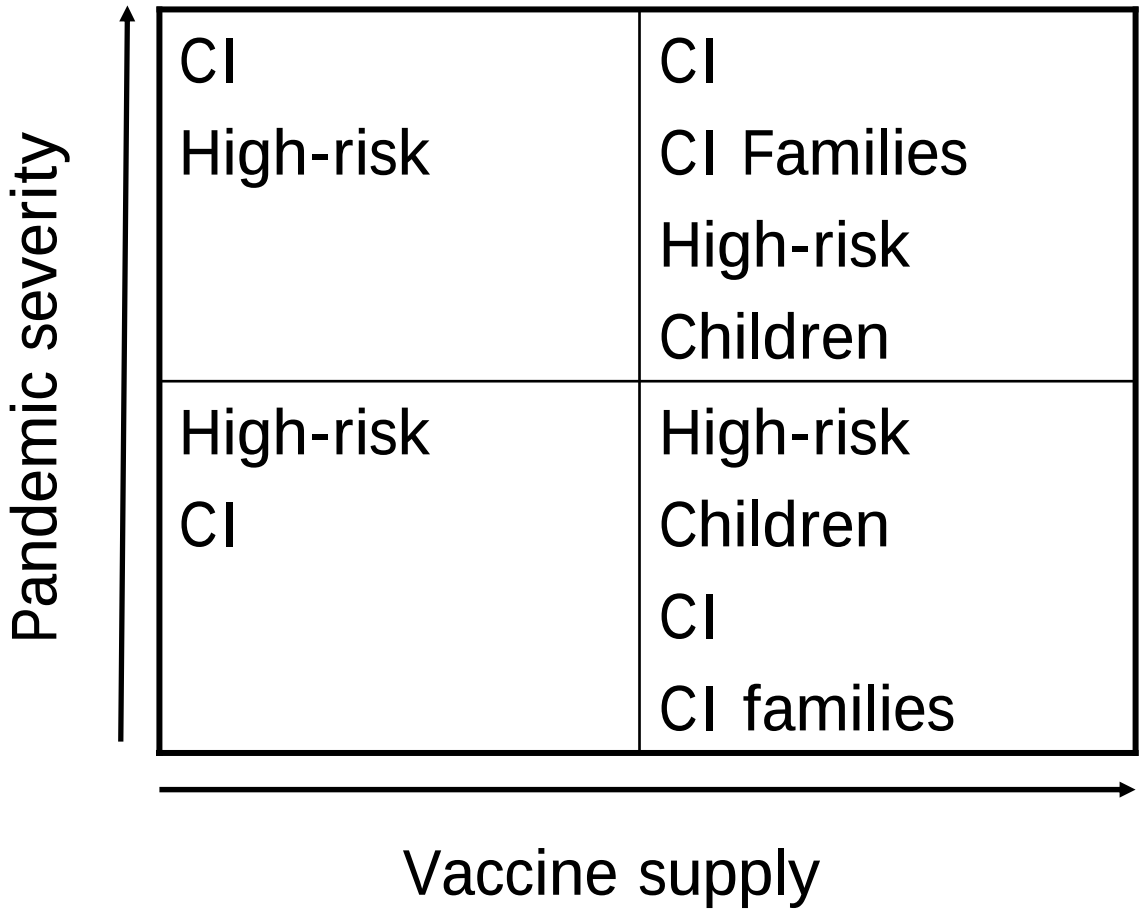
ACIP & NVAC Recommended Pandemic Vaccine Priority Groups

Tier	Priority groups	Popn. (10^6)	Cum pop
1	A. Essential HCW; vaccine & antiviral mfrs.	9	9
	B. Highest risk persons (age & underlying dis.)	26	35
	C. Household contacts of <6 mo & severely immunocompromised; pregnant women	11	46
	D. Key govt. leaders & pandemic responders	<1	47
2	A. Other high risk persons	59	106
	B. Critical infrastructure & other pandemic resp.	9	115
3	Key govt. health decision-makers; mortuary	NA	NA
4	Healthy 2-64 yr old not in other groups	186	300

Sec. Leavitt's Pandemic Vaccine Principles and Proposed Allocation

- Pandemic vaccine principles
  - Target pre-pandemic and pandemic vaccine to preserve national security, constitutional government, and critical infrastructures
  - State decision making on specific priority groups
- Proposed vaccine allocation
  - Preserve constitutional government (5%)
  - Support federal health care providers (5%)
  - Allocate to states *pro rata* (90%)

National Plan: “Pivot Points” for Vaccine Priority Groups



Pandemic Vaccine and Blood Supply

- ACIP/NVAC discussions
  - Blood center personnel included as priority group
  - Other groups (e.g., platelet or stem cell donors) not discussed
- HHS and national discussions
  - Principles but no specific target groups identified

Pandemic Antiviral Drugs

- Doctrine: stockpiled antiviral drugs for 25% of the population and for containment & outbreak control
  - 75 million treatment courses
  - 6 million courses for containment & outbreak control
- SNS assets and U.S. production capacity
  - 4.4 million neuraminidase inhibitor courses in the SNS
  - For oseltamivir, ~2 million courses in pharmacies and at distributors; and U.S. based production capacity ~1.5 million courses/mo

Proposed Approach to Antiviral Drug Purchasing

- HHS to purchase 44 M treatment courses and 6 M courses for containment
- States to purchase remaining 31 M courses
  - 1 to 3 federal funding match

NVAC Recommended Antiviral Drug Priority Groups & Strategies

Target Group	Est. Pop. (10^6)	Strategy	# Courses (10^6)	
			Group	Cumulative
Admitted patients	10.0	T	7.5	7.5
HCWs w/ patient contact	9.2	T	2.4	9.9
Highest risk outpatients	2.5	T	0.7	10.6
Pub health, pub safety & key govt decision makers	3.3	T	0.9	11.5
Increased risk outpatients	85.5	T	22.4	33.9
Outbreak response in LTCF	NA	PEP	2.0	35.9
HCWs in ER, ICU, EMS	1.2	P	4.8	40.7
Infrastructure & other HCWs	10.2	T	2.7	43.4
Other outpatients	180.0	T	47.3	90.7
Highest risk outpatients	2.5	P	10.0	100.7
HCWs w/ patient contact	8.0	P	32.0	132.7

Sec. Leavitt's Antiviral Drug Use Principles and Allocation

- Antiviral drug use principles
  - Contain at initial outbreak and delay spread, if feasible
  - Reserve for treatment rather than prophylaxis
  - State decision on targeting
- Proposed antiviral drug allocation
  - Contain an initial pandemic outbreak (5%)
  - Slow spread following first U.S. cases (5-10%)
  - Preserve constitutional government (5%)
  - Support federal health care providers (5%)
  - Allocate remainder to states *pro rata*

Pandemic Antiviral Drugs and Blood Supply

- NVAC discussions
  - Blood center personnel included as priority group
  - Other groups (e.g., platelet or stem cell donors) not discussed
- HHS and national discussions
  - Principles but no specific target groups identified

Conclusions and Next Steps

- HHS doctrine and pandemic vaccine and antiviral drug supply goals will minimize need for targeting & priority groups
- But a significant vaccine supply gap will remain for >5 years and antiviral drug gap for ~2 years
- Specificity of federal and HHS guidance on priorities is unclear
- Integrating blood community into discussions at national and state levels would be important