# INTERIM UPDATED PLANNING GUIDANCE ON • Allocating and Targeting Pandemic Influenza Vaccine During an Influenza Pandemic





U.S. Department of Health and Human Services Centers for Disease Control and Prevention

# **Executive Summary**

During a future influenza pandemic, effective allocation and administration of pandemic influenza vaccine will play a critical role in preventing influenza and reducing its effects on health and society. Although the overarching aim of the national pandemic influenza vaccination program is to vaccinate all persons in the United States (U.S.) who choose to be vaccinated, prior to the peak of disease, the vaccine supply to meet this goal may not be sufficient early in a pandemic.

Therefore, the U.S. government is investing significant resources to create and evaluate new vaccine development approaches and production technologies and to establish and maintain a pre-pandemic influenza vaccine stockpile of bulk vaccine against viruses with pandemic potential. Recognizing that demand may exceed supply at the onset of a pandemic, federal, state, tribal and local governments, communities, and the private sector have asked for planning guidance on who should receive vaccination early in a pandemic.

Given that influenza vaccine supply will increase incrementally as vaccine is produced during a pandemic, targeting decisions may have to be made. Such decisions should be based on vaccine supply, pandemic severity and impact, potential for disruption of community critical infrastructure, operational considerations, and publicly articulated pandemic vaccination program objectives and principles. The overarching objectives guiding vaccine allocation and use during a pandemic are to reduce the impact of the pandemic on health and minimize disruption to society and the economy.

These guidelines replace the 2008 *Guidance on Allocating and Targeting Pandemic Influenza Vaccine*. This document was developed to update and provide interim guidance for planning purposes and to provide the rationale for a national vaccination program during a pandemic that also allows for local adjustment where appropriate. National guidance for targeting pandemic influenza vaccination planning is provided with the understanding that the numbers of people within each group are estimates for planning purposes and actual recommendations may change for a future pandemic and as the pandemic progresses.

The 2008 Guidance was developed based on key scientific information and extensive input from the public and stakeholders, including businesses and community organizations, who provided key perspectives on public values and priorities about which subgroups would require the earliest vaccine protection in the event of an influenza pandemic. The principles about the core objectives and guiding principles established previously with stakeholders are preserved in this document.

Several new elements have been incorporated into the 2018 guidelines. First, the guidance uses updated pandemic severity categories based on the current CDC Pandemic Severity Assessment Framework<sup>1</sup>. Second, the updated guidance incorporates lessons learned from the 2009 H1N1 pandemic response, such as the unpredictability of pandemic severity and timing, variability of the impact of pandemic severity on critical infrastructure functions, challenges with vaccine supply overall and variability among manufacturers, and the need for flexibility at the state, tribal, and local levels to best manage vaccine supplies to meet local needs. Third, this document includes the consideration that two doses of vaccine and co-administration of adjuvant may be required to produce protective immunity in some scenarios. Fourth, pharmacists and pharmacy technicians are included in Tier 1<sup>ª</sup>, since pharmacists (and pharmacy technicians) will be crucial to antiviral dispensing and many pharmacists will be pandemic vaccine immunizers. Finally, the estimated numbers of population groups are based on 2015 U.S. Census population estimates.

<sup>&</sup>lt;sup>a</sup> Tier 1 includes the highest priority population groups to receive vaccination if there is limited vaccine supply for any level of pandemic severity. See Table 1.

### Introduction

T ffective allocation of pandemic influenza vaccine will play a critical role in preventing influenza and reducing its effects on health and society during a future pandemic. Although the timing and severity of a future pandemic and characteristics of the next pandemic influenza virus strain are not known, it is important to plan and prepare. The overarching *aim* of the national pandemic influenza vaccination program is to vaccinate all persons in the United States (U.S.) who choose to be vaccinated, prior to the peak of disease. The U.S. has established a goal of having sufficient pandemic influenza vaccine available for an effective domestic response within 4 months of a pandemic declaration with first doses available in 12 weeks of the President or the Secretary of Health and Human Services declaring a pandemic<sup>2</sup>. To meet this goal, the U.S. government is investing significant resources to create and evaluate new vaccine development approaches and production technologies and to establish and maintain a pre-pandemic influenza vaccine stockpile of bulk vaccine against viruses with pandemic potential.

Despite these investments, the vaccine supply to meet this goal may not be sufficient early in a pandemic. Pandemic vaccine availability will depend on the degree to which any stockpiled vaccines matches the circulating pandemic strain, vaccine characteristics (e.g., amount of antigen, number of doses required, and use of adjuvant needed to produce an acceptable immune response), the type of pandemic vaccine being developed, growth properties of the candidate vaccine virus, and existing influenza vaccine manufacturing capacity. The Advisory Committee on Immunization Practices (ACIP), a federal advisory committee that develops recommendations for the director of the Centers for Disease Control and Prevention (CDC) on how to use vaccines to control diseases in the United States, would serve as the advisory committee for developing recommendations for use of pandemic vaccine. However, recognizing that demand may exceed supply at

the onset of a pandemic, federal, state, tribal, and local governments, communities, and the private sector have asked for planning guidance on who should receive vaccination early in a pandemic. Given that influenza vaccine supply will increase incrementally as vaccine is produced during a pandemic, targeting decisions may have to be made. Such decisions should be based on vaccine supply, pandemic severity, potential for disruption of community critical infrastructure, and publicly articulated pandemic vaccination program objectives and principles. The overarching objectives guiding vaccine allocation and use during a pandemic are to reduce the impact of the pandemic on health and minimize disruption to society and the economy. Specifically, the targeting strategy aims to protect those who will maintain homeland and national security, are essential to the pandemic response and provide care for persons who are ill, maintain essential community services, be at greater risk of infection due to their job, and those who are most medically vulnerable to severe illness such as young children and pregnant women.

Issues to consider in drafting interim guidance on pandemic influenza vaccination are different and more complex than in developing recommendations for annual vaccination against seasonal influenza. In contrast with seasonal influenza, a pandemic is caused by a novel virus that has not circulated in humans, and it is assumed that the majority of the population may not have immunity to the virus, that many more people will become ill, and that rates of severe illness, complications, and death may be much higher and more widely distributed throughout the population.

The greater frequency and severity of disease will increase the burden on the health care system and, combined with concerns about the risk of ongoing transmission in the community, may increase rates of absenteeism and disruptions in the availability of critical products and services in health care and other sectors. Similarly, homeland and national security and other critical infrastructure (e.g., transportation and power supply) could be threatened if illness among critical personnel reduces their capabilities.

This document was developed to update and provide interim guidance for planning purposes and to provide the rationale for a national vaccination program during a pandemic that also allows for local adjustment where appropriate. It is important that national-level interim guidance acknowledges that plans need to include flexibility to adjust to changing circumstances during a pandemic, because many factors will remain unknown prior to the emergence of a novel pandemic virus, including the status of the pandemic vaccine supply, the severity of illnesses caused by the pandemic virus (including an assessment of population segments at highest risk for severe disease), vaccine effectiveness, operational considerations, and differences among local situations. Therefore, in addition to articulating the principles that guide pandemic vaccine allocation, this document also outlines a process to develop and adjust vaccination recommendations at the onset and during a pandemic.

Vaccination remains the most effective tool used to fight the spread of influenza. Additional public health measures taken by communities, businesses, and households in a severe pandemic may help reduce potential exposure to the pandemic influenza virus and slow the spread of infection. These measures include the isolation (including self-isolation) of ill persons while contagious, social distancing (as warranted by the severity of the pandemic), using facemasks and respirators in appropriate settings, washing hands, and covering coughs and sneezes. These strategies will be the initial mainstay of a pandemic response before vaccine is available and will continue to have important effects throughout a pandemic. Guidance on vaccine use is meant to be applied in conjunction with and in the context of these other pandemic response efforts. In particular, a successful pandemic vaccination program will require a well-organized, coordinated, and comprehensive communication effort with stakeholders and the general public, during the planning process and throughout all phases of the pandemic as it progresses. More information about pandemic planning and response measures is provided at https://www.cdc.gov/ flu/pandemic-resources/index.htm.

#### **Guidance Development and Revision**

**F** ollowing the experience gained in responding to the emergence of the Severe Acute Respiratory Syndrome (SARS) in 2003 and the global spread of the avian influenza A (H5N1) virus that began in 2003, the U.S. government initiated a process to develop guidance in a number of areas for the public and private sectors to prepare for an influenza pandemic.

The initial draft of this vaccine allocation guidance was published in 2008 by a federal interagency working group whose members represented all sectors of the government. Their approach was based on the best scientific information available at that time (e.g., historical data, vaccine supply, vaccine impact in differ-

ent scenarios, and different population groups), and directly considered the values of our society and the ethical issues involved in planning a phased approach to pandemic vaccination that, by necessity, means that some people will receive vaccine before others. Information considered by the working group included assessments of candidate pandemic vaccines, national and homeland security issues, essential community services and the infrastructure and workforce critical to maintaining them, and the perspectives of state and local public health and homeland security experts. Historical analysis of the influenza pandemics of 1918, 1957, and 1968 and their impacts also provided valuable insights to this guidance.

In addition to key scientific information, meetings with the public and stakeholders, including businesses and community organizations, provided key perspectives on public values and priorities about which subgroups would require the earliest vaccine protection in the event of an influenza pandemic. Meeting participants discussed and rated the importance of potential vaccination program objectives based on a severe pandemic scenario. A key principle established by the working group and reinforced by public and stakeholder input (http://ppc.unl. edu/wp-content/uploads/2008/02/Pandemic-Infuenza-Evalaution-Report.pdf) was that the goals to reduce illness and associated disruption to society and the economy, "cannot be achieved by targeting vaccine to one occupational or risk group at the exclusion of others." Notably, pandemic planning working groups, public engagement meetings, and stakeholder meetings came to the same conclusions about which program objectives were the most important:

- Protecting those who are essential to the pandemic response and provide care for persons who are ill,
- Protecting those who maintain national security and essential community services,
- Protecting children and pregnant women, and
- Protecting workers who are at greater risk of infection due to their job.

Working group discussions also highlighted the important federal objective of maintaining homeland and national security.

# General Principles and Interim Guidance on Pandemic Vaccination

(Established in 2008)

• At the time of the next pandemic, CDC, with input from across the U.S. Department of Health and Human Services (HHS), U.S. Department of Homeland Security (DHS), other relevant federal agencies will:

- o Assess pandemic severity,
- Determine whether the pandemic is likely to result in significant and disruptive workplace absenteeism (especially among critical workforce),
- Advise whether vaccine targeting guidance should be used, and if so, how it should be modified based on the characteristics of the emerging pandemic and pandemic vaccine availability, and
- Assess vaccine in the federal stockpile to determine whether it can be used to reduce the impact of the pandemic.
- The need to target vaccine to maintain national security, health care, and other essential community services and to preserve critical infrastructure will depend on the severity of the pandemic and vaccine availability, as rates of absenteeism and the ability to supply essential products and services will differ for more or less severe pandemics. As a result, groups identified for earlier vaccination will differ depending on pandemic severity and vaccine supply.
- Allocation of pandemic vaccines by the U.S. government to states and territories will likely be in proportion to states and territories' populations.
- States should follow the national guidance to ensure fairness and uniformity across the U.S. and minimize confusion, as much as possible. Within the parameters of the guidance, states will have the authority to approve vaccine orders from providers in their jurisdiction in order to distribute vaccine to meet the specific needs in their populations. In past pandemics, groups at increased risk for serious illness and death have differed by age and health status. Because the high-risk groups in the next pandemic are not known in advance, planners should consider how the guidance might be modified for different pandemic scenarios (see Implementation of this guidance during a future pandemic, page 14).

• Guidance on pandemic vaccine allocation and targeting will be reassessed periodically before and throughout a pandemic to consider new scientific information, including risk of severe outcomes by age and risk groups, changes in vaccine production capacity, and advances in other health and public health response measures.

This revised guidance updates the prior 2008 guidance with the following major changes:

- Updates severity categories based on the current CDC Pandemic Severity Assessment Framework<sup>2</sup>. (https://www.cdc.gov/flu/ pandemic-resources/national-strategy/ severity-assessment-framework.html)
- Incorporates lessons learned from the 2009 H1N1 pandemic response, such as the unpredictability of pandemic severity and timing, variability of the impact of pandemic severity on critical infrastructure functions, challenges with vaccine supply overall and variability among manufacturers, and the need for flexibility at the state, tribal, and local levels to best manage vaccine supplies to meet local needs.
- Includes the consideration that two doses of vaccine and co-administration of adjuvant may be required to produce protective immunity in some scenarios.
- Moves pharmacists and pharmacy technicians to Tier 1<sup>b</sup>, since pharmacists and pharmacy technicians will be crucial to antiviral dispensing, and many pharmacists will be pandemic vaccine immunizers.
- Updates U.S. population numbers based on the 2005 U.S. population of 300 million to the population estimates from the 2015 U.S. Census (321 million)<sup>3</sup>.

Input from multiple sectors and public health officials also informed this revision. Importantly, however, the 2009 H1N1 pandemic and subsequent discussions with stakeholders reinforced the core objectives and guiding principles established previously with stakeholders, and preserved in this document.

The guidance also includes consideration for allocating stockpiled pre-pandemic vaccine (i.e., vaccine produced against novel influenza A viruses with pandemic potential), if stockpiled vaccine is likely to be effective against the pandemic virus. In addition, the guidance now includes the consideration that two doses of vaccine and co-administration of adjuvant may be required to produce protective immunity in some scenarios.

#### Framework for Targeting Pandemic Influenza Vaccine

Revised guidance for allocating and targeting initial vaccination of certain groups includes a structure, as in the 2008 guidance, that defines population groups in four broad categories that correspond with the objectives of a pandemic vaccination program – to protect people who 1) maintain homeland and national security, 2) provide health care and community support services, 3) maintain critical infrastructure, and 4) are in the general population.

Each broad category includes specific populations that are defined by their occupation or by their age and health status (see Table 1) for the purpose of organizing the vaccination program and targeting of vaccination when the initial supply of vaccine is limited. As identified in Table 1, population groups are offered vaccine in "tiers" based the severity of the pandemic. Reflecting public values and the need to address multiple important objectives with the pandemic vaccination program, each of the top tiers includes populations from all four categories for a severe pandemic.

<sup>&</sup>lt;sup>b</sup> Tier 1 includes the highest priority population groups to receive vaccination if there is limited vaccine supply for any level of pandemic severity. See Table 1.

#### **Guidance Framework At-A-Glance**

**Categories** – Pandemic vaccination population groups are clustered into four broad categories (homeland and national security, health care and community support services, other critical infrastructure, and the general population). These four categories together cover the entire population.

**Population Groups** – People targeted for vaccination defined by occupation, age group, or risk level.

**Tiers** – Across categories, vaccine will be allocated and administered according to tiers where all groups designated for vaccination within a tier have equal priority for vaccination. Groups within tiers vary depending on pandemic severity.

**Critical Workforce** – Workers with critical skills, experience, certification or licensure status whose absence would create severe bottlenecks in or the collapse of critical functions.

Critical workforces are more specifically targeted in a more severe pandemic than when the pandemic severity is lower and the risk to societal and community functioning is also lower. Once a novel influenza virus has emerged and is circulating in human populations, the risk posed by the epidemic itself can be assessed. Pandemic vaccine target groups will differ depending on pandemic severity and vaccine supply. In all levels of pandemic severity, public health and front-line healthcare providers, emergency services personnel, deployed and mission essential personnel; manufacturers of pandemic vaccine and antivirals; and pregnant women, infants and toddlers would be targeted for early receipt of vaccine. However, targeting of other critical workforce groups would depend on pandemic severity, the risk of severe illness by age group, vaccine supply, and the accompanying disruption to security, society, and the economy. For instance, there likely would be more focused targeting of critical workforce in a pandemic with a high or very high level of severity and limited early supply of pandemic vaccine, and less need for targeting critical workforce in less severe pandemics as threats to security, society, and the economy will be less significant in those pandemics. CDC will utilize the Pandemic Severity Assessment Framework (PSAF)1 https://www.cdc.gov/flu/pandemicresources/national-strategy/severity-assessmentframework.html, which incorporates an assessment of influenza transmissibility and clinical severity, to determine pandemic severity. The U.S. government

will use this assessment to develop more specific guidance on vaccination prioritization and determine how the tier schema outlined in this document will be adapted to an actual pandemic.

#### Defining Who is Included in Each Population Group

Everyone in the United States is included in at least one vaccination population group. Individuals not included in an occupational group will be vaccinated as part of the general population based on their age and health status. When a person is included in more than one population group, they will be vaccinated in the highest tier group in which they are included. Occupationally-defined groups (i.e., those defined in the homeland and national security, health care and community support services, and other critical infrastructure categories) do not include the entire workforce, but rather only persons who, based on the nature of their role or occupation, are individually critical for providing essential services during a pandemic (Appendix A). Preliminary identification of critical functions was partly based on an analysis of critical sectors and workforces conducted by DHS's National Infrastructure Advisory Council (NIAC) (www. dhs.gov/niac), along with input from other federal agencies. Additional planning in each community, in coordination with its state, tribes, or territory, is recommended to more specifically determine and identify the individuals in critical occupations and

other potentially prioritized groups who should receive early vaccination so that employers and public health emergency planners can reach those individuals quickly and without confusion when necessary. Because an influenza pandemic differs from other national emergencies in the threat it poses and the duration over which it will affect our nation and communities, populations targeted for vaccination within each sector may be different from those defined in other emergency response plans.

It should be noted that members of occupational groups are defined by the functions that persons within that group are anticipated to perform during the pandemic; it does not distinguish among staff performing these duties as part of their usual functions, those being reassigned to perform the function as a new response role, or those performing the function as a volunteer. It should also be noted that vaccine does not replace, but adds to other measures taken to protect the workforce and general population.

The primary objective of vaccinating persons in critical infrastructure sectors is to protect workers with critical skills, experience, certification or licensure status whose absence would create severe bottlenecks in or the collapse of critical functions and to protect workers who are at especially high occupational risk (e.g., emergency services personnel and essential utility services personnel). Other pandemic response strategies (e.g., prompt treatment, asking sick workers to stay home and away from the workplace, antiviral post-exposure prophylaxis, engineering controls in workplaces, changing work practices to reduce close contact with others, good hand washing, or worker education) are likely to be effective in decreasing absenteeism and are recommended for the entire workforce, not just those fulfilling critical functions.

#### Guidance for Targeting Pandemic Vaccination

National guidance for targeting pandemic influenza vaccination planning is provided in Table 1, with the understanding that the numbers of people within each group are estimates and actual recommendations may change for a future pandemic and as the pandemic progresses. In general, all groups designated for vaccination within a tier have equal priority for vaccination. However, an important lesson learned from the 2009 H1N1 pandemic and other public health emergencies is that decisions at the state, local, and provider level may be appropriate to adapt these designations to local realities. State and territorial health departments, in coordination with local health departments, will be responsible for allocating vaccine to providers who agree to target vaccine to persons in the targeted groups or who care for persons in a targeted group (e.g., allocate vaccine to obstetricians to reach pregnant women). These decisions are likely to vary among states as situations and plans vary among states. During a severe influenza pandemic, the most critical workforce will likely be vaccinated in temporary closed mass vaccination clinics or in existing occupational health clinics as coordinated through the local/state health department.

Recommendations regarding those groups targeted for early vaccination are tailored to pandemic severity and transmissibility and based on vaccine supply in order to best achieve national pandemic response goals and objectives. The targeting approach will depend on the pandemic severity assessment and the risk that the pandemic poses to groups at highest risk of complications from influenza and those who maintain critical functions of society. If the severity of a pandemic is high or very high, it will also be important to emphasize measures to preserve critical societal functions. However, flexibility in planning is needed as it is not possible to predict in advance the severity of a future pandemic, or the impact that the pandemic will have on certain population sub-groups. Therefore, this pre-pandemic interim planning guidance will need to be re-assessed at the time of an emerging pandemic.

Table 1 illustrates pandemic vaccination tiers and population groups for a pandemic based on pandemic severity for planning purposes. The Appendix A includes additional information on how population groups were defined.

#### Table 1. Category, vaccination population groups, estimated number in population group, and tiers for low, moderate, and high/very high pandemic severity

Accessible version at https://www.cdc.gov/flu/pandemic-resources/national-strategy/planning-guidance/guidance\_508.html#table-1

TIER 1 <sup>1</sup>	TIER 2	TIER 3

TIER 4 TIER 5

Not Targeted<sup>2</sup>

Category	Population Group	Estimated Number	Low Severity ⁴	Moderate Severity	High/ Very High Severity
	Deployed <sup>5</sup> & mission essential personnel	850,000			
	Essential military support & sustainment personnel	650,000			
Homeland	Intelligence services	150,000			
security	National Guard personnel	500,000			
,	Other domestic national security personnel	150,000			
	Other active duty military & essential support	1,500,000			
	Public health personnel	300,000			
	Inpatient health care providers	3,200,000			
Health	Outpatient & home health providers	2,600,000			
care and	Health care providers in long-term care facilities	1,600,000			
support	Pharmacists & pharmacy technicians	725,000			
services	Community support & emergency management	600,000			
	Mortuary services personnel	50,000			
	Other health care personnel	350,000			
	Emergency services & public safety sector personnel (EMS, law enforcement, & fire services)	2,000,000			
	Manufacturers of pandemic vaccine & antivirals	50,000			
Other critical	Communications/information technology (IT), electricity, nuclear, oil & gas, water sector personnel, & financial clearing & settlement personnel	2,200,000			
infrastructure	Critical government personnel - operational & regulatory functions	425,000			
	Banking & finance, chemical, food & agriculture, pharmaceutical, postal & shipping, & transportation sector personnel (critical infrastructure with greater redundancy)	3,400,000			
	Other critical government personnel	400,000			
	Pregnant women	4,000,000			
	Infants & toddlers 6-35 months old	11,000,000			
	Household contacts of infants <6 months old	4,500,000			
Conoral	Children 3-18 years old with high risk condition	7,000,000			
population	Children 3-18 years old without high risk condition	62,000,000			
	Adults 19-64 years old with high risk condition	38,000,000			
	Adults ≥65 years old	41,000,000			
	Healthy adults 19-64 years old	132,000,000			

NOTES: (See Appendix A for description of Population Groups)

<sup>1</sup>Across categories, vaccine will be allocated and administered according to tiers where all groups designated for vaccination within a tier have equal priority for vaccination. Groups within tiers vary depending on pandemic severity. Tier 1 is the highest priority group to receive vaccination if there is limited vaccine supply for any pandemic severity. <sup>2</sup>Persons not targeted for vaccination in an occupational group would be vaccinated as part of the General Population based on their age and health status.

<sup>3</sup>Estimates rounded to closest 50,000. Occupational population group sizes may change if worker populations fluctuate or as plans are developed further and population groups may change in number over time.

4CIP recommendations for prioritization would guide tiered vaccination during pandemics with low to moderate levels of severity.

(http://www.cdc.gov/sacines/hcp/acip-recs/index.html).
Includes military forces and other mission critical personnel, not limited to active duty military or US government employees, who are critical to protecting national security.

#### Figure 1. Vaccination tiers and population groups for a high/very high level of pandemic severity.

Accessible version at https://www.cdc.gov/flu/pandemic-resources/national-strategy/planning-guidance/guidance\_508.html#figure-1

This figure illustrates how vaccination is administered to population groups by tiers until the entire U.S. population has had the opportunity to be vaccinated during a pandemic with a high or very high level of severity, and how tiers integrate population groups, balancing vaccine allocation to occupationally defined groups and the general population. (See Appendix A for description of Occupational and High Risk Population Groups)



\* Based on 2015 U.S. population of 321 million people. https://factfinder.census.gov/bkmk/table/1.0/en/PEP/2015/PEPAGESEX

### Vaccination of Tier 1 at All Pandemic Severities

Tier 1 includes the highest priority population groups identified in each of the four categories (Table 1) and may vary based on pandemic severity and supply. However, Tier 1 is the highest priority group to receive vaccination if there is limited vaccine supply for any level of pandemic severity; groups within Tier 1 may change depending on the characteristics and epidemiology of the pandemic and its impact. For instance, people over age 65 years are in Tier 2 for a low level of pandemic severity, but are in Tier 4 for a pandemic with high/very

high level of severity. Occupationally-defined groups are included in Tier 1 during a high or very high level of pandemic severity as societal disruption is likely during those scenarios, and they are critical to maintaining the effective functioning of society. The burden of illness and absenteeism may be markedly increased in a pandemic, and the risk of occupational exposure and infection may be high because of contact with ill persons, living conditions, or geographic location. In addition to targeting vaccination in Tier 1 to groups that provide critical societal goods and services, public and stakeholder groups also reinforced the value of including pregnant women and young children in this tier when they are likely to be at high risk of pandemic influenza-related hospitalizations or death.

#### Potential sub-targeting of Tier 1

Recognizing that it is possible that vaccine may be in extremely short supply when first available, it may be necessary to sub-prioritize vaccination of groups within Tier 1 (Box 1). Further guidance may be issued during a pandemic to specify which persons and groups should be included if more focused targeting is needed.

For example, hospital-based "front-line" healthcare providers who are essential for maintaining emergency departments and intensive care units and providing medical and nursing care on inpatient units may be vaccinated earlier than other healthcare providers. In a scenario such as the 2009 H1N1 pandemic when the risk to the effective functioning of society was minimal, vaccine might be sub-targeted for those who are most medically vulnerable to severe illness such as pregnant women and children 6-35 months and critical healthcare personnel over some other groups in this tier. This proposed ranking of groups within Tier 1 balances allocation to achieve multiple pandemic response goals and protects persons who are at highest occupational risk of becoming infected.

Vaccine in short supply	Vaccine in extremely short supply
(Sufficient to vaccinate all of Tier 1)	(Insufficient to vaccinate all of Tier 1)
<ul> <li>All groups would be offered vaccine at the same time:</li> <li>Deployed and mission critical personnel</li> <li>Critical healthcare (inpatient, outpatient, long-term care, pharmacists, pharmacy technicians)</li> <li>Public health personnel</li> <li>Emergency Medical Services (EMS)</li> <li>Law enforcement</li> <li>Fire services</li> <li>Manufacturers of vaccine and antivirals</li> <li>Pregnant women</li> <li>Infants and toddlers</li> </ul>	<ul> <li>Proposed ranking of groups within Tier 1:</li> <li>1. Front-line inpatient and hospital-based health care personnel caring for sickest persons; health care personnel with highest risk of exposure</li> <li>2. Deployed and mission critical personnel who play essential role in national security</li> <li>3. Front-line EMS</li> <li>4. Front-line outpatient health care personnel, pharmacists and pharmacy technicians, and public health personnel who provide immunizations and outpatient care</li> <li>5. Front-line law enforcement and fire services personnel</li> <li>6. Pregnant women and infants aged 6 -11 months old</li> <li>7. Remaining groups in Tier 1 (includes other Tier 1 inpatient and outpatient healthcare personnel not vaccinated previously; public health; EMS, law enforcement, and fire services personnel; manufacturers of pandemic vaccine and antiviral drugs; and children aged 12-35 months old</li> </ul>

#### Box 1. Prioritization of vaccination groups within Tier 1 based on availability of vaccine supply

# Vaccination Tier 2 through 5 by Pandemic Severity

Population groups included in Tiers 2 through 5 will vary depending on pandemic severity (see Box 1 and Figure 1). When vaccination has been completed for all five tiers, at any pandemic severity, everyone in the United States will have had the chance to be vaccinated.

### Guidance for a pandemic with a high or very high level of severity

Tier 2 targets groups in the homeland and national security category that are critical to maintaining our country's safety and security. Critical community support service personnel are prioritized because they are needed to assist in a community pandemic response and support vulnerable populations such as the elderly, persons living alone, and households complying with voluntary quarantine when a household member is ill (recommended as part of the community mitigation strategy). Mortuary services personnel also are targeted when excessive fatalities are anticipated and risk overwhelming mortuary services. Critical infrastructure sectors targeted in Tier 2 are those that provide "just-in-time services" (e.g., products like electricity and natural gas that cannot be stored), are relied on by all other infrastructures for their essential operations, and contribute to public health and safety. The highest risk children, whose underlying medical conditions increase their risk of complications or death from influenza infections, and household contacts of infants aged less than 6 months old, are included in this tier.

Tier 3 includes the remaining population groups that protect homeland and national security, provide health care, and maintain critical infrastructures. Critical infrastructure sectors targeted in Tier 3 are those that provide essential products and services where there generally is greater "redundancy" than in Tier 2 in infrastructure (e.g., there are many bakeries, dairies, gas stations) or personnel (e.g., there are many truck drivers); or where burden is likely to decrease in a pandemic (e.g., less demand for mass transit). Many businesses in these sectors can take other measures to protect employees, such as using alternate work schedules, teleworking, and reducing in-person meetings and other contacts in the workplace. In the general population, children without high-risk medical conditions are targeted in this tier.

Tiers 4 and 5 are focused on groups in the general population that have not yet been vaccinated. During a pandemic with a high/ very high level of severity, Tier 4 includes high risk adult populations such as persons aged 19 to 64 years old who have underlying medical conditions and older adults aged 65 years or older. Tier 5 included healthy adults aged 19 – 64 years old.

Because the characteristics of a future pandemic are difficult to predict, planning for a range of options is prudent. In some pandemic scenarios, targeting healthy adults aged 19 to 64 years ahead of those who are older may be appropriate. For instance, in the 2009 H1N1 pandemic, persons born prior to the 1940s had been previously exposed to an H1N1 influenza virus, which was similar to the 2009 H1N1 virus. Thus, older persons were better able to mount an immune responses to the H1N1 virus compared to younger persons. In a pandemic with a high or very high level of severity, vaccinating younger adults first may have several additional advantages: working age adults contribute more to maintenance of societal functions and economic well-being; they provide most care for children; and they often have a higher risk of infection because of their greater number of contacts at work and in the community. Based on these considerations, most of the participants in the public engagement sessions valued vaccinating younger adults before older adults (> 65 years old) in a very severe pandemic. However, given the much higher risk of severe illness and death experienced by older adults in all four of the previous pandemics, plans that target older adults before younger healthy adults would be appropriate in some pandemics. Given these considerations, pandemic planners should consider developing and exercising alternate plans to be prepared to target healthy younger adults over older adults or vice versa, depending on how the pandemic affects these age groups.

# Guidance for pandemics with a moderate level of severity

Moderate level severity pandemics also may pose threats to maintaining security and providing public health, healthcare, and community support services, but (based on experience with the 2009 H1N1 pandemic) will probably not pose a threat to disruption of critical services. As in more severe scenarios, any vaccine targeting effort needs to consider the specific epidemiology of the pandemic.

Population groups in Tier 2 for a moderate pandemic include homeland and national security, health care and community support services, household contacts of young infants, and all children 3 to 18 years old (including those with and without a high risk condition) (Table 1). Because of the large population of children, if vaccine supply is limited, children with medical conditions that increase their risk of severe illness may be vaccinated before those without such conditions.

Tier 3 includes the remaining occupational groups that protect homeland and national security (e.g., active duty personnel not includ-

ed in higher priority groups and essential support personnel) and persons aged 19 to 64 years who are at higher risk of severe illness due to underlying medical conditions and persons 65 years old and older. Similar to the situation for severe/very severe pandemics, if vaccine supply is limited, younger high-risk adults may be vaccinated before older adults because of the greater vaccine effectiveness in the former group. Healthy adults are included in Tier 4.

# Guidance for a pandemic with a low level of severity

A pandemic with a low level of severity poses less threat to community support and other essential services. The greater priority assigned to general population groups relative to occupationally defined groups reflects this shift in the threat to the delivery of essential services. Review of the 2009 H1N1 pandemic indicates that healthcare providers were targeted for receiving vaccine early because of possible occupational exposure, but other essential community services were effectively maintained. Because of this, during a pandemic with a low level of severity, non-healthcare related occupational groups in the community support services critical workforce categories would not be specifically targeted, and workers in these groups would be vaccinated based on their age and health status as part of the general population.

In contrast with more severe pandemics where certain occupational groups are vaccinated before general population groups, in a pandemic with a low level of severity, guidance for targeting of vaccination will likely focus on groups at highest risk of complications from influenza, based on the epidemiology of the outbreak.

# Implementation of this Guidance during a Future Pandemic

s noted earlier, numerous decisions on vaccine allocation will be required as information about the epidemiology and impact of the pandemic and vaccine supply issues evolve. ACIP will provide recommendations to the director of the CDC (and revise recommendations, if needed), regarding use of stockpiled and pandemic vaccine after a pandemic virus emerges. Adapting this guidance to such an evolving situation will require close interagency coordination and clarity on the roles that various agencies will play.

Seven discrete activities may be needed, and some will occur simultaneously:

- Determine Severity: Public health scientists at CDC will collect and analyze epidemiologic and laboratory data to determine pandemic severity using the PSAF.<sup>1</sup> This analysis will be reviewed and revised as necessary as more information about the virus and its impact becomes available. With a focus on community impact and the likelihood of broad absenteeism, this information will be critical to guide the approach taken to vaccine allocation and targeting.
- 2. Recommend Vaccine Viruses: The World Health Organization (WHO) Collaborating Centers will recommend the appropriate pandemic virus for use in vaccine manufacturing. The Food and Drug Administration's (FDA) Vaccine and Related Biological Products Advisory Committee (VRBPAC) will review the WHO recommendation and make a recommendation to the Commissioner of Food and Drugs at FDA for viruses to include in the pandemic vaccine for the United States. In addition, VRBPAC will assess vaccines in the U.S. pandemic stockpile and determine whether vaccine in the stockpile should be used for vaccine priming and/or boosting.

- 3. Recommend Vaccine and Identify High Risk Groups: An assessment will also be needed to identify groups at increased risk of severe illness from pandemic influenza; these groups may differ from groups at high risk of severe illness from seasonal influenza. For a pandemic of any severity, the ACIP will recommend vaccine use and develop guidance regarding groups at higher risk for complications and risk of exposure to pandemic influenza virus infection, based on the epidemiology of the emerging pandemic. This guidance from ACIP will be incorporated, upon adoption by the CDC director, into the overall U.S. plan for pandemic vaccine allocation and targeting. The number of people in these groups may also change and need to be reassessed as the U.S. population grows over time.
- 4. Assess Tiers for Vaccination: If the severity of the pandemic is projected to be severe or very severe, the U.S. government may develop additional guidance, based on ACIP's recommendations, for allocating and targeting pandemic vaccine to certain groups (as outlined in this document). These additional recommendations will be based on an assessment of the impact of the pandemic on critical functions of society and availability and timing of pandemic vaccine. As previously mentioned, recommendations issued during a pandemic may differ from the planning schema as presented in Table 1 (see item 6 below).
- 5. Determine Vaccine Formulation: Results of clinical trials conducted by HHS, and other available data, will be used to determine the appropriate formulation of a pandemic vaccine (e. g., specific virus(es), antigen content, whether an adjuvant is required, and dosage) and number of doses required to elicit a protective immune response. Clinical trial results will inform any adjustments needed in the targeting strategy and FDA-licensure of a pandemic vaccine.

6. Monitor Vaccine Availability: Allocation of pandemic vaccines by the U.S. government to states and territories will likely be in proportion to state's populations. Following initial allocation and targeting recommendations and the start of vaccine delivery, HHS will conduct a weekly review of information provided by the vaccine manufacturers on the status of vaccine supply, information from states and territories on vaccine demand, and the evolving epidemiology of the pandemic in the United States and globally. Based on this weekly review, HHS will periodically reassess recommendations for allocating and targeting vaccine and when to expand vaccination to additional tiers as vaccine

supply increases, demand for vaccination changes, or information on the epidemiology and impact of the pandemic changes. State, local, and territorial immunization programs will have the ultimate responsibility for implementing this guidance, but given the likely variation in vaccine demand among states, it is necessary to have a flexible approach to respond to local needs.

7. **Communicate Regularly:** Timely and comprehensive communication with the public and with stakeholder groups through the entire process of developing and implementing the vaccination recommendations is critical to the success of the program.

# Next Steps for the U.S. Government, States, and Communities

his interim guidance is the result of methodical and rigorous consideration of scientific data, historical analyses, ethical issues, and input from key stakeholders at the national, state, local, and community levels, and the general public. In addition, experience gained through numerous pandemic exercises and the response to the 2009 H1N1 pandemic has informed this updated guidance. The development of this interim guidance on allocating and targeting pandemic vaccine, however, is only one step in the planning process. Implementing this guidance to carry out an effective and efficient pandemic vaccination program will require many additional planning considerations in each community, including:

• Developing strategies and testing approaches for how persons in occupationally defined groups will be identified (in alignment with national guidance) and notified, including identifying and preparing vaccine providers who will vaccinate these targeted groups so that those groups are rapidly vaccinated during a pandemic;

- Considering if expanding access to vaccination may require policy and other approaches to increase the number of potential immunizers and sites that can provide vaccinations;
- Planning by state, tribal, and local officials on allocation and distribution of vaccine to providers and sites where it will be administered;
- Determining effective methods for administration of pandemic vaccines to targeted groups, including the possible use of vaccination clinics in closed Points of Dispensing (PODs)<sup>c</sup> mass vaccination clinics, occupational health clinics, hospitals, pharmacies, or other selected sites;
- Determining how a two-dose vaccination program for targeted persons will be implemented, if it is needed (e.g., communication/outreach ensuring that those who receive a first dose return for their second dose in a timely manner to achieve full immunity);

<sup>&</sup>lt;sup>c</sup> Closed PODs are in locations that are operated by a private organization for a target group which may include employees and their families and/ or clients/members they serve. Closed PODs are not open to the public.

- Preparing vaccinators to document pandemic vaccine administration and to report information to their jurisdiction's immunization information system and to utilize such systems to assess two-dose series completion and use of adjuvants, if required;
- Developing communication strategies and approaches to inform planners, vaccinators, and the public about pandemic influenza vaccine recommendations and changes that are made in order to facilitate implementation of guidance as it evolves;
- Developing strategies and materials for employers that have occupational health providers or will use mass vaccinators to immunize their critical workforce in alignment with this strategy; and
- Developing strategies and materials for healthcare providers, public health partners, and the public to clearly communicate the vaccine targeting strategy and support its implementation.

## **References:**

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- 2. Department of Health and Human Services. Pandemic Influenza Plan 2017 UPDATE. Available at: https://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf.
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# Appendix A

# Description and Rationale for Population Groups Targeted for Pandemic Vaccination

uidance for targeting vaccination defines population groups in four broad categories that correspond with the objectives of a pandemic vaccination program - to protect people who: 1) maintain homeland and national security, 2) provide health care and community support services, 3) maintain critical functions of society, and 4) are in the general population. The population groups are to be vaccinated in "tiers". Reflecting public values and the need to address multiple important objectives with the pandemic vaccination program, each of the top tiers includes populations from all four categories for a very severe pandemic. The table below provides further definition of population groups for pandemic vaccination by tier for a pandemic with a high or very high level of severity, the estimated size of the group, and a brief description of

the working group's rationale for prioritizing that group. For planning purposes, note that the estimated number of persons in occupational groups are only those who are critical to maintaining essential functions. This interim guidance and table are provided for planning purposes. The Advisory Committee on Immunization Practices (ACIP), a federal advisory committee that develops recommendations for the director of the Centers for Disease Control and Prevention (CDC) on use of vaccines to control diseases in the United States, would serve as the advisory committee for developing recommendations for use of pandemic vaccine If needed during a future pandemic, more specific guidance will be provided by CDC; the tiered schema outlined in this document will be adapted to provide guidance on targeted vaccination during the pandemic.

# Table 3. Tiers, definition, and rationale for target population groups during a high/very high severity pandemic

TIER (HIGH/ VERY HIGH SEVERITY)	GROUP <sup>1</sup>	DEFINITION	ESTIMATED NUMBER IN GROUP	RATIONALE
1	Deployed and mission critical personnel for national security	Military forces and other mission critical personnel not limited to active duty military or U.S. government employees. Includes some diplomatic and intelligence service personnel, and public and private sector functions identified by federal agencies as unique and critical to national security	850,000	Critical to protect national security, unable to tolerate projected pandemic personnel loss and fulfill mission, potential greater risk of infection due to geographic location and crowded living or working conditions.

Accessible version at https://www.cdc.gov/flu/pandemic-resources/national-strategy/planning-guidance/appendix-a.html

TIER (HIGH/ VERY HIGH SEVERITY)	GROUP <sup>1</sup>	DEFINITION	ESTIMATED NUMBER IN GROUP	RATIONALE
1	Public health personnel	Public health responders at federal, state, and local levels	300,000	Essential to implementing the pandemic response, including the vaccination program and other pharmaceutical and non-pharmaceutical response measures; also provide care for low income and underserved populations; personnel at increased risk of exposure to persons with pandemic illness, and also increased work load to respond to the pandemic.
1	Inpatient healthcare providers	Includes two-thirds of personnel at acute care hospitals who would be identified by their institution as critical to provision of inpatient health care services; primarily will include persons providing care with direct patient exposure but also will include persons essential to maintaining hospital infrastructure	3,200,000	Maintaining quality inpatient health care is critical to reducing mortality from pandemic influenza and from other illnesses that will occur concurrently with the pandemic; inpatient healthcare burden will likely be markedly increased during a pandemic; studies show health outcomes are associated with staff-to- patient ratio; personnel have increased risk of exposure, including to infectious aerosols; infected healthcare personnel may transmit infection to vulnerable persons hospitalized for non-influenza illnesses.

TIER (HIGH/ VERY HIGH SEVERITY)	GROUP <sup>1</sup>	DEFINITION	ESTIMATED NUMBER IN GROUP	RATIONALE
1	Outpatient and home health providers	Includes two-thirds of personnel identified by their organization at outpatient facilities, including but not limited to physicians' offices, primary care clinics, dialysis centers, urgent care centers, retail health clinics, and blood donation facilities; and skilled home health care personnel providing care with direct patient exposure	2,600,000	Maintaining outpatient and home health care is critical to reducing pandemic mortality and morbidity and reducing the burden on inpatient services; outpatient healthcare burden will be markedly increased during a pandemic; personnel have increased risk of exposure, possibly including to infectious aerosols; infected health care personnel may transmit infection to vulnerable persons receiving care for non-influenza illness
1	Health care providers in long term care facilities (LTCFs)	Includes two-thirds of personnel at LTCFs identified by their organization as critical to the provision of care	1,600,000	Essential to provide care to more than 3 million persons in LTCFs who are particularly vulnerable to influenza illness and death; risk of pandemic outbreaks in LTCFs may best be reduced by vaccinating staff and limiting exposure of residents to infection; if outbreaks occur, personnel have increased risk of exposure, possibly including to infectious aerosols, and can spread pandemic influenza to their highrisk patients.
1	Pharmacists and pharmacy technicians	Includes pharmacists dispensing drugs at retail locations and pharmacy technicians who interact with the public and are essential for pharmacy operations (note that pharmacists in hospitals or outpatient centers may be targeted as part of those groups)	725,000	Essential to dispense medications and administer vaccinations for pandemic influenza and other illnesses; demand for pharmacist services would be expected to increase during a pandemic. Pharmacists and pharmacy technicians may have increased exposure risk to persons with pandemic infection given their exposure to the public for provision of services.

TIER (HIGH/ VERY HIGH SEVERITY)	GROUP <sup>1</sup>	DEFINITION	ESTIMATED NUMBER IN GROUP	RATIONALE
1	Emergency services and public safety sector personnel (e.g. emergency medical service, law enforcement and fire services)	Includes groups supporting emergency response and public safety. Emergency medical service personnel include those who are fire department based, hospital- based, or private; firefighters include professional and volunteers; law enforcement includes those who are local police, sheriff officers, state troopers; and corrections officers include those in prisons and jails.	2,000,000	Provide critical public safety and emergency response services; contribute to pandemic response activities by maintaining public order and contributing to medical care services; increased occupational risk for emergency medical services due to exposure to persons with pandemic illness.
1	Manufacturers of pandemic vaccine and antiviral drugs	Includes critical personnel required for ongoing production of pandemic medical countermeasures to support a pandemic response	50,000	Reducing pandemic health impacts requires production of pandemic vaccine and anti-influenza drugs.
1	Pregnant women	Women at any stage of pregnancy	4,000,000	Pregnant women are at high risk of severe complications or death from pandemic influenza due to immunological, circulatory, and respiratory changes that occur during pregnancy; vaccinating pregnant women also reduces the risk of influenza in infants up to 6 months of age.
1	Infants and toddlers (6-35 months old)	Infants and toddlers in the specified age group	11,000,000	Persons in this age group are at high risk of severe complications or death from pandemic influenza; vaccination may require a lower dose than used to protect older children and adults; public values prioritize children highest among groups defined by age and disease status.

TIER (HIGH/ VERY HIGH SEVERITY)	<b>GROUP</b> <sup>1</sup>	DEFINITION	ESTIMATED NUMBER IN GROUP	RATIONALE
2	Essential military support and sustainment personnel	Military and other essential personnel needed to support and sustain deployed forces	650,000	Maintaining function is essential to mission success for deployed personnel; risk of infection may be less based on geographical location and living conditions.
2	Intelligence services	Critical personnel in the intelligence community serving at domestic and international posts that are not included in Tier 1.	150,000	Essential to homeland and national security; opportunities for social distancing limited because of inability to telework due to need for secure facilities; some personnel may be at increased risk based on geographical location.
2	National Guard personnel	National Guard Personnel not included in Tier 1, but who are likely to be activated to maintain public order during a pandemic or to support pandemic response services or critical infrastructure	500,000	Likely to be activated in a pandemic to support critical response or community functions; may be at increased risk of exposure and infection based on mission.
2	Other domestic national security personnel	Includes other groups that are essential to national security such as guards at nuclear facilities and critical personnel providing border protection	150,000	Essential to national and homeland security and includes critical personnel in agencies providing U.S. border security.

TIER (HIGH/ VERY HIGH SEVERITY)	GROUP <sup>1</sup>	DEFINITION	ESTIMATED NUMBER IN GROUP	RATIONALE
2	Community support service personnel (emergency management and community and faith- based support and response organizations)	Personnel from community organizations who will provide essential support and have direct contact with persons and families affected during community pandemic outbreaks, and emergency management personnel who coordinate pandemic response and support activities	600,000	Community level support will be critical for persons who are ill and isolated in their homes or are complying with recommendations for voluntary household quarantine during community pandemic outbreaks, for elderly persons who live alone and cannot or may be afraid of leaving their home during a pandemic, for persons who are homeless, and for other vulnerable populations; support may include providing food and medications, as well as other social and mental health services; personnel will be at increased risk of exposure to ill persons and, if infected could transmit illness, to a high risk population.
2	Mortuary services personnel	Includes funeral directors	50,000	Increased burden likely during a pandemic; may have increased occupational exposure to ill family members of deceased persons.
2	Communications, information technology (IT), electricity, nuclear, oil & gas, and water sector personnel, and financial clearing and settlement personnel	Personnel who are critical to support essential communications, information technology, utility, financial and other services provided by the defined sectors	2,200,000	These sectors provide products and services that generally cannot be stored, are required for community health and safety, and are essential to the functioning of other critical infrastructure sectors.

TIER (HIGH/ VERY HIGH SEVERITY)	GROUP <sup>1</sup>	DEFINITION	ESTIMATED NUMBER IN GROUP	RATIONALE
2	Critical government personnel – operational and regulatory functions	Federal, state, tribal, and tribal government employees and contractors who perform critical regulatory or operational functions required for essential operations of other critical infrastructure sectors	425,000	Government personnel are critical for implementing and monitoring components of the pandemic response and performing regulatory or operational functions essential to critical infrastructure that protect public health and safety and preserve security.
2	Household contacts of infants under 6 months old	Household contacts of infants under 6 months old.	4,500,000	Infants under 6 months old cannot be directly protected by vaccination, and influenza antiviral drugs are not approved for infants < 2 weeks old; therefore, vaccinating contacts can protect infants. Public values prioritize protection of children highest among groups at increased age risk of influenza-related complications based on age or disease status.
2	Children 3 – 18 years old with a high risk medical condition	Children in the specified age group with a chronic medical condition that increases their risk of severe influenza disease, including heart and lung disease, metabolic disease, renal disease, and neuromuscular diseases that may compromise respiratory function, as defined by ACIP recommendations for seasonal influenza vaccination.	7,000,000	Children with these conditions are at increased risk of severe complications or death from influenza disease; public values prioritize children highest among groups defined by age and disease status.
3	Remaining active duty military and essential support	Active duty personnel not included in higher priority groups and essential support personnel	1,500,000	Essential to national and homeland security.

TIER (HIGH/ VERY HIGH SEVERITY)	GROUP <sup>1</sup>	DEFINITION	ESTIMATED NUMBER IN GROUP	RATIONALE
3	Other health care personnel	Includes groups that provide important health care services but are at less occupational risk, such as laboratory personnel	350,000	Personnel provide important health care services but are not as likely to have close contact with ill persons and are therefore at less risk of occupational infection compared to other healthcare sectors.
3	Banking and finance, chemical, food and agriculture, pharmaceutical, postal and shipping, and transportation sector personnel. (Critical infrastructure with greater redundancy)	Personnel who are critical to support essential services provided by the defined sectors	3,400,000	These sectors provide essential products and services; however, compared with Tier 2 sectors, products can more likely be stored, facilities and personnel are more fungible and better able to maintain essential functions with high absenteeism, and other strategies can be implemented to protect workers.
3	Other critical government personnel	Federal, state, tribal, and local government employees and contractors who perform important government functions included in agency continuity-of- operations plans	400,000	Continuity of key government functions is important to support communities and critical infrastructures.
3	Children 3–18 years old without a high risk medical condition	Children in the specified age group who do not have a chronic medical condition that increases their risk of severe influenza disease.	62,000,000	Public values prioritize protection of children highest among groups defined by age and disease status; vaccinating children may reduce transmission of pandemic influenza to household contacts and in communities; if a substantial number of children are protected by vaccine, schools can re-open mitigating secondary adverse consequences of closing schools.

TIER (HIGH/ VERY HIGH SEVERITY)	GROUP <sup>1</sup>	DEFINITION	ESTIMATED NUMBER IN GROUP	RATIONALE
4	Adults 19 – 64 years with a high risk condition	Adults in the specified age group with a chronic medical condition that increases their risk of severe influenza disease, including heart and lung diseases, metabolic diseases, renal disease, and neuromuscular diseases that may compromise respiratory function, as defined by ACIP recommendations for seasonal influenza vaccination	38,000,000	Adults with these conditions are at high risk of severe complications or death from pandemic influenza.
4	Adults 65 years and older	Older adults in the specified age group	41,000,000	Persons in the age group are at high risk of severe complications or death from pandemic influenza.
5	Healthy adults, 19–64 years old <sup>2</sup>	Adults in the specified age group not included above	132,000,000	Persons in this group lack age, health condition, and occupational rationales for priority pandemic vaccination.

<sup>1</sup> Estimates of group size from information provided by Department of Defense, Department of Homeland Security, Department of Health and Human Services, and U.S. Census Bureau. <sup>2</sup> The target group "Healthy adults 19-64 years old" does not include persons defined by occupation and pregnant women who are included in other target groups.