

Guidance on Antiviral Drug Use and Stockpiling of Antiviral Drugs and Respirators and Facemasks

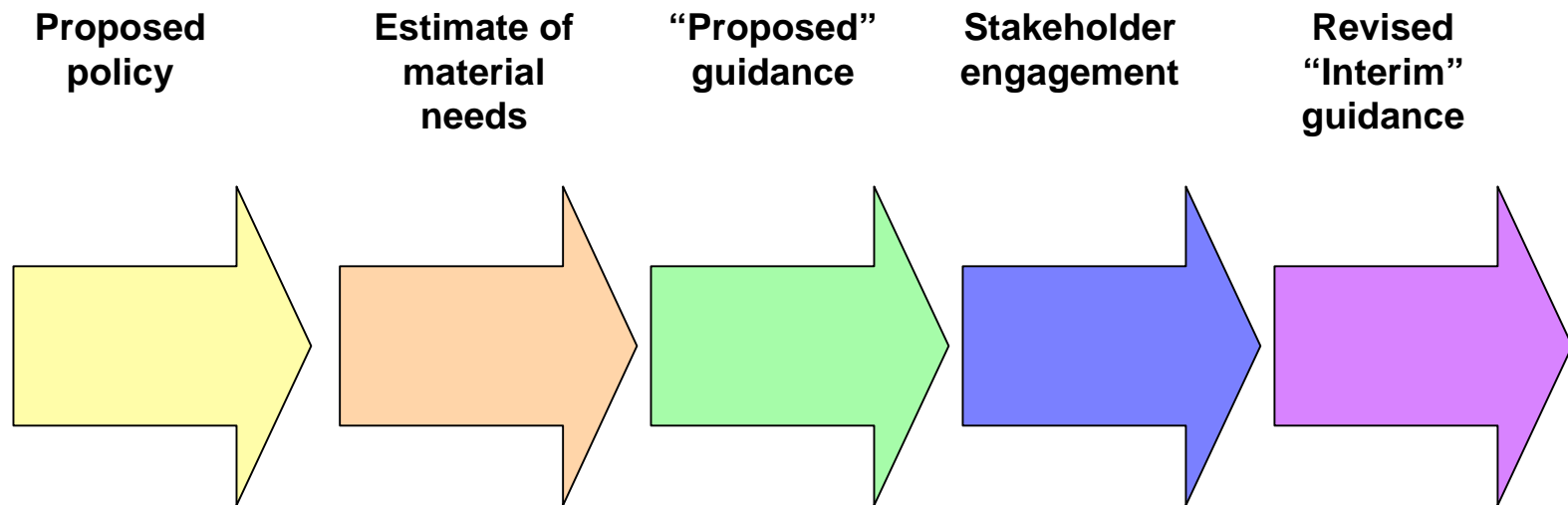
National antiviral drug use guidance	Ben Schwartz, HHS bxs1@cdc.gov
Guidance on stockpiling antiviral drugs	Lisa Koonin, CDC lmk1@cdc.gov
Guidance on stockpiling respirators and facemasks	Jim Maddux, DOL/OSHA Maddux.Jim@dol.gov



Meeting Agenda

- Presentation
 - Updated proposed guidance on antiviral drug use strategies
 - Proposed guidance on antiviral drug stockpiling for employers
 - Proposed guidance on stockpiling of respirators and facemasks by employers
- Discussion
 - Does the guidance align with pandemic preparedness priorities?
 - How effectively is the guidance likely to be implemented by employers?
 - What barriers may limit the ability of employers to implement the guidance?
 - What can the Federal government do to help overcome those barriers?

Policy Development on Antiviral Drug Use and Stockpiling of Antiviral Drugs, Facemasks, and Respirators



- Meetings with State/local govt, healthcare, emergency services, business, labor
- Report to HHS leadership
- Consideration in decision-making

Background on Antiviral Drug Use

- Treatment
 - Shortens illness duration by 1 – 4 days depending on how early it's begun
 - Reduces complications and hospitalization
- Prophylaxis (preventive use)
 - Types of prophylaxis
 - Before exposure for the duration of the influenza outbreak (outbreak prophylaxis) – uses up to 8 drug regimens per person
 - Post-exposure (PEP) – uses 1 drug regimen per person
 - Impacts
 - Reduces risk of becoming ill by 70 – 90% among family contacts of an influenza patient
 - Decreases transmission among contacts and in communities

Reconsideration of Antiviral Drug Strategies

- Current national strategies
 - Use antiviral drugs for containment and treatment
- Rationale for reconsideration
 - Allowed by increased manufacturing capacity
 - Recognizes potential value of prophylaxis to 1) maintain healthcare and other critical services; 2) reduce rates of illness as part of community mitigation
- Interagency working group on antiviral drug use
 - Representatives from Federal agencies, State/local/tribal public health
 - Consider drug effectiveness & resistance, mathematical modeling results, potential absenteeism & continuity of operations, ethics & values, and stakeholder preferences

Antiviral Working Group Assumptions

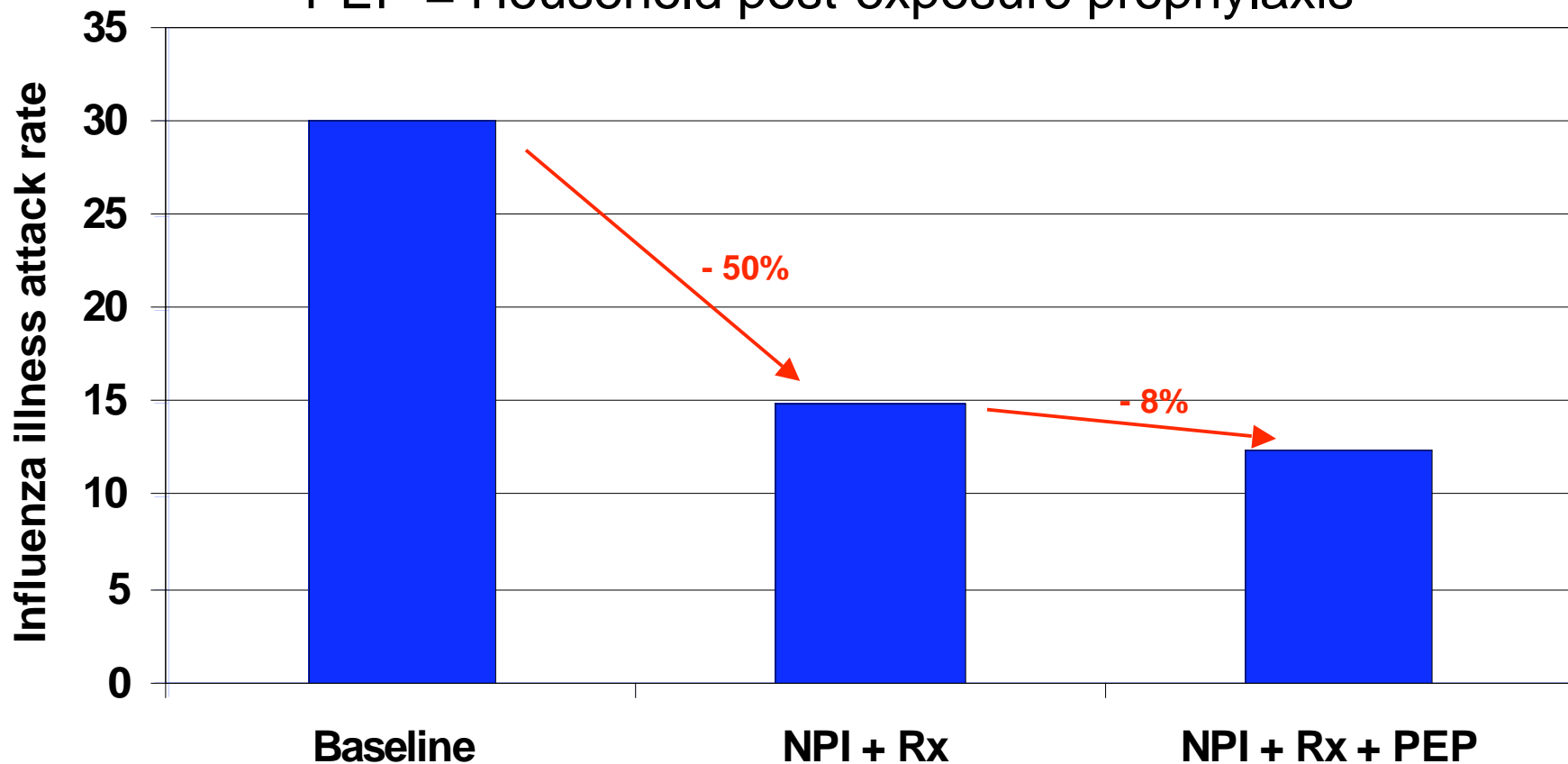
- Severe pandemic
- Antiviral drug strategies implemented with other response measures
 - Community mitigation
 - Infection control
 - (Vaccination)
- 60% of cases will present for care and be treated and household members could receive prophylaxis
- Community outbreaks last 12 weeks

Proposed Expansion of National Antiviral Drug Strategies

- Outbreak prophylaxis
 - Front-line healthcare workers
 - Emergency responders (EMS, Fire, Law enforcement)
 - Small cadre of unique/specialized critical infrastructure workers
- Post-exposure prophylaxis
 - Household contacts of influenza patients
 - Persons who are severely immunocompromised
 - In closed settings (nursing homes or prisons) when disease outbreaks occur

Modeled Impact of PEP on Pandemic Influenza Illness Rate

NPI = Non-pharmaceutical interventions; Rx = treatment;
PEP = Household post-exposure prophylaxis



See Community Mitigation Guidance; impact of PEP based on model by N. Ferguson

What is Not Included as a National Requirement

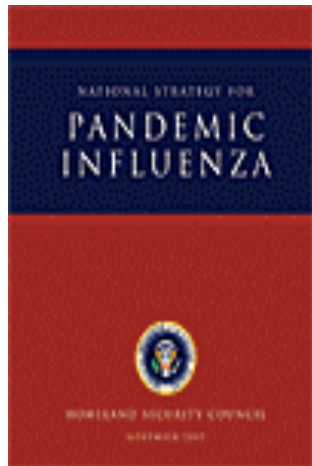
- Prophylaxis for workers generally
 - Continuity of operations planning expected for businesses generally; especially those providing critical services
 - Various approaches to protect workers
 - May choose to include prophylaxis
 - HHS guidance will be available
- Prophylaxis for family members of healthcare or emergency response workers
 - No increased risk to families if the worker is protected
 - Treatment and PEP available for families

Shared Responsibility for Implementation

- What is the role of government, organizations, employers, and individuals?
- If employers are responsible for a component of this national requirement...
 - How effectively is the guidance likely to be implemented?
 - What barriers may limit the ability of employers to implement the guidance?
 - What can the Federal government do to help overcome those barriers?

**Proposed Considerations for
Antiviral Drug Stockpiling by
Employers
In Preparation for an Influenza
Pandemic**

Draft Guidance for Stakeholder Discussion



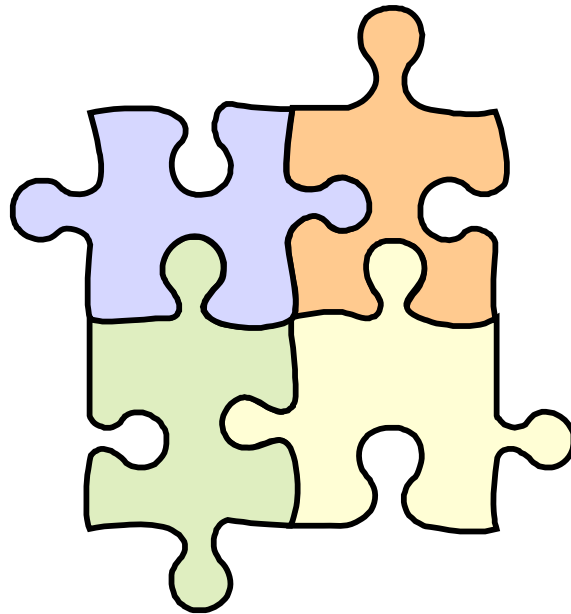
Role of Businesses/Employers in Pandemic Planning and Response

- Protect employees' health and safety
- Maintain business continuity
- Preserve function of critical infrastructure

How can private sector caches complement public sector stockpiles to improve community response?

Proposed Guidance

- Encourage employers to consider stockpiling antiviral drugs for use during an influenza pandemic as a part of comprehensive pandemic planning



Employers may choose to purchase antiviral drugs for stockpiling for several reasons:

- Assure early treatment to employees who are ill;
- Provide pre-exposure prophylaxis for employees:
 - probable occupational exposure/risk to ill persons,
 - essential to a business' operations,
 - certain critical infrastructure workers, or
 - all of workforce;
- Provide post-exposure prophylaxis following household* or workplace exposure; and
- Protect overseas employees and operations where U.S. government pandemic response activities will not reach.

* As described by the *Community Mitigation Guidance*

Special considerations for U.S. businesses with overseas operations

- *“American citizens should take note that the Department of State cannot provide Americans traveling or living abroad with medications or supplies even in the event of a pandemic.”*
- *“U.S. embassies and consulates do not have supplies of this drug [oseltamivir (Tamiflu ®)] for use by private American citizens abroad.”*

For more information see:

http://www.travel.state.gov/travel/tips/health/health_1181.html

Key Issues for Employer Planning for Antiviral Stockpiles

- Plan for collaboration with State/local public health
- Comply with State/Federal prescribing and dispensing laws and regulations
- Consider ethical and equity concerns
- Cost and logistical concerns
- Develop stockpiling and dispensing models
 - Utilize existing health care or pharmacy facilities (preferred)
 - Contract with a wholesale drug distributor
 - Stockpile onsite by businesses
 - Dispense pre-pandemic
- Educate employees

Final thoughts

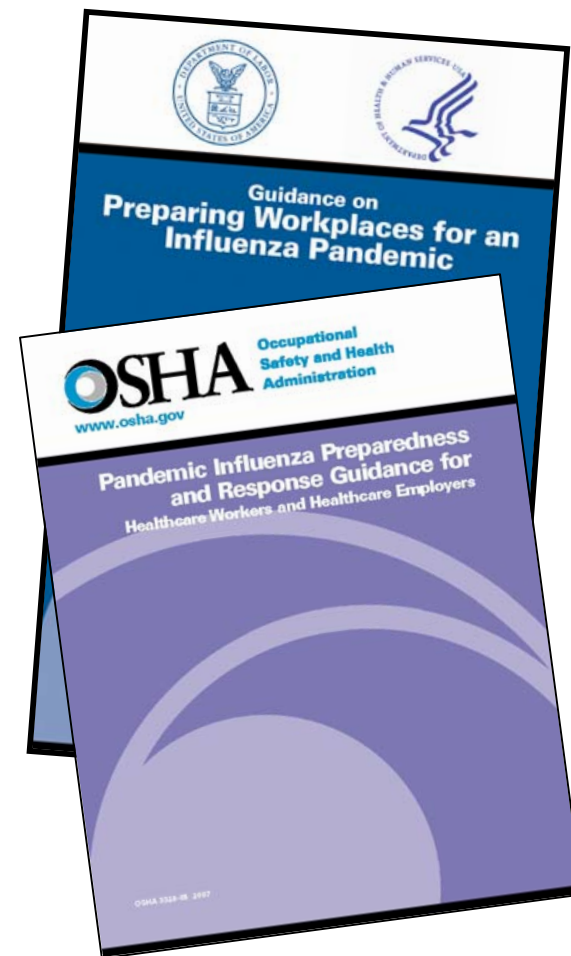
- Guidance does not establish the requirement or expectation that all businesses/employers stockpile antiviral drugs.
- Key considerations for employer stockpiling include issues of: risk of exposure and continuity of operations
- If antivirals are stockpiled, assure drugs are used:
 - As part of a comprehensive pandemic planning strategy in conjunction with other measures (e.g. *Community Mitigation* measures, PPE, hand hygiene)
 - In compliance with State laws and regulations
 - With consideration to ethical issues
 - In coordination with State and local pandemic plans

**Proposed Considerations for
Respirator and Facemask
Stockpiling by Employers
In Preparation for an
Influenza Pandemic**

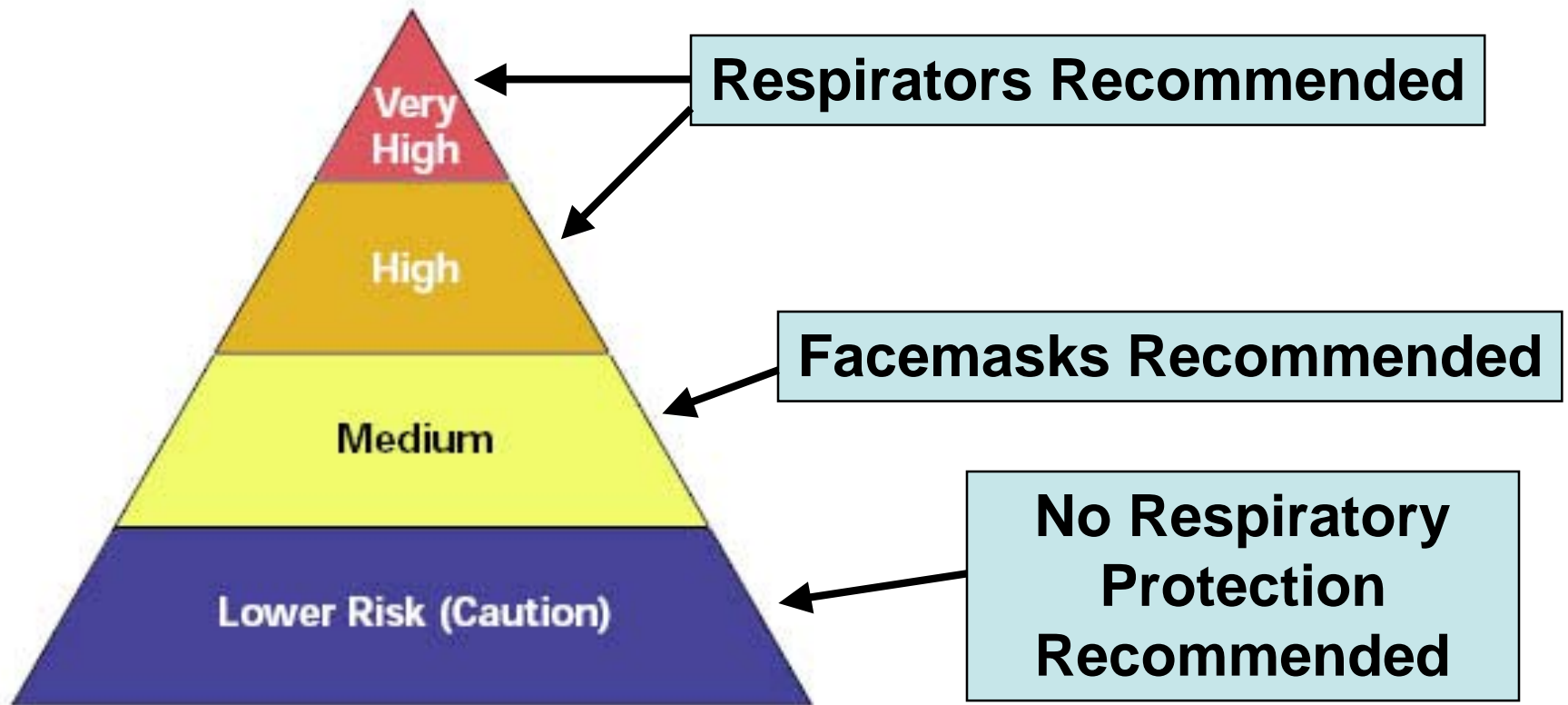
Proposed Guidance for Stakeholder Discussion

Earlier Guidance

- Earlier this year, DOL-OSHA in collaboration with HHS published a guidance product titled, *Preparing Workplaces for an Influenza Pandemic*.
 - Provides guidance for general industry employers
- DOL-OSHA also published a guidance product titled, *Pandemic Influenza Preparedness and Response Guidance for Healthcare Workers and Healthcare Employers*.
 - Provides guidance for healthcare employers



Occupational Risk Pyramid for Pandemic Influenza



Proposed Respirator and Facemask Stockpiling Guidance

- Encourages employers to stockpile respirators and facemasks so they can protect employees during a pandemic.
- Discusses various types of respirators and facemasks available for use.
- Provides estimates of the quantity of N95 respirators and/or facemasks employers should stockpile.

Device Estimates for Employees

Occupational setting	Proportion of medium or higher risk employees	Number of respirators or facemasks per employee per work shift		Number of respirators or facemasks per employee for a pandemic (120 work days)	
		N95 Respirators (high or very high risk)	Facemasks (medium risk)	N95 Respirators (high or very high risk)	Facemasks (medium risk)
Healthcare					
Hospital	67%	2	0	240	0
Outpatient office/clinic	67%	4	0	480	0
Long term care	25%	1	3	120	360
Home healthcare	90%	2	4	240	480
Emergency medical services	100%	8	0	960	0
First responders					
Law enforcement	90%	2	2	240	240
Corrections	90%	1	3	120	360
Fire department (non-EMS, career and volunteer)	90%	2	2	240	240
Medium risk employees	NA	0	2	0	240

Facemasks Estimates for Patients and Other Contacts in High Exposure Risk Settings

Occupational setting	Facemasks needed
Healthcare	
Hospital (inpatient)	2 per patient per day
Essential visitors	3 per visitor per day
Emergency Rooms	1 per ill person
Outpatient office/clinic	2 per patient visit
Long term care	1 per patient per day
Home healthcare	1 per patient visit
Emergency medical services	1 per ill person
First responders	
Law enforcement	1 per ill person
Corrections	2 per ill inmate per day
Fire department	1 per ill person

Questions for Discussion

- Does the guidance align with pandemic preparedness priorities?
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