Infection:
Don't Pass It On

VA INFLUENZA MANUAL 2012/2013

VA HEALTH CARE | Defining EXCELLENCE in the 21st Century

faces that fight FLU

This year's flu manual features pictures of the many staff members who contribute to influenza vaccination campaigns across VHA. You'll see the faces of individuals who have dedicated many hours of planning, promoting, and steadfast execution of flu prevention and vaccination programs. You'll see the faces of flu teams having fun with messaging and events to provide services related to flu. Most of all, notice that behind all of these faces that fight flu are champions who are committed to caring for our staff and Veterans by working to keep them safe from influenza and other infections. This manual is dedicated to all the faces--all the individuals--that fight flu in each and every VHA facility.

VA INFLUENZA MANUAL
2012/2013

INFECTION: DON'T PASS IT ON

A Campaign for Public Health

Clinical Public Health
Office of Public Health
Veterans Health Administration
U.S. Department of Veterans Affairs
November 2012

Infection: Don't Pass It On

VA HEALTH CARE | Defining EXCELLENCE in the 21st Century

CONTENTS

FOREWORD

A MESSAGE FROM THE UNDER SECRETARY FOR HEALTH

As another flu season begins, I want to take the time to thank those of you who have worked tirelessly to promote not only the health of our Veterans but of our entire staff. Without the good health of our health care personnel, the Veterans Health Administration (VHA) would never be able to fulfill its mission of providing Veterans with exceptional health care that improves their health and well-being. As we continue to transform the Department of Veterans Affairs (VA) in the 21st Century, whole-person care and lifelong wellness are central to our efforts. It is vital that you continue to keep up your amazing work. On behalf of all VHA, thank you.

Here are some key points I would like to emphasize as we move forward into the 2012-2013 flu season:

CULTURE CHANGE

When children are sick, it is common for parents to keep them home from school to avoid contact with other children. It is a basic concept, one that more adults need to apply to themselves. Coming to work while sick, especially in a health care setting, can result in transmission of that disease to Veterans, other health care personnel and visitors. Part of this overarching theme of creating a culture change includes allowing ourselves to stay home and not infect others. When we do so, you will be fostering a culture of safety, not only for our Veterans, but for other health care personnel as well.

We cannot forget about working together as a team. As I affirmed at the VHA 2012 Flu Summit here in Washington, DC, in June, patient-centered care is one of our priorities as we begin to transform VHA for the 21st Century. The Patient Aligned Care Team puts the patient first. Without a doubt, provider-patient relationships are vital to the success of our transformation. This bond can create an integrated team that includes you and your passion for flu prevention. It is the cooperation of the entire team that will enable Veteran-centered care. By promoting VHA values and incorporating this culture change, patients will be drawn to us and our passionate, patient-based care.

MARKET OUR PASSION

If we are all concerned about the health of our Nation's Veterans then we need to market our passion. Make the most of the resources around you such as the "Infection: Don't Pass It On" materials (highlighted at the end of this manual) to promote the practice of hand hygiene, respiratory hygiene, and flu vaccination. Meet with your flu teams throughout the year and use the Flu Campaign Calendar to ensure that your flu campaign is on track. Employ all resources at the facility, Veterans Integrated Service Networks, and Central Office level to promote, educate, and execute the best flu campaign.

Robert A. Petzel, MD
Under Secretary for Health
Veterans Health Administration

QUALITY IMPROVEMENT

Lastly, embrace change. If the center of our 21st Century transformation is our Veterans, then it is important we continue with tracking, monitoring, and measurement of how we take care of our patients, and the health of our workforce. Be sure to evaluate such things as resources (both human and material), access to vaccinations, documentation of staff and patient vaccinations, marketing, and education that are part of your flu program.

It is essential that we do all we can to prevent influenza from harming our Veterans, and those needed to care for them. Your resourcefulness and energy in preventing influenza has been wonderful. Keep up your efforts to improve Veterans' health and promote a culture of safety.

INTRODUCTION

VHA'S COMMITMENT TO PREVENTING INFLUENZA

Achieving a culture of safety within VHA facilities begins with the individual and the commitment to vaccination as a responsibility to protect yourself, coworkers, patients, and others in the VA community.

Every year, influenza has significant impact on our patients and staff. So many suffer from illnesses related to influenza, including pneumonia. And, occasionally we ourselves may know of a patient, friend, a family member or colleague who dies from flu-related illness. Vaccination to protect against influenza has been available and widely recommended in the United States and globally for decades. In fact, over a billion doses of influenza vaccine have been given and provide us with great confidence in its safety. Vaccination remains the single most important intervention to help protect ourselves, our families, and our patients from influenza. The Veterans Health Administration (VHA) is committed offering free vaccination as a key to preventing influenza.

We must keep in mind that vaccination against influenza, while the best action we can take, is not the only way to prevent flu. We must take a comprehensive approach to combating the spread of influenza in our homes, our hospitals, our clinics, and offices. In addition to getting vaccinated against influenza, we need to ensure that we also wash our hands properly and frequently, and exercise and promote proper respiratory etiquette. In the health care environment, we need to recognize patients who may be sick with influenza, or contagious with another communicable disease, and make sure the appropriate precautions are used to prevent the spread of infection. Finally, when we are sick, we need to stay home and get better so as not to place our colleagues or patients at risk.

Dr Robert Petzel, Under Secretary for Health, is committed to safety and health within VHA facilities and believes that a good start is through influenza prevention and vaccination. At this time, he does not believe that it is appropriate to mandate influenza vaccination throughout VHA. However, it is his expectation that every VHA staff member who does not have a medical contraindication will be vaccinated.

Over the years, the Office of Public Health, through the *Infection: Don't Pass It On* (IDPIO) campaign, has provided leadership and resources that support and promote vaccine uptake, hand hygiene, and other mitigation strategies to prevent infection. This flu manual represents one of the IDPIO resources and serves as a comprehensive and up-to-date guide to influenza and influenza prevention. It contains VHA guidance and recommendations along with key Centers for Disease Control and Prevention (CDC) publications. It provides in depth guidance

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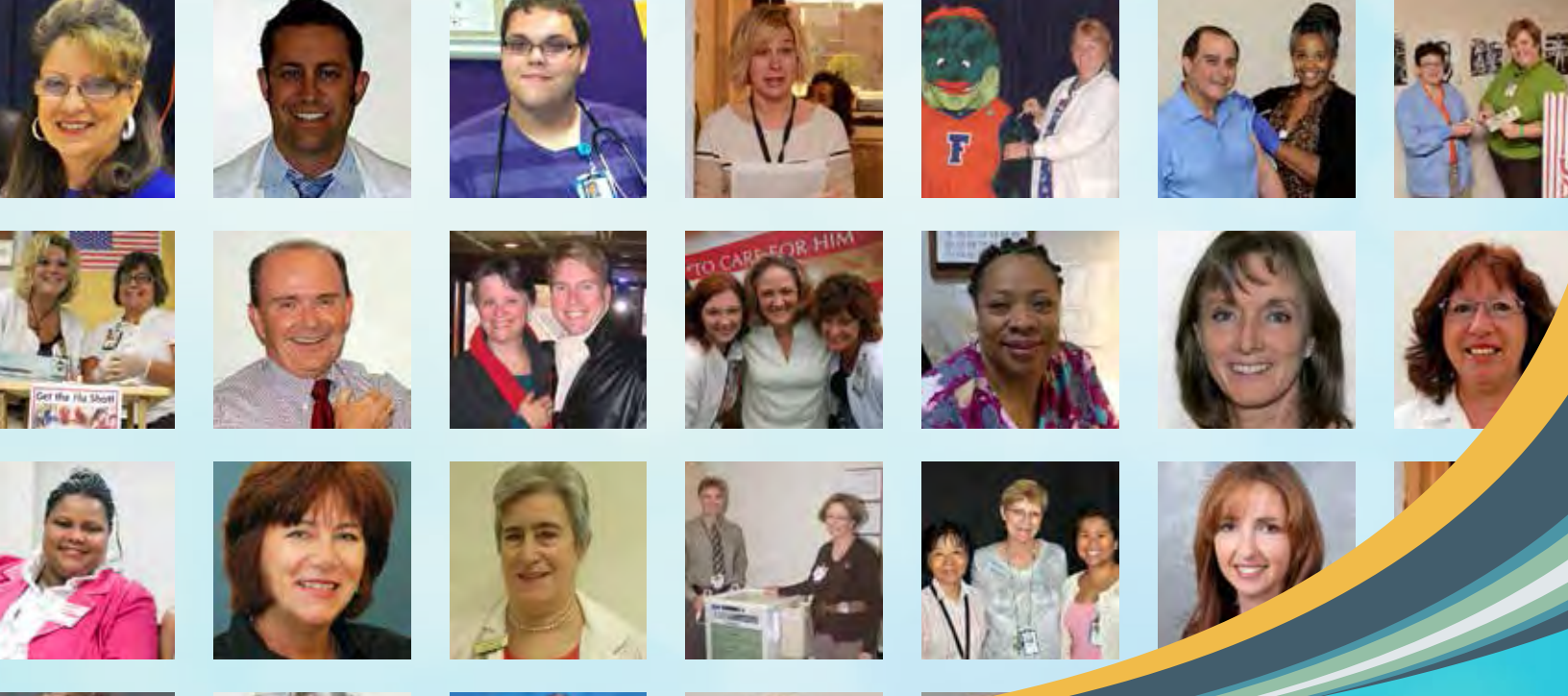
Our job as health care personnel (HCP) is to not only to heal and comfort, but also to prevent infections. Influenza can be prevented.

on the development and management of influenza vaccination programs, tools, and strategies to overcome vaccination hesitancy and much more to guide programs aimed at preventing influenza. This manual and other IDPIO resources can be found at www.publichealth@va.gov/flu.

As information technology continues to advance our data tools now include the Healthcare Associated Infections and Influenza Surveillance System (HAIISS) and the Occupational Health Record-Keeping System (OHRS). Using HAIISS, the Office of Public Health (OPH) measures and analyzes influenza disease and patient vaccination activity throughout the VA system and uses this to generate weekly reports that are widely distributed to VA frontline staff and leadership. OHRS is used to document health care personnel (HCP) influenza vaccination in addition to serving as the new, primary medical record system for VHA Occupational Health teams. OHRS users and OPH are able to generate near real-time reports on influenza vaccination receipt by VHA HCP system-wide. Through these systems, VHA and individual facilities will be better able to understand vaccination activities and refine strategies for improving staff and patient vaccination.

Clinical Public Health and Occupational Health are especially focused on maximizing HCP vaccination and other activities to prevent the spread of influenza throughout the VHA health care system. From a public health perspective, achieving a culture of safety within VHA facilities begins with the individual and the commitment to vaccination as a responsibility to protect yourself, coworkers, patients, and others in the VA community. Getting vaccinated against flu is the first step.



Section One 1

OVERVIEW
VA INFLUENZA MANUAL 2012-13

SECTION ONE

OVERVIEW: VA INFLUENZA MANUAL 2012-13

This manual is produced every year by the VA Infection: Don't Pass It On (IDPIO) team, a dedicated group of staff from both the VA facilities, VISN offices, and several VA Central Office programs that represent many disciplines and perspectives (see the Acknowledgements section for who we are).

The flu manual has been revised to provide updated factual information about flu vaccination and guidance on how to implement successful influenza prevention campaigns throughout VHA.

INFLUENZA (THE FLU)

Influenza is a common, often miserable, and sometimes very serious and even a deadly illness. Every year 5% to 20% of the US population gets infected by the influenza virus. In healthy younger adult populations, influenza's impact on daily life can be substantial. Not surprisingly, influenza is a common cause of work absenteeism.

Some people don't take the flu seriously. Each year we hear about the flu and "message fatigue" does occur. Nevertheless, we hear about flu each year because its impact is so significant. While flu is a serious cause of illness, loss of work, hospitalization and mortality for those who are older or have serious underlying health problems, it also can cause serious infections and even death in those who are young and otherwise healthy.

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2012-2013 Goals for VA Influenza Vaccination Program

Each year the *Infection: Don't Pass It On* team, in conjunction with the leadership of our public health programs, develop goals for the campaign. This year's goals are as follows:

1. Within each VA health care facility, gradually increase the seasonal influenza vaccination rate of health care personnel toward the 2020 Healthy People goal of 90%.[++]

2. Promote seasonal influenza vaccination to all Veteran patients. *Note: This is based on the Federal recommendation of universal influenza vaccination of all people age 6 months and older.*

3. Reduce disparity of influenza vaccination rates by increasing the rate of vaccine uptake within female patients and those patients under age 50.

4. Promote consistent and proper documentation and tracking for all influenza vaccinations.

5. Promote non-vaccine methods of preventing infection, particularly hand hygiene and respiratory etiquette.

6. Encourage the entire VA health care community to promote and support influenza vaccination.

[++] Beginning FY 13, VHA facilities are expected to align their influenza vaccination for HCP with the 2020 Healthy People goal which is to achieve a rate of 90% by 2020. Facilities will need to look at their vaccination rates for the previous year and set a goal which will meet the Joint Commission standard. For example, a site may strive to raise HCP flu vaccination rates by 5% each year until 90% is attained by 2020. For most VHA health care facilities, this will translate into a gradual increase of the seasonal influenza vaccination rate of health care personnel to meet the 2020 Healthy People goal of 90%. To view these objectives for health care personnel, visit http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23.

VHA Performance Measures* FY 13 Patient Vaccination

Performance data on influenza vaccination is collected annually. The period of measurement is September 1, 2012 to March 31, 2013. The External Peer Review Program (EPRP) is the patient chart review process to evaluate care provided, including influenza vaccination for the populations listed below. Current influenza performance measures are:

- p22h Flu Shot Adult (50-64)
- p25h Flu Shot Older Adult (65+)
- p19s Flu Shot- Spinal Cord Injury and Disorder
- Refusals
  - Spinal Cord Injury (p23s)
  - General population (p23).

*There is no longer a national target for these performance measures. Unless any of these measures were selected by your Network Director or Facility Director, performance on these is not used for national accountability purposes.

VHA Influenza Vaccinations vs. National Influenza Vaccination Rates

	2005/06	2006/07	2007/08	2008/09	2009/10	2010/11	2011/12
VHA 65+*	na	na	84%	83%	82%	79%	77%
U.S. 65+***	65%	66%	66%	66%	70%	69%	65%
VHA 50-64*	na	na	69%	69%	71%	65%	65%
U.S. 50-64***	32%	37%	38%	40%	45%	46%	43%
VHA HCW**	53%	54%	65%	64%	77%	54%****	54%****
U.S. HCW***	42%	44%	49%	na	62%	64%	67%

*VHA Office of Quality & Performance; EPRP sampling of outpatient populations
**VHA Occupational Health, all paid employee populations
***National Health Interview Survey, and National Immunization Survey
****Note: Not all facilities documented seasonal influenza vaccination into the Occupational Health Record-keeping System (OHRS). Some facilities did not document all seasonal influenza vaccination in OHRS.

THE FLU TEAM

No one person, or even a couple of people, can manage a comprehensive flu vaccination campaign. The most effective campaigns have teams that are led by a designated "Flu Coordinator." Usually the flu coordinator is a "champion" of flu prevention and vaccination. Successful teams involve or represent the following clinical areas and departments:

- Facility Leadership
- Pharmacy
- Infectious Diseases
- Occupational Health
- Health Promotion/Disease Prevention (HPDP) Coordinator
- Infection Prevention and Control
- Facility Management Service (for setting up tables and areas for walk-in clinics),
- Nurse Managers (to assist with support for nurses to help administer flu vaccine),
- Clinical Applications (to ensure computer templates and reminders updated and planned for the upcoming flu vaccination season)
- Business Office (spacing needs)
- Public Affairs Officer (PAO)
- Human Resources (staffing needs)

A team approach is most successful in achieving substantial vaccination rates.

Make sure the communication between the team works well via planned meetings and coordinated email communications. Also ensure that messages that go out to staff and patients are seen by the team.

Villages VA Outpatient Clinic Team.

THEMES AND RECOMMENDATIONS

A "Flu Summit" was held this year, bringing together a host of VHA experts from across the country to consider the important topic of "Maximizing Vaccination Among VHA Health Care Personnel (HCP)." VHA has continued to have significantly high rates of vaccination among patients, but rates for HCP have been lower in recent years. This Summit was held to examine factors that influence HCP vaccination and identify best practices to increase HCP vaccination. Several key points emerged from the Summit that apply to both target groups for flu vaccination – patients as well as health care personnel. Themes to promote and improve flu vaccination rates are highlighted below:

- **Culture change** – Advancing and promoting a culture of safety is a primary component of increasing flu vaccination rates and reducing the spread of infections.
- **Leadership visibility and advocacy** – Working with leaders in the VISNs and facilities, as well as unions and Veteran Service organizations, advances a culture of safety.
- **Data feedback and management** – Using data on patient and health care personnel vaccination can drive vaccine rates and inform and direct program decisions.
- **Effective campaign development** – At the core of successful vaccination efforts is the designated "flu coordinator" and a host of individuals on the "flu team" that plan, implement, and evaluate flu campaigns each year.
- **Bundling vaccination efforts** – This refers both to including other measures of flu prevention, such as hand hygiene, as well as coordinating vaccination efforts for both patients and health care staff.
- **Communication** – this is essential to obtaining active leadership support, involving your flu team, informing your target audiences, and generally making your program work.

In his opening remarks at the Summit, Under Secretary for Health (USH) Dr. Robert Petzel reviewed the elements of a successful flu vaccination program:

- **Program planning** – Enlisting leadership, naming flu champions, and having sufficient staff and resources.
- **Implementation/vaccine delivery** – Make it available to all shifts, hold kick off events and events throughout the seasons.
- **Education/social marketing** – Make it multifaceted, use target messages appropriate to the audiences, and sustain interest over the season.
- **Program evaluation** – Know your rates, determine why rates may be low, look at strengths and areas for improvement.

The key strategies below were identified at the Summit as being effective for health care provider vaccination programs in particular, but applicable to patient programs as well.

- **Leverage partnerships** – Help foster and maintain partnerships between VHA and labor leadership, Veteran Service Organizations, the community, staff, and patients and families.
- **Integrate vaccination programs** – Link patient and health care staff programs.
- **Promote a comprehensive approach** to flu prevention – Besides promoting vaccination, educate your audiences about other methods of mitigating the disease, such as respiratory etiquette, hand hygiene, and encouraging people to stay home when ill.
- **Engage resources** – Seek ways to efficiently and effectively use facility staff, information technology, and VACO program office resources.

VHA Public Health Influenza Vaccination: Guiding Principles

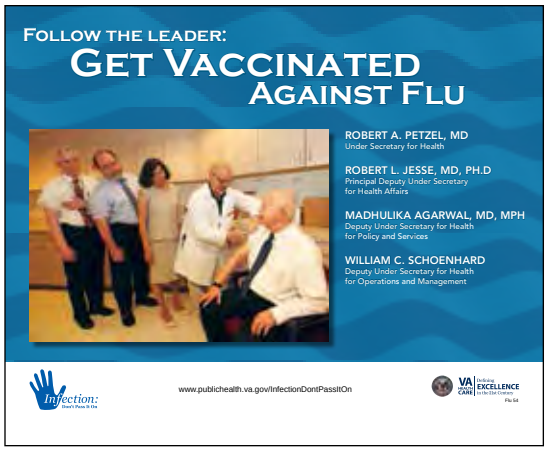
1. VHA supports the DHHS Healthy People 2020 and Joint Commission goal of achieving a seasonal influenza vaccination rate of 90 percent or higher.
2. Vaccination is the most important and effective tool we have for preventing influenza.
3. Vaccination is not 100% effective necessitating additional measures to control the spread of influenza and other infectious diseases. These effective control measures include respiratory hygiene, hand hygiene and staying out of the workplace when ill with influenza like symptoms.
4. Health care personnel should not be in the workplace when they have influenza-like symptoms.
5. Managers/supervisors should refer health care personnel with influenza-like symptoms to occupational health for evaluation or send them home.
6. Currently, evidence in the medical literature does not sufficiently support wearing of masks or respirators as a substitution for influenza vaccination.
7. Additional resources will be needed to meet and sustain a seasonal health care personnel influenza vaccination goal of 90 percent.
8. Influenza Vaccination is a critical tool in *Promoting and Protecting the Health of Veterans and Staff.*

A FRAMEWORK FOR COMMUNICATION

One key aspect of successful flu vaccination programs that permeate this manual is the importance of communication. Effective communication between leadership and the flu team will cultivate a more successful flu prevention campaign. Numerous messages and approaches are described in this manual, principally in Sections 4 and 5, and information and materials are also provided via the IDPIO team emails ("flu tips") over the course of each season.

As your facility integrates and/or coordinates your HCP and patient vaccination campaigns, it is important to make sure your leadership, team, staff, and patients are well informed about flu prevention and vaccination programs over the course of the season. Inform people early and often; carry out a sustained communications effort. Your Public Affairs Officer (PAO) is an essential part of this effort and knows best practices in internal staff communications, communications with Veterans, updating of intranet and Internet sites, and use of multiple means of traditional and social media to get the word out.

During flu season, note the key opportunities below that you and your PAO can use to frame campaign communications with leadership, health care personnel, and patients.



- **Campaign planning** – Enlist the support of your leadership by keeping them informed and seeking their support. Make sure that the team of people your recruit to help you are communicating early and often.
- **Campaign start up** – Use the days and weeks before you get your vaccine supply to inform patients and health care personnel about the importance and availability of vaccination.
- **Sustained reminders** – Seek opportunities for regular reminders about flu vaccination. Put out reminders to key audiences over time and in plenty of locations throughout your facility and by multiple means including; email, newsletters, handouts, and electronic bulletin boards and signage around your facility.
- **National efforts** – Participate in national campaigns that help you promote flu vaccine.
  - National Influenza Vaccination Week – December 2-6, 2012
  - VA Staff Vaccination Week – January 7-11, 2013
- **It's not too late** – Flu has been known to peak as late as May (but usually around February) and it is useful to continue to let people know they can be vaccinated later in the season.
- **Wrap up and restart** – Collect and monitor flu vaccination rates and share your successes with leadership, patients and staff. Use data to drive areas for improvement as well.

The full range of steps for carrying out your campaign, from planning and ordering supplies to monitoring and reporting progress, are presented in a new "Campaign Calendar" at the end of this section. The Campaign calendar can be used to develop and carry out your campaign over the course of the whole year. The calendar can be viewed, downloaded, or printed from www.publichealth.va.gov.

HOW TO USE THIS MANUAL

We recommend you go over each manual section to refresh your memory (or if you are new to this, get up to speed), find new information, and think through your program and your approaches. Use this manual at flu meetings, as a resource to answer flu-related questions, and to find resources and references to policies, guidance, and best practices.

Messages from the Under Secretary for Health (USH) Dr. Robert Petzel and from one of VA's influenza experts, Dr. Richard Martinello. These provide important perspectives on how flu vaccination fits into the mission of VHA and insight on the science underlying flu prevention.

Section 1 offers an overall framework to plan and conduct a successful flu vaccination campaign. It provides this year's goals for VA's Influenza Vaccination Program, the flu team, key elements and recommendations for flu programs, guiding principles from the Office of Public Health for influenza vaccination, and a framework for communication over the course of the season. It contains a newly developed ***Seasonal influenza Campaign Calendar*** that we hope provides a structure for your program.

Section 2 provides a clinical overview of influenza, the virus, and the vaccine. It outlines efficacy and effectiveness of the vaccine, how flu is spread, influenza illness, and vaccine safety.

Section 3 provides detailed information from CDC and other key sources on this year's influenza vaccine, including who should receive vaccine, clinical information about each form of flu vaccine, as well as the CDC's Vaccine Information Statements (which vaccine administrators are required to give vaccine recipients).

Section 4 provides in depth information on flu vaccination programs for health care personnel. This section reviews strategies for success, provides campaign messages, describes The Joint Commission standards and program evaluation, and has a question and answer section.

Section 5 describes strategies for successful patient flu vaccination programs.

Section 6 outlines two other mitigation strategies to prevent the spread of flu and support a culture of safety within VHA facilities: hand hygiene and respiratory etiquette.

Section 7 focuses on the importance of proper documentation of patient vaccination in the Computerized Patient Record System (CPRS) and documentation for employees and volunteers into the Occupational Health Record-Keeping System (OHRS). These contain instructions for documentation and CPT codes for flu vaccine.

continued on next page

Section 8 outlines the abundance of resources available from the IDPIO library to support flu vaccination campaigns. You'll find web and SharePoint information for locating posters, videos, fact sheets and brochures for clinical and patient audiences. Learn how to order print materials through the Training Management System (TMS).

Section 9 provides guidance on the importance of pneumococcal vaccination.

Appendices in Section 10 cover administration of influenza vaccines, policy and guidance from the Centers for Disease Control (CDC), and VHA. You'll find a plethora of resources, references, and Web sites listed on various topics related to flu, flu vaccine, and prevention. Also provided is a script for clinicians to use as a guide to answering difficult questions related to flu and flu vaccine.

The VA *Infection: Don't Pass It On* (IDPIO) team intends for this manual to be a rich resource of ideas, inspiration, facts, and new information. In revising and updating it each year, we look for developments in all aspects of flu prevention, from the vaccine, to the disease, to prevention, to ways to run successful programs. We welcome your comments and suggestions for ways to improve and refresh this manual, not to mention better ways to run flu prevention programs. Please send your comments and suggestions to troy.knighton@va.gov or publichealth@va.gov. Here's to a successful flu prevention campaign!

Flu Poster
Boise VA Medical Center, Boise, Idaho

SEASONAL INFLUENZA

Campaign Calendar

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Use this as a planning guide for your seasonal influenza vaccination campaigns. It contains helpful activities within a timeline to assist you and your flu teams to plan, implement and evaluate your facility's campaign for vaccinating all health care personnel (HCP) and enrolled Veterans.

- April: Evaluate & Review the Campaign (that just ended)
- May: Initiate the Planning Process
- June: Plan the Campaign
- July/Aug: Promote the Campaign
- September: Start the Campaign
- October/November: Conduct the Campaign
- December: Continue the Campaign
- January/February: Reinforce the Campaign
- March/April: Complete the Campaign

APRIL Evaluate & Review the Campaign (that just ended)

- ❑ Review current year vaccination rates among different services/departments and types of health care personnel and Veterans for opportunities to increase vaccination.
- ❑ Identify strengths and opportunities for improvement.
- ❑ Review various aspects of your flu vaccination program.

✓MAY Initiate the Planning Process

- ❑ Obtain support from administration/leadership to identify/verify the health care system flu vaccine coordinator and flu partners/team.
- ❑ Assemble a seasonal flu vaccination campaign team – advertise via email announcements.
- ❑ Establish your team email group for efficient email communications.
- ❑ Schedule and hold a committee kick-off meeting for upcoming flu vaccine season. Some flu vaccine teams meet year-round.
- ❑ Identify and discuss your two basic flu vaccination target audiences:
  - **1.)** Enrolled VETERANS: Identify your target patient groups by gender, age, race, or by location such as inpatient areas, outpatient areas, Community-based Outpatient Clinics (CBOC), Community Living Centers (CLC).
  - **2.)** HCPs: employees, volunteers, and academic affiliates in all areas. NOTE: Some facilities have lead people for each target group (HCP vs Veterans) and areas (CLC, CBOCs, etc).
- ❑ Choose and order educational and promotional materials (posters, brochures, t-shirts, pens, coupons, etc).
- ❑ Talk to administration to organize incentives and awards (coupons, time off awards, etc).
- ❑ Talk to administration for approval and budgeting for any temporary or other staff needed to meet increased human resource needs for vaccinations in the fall.
- ❑ Begin monitoring influenza updates from the Centers for Disease Control and Prevention (CDC), The Joint Commission (TJC), and VHA.
- ❑ Talk to pharmacy about types and amounts of flu vaccine to be ordered.
- ❑ Order your vaccine. Consider multi-dose vials versus single use pre-filled syringes, discussing pros and cons of ordering each. Consider high dose, intradermal, and standard dose flu vaccine, considering pros and cons of providing each and target groups.
- ❑ Also order additional supplies needed for flu vaccination: gauze, band-aids, alcohol wipes, safety needles and syringes, if needed for type of flu vaccine formulation ordered.
- ❑ Order/acquire additional flu vaccine equipment, such as a flu vaccine cart, sharps containers, clipboards.
- ❑ Reserve space for walk-in flu vaccine clinic (usually held in October or November, depending on final delivery date for flu vaccine contract for the year).
- ❑ Schedule educational offerings for August, September, and the upcoming flu season.

Consider a Flu Vaccine Campaign Planning Team with representatives from:

- ✔ Pharmacy,
- ✔ Infectious Diseases physician,
- ✔ Occupational Health,
- ✔ Health Promotion/Disease Prevention (HPDP) Coordinator,
- ✔ Infection Prevention,
- ✔ Facility Management Service (for setting up tables and areas for walk-in clinics),
- ✔ Nurse Managers (to assist with support for nurses to help administer flu vaccine),
- ✔ Clinical Applications Coordinator (CAC) -to ensure computer templates and reminders updated and planned for the upcoming flu vaccination season,
- ✔ Business Office (spacing needs),
- ✔ Public Affairs Officer,
- ✔ Human Resources (staffing needs).
- ✔ Facility Leadership.

JUNE Plan the Campaign

The VA Influenza Manual, hand and respiratory hygiene, flu, and other educational resources are available at va **www.publichealth.va.gov** or for order through **www.tms.va.gov**.

- ❑ Review what was done the previous year-successes and failures.
- ❑ Review strategies and best practices utilized by successful health care facilities.
- ❑ Consider innovative approaches for the upcoming season, such as drive-through flu vaccine clinics, partnering with local public health agencies (look for ideas in the VA Influenza Manual).
- ❑ Define all resources and supplies needed to support your campaign (including budget and human resources).
- ❑ Refer to the latest version of the VA Influenza Manual to garner campaign ideas and checklist of activities and strategies to implement your campaign.
- ❑ Continue monitoring influenza updates from VHA, CDC and TJC.
- ❑ Discuss communications about how to meet goals and requirements.
- ❑ Email facility staff to solicit their input and to let staff know who is on the planning team.

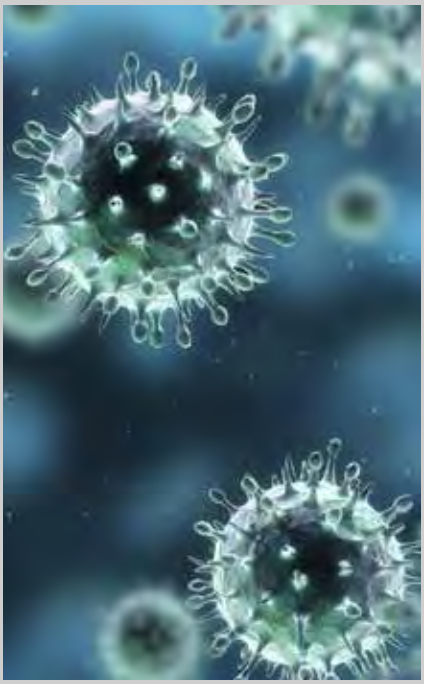
JULY/AUG Promote the Campaign

Plan for and begin offering flu vaccine when your first shipment arrives.

- ❑ Update your influenza vaccine protocols such as standing orders, etc.
- ❑ Gather promotional materials and resources.
- ❑ Obtain the current year's CDC Vaccine Information Statements (VIS).
- ❑ Determine campaign dates, theme, and a preliminary promotion plan based on the date when flu vaccine is to arrive and quantities are available.
- ❑ Finalize logistics and staffing plans for the campaign week/kick-off event.
- ❑ Identify and train nurses and other staff who may be vaccinating.
- ❑ Train all providers who administer flu vaccine on proper documentation in health records – Computerized Patient Record System (CPRS) for patients and the Occupational Health Recording-keeping System (OHRS) for HCP.
- ❑ Communicate and distribute campaign plan and information.
- ❑ Educate HCP and Veterans about influenza and the influenza vaccine.
- ❑ Notify patients and staff about flu, flu vaccine and where to get vaccinated using a variety of media or mail (send facility-wide emails, postcards, and other reminders).
- ❑ Communicate clinic times and offerings via newsletter, daily facility email message system etc.
- ❑ Based on available supply, determine a plan as needed to identify which groups will receive the first doses of flu vaccine that arrive. This initial group may include HCP, high risk patients, such as those on dialysis, those in home-based primary care, or patients who arrive in outpatient clinics who are not anticipated to return for health care appointments for several months.
- ❑ Plan a kick-off event when sufficient vaccine is available to sustain the program.
- ❑ Monitor all communications from VHA and CDC regarding seasonal influenza.

SEPTEMBER Start the Campaign

- ❑ Hold a kick-off event if sufficient vaccine is available.
- ❑ Operate occupational health clinic with extended hours for influenza vaccination.
- ❑ Administer vaccination at alternative sites, in lobbies, clinics and other areas.
- ❑ Monitor daily operations and identify ways to improve efficiency.
- ❑ Document vaccinations in CPRS (Veterans) and OHRS (health care personnel).
- ❑ Review and communicate all polices, recommendations and procedures for flu vaccinations BEFORE executing your campaign.
- ❑ Maintain campaign communication and emphasize the need to vaccinate throughout the entire influenza season.



OCTOBER/NOVEMBER Conduct the Campaign

- ❑ Monitor vaccination rates, identify problems, and brainstorm ways to reach all who have not been vaccinated.
- ❑ Continue to document all vaccinations into health records.

DECEMBER Continue the Campaign

- ❑ Maintain the campaign and communicate that it is not too late to be vaccinated.
- ❑ Hold an event during the National Influenza Vaccination Week (first week of December).
- ❑ Plan for VA Staff Vaccination Week (second week of Jan).
- ❑ Track and analyze vaccination rates and communicate findings.
- ❑ Monitor and communicate levels of seasonal influenza in your community.

JANUARY/FEBRUARY Reinforce the Campaign

- ❑ Execute strategies for VA Staff Vaccination Week in January.
- ❑ Identify those who have not been vaccinated and may have received the influenza vaccine elsewhere. Document those vaccinated elsewhere in CPRS and OHRS.
- ❑ Continue to monitor and communicate levels of seasonal influenza in your community.
- ❑ Maintain the campaign and communicate that it is not too late to be vaccinated.

MARCH/APRIL Complete the Campaign

- ❑ Continue to vaccinate as long as flu is circulating in your communities, or until your flu vaccine expires or until vaccine quantities are depleted.
- ❑ Continue to monitor and communicate levels of seasonal influenza in your community.
- ❑ Maintain the campaign and communicate to health care personnel that it is not too late to be vaccinated if the influenza virus is still prevalent in the community.
- ❑ Meet with the planning committee.
- ❑ Evaluate campaign, identify challenges, and celebrate successes.
- ❑ Communicate results of your seasonal influenza vaccination campaign.

RESOURCE LINKS

VA Influenza Home page:
www.publichealth.va.gov/flu

VHA Influenza Directive:
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2335

VA Influenza Manual:
www.publichealth.va.gov/flu

VHA Poster, brochures, and other education materials:
www.publichealth.va.gov/flu/materials

Centers for Disease Control and Prevention (CDC) Resources:
www.cdc.gov/flu/freeresources

The Joint Commission:
http://www.jcrinc.com/fluchallenge/

CDC:
http://www.cdc.gov/flu/

Infection: Don't Pass It On Campaign

Veterans Health Administration
U.S. Department of Veterans Affairs
Clinical Public Health (10P3b)
810 Vermont Ave, NW
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May 2012

Section Two 2

INFLUENZA AND FLU VACCINE

SECTION TWO

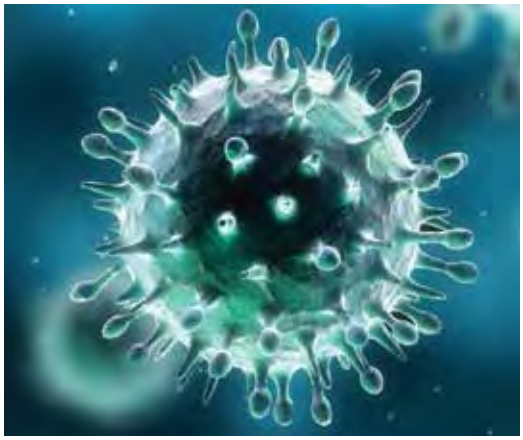
INFLUENZA AND FLU VACCINE

WHAT IS INFLUENZA?

Influenza is a common, often miserable, and sometimes very serious and even deadly illness. The viruses that cause influenza occur in three major types: types A,B, and C. Types A & B commonly cause illness in humans whereas type C is rarely associated with significant clinical illness. Type A influenza also circulates in bird and mammal populations.

Influenza viruses are always changing, and this helps to account for the annual seasonal epidemics that we see in temperate climates. Antigenic mutations on the viral RNA segments are responsible for the so-called "drift" or minor variation from year-to-year that is responsible for epidemics.

Antigenic "shifts" represent a major change in influenza viruses and are the result of the exchanging of genetic segments between influenza A viruses. Such shifts can cause world-wide pandemics.



HOW IS INFLUENZA SPREAD?

The primary mode of influenza transmission is thought to be the respiratory route through large, virus-laden particles called droplets. When an infected person coughs or sneezes they generate these particles that can travel up to 5 or 6 feet or more. These particles may then settle on the mucosal surfaces of another person's upper respiratory tract, thereby infecting that other person.

In addition to droplet transmission, influenza may also be transmitted through small, aerosol particles as well as through contaminated surfaces.

The incubation period before the onset of symptoms is typically 2 days. Infected adults can begin shedding virus within 24 hours of becoming infected and up to 1 day before the onset of symptoms, and virus may be shed for about 5 days after the onset of symptoms. This means that adults could infect other people beginning 1 day before illness onset and for 5 days after illness onset.

WHAT IS INFLUENZA ILLNESS?

Every year 5% to 20% of the US population develops influenza illness. The symptoms of classic influenza include the abrupt onset of fever, sore throat, headache, cough, muscle aches, and fatigue. This acute

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The annual health and economic burden attributable to influenza across all age groups is huge.

respiratory illness generally lasts about 5 to 7 days, with sufferers often confined to bed for 1 or 2 of those days. About 10% to 20% of people may have some symptoms that linger beyond 10 days.

In healthy younger adult populations, influenza's impact on daily life can be substantial. Not surprisingly, influenza is a common cause of work absenteeism. It is also a common cause of presenteeism (working while ill). In one study of working adults, people with influenza-like illness (fever/feverish plus cough or sore throat) were sick on average for 8 days. During their illness, they missed on average 1.5 days of work and then returned to work while still ill for an additional 4.4 days. In college and university students, influenza-like illness has also been reported to interfere with academic performance including taking exams and doing homework.

WHAT ARE SOME OF THE COMPLICATIONS OF INFLUENZA?

Most people who develop influenza recover without any complications. However, the elderly, young children, and others with chronic medical conditions such as chronic heart or lung disease or diabetes are more susceptible to the serious complications of influenza. These complications can include primary influenza pneumonia, secondary bacterial pneumonia, and exacerbations of underlying medical conditions. The consequences of these complications include increases in outpatient and emergency department visits, hospitalization, and even death.

WHAT ARE THE BEST WAYS TO PREVENT INFLUENZA?

Annual vaccination against influenza represents the mainstay of prevention efforts against this virus. In the United States, vaccination is recommended every year for all people 6 months of age and older who otherwise have no contraindication to receiving the vaccine.

In addition to annual vaccination, attention to good hand hygiene, respiratory/cough etiquette and judicious use of antiviral medications are also important. Avoiding contact with others who are ill and staying home when ill oneself are also important measures.

Do you know what the "H" and the "N" represent in H1N1 and other flu viruses?

They are 2 surface glycoproteins

Hemagglutinin (HA) and Neuraminidase (NA).

Vaccine Type	Packaging/Administration	Standard or High Dose
TIV	Multi-dose vials	Standard dose
TIV	Pre-filled syringes	Both
TIV	Intradermal	Standard dose
LAIV	Pre-filled nasal syringes	Standard dose

Currently flu vaccines contain antigens to three types of influenza viruses – two type A and one type B virus. For the 2012-2013 season, these are

- A/California/7/2009 (H1N1)pdm09-like virus;
- A/Victoria/361/2011 (H3N2)-like virus;
- B/Wisconsin/1/2010-like virus (from the B/Yamagata lineage of viruses).

WHAT TYPES OF INFLUENZA VACCINES ARE AVAILABLE?

There are two basic types of influenza vaccines currently used in the United States: inactivated trivalent (TIV) vaccines made from dead viruses and live attenuated influenza vaccines (LAIV) made from living but weakened viruses. The former are available as intramuscular and intradermal formulations and the latter is available as a nasal spray vaccine. In addition there is a high-dose inactivated intrmuscular influenza vaccine approved for use in elderly populations – those age 65 years and older.

In the future, quadrivalent vaccines containing antigens to two type A and two type B viruses will likely be available.

Healthcare providers should consult product inserts to confirm appropriate use of specific vaccines given the age and other characteristics of their patients

HOW WELL DO INFLUENZA VACCINES WORK?

Modern influenza vaccines are clearly efficacious. However, reported vaccine efficacy will depend on the clinical endpoint used. Among the different kinds of endpoints used in studies are laboratory confirmed influenza illness, influenza-like illness (ie respiratory illness without laboratory confirmation), hospitalization for pneumonia and influenza, and death. For each of these outcomes, the reported vaccine efficacy will depend on the outcome's sensitivity and specificity for being caused by influenza.

Recently it has reported that, for studies reporting efficacy against laboratory confirmed influenza, real-time polymerase chair reaction (rtPCR) represents the best laboratory test for confirming influenza infection. Other laboratory tests that have been used in studies assessing influenza vaccine efficacy include culture (which suffers from a lower sensitivity than rtPCR) and serology (which may result in biased outcome ascertainment due to the fact that vaccinated persons may be less likely to show serologic evidence of infection than unvaccinated persons). Thus previously published studies assessing laboratory confirmed outcomes must be carefully scrutinized with regard to the exact method of laboratory confirmation used.

Other challenges in interpreting influenza vaccine efficacy or effectiveness studies relate to the type of study design used. Randomized clinical trials represent the gold standard for study design. But for assessing influenza vaccine effectiveness in the elderly, most published studies are not clinical trials but observational studies that are more susceptible to residual confounding and bias.

Despite these challenges, we know that, while they are not perfect, influenza vaccines do work. A recent systematic review of randomized placebo controlled trial and observational studies of influenza vaccine efficacy for reducing laboratory confirmed influenza illness (culture or rtPCR confirmed) found that the efficacy of trivalent inactivated vaccine in adults under age 65 was 59% (95% confidence interval of 51% to 67%. In the same systematic review several observational studies of influenza vaccination were reviewed. In one study of adults 50 years of age and older, vaccination was associated with reductions in hospitalization for laboratory confirmed influenza of 56% to 73% over 3 study years. While the results for individual years were not statistically significant, the pooled estimate of vaccine effectiveness reported in the original study was statistically significant at 61.2% with a 95% CI 17.5% to 81.8%.

Some clinical trials have also assessed influenza vaccine efficacy for reducing symptomatic respiratory illnesses (eg influenza-like illnesses) during the influenza season without relying on laboratory confirmation. These outcome case definitions include a lot of "noise" since many winter respiratory illnesses are caused by non-influenza viruses. In healthy younger adults, influenza vaccination reduces these clinical influenza-like illnesses on average by 30% (95% confidence interval 17% to 41%). For the elderly, only one clinical

trial has reported a similar outcome, and vaccination in that study had an efficacy of 31% to 47% depending on the clinical case definition used.

HOW SAFE ARE INFLUENZA VACCINES?

Current influenza vaccines are very safe. Each year tens of millions of doses of vaccine are used in the United States, and cumulatively over the past decade almost 1 billion doses of influenza vaccine have been administered in this country. We have a substantial experience with these vaccines including a large amount of data demonstrating their safety.

With standard dose trivalent inactivated influenza vaccines, for example, randomized placebo controlled trials have demonstrated that healthy younger adults and the elderly do not experience significant increases in systemic symptoms following a flu shot than after a placebo injection. You don't get the flu from a flu shot. However, following the injection some people may experience local reactions such as arm soreness or tenderness that are usually mild to moderate and resolve in 1 to 2 days.

With the live attenuated influenza vaccine (the nasal spray vaccine), healthy adults experienced somewhat higher rates of runny nose and sore throat following receipt of the vaccine when compared to placebo. These symptoms were generally mild with resolution within a few days.

The Centers for Disease Control and Prevention and the Food and Drug Administration closely monitor vaccines for safety in cooperation with state and local health departments, healthcare providers, and other partners including the Department of Veterans Affairs. In addition to published research studies, other sources of data on vaccine safety include the national Vaccine Adverse Events Reporting System (VAERS) and the national Vaccine Safety Datalink (VSD) project sponsored by the Centers for Disease Control and Prevention.

HOW CAN WE INCREASE VACCINATION RATES?

Adult influenza vaccination rates in the United States remain suboptimal. vaccination rates for persons 65 and older, for example, have generally remained at a plateau around 70% over the last decade – well short of the 90% goal. Vaccination rates for persons under 65 are even lower, and disparities by race/ethnicity persist.

In order to improve vaccination rates, providers and patients must be educated about the importance of influenza and its complications and the benefits of vaccination. However, education alone is rarely sufficient for increasing vaccination rates. Among the most potent predictors of receipt of vaccination is whether a patient's provider has recommended vaccination. Providers should take advantage of every opportunity to assess their patients and recommend (and administer) vaccinations. Other evidence-based strategies include the use of standing orders for vaccination, the use of reminder/recall systems, and regular assessments of vaccination coverage levels with feedback. And of course, healthcare providers should practice what they preach and protect their vulnerable patients by getting vaccinated themselves.

HOW DO I REPORT AN ADVERSE REACTION FROM FLU VACCINATION?

Providers report the adverse event through the Adverse Event Tracking Package (ART) in CPRS and also through the VA Adverse Drug Event System (VA ADERS). Providers have direct access to CPRS. The Chief of Pharmacy (or designee) at every facility inputs adverse reactions into VA ADERS for drugs and vaccines. A Vaccine Adverse Event Reporting System (VAERS) form for all vaccines should be submitted anytime an adverse event occurs. The VAERS form is available at http://vaers.hhs.gov/pdf/vaers_form.pdf. On-line reporting is available at https://secure.vaers.org/. In addition, all adverse events must be documented in OHRS.

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Section Three 3

VACCINE INFORMATION

SECTION THREE

VACCINE INFORMATION

NEW INFORMATION FROM THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

1. The Advisory Committee on Immunization Practices (ACIP) for seasonal flu year 2012-2013 continues to recommend annual influenza vaccination of all persons ages 6 months and older. This recommendation is outlined with other information and guidance in the MMWR / August 17, 2012 / Vol. 61 / No. 33; Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm?s_cid=mm6132a3_x.

There is evidence supporting that annual influenza vaccination is safe and an effective preventive health action with potential benefits to all age groups. Vaccination of children protects those that come into contact with them and should follow ACIP recommendations for ages, timing, and number of doses. **Note: Children less than 6 months old cannot receive influenza vaccination.**

2. Annual influenza vaccination is recommended for optimal protection against getting the flu. Several studies have determined the vaccine efficacy will begin to decline over the course of one year and yearly vaccination to prepare for the upcoming seasonal flu is the safest action available. The 2012-2013 influenza vaccine will contain the following strains of influenza:

- A/California/7/2009 (H1N1)pdm09-like virus;
- A/Victoria/361/2011 (H3N2)-like virus;
- B/Wisconsin/1/2010-like virus (from the B/Yamagata lineage of viruses).

While the H1N1 virus used to make the 2012-2013 flu vaccine is the same virus that was included in the 2011-2012 vaccine, the recommended influenza H3N2 and B vaccine viruses are different from those in the 2011-2012 influenza vaccine for the Northern Hemisphere. This was decided by the WHO Vaccine Composition Meeting which met February 23, 2012 and was supported by the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) February 28, 2012.

3. There are three routes available for delivery of the vaccination in the 2012-2013 influenza season: Traditional injection method using the intra-muscular route for all age groups, an intra-dermal route for ages 18 to 64; and the intra-nasal spray for healthy individuals ages 2 – 49 years of age. The intra-dermal route formulation is available by special request through your Chief Pharmacist.

4. The high dose formulation of the inactivated trivalent (TIV) vaccine for persons age 65 and older was offered for VA National Contract purchasing for this

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Memphis VAMC

Commitment to a Healthy VA Community

Staying healthy includes getting vaccinated for diseases that are vaccine preventable. Getting vaccinated for seasonal influenza is just one step individuals can take toward keeping their immune systems strong. VA's active seasonal flu campaign is an example of our commitment to save lives and resources, and to keep our VA community healthy.

Flu vaccine is a primary defense against influenza. Other mitigation strategies include promoting effective hand hygiene practice and proper respiratory etiquette.

year's influenza vaccine campaign. It contains four times the amount of antigen as standard inactivated vaccine. Not all facilities have purchased the Fluzone™ High-Dose [Sanofi Pasteur] formulation. Check with your facility Pharmacy Chief to see if the high dose flu vaccine is available for use at your facility.

5. A Quadrivalent (four component) formulation has been approved by the FDA for use in the USA and is being developed by manufacturing companies. This formulation will not be available for the 2012 – 2013 season.

6. Increasing vaccination rates for health care personnel, persons at risk for complications from influenza infection, contacts of persons at risk for influenza complications and children should be a high priority, while encouraging annual vaccination of all age groups. ACIP continues to emphasize influenza vaccinations and vaccination clinics should be scheduled as early as vaccine is available and continue throughout the remainder of the influenza season.

7. A second strategy, antiviral agents, is useful as an adjunct in the prevention of influenza – especially when influenza exposure has occurred and treatment with antivirals is indicated. However, annual vaccination still remains the best defense against seasonal influenza. Antiviral medications can be used for chemoprophylaxis and have been demonstrated to prevent influenza illness in certain circumstances. When used for treatment, antiviral medications have also been demonstrated to reduce the severity and duration of illness, particularly if used within the first 48 hours after illness onset. In an article published February 7, 2012 on the CDC website, http://www.cdc.gov/media/haveyouheard/stories/Influenza_antiviral.html?s_cid=ccu021312_017, it was stated that "….After careful consideration of all available evidence, CDC guidance on the use of antiviral medications remains unchanged. The Centers for Disease Control and Prevention (CDC) continues to recommend the use of the neuraminidase inhibitor antiviral drugs (oral oseltamivir and inhaled zanamivir) as an important adjunct in the prevention and treatment of influenza." For the full document outlining ACIP and CDC recommendations and references supporting the statements in this "Have You Heard," see: Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP) ACIP antiviral recommendations, see: http://www.cdc.gov/mmwr/pdf/rr/rr6001.pdf.

CDC's updated recommendations for use of influenza antiviral medications can be consulted for guidance. The Infectious Diseases Society of America (http://www.idsociety.org/uploadedFiles/IDSA/Guidelines-Patient_Care/PDF_Library/HIV%20Primary%20Care.pdf) and the World Health Organization also offer guidance on clinical management of influenza, including use of antivirals. Because antiviral resistance patterns can change over time, clinicians should monitor local antiviral resistance surveillance data.

8. Live attenuated seasonal influenza vaccine (LAIV) is only recommended for healthy person's ages 2 – 49 years of age who are not pregnant.

9. Trivalent inactivated influenza vaccine (TIV) is still indicated for patients 6 months and older including those with high risk conditions. Please read individual manufacturer guidelines for restrictions and recommendations associated with vaccinating children.

10. CDC Guidelines has developed a contingency plan for timing and prioritization of administering influenza vaccine if supply is delayed or reduced. This plan is located on page 48.

11. Persons who have previously reported an egg allergy as a contraindication to getting the vaccine may be able to be vaccinated. An allergy to eggs must be distinguished from allergy to influenza vaccine. Those who have had a severe allergic reaction to influenza vaccine components must NOT take the influenza vaccine. Persons who have had a severely allergic response

(anaphylaxis) to egg protein are still contraindicated. However, those who have a hypersensitivity to eggs may be able to tolerate receiving the TIV vaccine. Several recently published studies have documented a safe receipt of TIV in persons with egg allergy. Several Manufacturer package inserts have updated their contraindications to include only ***severe allergic reactions to egg proteins.*** In several studies evaluating influenza vaccine in persons with egg allergy, additional safety measures have been taken, such as skin prick testing with vaccine and administering the vaccine in 2 doses.

RECOMMENDATIONS REGARDING PERSONS WITH EGG ALLERGY

Each of the following recommendations applies when considering influenza vaccination of persons who have or report a history of egg allergy.

1. Persons who have experienced only hives following exposure to egg should receive influenza vaccine with the following additional measures (Figure 1):

- **a)** Because studies published to date involved use of TIV, TIV rather than LAIV should be used.
- **b)** Vaccine should be administered by a health-care provider who is familiar with the potential manifestations of egg allergy.
- **c)** Vaccine recipients should be observed for at least 30 minutes for signs of a reaction following administration of each vaccine dose.

Other measures, such as dividing and administering the vaccine by a two-step approach and skin testing with vaccine, are not necessary.

2. Persons who report having had reactions to egg involving angioedema, respiratory distress, lightheadedness, or recurrent emesis, or persons who required epinephrine or other emergency medical intervention, particularly those that occurred immediately or within minutes to hours after egg exposure are more likely to have a serious systemic or anaphylactic reaction upon re-exposure to egg proteins. Before receipt of vaccine, such persons should be referred to a physician with expertise in the management of allergic conditions for further risk assessment (Figure 1).

3. All vaccines should be administered in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available. ACIP recommends that all vaccination providers be familiar with the office emergency plan.

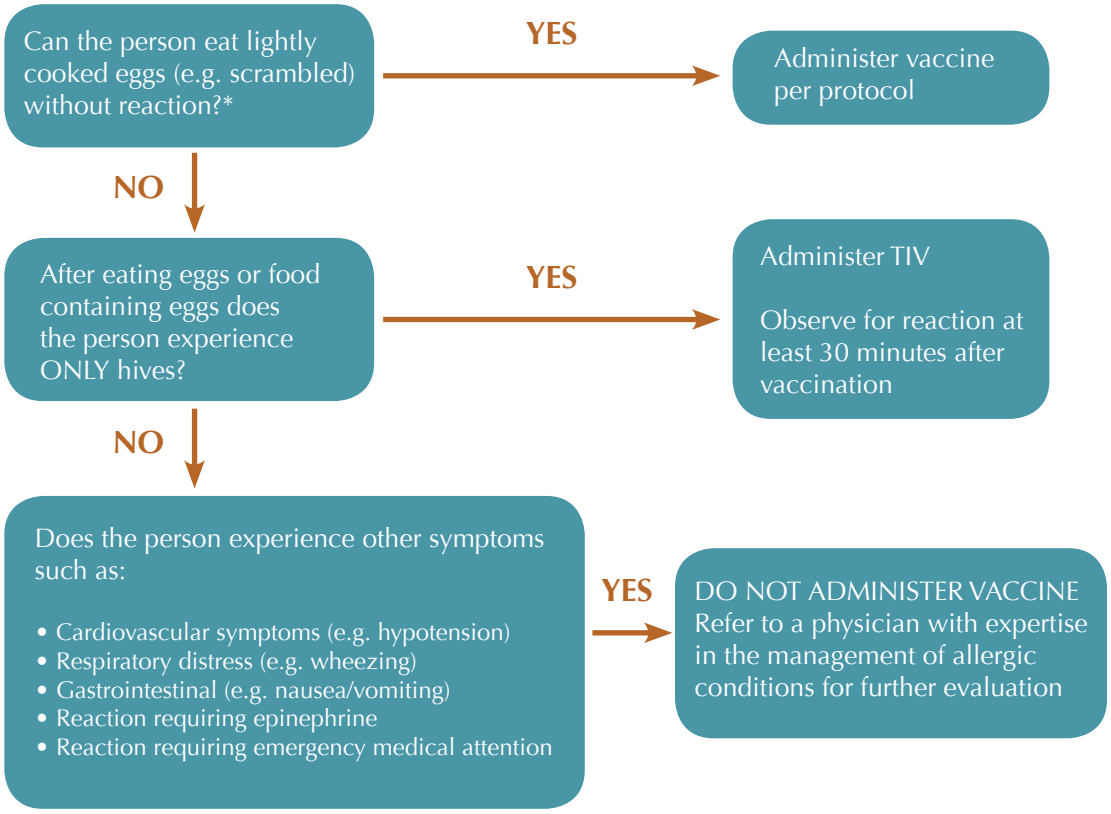
4. Some persons who report allergy to egg might not be egg allergic. Those who are able to eat lightly cooked egg (e.g., scrambled eggs) without reaction are unlikely to be allergic. Conversely, egg-allergic persons might tolerate egg in baked products (e.g., bread or cake); tolerance to egg-containing foods does not exclude the possibility of egg allergy. Egg allergy can be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, plus skin and/or blood testing for immunoglobulin E antibodies to egg proteins.

5. A previous severe allergic reaction to influenza vaccine, regardless of the component suspected to be responsible for the reaction, is a contraindication to receipt of influenza vaccine.

VA Flu Updates

VA staff and providers can review the latest information on 2012-2013 influenza vaccine found in flu advisories, tips, and other updates on email and on the Web: www.publichealth.va.gov/flu

Figure 1: Recommendations regarding influenza vaccination for persons who report allergy to eggs — Advisory Committee on Immunization Practices (ACIP), 2011–12 influenza season



* Persons with egg allergy might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy.

Figure 2: 2012-13 Influenza Vaccine Dosage Chart

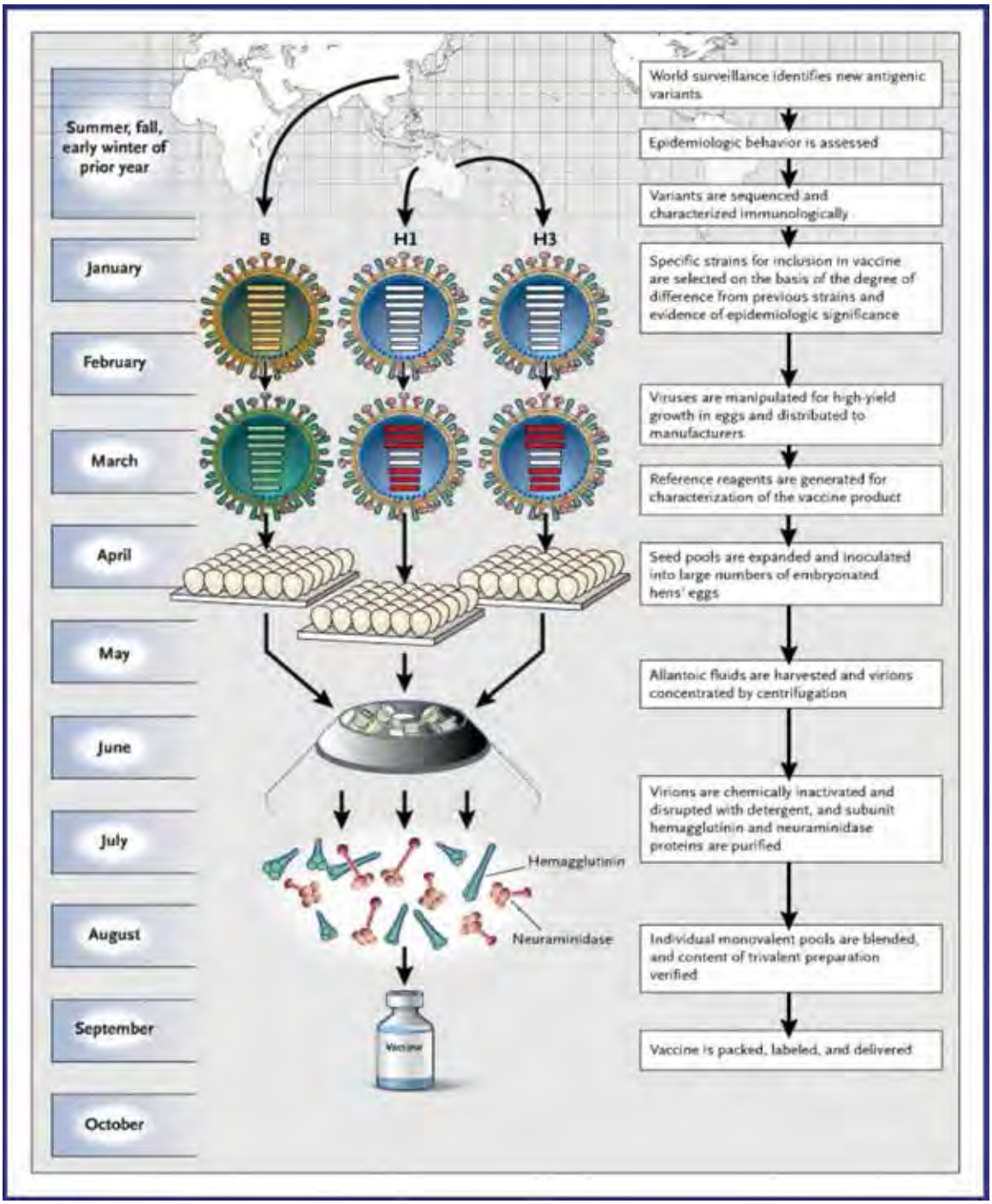
Vaccine Type	Route–Site	Appropriate Veteran Age	Adult Dosing Recommendations	Thimerosal Yes / No	Latex Yes / No
Inactivated injectable (pre-filled syringe)	Intramuscular[1]	18 years and older	0.5mL – prefilled syringe	No	Yes (Syringe Tip Cap) for these brands: Fluarix, Fluvirin, Fluzone, Agriflu
Inactivated injectable (multi-dose vials)	Intramuscular[1]	18 years and older	Multi-dose vial 0.5mL per dose	Yes	No
Inactivated injectable (high dose)*	Intramuscular[1]	65 years and older	0.5mL – High-Dose prefilled syringe	No	Yes (Syringe Tip Cap)
Inactivated injectable (intradermal)	Intradermal (instructions with device)	18 to 64 years	0.1 ml – prefilled microinjection systems	No	No
Live attenuated (nasal)	Intranasal	2 through 49 years if healthy and non-pregnant	0.2 mL – Spray ½ of dose into each nostril as indicated on the syringe.	No	No

1 Adults should be vaccinated in the deltoid muscle if muscle mass is adequate. The anterolateral aspect of the thigh may be used as an alternative.

± NOTE: The above vaccination codes should be reported in addition to the code for the actual administration of the vaccine, 90471.

* Trivalent inactivated vaccine **high dose.** A 0.5 ml dose will contain, A/California/7/2009 (H1N1)pdm09-like virus; A/Victoria/361/2011 (H3N2)-like virus; and B/Wisconsin/1/2010-like virus (from the B/Yamagata lineage of viruses).

Figure 3: Influenza Vaccine Production



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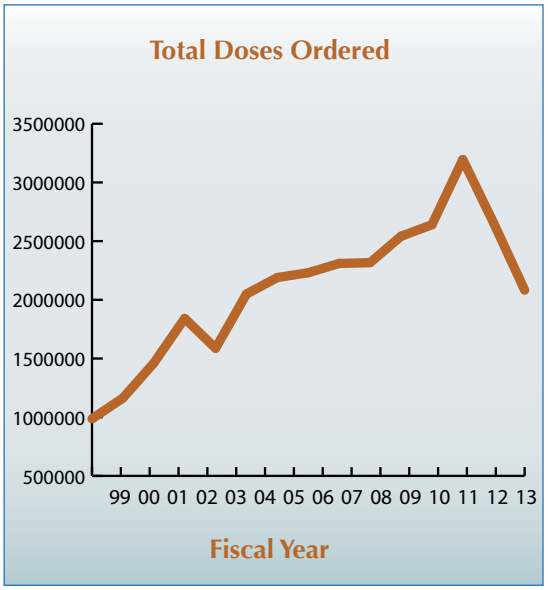
INFLUENZA VACCINE SUPPLIES

The 2012-13 National Mandatory Contract for influenza virus vaccine has been awarded to Sanofi Pasteur, Inc. and Novartis Vaccines & Diagnostics, Inc. Sanofi was contracted to provide the **high dose** vaccine formulation delivered in Pre-filled single dose syringes (High Dose adult dosage) that are preservative, Thimerosal, and mercury free (Latex free syringe tip cap). Novartis Vaccines & Diagnostics, Inc was contracted to provide **standard formulation** of 10 dose Multi-dose vials (Latex free) and Pre-filled single dose (standard formulation Adult dose) Latex, preservative, Thimerosal, and mercury free (May contain trace amounts of natural rubber latex in the syringe tip cap).

The National Contracts did not include the intra-dermal formulation. To order the intradermal formulation, talk to your Pharmacy Chief.

Figure 4: VA Influenza Vaccine Order History



VACCINE DELIVERY

Facilities ordering the Sanofi Pasteur High Dose vaccine: Shipment will be made with each facility receiving 100% of their requirements by September 15, 2012.

Facilities ordering Novartis vaccines should receive 1/3 of their influenza vaccine supply by September 1, 2012 with the second 1/3 by October 1st and the final 1/3 by November 1st. Flu coordinators and other VA staff involved in implementing the influenza vaccination campaign at each facility should contact their Pharmacy Chief regarding vaccine availability, type of vaccine dosing ordered, and quantities. Influenza vaccine is now available in a trivalent inactivated standard dose (suitable for all ages 6 months old and up), a higher dose formulation of inactivated seasonal influenza vaccine (Fluzone™ High-Dose) (for ages 65 years old and up), and an intra-dermal route of trivalent influenza (used in ages 18 to 64 years of age). Live attenuated influenza virus (FluMist®) (2 years of age thru 49 years of age for healthy persons only) is a nasal spray that may also have been ordered. Check with your Pharmacy Chief for delivery information and quantities ordered/available.

ADDITIONAL MATERIAL AND SUPPLY CONSIDERATIONS

Facilities should consider what additional supplies are necessary to implement their seasonal influenza vaccination program, such as safety needles for vaccine packaged in individual doses, and safety needles and syringes for vaccines that come in multidose vials. Other supply needs for vaccination such as alcohol swabs, gloves, sharps disposal containers, alcohol-based hand rub, vaccine information sheets, tables, chairs, clipboards and personnel responsible for giving and documenting vaccinations should be planned.

Finally, in planning influenza vaccination events and clinics, facilities should keep in mind the delivery dates and quantities of vaccine.

Facilities should begin offering seasonal flu vaccination as soon as vaccine arrives.

REMINDER:

Give the CDC Vaccine Information Statement (VIS) prior to administration of vaccine and document that the patient received the VIS, including the date of the VIS. Copies of the VIS are included in this section and can be found on-line at www.cdc.gov/vaccines/pubs/vis/default.htm

As with all vaccines, monitor and maintain the vaccine temperature between 2-8 degrees Centigrade (35°-46°F) when received and use before the expiration date. Monitor temperature 2 times daily.

VA vaccine programs can use any form of influenza vaccine available that their facility determines appropriate for their Veteran clients and are used in accordance with the recommendations associated with that type of vaccine. For the 2012-2013 influenza season the vaccine can be given IM (intra-muscular), intra-dermal or by the nasal spray route. Given the mutagenic nature of the influenza virus, careful observation during the upcoming seasonal influenza season may result in a change in strategy. Should this occur, information will be provided once the CDC strategic plans are in place. Additional recommendations, updates or supplements that might be required during the 2012-2013 influenza season can be found at: (http://www.cdc.gov/flu). The injectable trivalent vaccine will be offered in the standard formulation for use in all age groups (IM) and in a higher dose formulation for use in persons over age 65 (IM). The intra-dermal route of seasonal influenza vaccine (for ages 18 to 64) is available and studies have proven it to be as effective as the injectable vaccine administered via the intramuscular route. Live attenuated nasal spray continues to be available as well for ages 2 years old through 49 years old and can only be given to healthy persons.

WHO SHOULD BE VACCINATED?

The CDC Advisory Committee on Immunization Practices (ACIP) recommends that all people age 6 months or older who have no contraindications to the vaccine should get vaccinated each year.

There is no anticipated shortage of influenza vaccine for the 2012-2013 flu season. However, if faced with a limited vaccine supply, focus vaccination on the following groups:

1. Persons aged 6 months to 4 years or ≥50 years.

2. Have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus).

3. Immunosuppressed (including immunosuppression caused by medications or by human immunodeficiency virus).

4. Pregnant during the influenza season.

5. Are aged 6 months–18 years and receiving long-term aspirin therapy.

6. Are residents of nursing homes and other chronic-care facilities.

7. Are American Indians/Alaska Natives.

8. Are morbidly obese (body-mass index ≥40).

9. Are health-care personnel.

10. Are household contacts and caregivers of children aged <5 years, adults aged ≥50 years, or persons with medical conditions that put them at higher risk for severe complications from influenza.

INACTIVATED (INTRAMUSCULAR OR INTRA-DERMAL INJECTABLE) INFLUENZA VACCINE 2012-2013

The 2012-2013 trivalent influenza vaccine (TIV) for the United States will contain:

- A/California/7/2009 (H1N1)pdm09-like virus;
- A/Victoria/361/2011 (H3N2)-like virus;
- B/Wisconsin/1/2010-like virus (from the B/Yamagata lineage of viruses).

A. TIV is made noninfectious (i.e., inactivated or killed) and thus cannot cause influenza.

B. TIV is administered by intramuscular injection or by a special formulation intra-dermal injection. For adults, the deltoid muscle of the arm is the preferred site for both routes.

C. The intra-dermal formulation of TIV is available for vaccination in the age group

18 to 64 years of age. This vaccine will be administered using the intra-dermal route into the subcutaneous tissue above the deltoid muscle. The vaccine is different in formulation and available as a single dose syringe with intra-dermal needle attached. Studies have indicated this formulation offers the same immunity levels as the intramuscular route of TIV. The intra-dermal vaccine may not have been purchased by your facility and was not available through the VA National Contract for 2012 – 2013.

D. TIV is licensed for use among persons aged ≥6 months and older including those who are healthy, those with chronic medical conditions, or are pregnant or post partum. A different dosing schedule for children is required until 9 years of age.

E. TIV should be given to children (6 – 59 months) who have asthma or medical conditions that put them at higher risk for influenza complications instead of the live vaccine found in LAIV nasal spray.

F. High-dose TIV is available during the 2012-2013 influenza season. This formulation is approved for use in people age 65 years and older. High-dose flu vaccine may not have been purchased by your facility. Check with your Pharmacy Chief prior to receipt of shipment when planning your 2012-2013 immunization clinics.

G. TIV can be given to persons at risk for medical complications including:

- All persons aged ≥50 years of age
- Women who will be pregnant during the influenza season
- Adults and children who have chronic pulmonary (including asthma), cardiovascular, renal, hepatic, cognitive, neurological/neuromuscular, hematologic or metabolic disorders (including diabetes mellitus). Adults and children who have immunosuppression (including caused by medications or HIV)
- Residents of nursing homes and other long-term-care facilities

For specific guidance on administration of TIV, see Appendix A.

****NEW** Large type version of the vaccine information statement for inactivated influenza vaccine**

New from the CDC this year is a large type version of the VIS for the inactivated trivalent influenza vaccine. You can view and print this at http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-flu-largetype.pdf.

VACCINE INFORMATION STATEMENT

Influenza Vaccine
Inactivated
What You Need to Know

2012 - 2013

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite http://www.immunize.org/vis

1 Why get vaccinated?

Influenza ("flu") is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Other illnesses can have the same symptoms and are often mistaken for influenza.

Young children, people 65 and older, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease, or a weakened immune system – can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from influenza and even more require hospitalization.

By getting flu vaccine you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Inactivated influenza vaccine

There are two types of influenza vaccine:

1. **Inactivated** (killed) vaccine, the "flu shot," is given by injection with a needle.

2. **Live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

A "high-dose" inactivated influenza vaccine is available for people 65 years of age and older. Ask your doctor for more information.

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. Flu vaccine will not prevent disease from other viruses, including flu viruses not contained in the vaccine.

It takes up to 2 weeks for protection to develop after the shot. Protection lasts about a year.

Some inactivated influenza vaccine contains a preservative called thimerosal. Thimerosal-free influenza vaccine is available. Ask your doctor for more information.

3 Who should get inactivated influenza vaccine and when?

WHO

All people **6 months of age and older** should get flu vaccine.

Vaccination is especially important for people at higher risk of severe influenza and their close contacts, including healthcare personnel and close contacts of children younger than 6 months.

WHEN

Get the vaccine as soon as it is available. This should provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur at any time, but most influenza occurs from October through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your doctor.

Influenza vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

4 Some people should not get inactivated influenza vaccine or should wait.

- Tell your doctor if you have any severe (life-threatening) allergies, including a severe allergy to eggs. A severe allergy to any vaccine component may be a reason not to get the vaccine. Allergic reactions to influenza vaccine are rare.

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

- Tell your doctor if you ever had a severe reaction after a dose of influenza vaccine.
- Tell your doctor if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your doctor will help you decide whether the vaccine is recommended for you.
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from inactivated influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:
• soreness, redness, or swelling where the shot was given
• hoarseness; sore, red or itchy eyes; cough
• fever • aches • headache • itching • fatigue
If these problems occur, they usually begin soon after the shot and last 1-2 days.

Moderate problems:
Young children who get inactivated flu vaccine and pneumococcal vaccine (PCV13) at the same time appear to be at increased risk for seizures caused by fever. Ask your doctor for more information.

Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Severe problems:
- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, a type of inactivated influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html and
www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

One brand of inactivated flu vaccine, called Afluria, **should not be given** to children 8 years of age or younger, except in special circumstances. A related vaccine was associated with fevers and fever-related seizures in young children in Australia. Your doctor can give you more information.

6 What if there is a severe reaction?

What should I look for?
- Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?
- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

People who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

8 How can I learn more?

- Ask your doctor. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/flu**

Vaccine Information Statement (Interim)
Influenza Vaccine
(Inactivated)
7/2/2012
42 U.S.C. § 300aa-26

Office Use Only

At this time, the VA does not have a national contract for purchasing LAIV for our seasonal flu vaccine programs. Individual facilities may choose to order and administer this type of flu vaccine for specific recommended groups.

LIVE, ATTENUATED INTRANASAL INFLUENZA VACCINE (LAIV)

The 2012-2013 Live Attenuated influenza vaccine (LAIV) for the United States will contain:

- A/California/7/2009 (H1N1)pdm09-like virus;
- A/Victoria/361/2011 (H3N2)-like virus;
- B/Wisconsin/1/2010-like virus (from the B/Yamagata lineage of viruses).

A single **LAIV** is licensed in the United States: FluMist® (MedImmune, Inc.). LAIV is a live, trivalent, intranasally-administered vaccine that induces broad mucosal and systemic immune response. The vaccine is composed of a cold-adapted, temperature-sensitive virus that is only efficient at replicating in the temperature present in the nasal mucosa. For the 2012-2013 influenza season, there are no changes from the basic formula, only changes in the influenza strains that are recommended yearly. LAIV should be stored in a refrigerator between 2-8 degrees Centigrade (35°- 46°F) when received and used before the expiration date. LAIV is Thimerosal free. **DO NOT FREEZE**.

1. In general, LAIV is an option for vaccinating healthy VHA staff, volunteers, and Veterans under the age of 50. VA health care facilities may use it whether or not there is a shortage of inactivated (injectable) vaccine. But, especially in the event of a shortage of inactivated vaccine, use of LAIV conserves inactivated vaccine for those who are not eligible to receive LAIV. For specific guidance on administration of LAIV, see Appendix A.

2. Side effects that may occur after administration of LAIV include runny nose, nasal congestion, headache, sore throat, and cough.

Important Notice about LAIV:
LAIV should be stored in a refrigerator between 2-8 degrees Centigrade (35-46°F) when received and used before the expiration date. DO NOT FREEZE.

CAUTION

- **LAIV should NOT be given to:**

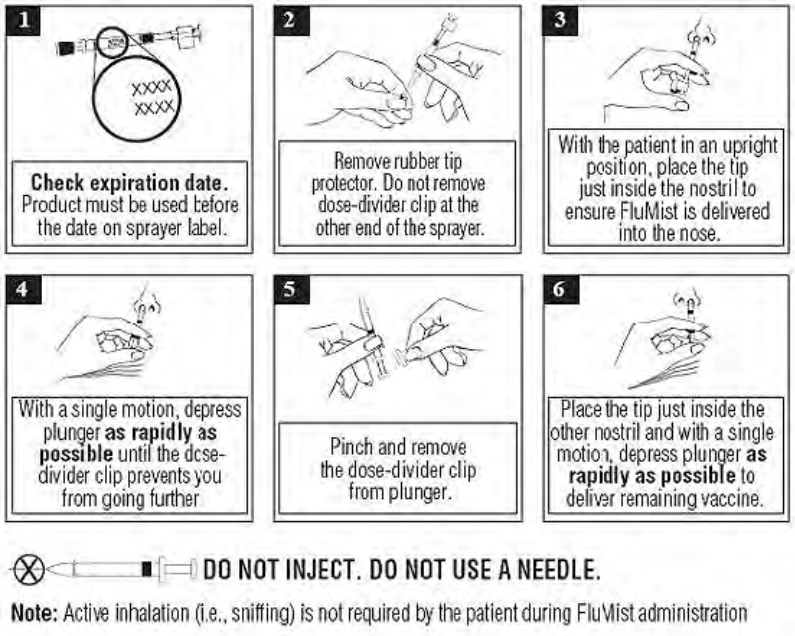
1. People who are 50 or over, or children under 2 years old.

2. Anyone with history of hypersensitivity, or anaphylactic reaction, to any component of FluMist® or any previous influenza vaccination.

3. Those allergic to eggs or egg products, gentamicin, gelatin, or arginine.

4. Persons who:
- ▫ Have had a severe allergic reaction to previous influenza vaccinations (e.g. rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips, or tongue)
- ▫ Are children and adolescents (6 months-18 years of age) receiving aspirin or aspirin-containing therapy (or another salicylate)
- ▫ Have asthma, or active wheezing, or children younger than 5 yrs with recurrent wheezing
- ▫ Are pregnant
- ▫ Have nasal congestion that impedes delivery of the vaccine to the nasopharyngeal mucosa (delay LAIV administration until resolved or offer TIV)
- ▫ Have a moderate or severe illness with or without fever
- ▫ Are a close contact of immunosuppressed persons who require a protected environment

5. Persons who have:
- ▫ Heart disease
- ▫ Lung disease
- ▫ Kidney disease
- ▫ Liver disease
- ▫ Immunosuppression/immunodeficiency disease
- ▫ Diabetes/metabolic disorders
- ▫ Anemia or other blood disorders
- ▫ Neurologic/neuromuscular disorders
- ▫ History of Guillain-Barré Syndrome



No transmission of LAIV in health-care settings has ever been reported.

- **Health care personnel who work with severely immunosuppressed persons requiring care in a protected environment should not be vaccinated with LAIV** (i.e., patients who are in hospital in a protective environment that is typically defined as a specialized patient-care area with a positive airflow relative to the corridor, high-efficiency particulate air filtration, and frequent air changes).
- **Severely immunosuppressed persons should *not* administer LAIV to others** because of the small risk of acquiring vaccine virus from the environment during administration.
- **LAIV *may* be administered to others by persons:** considered at high risk of influenza complications or persons with underlying medical conditions placing them at high risk or who are likely to be at risk, (this includes persons 50 years old or older, pregnant women, those who have asthma, cystic fibrosis, or chronic obstructive pulmonary disease; those with chronic metabolic disease like diabetes, those with renal disease, etc.).
- **Consideration for *restrictions* of health-care personnel at work after receiving LAIV:** The precaution regarding use of LAIV in protected environments is based on a theoretic concern of transmission of the live attenuated virus to severely immunocompromised persons. However, no transmission of LAIV in health-care settings has ever been reported. These viruses are cold-adapted and cannot replicate at normal body temperature making the risk for transmitting a vaccine virus to a severely immunocompromised person extremely low. Health-care personnel working in environments such as neonatal intensive care, oncology, HIV, or labor and delivery units can receive LAIV without restriction.
- **VA does not have a specific contract for purchasing LAIV** for our seasonal flu vaccine programs. Individual facilities may choose to order and administer LAIV flu vaccine for specific recommended groups. The use needs to be according to the current CDC ACIP guidelines. The ordering and administration of this formulation of flu vaccine would be coordinated through your pharmacy and flu vaccination planning committee.

REFERENCES

Package Insert (Circular); FluMist® Influenza Vaccine Live, Intranasal Spray 2011-2012 Formula, Initial U.S. Approval: 2003

Flu Mist prescribing information: http://www.medimmune.com/pdf/products/flumist_pi.pdf

Influenza Vaccination of Health-Care Personnel: Recommendations of the Health Care Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP), MMWR, Feb 24, 2006. Vol. 55/No RR-2. MMWR, July 17, 2008/57 (Early Release);1-60 http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e717a1.htm

Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR / August 17, 2012 / Vol. 61 / No. 33; found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm?s_cid=mm6132a3_x

Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza, Recommendations of the Advisory Committee on Immunization Practices (ACIP), *Recommendations and Reports*; January 21, 2011 / 60(RR01);1-24 http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6001a1.htm

VACCINE INFORMATION STATEMENT

Influenza Vaccine
Live, Intranasal
What You Need to Know

2012 - 2013

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite http://www.immunize.org/vis

1 Why get vaccinated?

Influenza ("flu") is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:

- fever/chills
- cough
- sore throat
- headache
- muscle aches
- runny or stuffy nose
- fatigue

Other illnesses can have the same symptoms and are often mistaken for influenza.

Young children, people 65 and older, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease, or a weakened immune system – can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from influenza and even more require hospitalization.

By getting flu vaccine you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Live, attenuated influenza vaccine - LAIV (nasal spray)

There are two types of influenza vaccine:

1. **Live, attenuated** influenza vaccine (LAIV) contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils.

2. **Inactivated** (killed) influenza vaccine, the "flu shot," is given by injection with a needle. *This vaccine is described in a separate Vaccine Information Statement.*

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year. Flu vaccine will not prevent disease from other viruses, including flu viruses not contained in the vaccine.

It takes up to 2 weeks for protection to develop after the vaccination. Protection lasts about a year.

LAIV does not contain thimerosal or other preservatives.

3 Who can receive LAIV?

LAIV is recommended for healthy people **2 through 49 years of age**, who are not pregnant and do not have certain health conditions (see #4, below).

4 Some people should not receive LAIV

LAIV is not recommended for everyone. The following people should get the inactivated vaccine (flu shot) instead:

- **Adults 50 years of age and older or children from 6 through 23 months of age**. (Children younger than 6 months should not get either influenza vaccine.)
- Children younger than 5 years with asthma or one or more episodes of wheezing within the past year.
- Pregnant women.
- People who have long-term health problems with:
  - heart disease
  - lung disease
  - asthma
  - kidney or liver disease
  - metabolic disease, such as diabetes
  - anemia, and other blood disorders
- Anyone with certain muscle or nerve disorders (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
- Anyone with a weakened immune system.
- Anyone in close contact with someone whose immune system is so weak they require care in a protected environment (such as a bone marrow transplant unit). *Close contacts of other people with a weakened immune system (such as those with HIV)* ***may*** *receive LAIV. Healthcare personnel in neonatal intensive care units or oncology clinics may receive LAIV.*
- Children or adolescents on long-term aspirin treatment.

Tell your doctor if you have any severe (life-threatening) allergies, including a severe allergy to eggs. A severe allergy to any vaccine component may be a reason not to get the vaccine. Allergic reactions to influenza vaccine are rare.

Tell your doctor if you ever had a severe reaction after a dose of influenza vaccine.

Tell your doctor if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your doctor will help you decide whether the vaccine is recommended for you.

Tell your doctor if you have gotten any other vaccines in the past 4 weeks.

Anyone with a nasal condition serious enough to make breathing difficult, such as a very stuffy nose, should get the flu shot instead.

People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 When should I receive influenza vaccine?

Get the vaccine as soon as it is available. This should provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur any time, but most influenza occurs from October through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your doctor.

Influenza vaccine may be given at the same time as other vaccines.

6 What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses very rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

Mild problems:
Some children and adolescents 2-17 years of age have reported:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.
- If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used it. Millions of doses of LAIV have been distributed since it was licensed, and the vaccine has not been associated with any serious problems.

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html
and
www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

7 What if there is a severe reaction?

What should I look for?
Any unusual condition, such as a high fever or behavior changes. Signs of a severe allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

8 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382**, or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

9 How can I learn more?

- Ask your doctor. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/flu**

Vaccine Information Statement (Interim)
Influenza Vaccine
(Live, Attenuated)
7/2/2012
42 U.S.C. § 300aa-26

Office Use Only

FREQUENTLY ASKED QUESTIONS (FAQS) ABOUT FLU VACCINE

1. What if a Veteran asks, "What everyday steps can I take to stop the spread of flu"?

Vaccination is the best way to protect yourself and your loved ones from the flu. Some additional steps you can take in your daily life include:

- Wash hands often with soap and water or an alcohol-based hand rub.
- Avoid touching your eyes, nose, or mouth. Germs spread this way.
- Try to avoid close contact with sick people.
- Practice good health habits like getting plenty of sleep and exercise, managing stress, drinking plenty of fluids, and eating a healthy diet.
- Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash afterwards.
- If you are sick with flu-like illness, stay home for at least 24 hours after your fever is gone without the use of fever-reducing medicine.

More information at http://www.flu.gov/prevention-vaccination/prevention/index.html

2. What should everyone know about the seasonal influenza vaccine?

- The most effective strategy for preventing influenza is annual seasonal influenza vaccination.
- One needs an influenza vaccination each year to get the latest protection for seasonal flu.
- Influenza vaccination can begin as early as August/September, per CDC guidelines, if vaccine is available.
- Flu vaccine can be given well into winter and spring as long as flu is circulating in your local area, or until the flu vaccine expires.
- The influenza vaccine is changed each year to match the current circulating type of influenza. The trivalent influenza vaccine (TIV) used each year is formulated to provide a close match to the known circulating strains of flu viruses and those anticipated to circulate that year.

3. When should flu vaccine be given?

Flu vaccine should be made available to both enrolled Veterans and VA health care personnel **as soon as flu vaccine is available** at the facility. Do not "hold" doses. Vaccination efforts should be structured to ensure the vaccination of as many persons as possible over the course of several months, with emphasis on vaccinating before influenza activity in the community begins. In any given year, the optimal time to vaccinate cannot be determined precisely because influenza seasons vary in timing and duration, and more than one outbreak can occur in a single community in a single year. More information is available http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm?s_cid=mm6132a3_x or Appendix XX.

4. How long does a flu vaccine provide protection?

The flu vaccine will protect you for one flu season. The flu vaccine is designed to protect you from the strains of flu that are expected to circulate that flu season. The components of the flu vaccine are updated every year in response to the most common circulating strains of flu virus. CDC recommends that seasonal influenza vaccine be administered to all age groups as soon as it becomes available.

5. Can the TIV be given with other vaccines?

- Yes, the inactivated influenza vaccine does not interfere with the immune response to other inactivated vaccines or to live vaccines.
- Inactivated or live vaccines can be administered simultaneously with live, attenuated influenza vaccine-LAIV (nasal spray).
- However, after administration of a live vaccine, another live vaccine should not be administered for at least four weeks.

6. How effective is the influenza vaccine?

Generally inactivated influenza vaccine will generate protective immunity in about two weeks. However, the effectiveness of inactivated influenza vaccine depends primarily on the age and immunocompetence of the vaccine

Vaccine should be offered when supplies arrive and as long as influenza is circulating; until your vaccine supplies are exhausted; until your vaccine expires; or until flu stops circulating in your area (sometimes flu season continues into late spring).

recipient, and the degree of similarity between the viruses in the vaccine and those in circulation. In years when the vaccine strains are not well matched to circulating strains, vaccine effectiveness is generally lower. The vaccine's effectiveness may also be lower among persons with chronic medical conditions and the elderly, as compared to healthy young adults and children. See Section XX for more information.

Overall, in years when the vaccine and circulating viruses are well-matched, influenza vaccines can be expected to reduce laboratory-confirmed influenza by approximately 70% to 90% in healthy adults <65 years of age. Several studies have also found reductions in febrile illness, influenza-related work absenteeism, antibiotic use, and doctor visits. For more information, visit http://www.cdc.gov/flu/professionals/vaccination/effectivenessqa.htm.

7. Are the eggs used for influenza vaccine production the same as eggs used for food consumption?

The eggs used for influenza vaccine production are different from eggs that are used for food consumption in that the eggs for the vaccine are embryonated. The influenza virus vaccine undergoes extensive testing. The vaccine manufacturing process is highly regulated under FDA's current good manufacturing practice requirements, including annual inspections of the manufacturing processes and facilities.

8. How do I report an adverse reaction from flu vaccination?

- Providers report the adverse event through the Adverse Event Tracking Package (ART) in CPRS and also through the VA Adverse Drug Event System (VA ADERS). Providers have direct access to CPRS. The Chief of Pharmacy (or designee) at every facility inputs adverse reactions into VA ADERS for drugs and vaccines. A Vaccine Adverse Event Reporting System (VAERS) form for all vaccines should be submitted anytime an adverse event occurs. Occupational health should also use this reporting structure. The VAERS form is available at http://vaers.hhs.gov/pdf/vaers_form.pdf. On-line reporting is available at https://secure.vaers.org/. In addition, all adverse events must be documented in OHRS for HCP and volunteers, and into CPRS for Veteran Patients.

9. Can we give flu vaccine to family members of enrolled Veterans?

No, at this time, flu vaccine purchased by the VA cannot be given to family members of enrolled Veterans.

Some VA facilities have partnered with local public health agencies in order to offer flu vaccine to family members and those not enrolled for VA care during flu vaccine campaigns.

The local public agencies *provide their own supply of flu vaccine,* records, and billing or cost accounting (i.e., billing Medicare or insurance). The local public health agency (i.e., "Visiting Nurse Association" or local county health department) provides its own staff to administer flu vaccines as well. The local public health agency may be available at a separate station/location within the VA facility during walk-in flu vaccine campaigns, for example.

10. What is the difference between standard-dose TIV and high-dose TIV?

High-dose flu vaccine contains four times the antigens as standard–dose flu vaccine. Standard-dose TIV preparations contain 7.5 mcg hemagglutinin antigen (HA) per vaccine strain (for children aged <36 months) or 15 mcg of HA (for persons aged ≥36 months) per vaccine strain. The high-dose TIV was approved recently for persons aged ≥65 years and contains 60 mcg per vaccine strain. They both contain the same amount of preservatives.

More information about high-dose flu vaccine is available on the following web sites:

- The Food and Drug Administration (FDA) web site on the Vaccines, Blood & Biologics page at: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm112854.htm.

- The U.S. Centers for Disease Control and Prevention (CDC) web page Questions & Answers Fluzone High–Dose Seasonal Influenza Vaccine at: http://www.cdc.gov/flu/protect/vaccine/qa_fluzone.htm.

11. Can I get the influenza from getting the influenza vaccine?

No, the influenza viruses contained in a flu vaccine are inactivated (killed), which means they cannot cause infection. Flu vaccine manufacturers kill the viruses used in the vaccine during the process of making vaccine, and batches of flu vaccine are tested to make sure they are safe. In randomized, blinded studies, where some people received flu vaccinations and others saline injections, the only differences in symptoms were increased soreness in the arm and redness at the injection site among some people who received the flu vaccination. There were no differences in terms of body aches, fever, cough, runny nose or sore throat. Some people may have coincidental respiratory illness around the time of receiving the influenza vaccine. This is not due to the influenza vaccine but due to concurrent exposure to other respiratory illness. http://www.cdc.gov/flu/about/qa/misconceptions.htm (accessed 7/20/12).

It's Federal Law!

You must give your patients current Vaccine Information Statements (VISs)

To obtain current VISs in more than 30 languages, visit the Immunization Action Coalition's website at www.immunize.org/vis

As healthcare professionals understand, the risks of serious consequences following vaccination are many hundreds or thousands of times less likely than the risks associated with the diseases that the vaccines protect against. Most adverse reactions from vaccines are mild and self-limited. Serious complications are rare, but they can have a devastating effect on the recipient, family members, and the providers involved with the care of the patient. We must continue the efforts to make vaccines as safe as possible.

Equally important is the need to furnish vaccine recipients (or the parents/legal representatives of minors) with objective information on vaccine safety and the diseases that the vaccines protect against, so that they are actively involved in making decisions affecting their health or the health of their children. When people are not informed about vaccine adverse events, even common, mild events, they can lose their trust in healthcare providers and vaccines. Vaccine Information Statements (VISs) provide a standardized way to present objective information about vaccine benefits and adverse events.

What are VISs?

VISs are developed by the staff of the Centers for Disease Control and Prevention (CDC) and undergo intense scrutiny by panels of experts for accuracy. Each VIS provides information to properly inform the adult vaccine recipient or the minor child's parent or legal representative about the risks and benefits of each vaccine. VISs are not meant to replace interactions with healthcare providers, who should answer questions and address concerns that the recipient or the parent/legal representative may have.

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination.

Source: www.cdc.gov/vaccines/pubs/vis/vis-facts.htm

Use of the VIS is mandatory!

Before a healthcare provider vaccinates a child or an adult with a dose of any vaccine containing diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) vaccine, the provider is required by the National Childhood Vaccine Injury Act (NCVIA) to provide a copy of the VIS to either the adult recipient or to the child's parent/legal representative.

How to get VISs

All available VISs can be downloaded from the website of the Immunization Action Coalition at www.immunize.org/vis or from CDC's website at www.cdc.gov/vaccines/pubs/vis/default.htm. Ready-to-copy versions may also be available from your state or local health department.

You can find VISs in more than 30 languages on the Immunization Action Coalition website at www.immunize.org/vis. To find VISs in alternative formats (e.g., audio, web-video), go to: www.immunize.org/vis/vis_sources.asp

Most current versions of VISs

As of July 2, 2012, the most recent versions of the VISs are as follows:

DTaP/DT 5/17/07	MMR 4/20/12
Hepatitis A 10/25/11	MMRV 5/21/10
Hepatitis B 2/2/12	PCV13 ..... 4/16/10
Hib 12/16/98	PPSV 10/6/09
HPV (H. papillomavirus)	Polio 11/8/11
Cervarix 5/3/11	Rabies 10/6/09
Gardasil 2/22/12	Rotavirus 12/6/10
Influenza (inactive) 7/2/12	Shingles 10/6/09
Influenza (live) 7/2/12	Td/Tdap 1/24/12
Japanese encephalitis .. 12/7/11	Typhoid 5/29/12
Meningococcal 10/14/11	Varicella (chickenpox) ... 3/13/08
	Yellow fever 3/30/11

Multi-vaccine VIS 9/18/08
(for 6 vaccines given to infants/children: DTaP, IPV, Hib, Hep B, PCV, RV)

Top 10 Facts about VISs

It's federal law!

Federal law requires that VISs must be used for the following vaccines when vaccinating patients of ALL ages:

- DTaP (includes DT)
- Td/Tdap
- Hib
- hepatitis A
- hepatitis B
- HPV
- influenza (inactivated and live vaccines)
- MMR and MMRV
- meningococcal
- pneumococcal conjugate
- polio
- rotavirus
- varicella

According to CDC, every time one of these vaccines is given — regardless of what combination vaccine it is given in — regardless of whether it is given by a public health clinic or a private provider — regardless of how the vaccine was purchased — and regardless of the age of the recipient — the appropriate VIS must be given out prior to the vaccination. There are also VISs for vaccines not covered by NCVIA: anthrax, Japanese encephalitis, pneumococcal polysaccharide, rabies, shingles, smallpox, typhoid, and yellow fever. CDC recommends the use of VISs whenever these vaccines are given. The VIS must always be used if vaccine was purchased under CDC contract.

> By using the VISs with your patients, you are helping to develop a better educated patient population and you are doing the right thing.

VISs are required for both public and private sectors

Federal law requires use of VISs in both the public and private sector settings and regardless of the source of payment for the vaccine.

VIS must be provided *before* vaccine is administered to the patient

The VIS provides information about the disease and the vaccine and should be given to the patient before vaccine is administered. It is also acceptable to hand out the VIS well before administering vaccines (e.g., at a prenatal visit or at birth for vaccines an infant will receive during infancy), as long as you still provide the VIS right before administering vaccines.

You must provide a current VIS for each dose of vaccine

The most current VIS must be provided before each dose of vaccine is given, including vaccines given as a series of doses. If five doses of a single vaccine are required, the patient (parent/legal representative) must have the opportunity to read the information on the VIS before each dose is given.

You must provide VISs for combination vaccines too

There is a VIS available for MMRV (ProQuad). An alternative VIS — the multi-vaccine VIS — is an option to providing single-vaccine VISs when administering one or more of these routine birth-through-6-month vaccines: DTaP, hepatitis B, Hib, pneumococcal (PCV), polio (IPV), or rotavirus (RV). The multi-vaccine VIS can also be used when giving combination vaccines (e.g., Pediarix, Pentacel, Comvax) or when giving two or more routine vaccines at other pediatric visits (e.g., 12–15 months, 4–6 years). However, when giving combination vaccines for which no VIS exist (e.g., Twinrix), give out all relevant single VISs. For example, before administering Twinrix give your patient the VISs for both hepatitis A and hepatitis B vaccines.

VISs are available in other formats, including more than 30 languages

You may use laminated copies of VISs for patients and parents to read and return before leaving the clinic, but you must **also** offer the patient (parent/legal representative) a printed copy of the VIS to take home.

If they prefer to download the VIS onto a mobile device, direct them to CDC's VIS Mobile Downloads web page: www.cdc.gov/vaccines/Pubs/vis/vis-downloads.htm

To download VISs in other languages, visit www.immunize.org/vis

Fact 7 Federal law does not require signed consent in order for a person to be vaccinated

Signed consent is not required by federal law (although some states may require them).

To verify that a VIS was given, providers must record in the patient's chart (or permanent office log or file) the following information:

- The published date of the VIS
- The date the VIS is given to the patient
- Name, address (office address), and title of the person who administers the vaccine
- The date the vaccine is administered
- The vaccine manufacturer and lot number of each dose administered

VISs should not be altered before giving them to patients

Providers should not change a VIS or write their own VISs. It is permissible to add a practice's name, address, or phone number to an existing VIS. Providers are encouraged to supplement the VIS with additional patient-education materials.

Provide VISs to all patients

For patients who don't read or speak English, the law requires that providers ensure all patients (parent/legal representatives) receive a VIS, regardless of their ability to read English. If available, provide a translation of the VIS in the patient's language.

Translations of VISs in more than 30 languages are available from IAC. Go to www.immunize.org/vis for VISs in multiple languages as well as in other formats.

CDC GUIDELINES LARGE-SCALE INFLUENZA VACCINATION CLINIC PLANNING

http://www.cdc.gov/flu/professionals/vaccination/vax_clinic.htm

To facilitate the most efficient and safe delivery of available vaccine via large community clinics, these recommendations and guidelines have been developed to assist with planning large-scale influenza vaccination clinics by public and private vaccination groups. Ideally, plans from private and public groups should be shared to identify best practices, avoid unnecessary overlapping of services, and maximize the effective and efficient delivery of influenza vaccinations.

This document provides general guidance to help ensure smooth operations at large-scale vaccination clinics under 8 major headings:

1. Leadership roles
2. Human resource needs
3. Vaccination clinic location
4. Clinic lay-out and specifications
5. Crowd management outside of the clinic
6. Crowd management inside of the clinic
7. Clinic security
8. Clinic advertising

Leadership Roles

- Designate local clinic leaders for overall vaccination campaign operations, and leaders for communications systems from both the public and private sectors
- Designate a clinic manager and a team leader each for supplies, logistics, medical personnel, support functions and their respective backups

Human Resource Needs

- Secure staff to fill the positions of greeters-educators, priority client screeners, registration personnel, medical screeners, form/payment collectors, clinic flow controllers, vaccination assistants, vaccination administrators, security and emergency medical personnel
- Meet the language needs of the community using multi-lingual staff
- Prepare staff members to know and execute their responsibilities and be able to correctly answer questions from clients
- Cross-train staff members, if possible, to enable flexibility in meeting needs at various stations as demands fluctuate
- Make provisions for surge capacity staffing, particularly at clinic opening time, where pre-scheduling will not be done or large numbers of unscheduled clients are anticipated
- Request surge capacity staff from out-of-area city/county agencies and health departments, local private nursing agencies, local nursing associations, local law enforcement, local medical community, health care worker and pharmacy students, volunteer groups and personnel working at the retail stores/corporations that might be used as the clinic sites
- Ensure staff well-being by scheduling times for rests and snacks in a designated area

Vaccination Clinic Location

- Seek out school gyms, churches, auditoriums, theaters or other large covered public spaces accessible to the elderly and persons with disabilities
- Ensure proximity to population centers and mass transit, ample parking, separate entry and exit doors, adequate lighting and heating, functional and accessible restrooms, and adequate space for all clinic functions such as screening, registration, vaccine storage, vaccination, and staff breaks
- Select a facility with space for reasonably large and well-delineated covered gathering areas outside and inside of the clinic

Clinic Lay-Out and Specifications

- Set up for unidirectional client flow from an external gathering area → eligibility screening area (multiple stations) → clinic entrance → facility waiting area(s) → registration/question and answer/form completion area (multiple stations) → medical screening/treatment area (as needed) → Medicare and other payment area (multiple stations) → vaccination area (multiple stations) → exit at a location distant from the entrance
- Use liberal amounts of rope, stands and signs in multiple languages, as needed, in outside waiting area(s) and inside clinic to delineate routes for clients to follow from station to station
- Provide seating for clients at each vaccination station and one or more vaccination stations with surrounding screens where over-clothed clients can discreetly bare their arms for vaccination
- Section off private area(s) where clients who experience acute adverse events after vaccination or who have medical problems can be evaluated and treated
- Ensure the presence of an onsite emergency medical kit and a designated trained physician, emergency medical technician (EMT), pharmacist, or nurse certified in basic cardiopulmonary resuscitation who can administer treatment for allergic reactions and address urgent medical problems

Crowd Management Outside of the Clinic

- Schedule staff to arrive 1 to 2 hours before clinic opening time to welcome and screen clients even if pre-scheduling is being used
- Arrange accommodations for special-needs clients (e.g., persons with disabilities, very advanced age or fragility) for expedited access into the clinic
- Direct arriving clients into several lines and use numerous signs and announcements to clarify who falls into high-risk groups
- Communicate the number of vaccine doses available at the clinic to the clients
- Instruct clients to assess their eligibility to receive vaccination by reviewing the CDC, or similar, self-screening form and vaccine information statement (VIS); provide language translation services where necessary
- Update clients on their estimated waiting times to be screened
- If vaccine supplies are limited and vaccine is being prioritized for certain groups, inform waiting clients that high-risk populations only will be served and a client numbering system will be in use. More information about ACIP's recommendations for priority groups in the setting of limited TIV vaccine can be found at: http://www.cdc.gov/flu/professionals/vaccination/vax_clinic.htm
- Schedule at least 2 screeners per line to reduce crowd size and waiting times by rapidly identifying and retaining high-risk clients and dispersing non-priority individuals
- Distribute sequentially numbered tickets, VIS or other forms in appropriate languages that permit entry into the clinic to high-risk clients only
- Provide clients who cannot be served for lack of vaccine an up-to-date listing of alternative clinics providing vaccinations

Crowd Management Inside of the Clinic

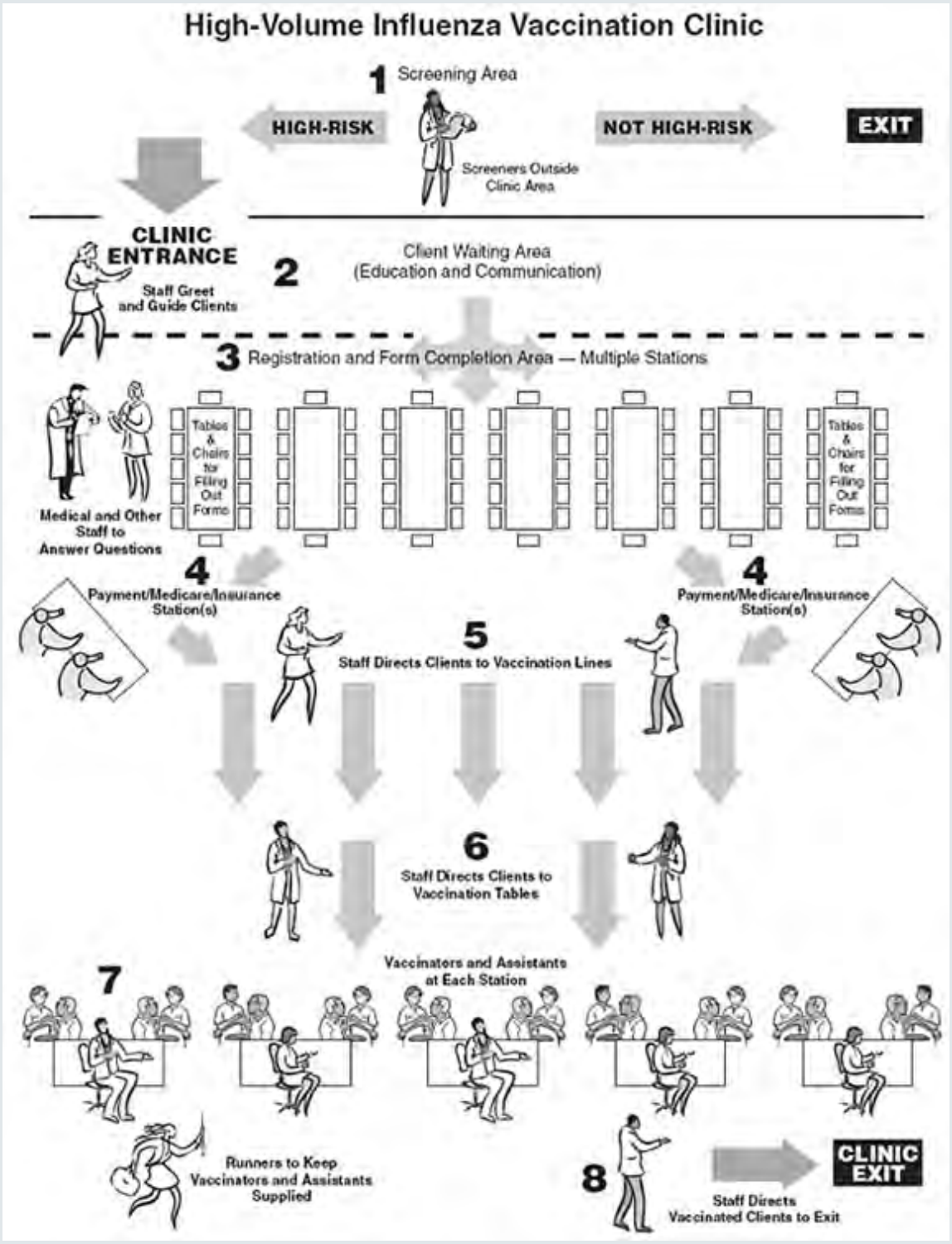
- Vaccinate clients in the order of their numbered tickets
- Arrange accommodations for special-needs clients (e.g., persons with disabilities, very advanced age or fragility) to receive expedited vaccination – consider a dedicated vaccination line
- Communicate clinic updates and wait times for vaccination so that clients are free to leave and return to be vaccinated
- Provide entertainment materials, TV and/or refreshments if wait times are anticipated to be long
- Assist clients in completing required forms (e.g., consent forms and/or vaccination cards) by having sufficient registration staff available
- Utilize runners to keep staff stocked with ample supplies so that they can remain at their stations
- Maintain a steady flow of clients through the clinic so that vaccinators are never without a client at their stations; redirect clients who create bottlenecks
- Fill syringes with vaccine at the time of vaccination only – prepare just enough vaccine to meet the clinic's ongoing needs if providers insist upon pre-filling syringes; never pre-fill before clinic opening hours
- Discard any vaccine-filled syringes remaining after the clinic closes
- Provide adequate facilities (e.g., waiting areas, restrooms, water) to meet the needs of the clients

Clinic Security

- Require all staff to wear identification cards color coded for their job functions
- Consider using uniformed presence to act as security and assist in managing crowds
- Employ security personnel to monitor the mood of waiting crowds and communicate deteriorating situations to the clinic manager
- Secure the vaccine and protect clinic staff and their valuables
- Recruit local volunteers familiar to clinic customers since they may be especially effective in diffusing crowd-related tension

Clinic Advertising

- Use multi-lingual and multimedia channels to widely post clinic purpose, dates, locations, times, and which populations will be served
- Provide instructions on how to set up appointments via telephone, in person, or other systems if pre-scheduling will be used
- Know how much vaccine is available for a scheduled clinic and how to reallocate vaccine through centralized or individual clinic efforts to meet the acute needs of other providers
- Recognize that scheduling may be overwhelmed and therefore not be maintainable or able to meet clients' needs during a time of severe vaccine shortage; direct clients to other facilities as required


High-Volume Influenza Vaccination Clinic
1 Screening Area
HIGH-RISK
NOT HIGH-RISK
EXIT
Screeners Outside Clinic Area
CLINIC ENTRANCE
Staff Greet and Guide Clients
2 Client Waiting Area (Education and Communication)
3 Registration and Form Completion Area — Multiple Stations
Tables & Chairs for Filling Out Forms
Medical and Other Staff to Answer Questions
4 Payment/Medicare/Insurance Station(s)
4 Payment/Medicare/Insurance Station(s)
5 Staff Directs Clients to Vaccination Lines
6 Staff Directs Clients to Vaccination Tables
Vaccinators and Assistants at Each Station
7
Runners to Keep Vaccinators and Assistants Supplied
8
CLINIC EXIT
Staff Directs Vaccinated Clients to Exit

REFERENCES:

These vaccination clinic planning considerations are a compilation of concepts and practices from many sources – published, unpublished and personal communication.

Published sources:

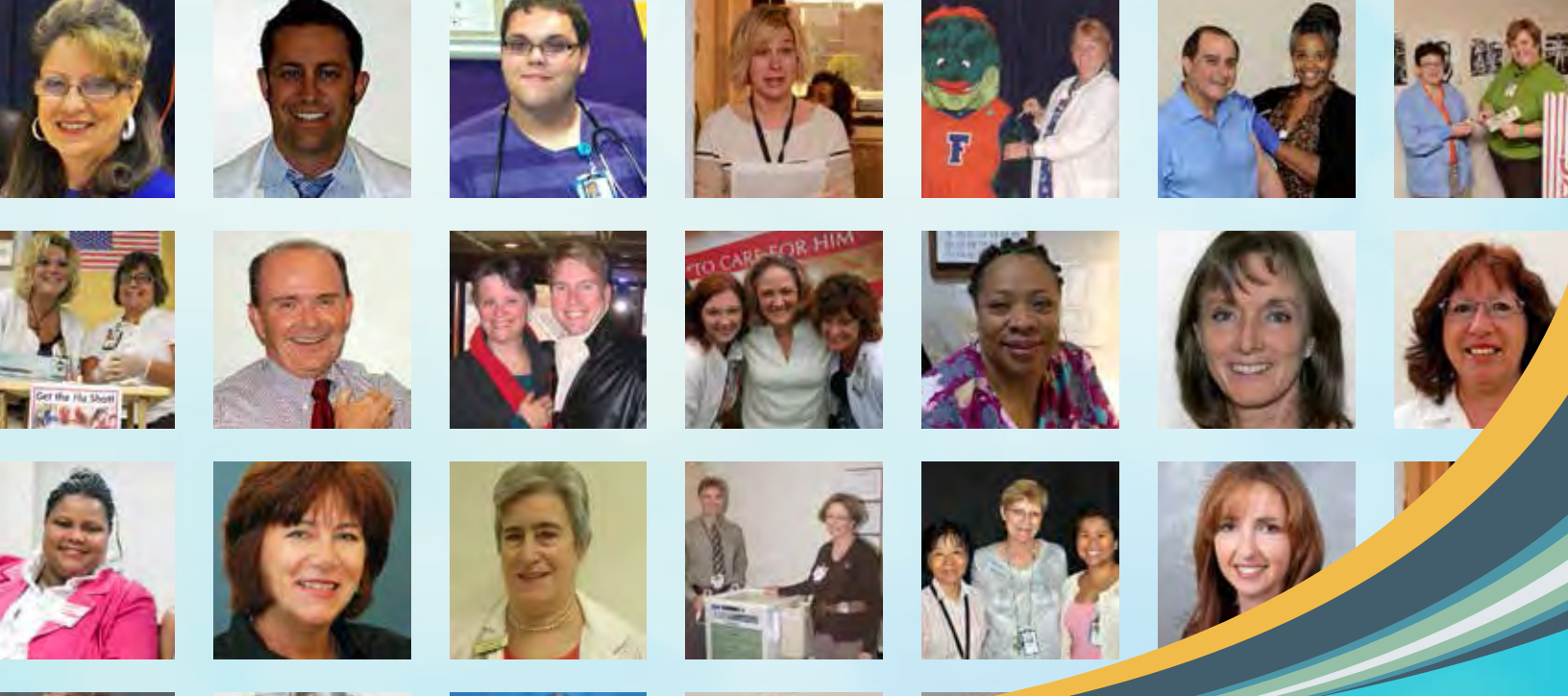
- Prevention and Control of Influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP)
- HHS Pandemic Influenza Plan [5.7MB, Pg 36]
- Vaccination Ventures: Explanation and Outcomes of Mass Smallpox Vaccination exercises. San Francisco Department of Public Health [3.09MB, Pg 27]

Unpublished draft document sources:

- Outbreak Control and Vaccination Campaign Management; Meningitis and Special Pathogens Branch, NCIS, CDC
- Community-Based Mass Prophylaxis: A Planning Guide for Public Health Preparedness. October 2004. Agency for Healthcare Research and Quality, Rockville, MD.
- General Guidelines for Pandemic Influenza Vaccination Clinics; Health Services Research and Evaluation Branch, NIP, CDC
- Pandemic Influenza: Clinic Preparation Checklists; Health Services Research and Evaluation Branch, NIP, CDC
- State and county health pandemic influenza preparedness plans; selected states
- State, county and city after action reports on exercises of mass prophylaxis and immunization plans; selected states

Here is an updated reference (although there may be another update in about a month):

Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2012. **August 17, 2012 / Vol. 61(Early Release)** Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm?s_cid=mm6132a3_x.



Section Four 4

HEALTH CARE PERSONNEL (HCP): HOW TO IMPROVE VACCINATION RATES

SECTION FOUR

HEALTH CARE PERSONNEL (HCP): HOW TO IMPROVE VACCINATION RATES

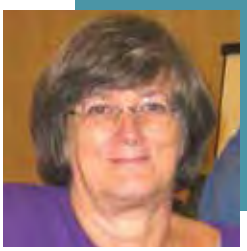
VHA health care personnel (employees, trainees, and volunteers) are at an increased risk of acquiring influenza because they are exposed to hospitalized and clinic patients who have influenza as well as to infected individuals in the community.

Even though influenza vaccination is not mandatory, each year VHA expects all HCP to get vaccinated for influenza. Advancing and promoting a culture of safety is a primary component of increasing influenza vaccination rates and reducing the spread of influenza and other infections. When health care personnel (HCP) make the decision to work for VHA, it should be with the understanding that they are making a commitment to work for the nation's premier health care system, where a culture of safety is expected. We recommend vaccination as a responsibility to protect our patients and others in the VA community, rather than as a personal preference.

Whether infected in the community or on the job, VA health care personnel (HCP) who are infected with influenza can transmit the virus to others. The Centers for Disease Control and Prevention (CDC) recommends that all HCP receive an annual influenza vaccination to prevent transmission. The goals of this strategy are to reduce the risk of patient and staff influenza exposure and to ensure that provision of health services to our Veterans are not disrupted. Nationally, influenza vaccination rates among HCP remain low. According to a CDC internet-based survey, vaccination rates for health care workers within the U.S. were approximately 63.5% in the 2010-2011 flu season.

VHA'S PERFORMANCE IN VACCINATING HEALTH CARE PERSONNEL (HCP)

From FY 06 to FY 12, VHA established a performance monitor for vaccinating employees against seasonal influenza. Graph 1 illustrates this performance over the last 7 years. Beginning FY 13, VHA facilities are expected to align their influenza vaccination for HCP with the 2020 Healthy People goal which is to achieve a rate of 90% by 2020. Facilities will need to look at their vaccination rates for the previous year and set a goal which will meet the Joint Commission standard. For example, a site may strive to raise HCP flu vaccination rates by 5% each year until 90% is attained by 2020. For most VHA health care facilities, this will translate into a gradual increase of the seasonal influenza vaccination rate of health care personnel to meet the 2020 Healthy People goal of 90%. To view these objectives for health care personnel, visit http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23. To capture accurate HCP vaccination data, the Occupational Health Record-keeping System (OHRS) must be used to document vaccination of VA health care personnel. This policy is contained in VHA Directive 2012-012, Occupational Health Record-Keeping System, April 11, 2012.



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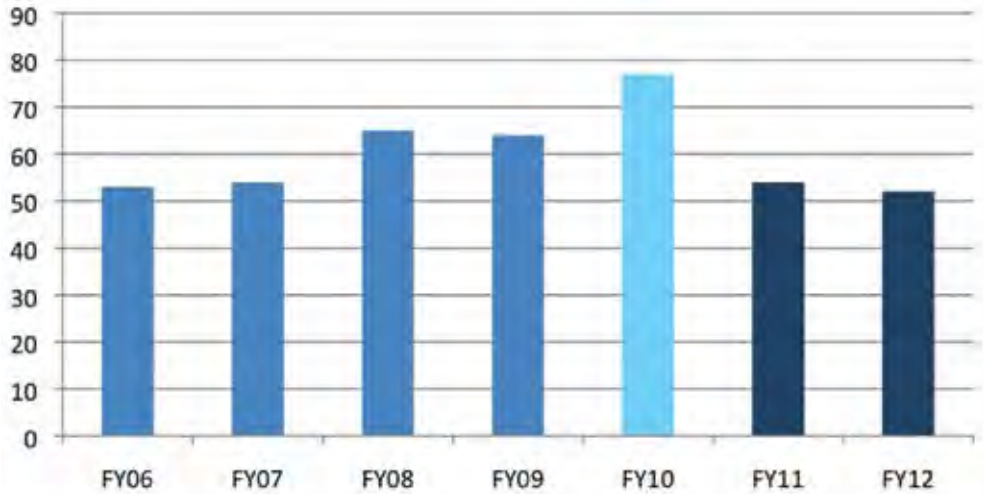
During the 2011-2012 influenza season 54% of VHA employees had documentation of influenza vaccination in the Occupational Health Recordkeeping System (OHRS). Others may have been vaccinated, but their vaccination was not recorded in OHRS.

VHA Employees Vaccinated Against Seasonal Influenza 2006-2012



FY06-FY09 vaccination data submitted by facilities

FY10 vaccination data from Voice of VA survey

FY11-FY12 vaccination data from OHRS *(Note: Not all facilities documented vaccination in OHRS.)*

The term health care personnel (HCP) within this manual is defined as all paid and unpaid persons (e.g. employees, volunteers, and trainees) working in health care settings who have the potential for exposure to infectious materials.

Leveraging partnerships with VISN and facility leadership is essential to advance a culture of demonstrated commitment to clinical care excellence and patient safety. VHA leadership, labor leadership, VSOs, and OPH's seasonal influenza program will work in tandem to promote vaccine uptake and provide strong messages to support VHA's goals for influenza vaccination at national and local levels. Leveraging these partnerships effectively includes approaches from "top down and bottom up." Facility leadership is essential to the formation and success of "The Flu Team."

WHY VHA HEALTH CARE PERSONNEL (HCP) SHOULD BE VACCINATED AGAINST SEASONAL INFLUENZA

1. Transmission of influenza in health care settings is a major concern. HCP who acquire influenza can spread the infection to patients, co-workers and their families and friends. Vaccination against influenza is an effective way to prevent influenza and its potential complications. In educating HCP on why they should be vaccinated, Occupational Health staff should stress:

- The vaccine is effective in preventing seasonal influenza.
- Transmission to patients, co-workers, family members, and friends is minimized when health care personnel are vaccinated.
- Individuals infected with the influenza virus may infect others without knowing it as they shed the influenza virus at least one day before any symptoms occur and continue until 4 to 5 days after symptoms begin.
- Absenteeism due to influenza decreases the number of staff available to take care of patients, which many see as a patient safety issue as it affects the delivery of care.

2. HCP should understand that personal responsibility includes protecting themselves against infectious disease such as influenza and thus protecting their patients. When promoting vaccination among HCP, Occupational Health staff should emphasize the following reasons to get the influenza vaccine:

- Protects you and your coworkers
- Protects patients
- Protects family and friends
- Decreases need to use sick leave
- Prevents severe illness
- Prevents death due to influenza

3. HCP may also have health problems and conditions that put them at increased risk of complications from influenza. These include:

- Chronic cardiac or pulmonary disorders severe enough to require regular medical follow-up care.
- Chronic health conditions such as diabetes mellitus and other metabolic diseases, cancer, immunodeficiency, liver disease, renal disease, anemia, and hemoglobinopathy.
- Any conditions that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration.
- Being pregnant.

Finally, Occupational Health staff should answer any questions that HCP have regarding the influenza vaccine. Influenza vaccine may be administered to all categories of HCP unless there is a contraindication for the vaccine. In some cases, live attenuated influenza vaccine (LAIV or FluMist®) may be administered to HCP. It is a good option for those HCP who are in good health, are not pregnant, have a dislike of needles, and meet the criteria for LAIV (see LAIV in Section 2). Another option is to be vaccinated using the intradermal route.

Vaccination is the primary method to prevent influenza, limit transmission, and prevent complications from influenza.

Challenges and Related Strategies to Improve Vaccination Rates Among Health Care Personnel (HCP)

Challenge Category	Specific Challenge	Strategies to Improve
1. Resources	Lack of vaccine available	Make vaccine available for staff vaccination earlier in vaccination season Plan a kickoff event for after first vaccine delivery so will not run out of vaccine and have to stop the campaign
	Lack of staff for documenting	Utilize nurses on transitional duty to vaccinate and document vaccination in OHRS
	Lack of staff to vaccinate employees during kickoff event	Use nursing students to supplement staffing at kickoff events Assign additional RNs to mobile cart during first month of vaccination season
2. Access	Limited hours offering vaccination	Make vaccine available to staff 24/7 Open occupational health early, stay open throughout the day and close later
	Vaccine not available at convenient location	Utilize mobile carts to bring vaccine to all areas several times during vaccination season

Challenges and Related Strategies to Improve Vaccination Rates Among Health Care Personnel (HCP), *continued*

Challenge Category	Specific Challenge	Strategies to Improve
3. Documentation and tracking	Improper data entry	Offer training about the proper way to record vaccination of employees in OHRS prior to the influenza season
	Inability to identify who received vaccine outside of Occupational Health	Utilize pop-up computer screens to remind HCP about vaccination Utilize postcards to capture data on HCP vaccinated elsewhere. Distribute postcards to supervisors to give to employees and have them instruct staff where to drop off postcards (at secure locations)
4. Marketing	Lack of advertising about vaccine availability and where can get vaccinated	E-mail advertising of kickoff event Display posters in lobby and cafeteria advertising kickoff and other vaccination events Craft messages targeted to groups of HCP with lower vaccination rates Make sure messages and any accompanying images send the consistent messages
5. Education	Employees are overheard repeating myths	Send regular messages with accurate information Make informational posters and brochures available Explain the risk of any side effect is much less risky than not receiving the flu vaccine Provide up-to-date information Explain any confusion and misconceptions Be sure to tell the truth: vaccination is not 100% effective nor 100% safe Try utilizing motivational interviewing as another method to change beliefs and attitudes about vaccination

Checklist of a Successful Influenza Vaccination Campaign

1. Identify a facility champion whose main responsibility is getting employees vaccinated against influenza.
2. Encourage top management to be active members of the influenza vaccination program.
3. Enlist peer vaccination champions to encourage influenza vaccination. Make sure they are trained and have access to the Occupational Health Record-keeping System (OHRS) to document vaccination.
4. Sponsor a kickoff event. Make it fun.
5. Set vaccination rate goals for departments/service lines and set up friendly competition among departments/services.
6. Make the vaccine accessible by increasing Occupational Health clinic hours, increasing the locations where vaccination is available, and taking the vaccine to HCP via mobile carts.
7. Advertise the dates, times, and locations of influenza vaccination in multiple message formats and multiple locations.
8. Provide training or educational materials on why it is important for HCP to get vaccinated.
9. Keep track of who is vaccinated so that targeted reminders can be sent to those who do not get vaccinated.
10. Identify why individuals do not wish to get the influenza vaccine and develop targeted messages to address those concerns.
11. Send postcards or e-mails to asking staff to inform Occupational Health staff if they were vaccinated somewhere else.
12. Track and report, on a daily basis, the number of HCP who are vaccinated. This can be easily accomplished in OHRS.

Some VISNs have created an **Interdisciplinary Flu Teams** with representatives from VISN medical centers/ clinics and national leadership. These groups unify and support facility flu campaign efforts at VISN level and create a forum for sharing strategies and program efforts. Conference calls are used to discuss and identify current issues, strategies and best practices.

STRATEGIES FOR INCREASING HEALTH CARE PERSONNEL INFLUENZA VACCINATION RATES

The following strategies have been shown to be effective for increasing influenza vaccination rates.

1. Use a team approach
2. Use organizational approaches
3. Make use of educational opportunities
4. Understand obstacles and individual beliefs
5. Consider timing of vaccination
6. Employ systems strategies
7. Make vaccination convenient
8. Communicate, remind, and reinforce

1. Use a team approach

"The Flu Team" is the collective driver to plan, implement, and evaluation flu vaccination campaigns. At the core of any successful flu team is the "Flu Coordinator." This position should have recognized authority and be the champion of increasing access to and uptake of flu vaccine. The most successful flu teams are comprised of key partners from various disciplines and services. Some VISNs have coordinated meetings to support local facilities and share resources.

Organizing an employee vaccination campaign does not need to be complicated. The educational component of the program may take more planning than other aspects of the campaign. Forming an interdisciplinary team to plan and oversee the campaign to immunize health

National Influenza Vaccination Week (NIVW)

is a national observance that was established to highlight the importance of continuing influenza vaccination, as well as fostering greater use of flu vaccine after the holiday season into January and beyond. NIVW will be held **December 2-8, 2012**. http://www.cdc.gov/flu/nivw/

care personnel against seasonal influenza is an approach that other hospitals have found useful. Members of the team might include: management, a facility champion, occupational health, infection control, infectious disease, hospital epidemiologist, pharmacy, public relations employees and union representatives. Make sure key partners are included on the team. Select a leader. The "Flu Coordinator" should have the authority to make decisions on strategies to increase vaccination and be the lead champion of increasing access to and update of the flu vaccine.

The team meets before the start of the influenza season to plan strategies, meets periodically during the season to make revisions to their plan and at the end of the season to identify any lessons learned. The team may also identify a "theme" which may change from year to year or sponsor a campaign slogan contest to raise awareness and increase interest. Health care organizations have found that having someone in charge of the staff influenza vaccination program is essential to be successful over time. Make sure the members of the team are enthusiastic champions for vaccination.

Consider having a VISN team. Coordination across a VISN aides in development of new ideas and strategies and provides peer support for those who are members of facility teams.

2. Use organizational approaches

Vaccination is one part of a comprehensive, measurable program to improve safety by reducing the risk for an individual to develop influenza disease and the risk for influenza transmission. Some facilities benefit from bundling vaccination efforts with other important methods used to mitigate influenza, including respiratory etiquette, hand hygiene, and asking HCP to stay home when sick.

Also, linking Veteran and HCP vaccination programs may strengthen VA's commitment to patient-centered care by building upon the energy, effort, and successes of our current Veteran patient vaccination programs. Vaccination policy, resources, and operational strategy can be leveraged to fully integrate and effectively target both Veterans and HCPs with designated leads for sub-populations (e.g. Veteran, employee, volunteer, trainees, contract staff, etc.). Our culture of safety involves everyone.

Bill Flanagan, Chief Pharmacist, VA Boston Healthcare System

Make influenza vaccination of HCP an organizational priority.

- Encourage the Network director, facility director, service chiefs, chief residents, other managers, voluntary service and union partners to lead the way by getting their vaccine and encouraging their HCP to get vaccinated.
- Provide written guidance stressing importance of vaccination for HCP with clear direction from leadership (i.e., Directive, letter from Facility Director to all employees, trainees, and volunteers, or Flu Advisory).
- Customize information for local distribution with local leadership buy-in and involvement. Use photos of hospital directors or other opinion leaders getting their influenza vaccine (newsletters, posters, TV/monitor displays).
- Enlist peer vaccination champions to encourage vaccination.

Sponsor a kickoff event at the start of influenza season.

Think about a theme for the event. For maximum exposure, hold the event in a high-traffic area. Arrange for the hospital Director and a union representative to provide opening remarks and get their vaccine.

Hold an event during National Influenza Vaccination Week (NIVW) and VA Staff Influenza Vaccination Week.

- Publicize the campaign activities often.
- NIVW will be held December 2-8, 2012.
- VA Staff Influenza Vaccination Week will be held January 7-11, 2013.

Take time in January to identify HCP who were vaccinated elsewhere.

- Provide performance feedback:
  - Set goals/benchmarks, encourage friendly competition among HCP in different clinical settings, provide incentives to HCP who receive vaccine through worksite or private source.
  - Consider giving incentives such as buttons, stickers, canteen vouchers, movie passes, or raffle tickets for specific items.
  - Thank everyone who contributed to the flu campaign efforts, and especially to employees who committed to keeping themselves, their patients, and families healthy by getting vaccinated. Send out congratulations to departments/services that achieved the highest vaccination numbers/rates.

3. Make use of educational opportunities

Provide training on importance and effectiveness of influenza vaccination. Below are examples of opportunities to educate HCP about influenza and the importance of vaccination. These include:

- New employee orientation
- Staff meetings
- Grand rounds
- Town Hall meetings
- Leadership/Supervisor meetings
- Special events such as Patient Safety/ Quality fairs
- Lunch and Learns
- Health Fairs
- Volunteer Service meetings
- Special Influenza Fair where people learn about the flu and flu vaccination

Other educational approaches include:

- Provide VHA Influenza Vaccine videos for display on CCTV, desktops, and at staff meetings.
- Add to standard curricula of annual staff training session.
- Emphasize the high risk to patients when HCP are not vaccinated.
- Emphasize the low risk of side effects from the vaccine.
- Send a letter, postcard, or e-mail to HCP prior to the start of the vaccine season reminding them of the importance of vaccination, where and when they will be able to get the influenza vaccine.
- Put an article in the employee newsletter or post information on staff bulletin boards.

Include training regarding the importance of getting a flu shot during new employee orientation.

VA Staff Influenza Vaccination Week

is held to encourage health care personnel (HCP) to receive flu vaccine. Within the U.S. public health community and the Veterans Health Administration (VHA), influenza (flu) vaccination is viewed as an important means available to prevent and control seasonal flu. Flu vaccination keeps staff healthy, reduces absenteeism, and enables us to keep taking care of Veterans. VA Staff Influenza Vaccination Week will be held **January 7-11, 2013**.

4. Understand obstacles and individual beliefs

Vaccine acceptance may vary by communities, occupational groups, and demographics. Understanding immunization patterns and demographics of HCP who work in VHA can guide the development of strategies to improve vaccine acceptance.

Reasons staff may accept seasonal influenza vaccination include:

- Wanting to stay healthy
- Desire to protect patients
- Desire to protect family and friends
- Desire to avoid missing work
- Wanting to serve as a role model for Veteran patients
- Previous seasonal influenza vaccination
- Perceived effectiveness of the vaccine
- Previous illness due to influenza
- Strong recommendation from leadership and peers
- Personal physician or health care provider recommendation

Reasons staff may decide not to get vaccinated against seasonal influenza include:

- Fear of vaccine side effects
- Fear of getting seasonal influenza from the vaccine
- Belief that the vaccine is not effective in preventing influenza
- Belief if they had a weakened immune system they should not get the vaccine
- Belief that it is not safe during pregnancy
- Fear of needles
- Perception that they are at low risk of getting seasonal influenza
- Belief that seasonal influenza is not a serious disease
- Inconvenience in obtaining the vaccine
- Lack of knowledge of CDC and other expert recommendations for vaccination

Some staff may consider getting the vaccine if they were convinced that:

- the vaccine was effective in preventing influenza
- the vaccine protected them against all strains of the virus
- they were in a high risk group or had a serious health condition
- they had a vulnerable household member
- their supervisor recommended the vaccine
- influenza is prevalent in the community
- the vaccine was safe

Therefore, there should be continuous and ongoing vaccine education updates emphasizing the seriousness of influenza and addressing misconceptions about influenza and the vaccine. Occupational Health staff should determine why HCP at their facility elect not to get vaccinated and develop strategies which address those concerns. Targeted messages which address common misconceptions must be addressed such as:

- "The flu vaccine does NOT give you influenza."
- "Influenza is the sixth leading cause of death in adults in the United States." Or
- "There is evidence that vaccinating HCP reduces mortality among patients in long term care facilities."

Occupational health should consider how staff at their facility prefer to receive information about influenza and the influenza vaccine. Feedback from focus groups held at 20 facilities in 2009 indicated that although most staff referred to the internet for health information, there was some variation between direct and non-direct patient care staff. Direct care staff was more likely to utilize Web sites, academic journals, and the CDC. Non-direct care staff was more likely to utilize media channels, signs, clinics, personal physicians, books and the radio for information.

In addition, the focus groups revealed that direct care staff wanted more information on the following:

- influenza vaccine strain coverage
- relationship between vaccination and reduced number of sick days
- when they should get vaccinated and how long they would be protected from influenza
- information to give patients with allergies
- FluMist and
- vaccine ingredients including preservatives

Non-direct care staff wanted more information on the following:

- influenza, its transmission and symptoms
- self care
- when to get vaccinated and
- vaccine ingredients

Both groups wanted information on the pros and cons of vaccination and the impact of illness on the workforce. They both wanted information tailored to their audience by their local community in bulleted format, easy to read and less than two pages.

5. Consider timing of vaccination

Even though influenza vaccination is not mandatory, each year VHA expects all HCP to get vaccinated for influenza. Occupational Health staff should offer the vaccine as soon as the vac¬cine becomes available. The seasonal influenza vaccine should be offered throughout the influenza season which often extends through spring.

Maintaining the vaccination effort is critical. Occupational Health staff have found it useful to have a kickoff event, remind staff to get vaccinated during the **"National Influenza Vaccination Week"** and to have a third effort in January, "**VA Staff Influenza Vaccination Week**," which includes capturing those who may have been vaccinated elsewhere. During these periods, staff may find it useful to sponsor podcasts, e-cards, and other electronic means to remind staff that the vaccine is available and encourage staff who were vaccinated elsewhere to report this to Occupational Health staff. In addition, facilities may consider providing vaccination at the same time as another required activity such as mandatory training and tuberculosis screening activities.

6. Employ systems strategies

- Ensure standing orders/protocols for influenza vaccine are in place.
- Work closely with Pharmacy to get your supply of vaccine for HCP
- Work closely with pharmacy staff to ensure that kick off events are planned after vaccine receipt.
- Monitor vaccination rates and provide feedback to specific clinics or settings.
- Secure support for any additional human resources.
- Consider utilizing FluMist as an alternative to influenza shots, for HCP under age 50 who do not routinely come in close contact with severely immunocompromised patients and have no contraindication. An intradermal influenza vaccine may also be ordered and supplied through your pharmacy.
- Document receipt of vaccination in the employee's medical record, OHRS. See Appendix B on page 143.

7. Make vaccination convenient

- Extend Occupational Health hours when vaccine is available to include all shifts and days of the week.
- Increase staffing in Occupational Health during peak hours.
  - Consider using volunteers to sign employees in and nurses with work related injuries to administer the vaccine if it is within their functional abilities. (Check with the workers' compensation specialist and nursing service for who might be able to assist.)
  - Consider utilizing nursing students to augment staff vaccinating employees.
  - Consider using pharmacists, who are authorized to vaccinate, to augment staff vaccinating employees.
- Increase the number of locations where the vaccine is given.
  - Hold drop-in vaccination days, or "drive-through" vaccination clinics for HCP.
- Use rolling carts to bring the influenza vaccine directly to the work setting, grand rounds, canteen entrance, and other locations where HCP congregate. Sending rolling carts to wards and clinics during each shift and on weekends should also be considered. Carts should be stocked with vaccine, safety syringes, vaccine information statements, sharps disposal containers, alcohol hand rub, alcohol wipes, adhesive bandages, documentation forms, and injectable epinephrine with orders for administration in the event of an acute hypersensitivity reaction.
- Send e-mail messages and post schedules of when the influenza vaccine will be available.
- Authorize nurses on units to give the influenza vaccine to coworkers.
- Allow employees to take the vaccine during veteran flu vaccine drives.
- Announce the availability of the vaccine via audible paging systems as available.
- Offer the vaccine to new HCP during orientation.

8. Communicate, remind, and reinforce

All Public Affairs Offices have the potential to be an active resource. In addition, all communication needs to be clear and goal driven. The use of catchy phrases, social media, screensavers/pop-ups and the word of mouth will aid your flu team in having a successful vaccination season. Additionally, there is a multitude of IDPIO resources available to your facility that will greatly add to efforts in planning a campaign. Include your Public Affairs Officer in the coordination and implementation of vaccination campaigns.

- Contact your facility Public Affairs Office to plan and execute marketing strategies and approaches that support your influenza vaccination campaign.
- Use multiple message formats, repeat announcements regarding dates, times, and locations of vaccination:
  - Provider e-mail, newsletters, posters, buttons, pens, cafeteria table tents.
  - Paycheck stubs, Web site messages.
- Post schedules ahead of time for mobile carts and influenza clinics.
- Work with your unions' leadership; have them promote vaccination of their members and recruit union members who are licensed to vaccinate to immunize their membership.
- Make appointments with departments and services to attend service meetings to educate HCP about the need to protect HCP and our Veteran patients from influenza.

- Add information to the Occupational Health Web site regarding influenza vaccination locations and times for HCP.
- Send letters, postcards, or e-mail messages to HCP prior to the start of the vaccine season reminding them of the importance of vaccination and where and when they will be able to get the influenza vaccine.
- Write short items for the employee newsletter or post information on staff bulletin boards.
- Provide factsheets with pay stubs to dispel misconceptions and increase acceptance of influenza vaccination.
- Add an influenza reminder to Occupational Health's telephone recording. When HCP call, they can automatically be reminded about the availability of the vaccine. If the recording capacity exists, add specific information regarding dates, times, and locations for influenza vaccination as well as any other pertinent information. These reminders can begin in September and conclude after the influenza season has peaked, which usually occurs in February or March.

- Create a computer "pop-up" message asking HCP if they have received the vaccine, wish to receive the vaccine or received the vaccine elsewhere. This data can be collected, collated and HCP contacted to verify and document they were vaccinated elsewhere or contact them to find a time which is convenient for them to be vaccinated. This "pop-up" message could be sent out near the beginning of the influenza season to all HCP, and during the mid and late influenza vaccination season to those who have not indicated they were vaccinated.
- In late November/December or later in the season, identify HCP not yet vaccinated and remind them by e-mail or a phone call that the influenza vaccine is available.
- Target groups with low vaccination rates.
- Keep facility leadership (Directors, Service Chiefs) informed on vaccination rates of their HCP on a monthly basis. Provide information of rates by wards, units, services etc.
- Create competition among services/product lines/units. Design a poster of a large syringe that can be used as an indicator of the number of individuals who have been vaccinated.
- Send out notices on which departments/ services are leading the way in the percent of HCP vaccinated.
- Send out daily or weekly bulletins to highlight the importance of getting vaccinated. Some examples include:
  - How is the flu spread? By coughing and sneezing—avoid the flu—get vaccinated.
  - Always, practice good hand washing and respiratory etiquette.
  - Did you know that in the United States, about 5% to 20% of the population becomes infected with the influenza virus annually? Avoid the Flu. Get vaccinated.

Approximately 36,000 Americans die each year from the flu—get vaccinated.

- No one likes getting the flu—fever, body aches, cough, sore throat—get vaccinated.
- Be a flu buster, get vaccinated, and stop the spread of influenza.
- If you have chronic pulmonary (including asthma), cardiovascular, renal, hepatic, hematological or metabolic disorder (including diabetes) it is recommended that you get vaccinated.
- If you care for someone at home like small children or family members with a medical condition that puts them at higher risk for severe complications from influenza, protect them, get vaccinated.
- CDC now recommends that everyone over the age of 6 months is vaccinated against seasonal influenza.
- Ask Occupational Health for information on where and when to receive your influenza vaccine.

ADDRESSING CONCERNS OF HEALTH CARE PERSONNEL (HCP)

"You know that the influenza vaccine works, so why don't more people get vaccinated?"

Some people are concerned about side effects. They think that the influenza vaccine will make them sick. However, mild soreness of the arm at the injection site is the most common side effect. The vaccine itself will NOT give you influenza. Influenza vaccination is the best protection against influenza. Protect VA patients, yourself, your co-workers and your family. Get vaccinated. Check with Occupational Health for information on how to get your influenza vaccine.

"Why should health care personnel be vaccinated against influenza?"

There are several reasons why health care personnel should be vaccinated against influenza every year:

- They can get the influenza virus from their patients resulting in absence from their positions.
- They can acquire influenza infection and not have any symptoms, but still be able to transmit the disease.
- Health care personnel who are ill with influenza often continue to work and spread the virus to other employees, volunteers, patients, and family members.
- Unvaccinated health care personnel have caused influenza outbreaks in health care settings.

"Did you get your influenza vaccine last year?"

If you didn't, you may have harmed the health of some of our patients, your co-workers, and family members. You can spread influenza to patients, putting them at risk for influenza and its complications. Studies show that vaccination of health care personnel is associated with decreased mortality among Community Living Center residents. Protect yourself and our Veterans; get a flu shot. Ask Occupational Health about when and where to receive your vaccination.

"I'm healthy. I don't need to get vaccinated for flu." Is this you?

Influenza can cause serious illness and death even in young, healthy people. It's not just a disease that affects the elderly. If you get influenza, you can spread it to your patients, putting them at risk for severe illness and complications from the influenza virus. Protect yourself, your co-workers, and your patients—get vaccinated for flu. Ask Occupational Health about when and where to receive your vaccination.

"The residents in long-term care need the influenza vaccine more than I do."

Wrong. Studies, especially in long-term care, have shown that it is as important for health care personnel to receive the vaccine as it is for residents.

"I don't want to get the vaccine because it has side effects."

Studies have shown that the influenza vaccine is not associated with higher rates of systemic symptoms than are seen with injections of placebos among healthy working adults. The most common side effects of influenza vaccination include: soreness, redness, or swelling at the injection site, mild or low-grade fever, and aches. The symptoms should only last a day or two. The most common side effects from the nasal influenza vaccine are a runny nose and nasal congestion. Allergic reactions (anaphylaxis) rarely occur (less than 1 in 1 million). Neurological reactions (Guillian Barré Syndrome) are also rare (1 in 1 million).

"I got the influenza vaccine before and I still got influenza, so why should I get it now?"

In years when there is a good match between the circulating viruses and the corresponding vaccine strains, vaccine efficacy for reducing illness has generally been between 70–90 percent. However, even when the viruses are not well matched, the vaccine can protect many people and prevent flu-related complications.

"I'm pregnant. Should I get the influenza vaccination?"

Yes. All pregnant women are at risk from influenza and its complications. It is important that pregnant health care personnel get the influenza vaccine to protect themselves and their babies. The influenza vaccine can be given any time during the pregnancy. However, pregnant women should NOT receive the nasal influenza vaccine.

"I don't like needles, so I don't want to get vaccinated."

Check with Occupational Health. You may be a candidate for the nasal spray that delivers live attenuated influenza vaccine (LAIV). This is an option for healthy employees, trainees, and volunteers up through age 49, especially when there is a shortage of inactivated influenza vaccine. There is also an intradermal vaccine available.

"I don't need the vaccine. If I get the flu, I'll just take an antiviral medication."

Antiviral medications do not eliminate flu symptoms. They do shorten the duration by about 3 days, so you will need to be off work. Like all medication, antivirals may have side effects. It's better to get the flu vaccine.

"I'm not in a high risk group."

CDC recommends influenza vaccination for all people over the age of 6 months. You may be at a high risk if you have a chronic health problem such as diabetes. Vaccination helps to protect the Veterans you care for, your co-workers and your family.

"My health care provider didn't recommend it to me."

Even though influenza vaccination is not mandatory, each year VHA expects all HCP to get vaccinated for influenza. The CDC recommends that all individuals who work in a health care setting get vacci¬nated annually.

"I always get 'the flu' when I take the vaccine."

When you are vaccinated, you may develop a temporary mild body aches, soreness at the injection site, and/or low grade fever. Any of these indicate a healthy normal response that may result in some mild discomfort, but this is different from actually getting influenza.

"My immune system is working just fine, thank you" or "I never get the flu."

Remember, you can transmit influenza to others before you become symptomatic. You may transmit the flu virus to others before you develop any symptoms of the flu. To protect your patients and family, you should get vaccinated.

"There are so many strains of flu that the vaccine can't cover them all."

The World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC) carefully select the H1N1, H2N3 and B component strains of the vaccine at the outset of each seasonal influenza season. Your immunogenic response for those identified strains helps provide more general protection during the winter months when influenza is more common. Although the vaccine may not exactly match the circulating influenza viral strains, if exposed to influenza, your symptoms will be milder than if you had not been vaccinated.

Sample Postcard/Email Text for Tracking Health Care Personnel's Receipt of Vaccine

Name: _____

Service: _____

Please check one:

❑ **I am an employee/veteran and have had the flu shot as a veteran at the VAMC on _____. (date)**

❑ **I am a volunteer/veteran and have had the flu shot as a veteran at the VAMC on _____. (date)**

❑ **I am a volunteer and have had the flu shot outside the VAMC on _____. (date)**

❑ **I am an employee and have had the flu shot outside the VAMC on _____. (date)**

❑ **I am an academic affiliate and have had the flu shot outside the VAMC on _____. (date)**

Please place this postcard in the Occupational Health flu shot drop box located in the lobby or bring to Occupational Health (email – reply to sender, indicate the appropriate response, press send)

ADDITIONAL MEASURES TO PREVENT THE SPREAD OF INFLUENZA

Remind all health care personnel (HCP) that although the influenza vaccination may be the best way to protect against influenza, there are other measures they should also take to protect themselves, their families, and patients. Here are some messages to use:

- **Stay at home when you are sick, especially if running a fever.** Not only can HCP with influenza transmit it to others, but studies have shown that people with influenza who return to work before fully recovered have less than optimal work performance.
- **Clean hands frequently with water and soap or alcohol-based rubs,** especially after using copy machines, fax machines, someone else's computer or phone; after sneezing, or making contact with your own secretions.
- **Exercise proper respiratory etiquette.** Cover coughs and sneezes and keep tissues at your desks. Dispose of used tissues properly.
- **Frequently wipe down surfaces with antimicrobial wipes** that include: keyboards, mouse devices, and phones.
- **Avoid and minimize contact with sick persons,** except of course the patients you are here to help.
- **Use proper personal protective equipment (PPE)** and work practices when caring for ill patients.

TRACKING HEALTH CARE PERSONNEL'S RECEIPT OF VACCINE

A key part of the VA seasonal influenza vaccination campaign is for Occupational Health staff to track vaccination rates among HCP and provide feedback during the influenza vaccination campaign. This assists Occupational Health staff increase vaccination rates and improve patient safety. Occupational Health must track who has received the vaccine so they can send messages to those who have not been vaccinated reminding of the vaccine's availability.

For additional information, visit: http://influenza.s3.amazonaws.com/start.html

It is beneficial for facility Occupational Health staff to identify why HCP in general, elect not to receive the influenza vaccine. This can be accomplished through focus groups, anonymous surveys, or a review of the literature. This will enable Occupational Health staff to develop focused educational programs and vaccination strategies to increase vaccination rates.

Document seasonal influenza vaccination of staff in the Occupational Health Record-keeping System (OHRS). For additional information refer to Appendix B on page 143.

Joint Commission: Infection Control Requirements for Offering Influenza Vaccination to Staff and Licensed Independent Practitioners

The Joint Commission approved an infection control standard that requires organizations to offer influenza vaccination to staff and licensed independent practitioners, applicable to critical access hospitals, hospitals, and long-term care. This standard conforms to recommendations made by the Centers for Disease Control and Prevention. The Standard states:

The organization offers vaccination against influenza to licensed independent practitioners and staff.

Elements of Performance for IC.02.04.01 include:

1. The organization establishes an annual influenza vaccination program that includes, at a minimum, staff and licensed independent practitioners.
2. The organization provides access to influenza vaccination on site.
3. The organization educates staff and licensed independent practitioners about influenza vaccination, non-vaccine control measures (such as hand hygiene, sneeze and cough etiquette), and the diagnosis, transmission, and potential impact of influenza.
4. The organization annually monitors vaccination rates and reasons for nonparticipation in the organization's immunization program.
5. The organization implements enhancements to the program to increase participation.

STAFF INFLUENZA VACCINATION PROGRAM REVIEW

Continuous quality improvement is an essential component of any program to ensure that the program meets requirements and expectations. The Joint Commission, Association for Professionals in Infection Control and Epidemiology (APIC), Health Care Infection Control Practices Advisory Committee (HICPAC), Centers for Disease Control and Prevention (CDC), and Society for Health Care Epidemiology of America (SHEA) note that measuring influenza vaccination rates is an important component of an organization's influenza vaccination program. A recent publication of The Joint Commission "Providing a Safer Environment for Health Care Personnel and Patients Through Influenza Vaccination: Strategies from Research and Practice," addresses practices that have been implemented in varied health care settings to improve seasonal flu vaccination rates among employees, http://www.jointcommission.org/assets/1/18/Flu_Monograph.pdf.

Quality improvement activities should be oriented toward the actual delivery of services and meeting the goals of VHA's program. Periodic reviews can identify strengths and areas for improvement. Occupational Health staff then can develop plans to adjust and carry out needed changes and re-evaluate the changes made to the program. In addition, it is beneficial to evaluate the vaccination program at the end of the vaccination period and identify overall program strengths and areas for improvement for the next year. Areas that should be evaluated include:

- Resources
- Access
- Documentation and Tracking
- Marketing
- Education

Key Elements of a Successful Health Care Personnel Influenza Vaccination Campaign

1. **Informing HCP about the free availability of the vaccine and the goals of the campaign (awareness).**
2. **Educating HCP about its importance (marketing).**
3. **Making the vaccine convenient (access).**
4. **Notifying HCP regarding the scheduling of administration (awareness).**
5. **Keeping track of who has been vaccinated (feedback/evaluation).**

As part of an evaluation program, occupational health staff should identify reasons why HCP at their facility choose not to be vaccinated. Focus groups are one way to identify reasons for not opting to be vaccinated. A second method is an anonymous survey.

One type of survey questions include why the individual chose not to be vaccinated. Survey statements might include:

- Fear of needles
- Fear of side effects
- Not being in a high risk group
- Concern about additives in the vaccine (thimerosal)

A second type of survey is one where HCP are asked what might increase their interest in receiving the seasonal influenza vaccine. Survey statements might include:

- If there was a flu epidemic in that year
- If I was shown reliable statistics about the benefits of vaccination
- If I was shown reliable statistics about the risks of not being vaccinated
- If I felt there was an increased likelihood of me getting the flu
- If I had frequent contact with vulnerable populations
- If I did not fear the potential side effects of the vaccine
- If I was able to receive the nasal spray
- If I was able to receive the intradermal injection
- If the vaccine covered all strains of the flu instead of just 3

Influenza Vaccination Evaluation – post-campaign assessment questions

1. Number of health care personnel vaccinated _____
2. Number of employees vaccinated _____
3. Number of volunteers vaccinated _____
4. Number of trainees vaccinated _____
5. Number of other staff vaccinated _____
6. Did you have a multidisciplinary strategic planning team? Were the right disciplines represented? Did we have enough vaccine for health care personnel? Were the team members champions?
7. Which departments/ services/product lines has the lowest vaccination rate among their health care personnel?
8. Which occupational groups (physicians, nurses, laboratory workers, maintenance workers, etc) had the lowest vaccination rates?
9. What were some of the reasons/barriers cited by this department/occupational group for not receiving the vaccine?
10. Brainstorm strategies to address the identified barriers
11. What were the strengths and weaknesses of the vaccination campaign?

FREQUENTLY ASKED QUESTIONS ON INFLUENZA VACCINATION FOR OCCUPATIONAL HEALTH STAFF

Should we vaccinate volunteers as part of our campaign?

Yes. Volunteers provide a vital service to our Veterans including the provision of direct patient care. Facilities should offer the influenza vaccine to volunteers.

Should we offer the influenza vaccine to medical residents, interns, nursing students and other trainees who provide services at the VA during the influenza season through our Occupational Health Department?

The decision with regard to resident, intern, nursing student and other trainees is an individual VA facility decision; it should take into account the contractual agreement with trainees, the availability of the vaccine, and the potential benefit to the VA. Facilities may want to make the same decisions about providing the influenza vaccine for trainees as they do for volunteers.

Should health care personnel who have contact with HIV/AIDS patients and other patients with compromised immune systems be vaccinated?

All health care personnel in health care settings should receive annual influenza vaccination unless they have a contraindication to the vaccine.

What are the recommendations for vaccination of health care personnel against influenza?

All health care personnel in health care settings should receive annual influenza vaccination unless they have a medical contraindication to the vaccine.

Why is vaccination recommended for health care personnel?

- They can give influenza to patients, coworkers, family members, and others.
- They are at risk of getting influenza from patients with influenza.
- Preventing influenza through annual vaccination keeps health care personnel healthy and available to come to work or to take care of patients.

Inactivated influenza vaccine (the flu shot) is the preferred vaccine for people coming into close contact with anyone who has a severely weakened immune system.

What are the recommendations for use of a declination form for health care personnel against influenza?

VHA **does not** have a national mandate requiring the use of declination forms. Analysis of VHA facilities that have used declination forms and those who did not, revealed no statistical difference in vaccination rates.

How do I report an adverse reaction from flu vaccination?

Providers report the adverse event through the Adverse Event Tracking Package (ART) in CPRS and also through the VA Adverse Drug Event System (VA ADERS). Providers have direct access to CPRS. The Chief of Pharmacy (or designee) at every facility inputs adverse reactions into VA ADERS for drugs and vaccines. A Vaccine Adverse Event Reporting System (VAERS) form for all vaccines should be

submitted anytime an adverse event occurs. Occupational health should also use this reporting structure. The VAERS form is available at http://vaers.hhs.gov/pdf/vaers_form.pdf. On-line reporting is available at https://secure.vaers.org/. In addition, all adverse events must be documented in OHRS.

Is LAIV an option for health care personnel?

Yes, LAIV is an option for healthy health care personnel up through age 49, especially when there is a shortage of inactivated influenza vaccine. Choosing LAIV, currently available as FluMist®, means you are helping to conserve when there is limited inactivated influenza vaccine for high-risk persons who do not have the option of live attenuated influenza vaccine. It is also a good option for health care personnel who may not get the vaccine because they are afraid of needles.

Is shedding the virus a problem for health care personnel?

The FluMist® package insert states that a person can shed the virus for up to three weeks because that is what the studies in humans showed, but shedding alone should not be equated with person-to-person transmission. In fact, studies have found that person-to-person transmission caused by shedding is very rare. In a study conducted in a Finnish day care center that was designed to maximize the chance of detecting vaccine virus transmission, one child shed the virus for 21 days. Other children in this study shed the virus a mean of 7.6 days. Estimated transmission rates were extremely low (0.6–2.4 percent). There was actually only one documented case of LAIV transmission. An additional small study of 40 adults conducted since licensure found that only 50 percent of the adults were shedding the vaccine influenza virus on day three after vaccination; one adult shed the virus on day seven. That means that half the adults had stopped shedding the virus by day three. These post licensure studies prompted the Advisory Committee on Immunization Practices (ACIP), an independent committee that advises the CDC, to reduce the recommended number of days health care personnel should avoid contact with patients requiring protective isolation from three weeks to seven days.

Should health care personnel who have a contraindication to LAIV administer it?

They can. Environmental contamination with LAIV during administration is probably unavoidable. However, because it is an attenuated virus (weakened) that is designed not to replicate at the warm temperatures of the lower respiratory tract, the ACIP does not believe that administration of LAIV by a person with one of the contraindications to it (such as asthma, chronic obstructive pulmonary disease, etc.) puts that person at risk from infection or illness from the vaccine virus.

Department of Veterans Affairs

Memorandum

Date: OCT 31 2012

From: Under Secretary for Health (10)

Subj: Influenza Vaccinations for Health Care Personnel within VA Health Care Facilities (VAIQ # 7287402)

To: All Veterans Health Administration (VHA) Staff

1. The mission of the Veterans Health Administration (VHA) is to honor America's Veterans by providing exceptional health care that improves their health and well being. Without question, it is critical that this care be provided in both an efficient and safe manner. Each year, influenza takes a heavy toll on both our Veterans, and on our staff. Our Veterans and staff expect that our facilities are safe and that we do all we can to minimize the chance for anyone to contract influenza. Getting your influenza vaccination is a critical step in keeping yourself, your family, your patients, and co-workers safe and healthy.

2. VHA has a long-standing commitment to providing free influenza vaccination to our staff each flu season. Vaccination remains our strongest defense against flu related illness and death. Over the past several years, many health care organizations have mandated that their staff get vaccinated against influenza. At this time, I do not believe it is appropriate to mandate influenza vaccination throughout VHA. However, that does not diminish the importance of vaccination, and it is my expectation that every VHA staff member who does not have a medical contraindication will be vaccinated.

3. Vaccination, hand and respiratory hygiene, proper use of personal protective equipment, keeping our facilities clean, and staying home when sick are all parts of a comprehensive program to prevent influenza. Over the years, the Office of Public Health, through the *Infection: Don't Pass It On* campaign, has provided leadership and resources that support and promote vaccine uptake, hand hygiene, and other elements of infection prevention. These resources can be found at: www.publichealth.va.gov/flu or http://vaww.vha.vaco.portal.va.gov/sites/PublicHealth/handhygiene/default.aspx. I encourage you to utilize them to strengthen your influenza prevention campaigns.

4. Our Veterans deserve the best, and it is our duty to serve them in a safe environment. Vaccination effectively prevents influenza and is a key component in a comprehensive program to protect our Veterans and the health care personnel who serve them.

Robert A. Petzel, M.D.

Section Five 5

VETERAN PATIENTS: HOW TO IMPROVE VACCINATION RATES

SECTION FIVE

VETERAN PATIENTS: HOW TO IMPROVE VACCINATION RATES

The following strategies have been shown to be effective for increasing influenza vaccination rates, especially when used in conjunction with each other.

1. Use a team approach
2. Use organizational approaches
3. Make use of educational opportunities
4. Understand obstacles and individual beliefs
5. Employ systems strategies
6. Make vaccination convenient
7. Communicate, remind, and reinforce

Alissa Sandefer and Sheri Marx
VA Illiana Healthcare System, Danville, IL

1. Use a team approach

"The Flu Team" is the collective driver to plan, implement, and evaluation flu vaccination campaigns. At the core of any successful flu team is the "Flu Coordinator." This position should have recognized authority and be the champion of increasing access to and uptake of flu vaccine. The most successful flu teams are comprised of key partners from various disciplines and services. Some VISNs have coordinated meetings to support local facilities and share resources.

Organizing an vaccination campaign does not need to be complicated. The educational component of the program may take more planning than other aspects of the campaign. Forming an interdisciplinary team to plan and oversee the campaign to immunize health care personnel against seasonal influenza is an approach that other hospitals have found useful. Members of the team might include: management, a facility champion, occupational health, infection control, infectious disease, hospital epidemiologist, pharmacy, public relations employees and union representatives. Make sure key partners are included on the team. Select a leader. The "Flu Coordinator" should have the authority to make decisions on strategies to increase vaccination and be the lead champion of increasing access to and update of the flu vaccine.

The team meets before the start of the influenza season to plan strategies, meets periodically during the season to make revisions to their plan and at the end of the season to identify any lessons learned.

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Some VISNs have created Interdisciplinary Flu Teams with representatives from VISN medical centers/ clinics and national leadership. These groups unify and support facility flu campaign efforts at VISN level and create a forum for sharing strategies and program efforts. Conference calls are used to discuss and identify current issues, strategies and best practices.

The team may also identify a "theme" which may change from year to year or sponsor a campaign slogan contest to raise awareness and increase interest. Health care organizations have found that having someone in charge of the staff influenza vaccination program is essential to be successful over time. Make sure the members of the team are enthusiastic champions for vaccination.

Consider having a VISN team. Coordination across a VISN aides in development of new ideas and strategies and provides peer support for those who are members of facility teams.

2. Use organizational approaches BEFORE your vaccination campaign begins

- Make influenza vaccination an organizational priority.
- Develop and provide written policy stressing importance and effectiveness of patient influenza vaccination with clear direction from VHA leadership (i.e., Directive, Flu Advisory or Medical Center Policy). Have any examples?
  - Establish an influenza vaccination campaign committee, with diverse clinical and support membership.
  - Schedule meetings prior to and during the vaccination season.
- Discuss successful strategies and what needs improvement.

Flu Team
James H. Quillen VA Medical Center
Mountain Home, TN

- Set goals/benchmarks, based on previous years' performance and current year's targets.
- Coordinate planned activities to coincide with the influenza vaccine delivery schedule.
- Develop a month-by-month calendar of activities to prepare for a vaccination campaign.
- Solicit local leadership buy-in and involvement.
  - Use photos of hospital director or other opinion leaders getting their influenza vaccine in newsletters, VA TV/monitor displays and on the Medical Center's internet home page.
- For each ward, clinic, domiciliary, Community Living Center and CBOC recruit a Flu Vaccination Champion who will help keep the momentum flowing in their area.
- Customize information for local distribution (e.g., bulletins, announcements, e-mail messages).
- Solicit information from Veterans for planning.
  - Consider a short questionnaire on the Medical Center's internet web page about what they liked, didn't like about last year's campaign and what was most helpful. Also ask for suggestions to improve this year's campaign.
- Consider creative approaches such as drive through clinics or enhanced transportation services to the drive through or clinic location.
- Flu vaccine should be made available to both enrolled Veterans and VA health care personnel **as soon as flu vaccine is available** at the facility. Do not "hold" doses. Vaccination efforts should be structured to ensure the vaccination of as many persons as possible over the course of several months, with emphasis on vaccinating before influenza activity in the community begins. In any given year, the optimal time to vaccinate cannot be determined precisely because influenza seasons vary in timing and duration, and more than one outbreak can occur in a single community in a single year. More information is available at http://www.cdc.gov/flu/professionals/acip/index.htm.

DURING your vaccination campaign

- Using performance feedback:
  - Monitor/assess the number and percent of high-risk patients vaccinated, and the number of women vaccinated.
  - Inform providers and teams regarding the number and percent of high-risk patients vaccinated, and the number of women vaccinated.
- Encourage friendly competition among providers or clinics.
- Provide incentives to providers, clinics, and wards with high patient vaccination rates.
- Use ***Infection: Don't Pass It On (IDPIO)*** campaign and annual flu resource materials such as buttons, stickers, posters, and flu manual. Distribute flu buttons to staff, hang posters throughout the facility. Offer stickers to all who receive the vaccination. See Section 8 for ordering information or the IDPIO web site to download and print materials at www.publichealth.va.gov/flu.
- Critically review what is and isn't working well. Make mid course corrections as needed.

AFTER your campaign

- Inform providers and teams re: the number and percent of high-risk patients and women vaccinated.
- Critically review and evaluate your campaign after flu season.
- Identify and document strategies that worked well as those that did not work well.
- Thank your flu champions.
- Celebrate your successes.

3. Make use of educational opportunities

- Provide fact sheets, brochures, and other flu information to Veterans and family sitting in clinic waiting areas. Written information should be direct and straightforward, using appropriate language and terminology, and at appropriate reading levels.
- Provide information on important everyday preventive actions: respiratory etiquette (cough in tissue or cough into sleeve) and hand hygiene (Clean hands often after coughing, sneezing or after touching items in a public place. Keep hands away from eyes nose and mouth).
- Broadcast information e.g., influenza vaccine administration sites/dates/times, facts vs. myths and use VA and CDC podcasts on vaccination, respiratory etiquette and hand hygiene presented on VA TV/monitors throughout the medical center to inpatients, employees, trainees, and volunteers.
- Enlist providers and clinical staff from multiple disciplines, as well as pharmacists, students, interns, and residents to assist with inpatient and outpatient education efforts.
- Have patient educational materials on flu immunization available; don't forget to include information on important everyday preventive actions: respiratory etiquette and hand hygiene.
- Work with nurse managers, health educators, prevention coordinator, and flu champion on using consistent educational materials.

Gale Hockman
Gainesville VA Medical Center, Gainesville, FL

Inform patients about:

- Vaccination as the best way to prevent getting the flu.
- Who should get vaccinated each year?
  - **All people over the age of 6 months should receive a flu shot each year.**
  - The following people are at high risk for complications from the flu and are a primary focus of flu campaigns to receive vaccination.
    1. All children aged 6 months – 4 years (or older) who are at increased risk of complications from influenza.
    2. Women who will be pregnant during the flu season.
    3. Adults 50 years of age and older.
    4. People of any age with underlying chronic medical conditions.
    5. People with weakened immune systems, certain cognitive muscle or nerve disorders, or a compromised respiratory function.
    6. People who live in Community Living Centers and other long term care facilities.
    7. People who live with or care for those at high risk for complications from flu.
    8. Are American Indians/Alaska Natives.
    9. Are morbidly obese (body-mass index is 40 or greater).
- Potential side effects.
  - The viruses in the flu shot are killed (inactivated) and cannot cause anyone to get the flu. Most people who receive the flu shot have no problems from it. Some people may get a low grade fever, and aches lasting one-two days after getting the shot – mild in comparison to the getting the flu. The injection may cause some discomfort, soreness, redness, or swelling where the shot was given, which resolves in a day or two. **Re-emphasize that one cannot get the flu from the flu shot.**
- Where to get flu shots – from their provider, at a walk-in flu clinic, or a drive-through clinic. Let them know about the convenience.

Inform providers about:

- How to respond effectively to patient questions and concerns regarding the vaccine, flu or other issues such as side-effects. Have a RN, LPN, or health tech screen, offer vaccination, and make referrals as appropriate regarding patient concerns.
- How to access and review the Veteran's vaccination history.
- High risk patients – use of clinical reminders and health factors to identify these Veterans.
- Annual seasonal influenza vaccination campaign goals and status reaching them.
- Proper procedures for administration of flu vaccine.
- How to document flu vaccination.

4. Understand obstacles and individual beliefs

- Vaccine acceptance may vary by individual, family, communities, or other demographic. Understanding attitudes on vaccination and demographics of patients can guide the development of strategies to improve vaccine acceptance.
- The most common reasons for getting vaccinated included:
  - Bad influenza experiences associated with weakened immune systems or aging.
  - Habit (often began in the military when flu shots were required).
  - Don't want to spread the flu to others.
  - Doctor recommendation.
- The most common reasons for not getting vaccinated included:
  - Fear of getting sick from the vaccine.
  - Vaccine not perceived as effective (doesn't protect against all types of flu).
  - Never got the flu.
  - Bad experiences with vaccines.
  - Don't want to have the influenza virus put in their bodies.
  - Belief that the immune system is strong enough to fight off the flu.
- Reasons patients may accept seasonal influenza vaccination include:
  - Wanting to stay healthy.
  - Desire to protect family and friends.

- Desire to avoid missing work.
- Previous seasonal influenza vaccination.
- Perceived effectiveness of the vaccine.
- Previous illness due to influenza.
- Strong recommendation from family and peers.
- Personal physician or health care provider recommendation.

- Reasons patients may decide not to get vaccinated against seasonal influenza include:
  - Fear of vaccine side effects.
  - Fear of getting seasonal influenza from the vaccine.
  - Belief that the vaccine is not effective in preventing influenza.
  - Belief if they had a weakened immune system they should not get the vaccine.
  - Belief that it is not safe during pregnancy.
  - Fear of needles.
  - Perception that they are at low risk of getting seasonal influenza.
  - Belief that seasonal influenza is not a serious disease.
  - Inconvenience in obtaining the vaccine.
  - Lack of knowledge of CDC and other expert recommendations for vaccination, including why influenza vaccination is needed yearly.
- Some individuals may consider getting the vaccine if they were convinced that:
  - The vaccine was effective in preventing influenza.
  - The vaccine protected them against all strains of the virus.
  - They were in a high risk group or had a serious health condition.
  - They lived with a vulnerable household/family member.
  - A loved one or family member recommended the vaccine.
  - Influenza is prevalent in the community
  - The vaccine was safe.
  - Yearly influenza vaccination is necessary.

Therefore, there should be continuous and ongoing vaccine education updates emphasizing the seriousness of influenza and addressing misconceptions about influenza and the vaccine. Flu Coordinators, Infection Preventionists, and other health care personnel should determine why patients elect not to get vaccinated and develop strategies which address those concerns. Targeted messages which address common misconceptions must be addressed such as:

- "The flu vaccine does NOT give you influenza."
- "Influenza is the sixth leading cause of death in adults in the United States."
- "Vaccination is the primary method to prevent influenza, limit transmission, and prevent complications from influenza."

5. Employ systems strategies

- Use computerized clinical record reminders.
- Use standing orders or protocols for inpatients (acute, community living center, and mental health settings), outpatients, and home care patients.
- Use patient reminders (postcards/letters) and recall systems.
- Print messages on the back of appointment reminder letters.
- Use postcards to inform veterans of dates/locations/times of flu clinics.
- Provide updates and information on the facility and VISN internet web sites.
- Place messages on facility Facebook page.
- Utilize My HealtheVet secure messaging for individual and group reminders.
- Remove actual and perceived barriers (e.g., provide easier parking for flu shot clinics).
- Clear signage with dates, times, location of and directions to flu clinics.
- Have CCHT (Care Coordination Home Telehealth) coordinators encourage vaccination when interacting with patients.

6. Make vaccination convenient

- Expand access/outreach.
  - Extend clinic hours/days / possibly try weekend clinics.
  - Schedule drop-in/walk-in vaccination days, 'drive-through' vaccination.
  - Good signage to direct veterans to the times and location of vaccinations/flu clinic.
  - Vaccinate in settings not routinely used for this purpose (hospital lobbies, Vet Centers, domiciliaries).
  - Bring the vaccine to residents' (if possible) in VA residential facilities.
  - Include influenza vaccination with home visits.
- Target all patients including special populations in clinics where they are likely to be seen (spinal cord injury (SCI), women's health clinics, HIV/ID clinics, hepatitis C clinics, homeless programs).
  - Include locations such as: all specialty clinics, dental clinic, triage and emergency rooms/departments.
  - Offer vaccination at convenient times and places, before and/or after a scheduled patient event, educational event or mental health group.
  - Offer vaccinations to inpatients prior to discharge, or as soon as medically feasible during hospital stay.
- Identify outside organizations to partner with—such as local health departments, visiting nurses associations, or even medical school students that you can work with to increase the impact of your vaccination campaign. The partner may be able to give vaccinations to family members and friends of Veterans that are not eligible for VA care.

7. Communicate, Remind, and Reinforce

Use multiple message formats and tools. Regularly provide reminders and updates. Educational materials such as a seasonal flu brochures or posters should be widely distributed and available for clinicians, Veterans, visitors and staff.

Tomeka Royster
Tuscaloosa VA Medical Center
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Marketing Tools for Clinicians

- Provider email, email blast to all staff to communicate awareness of influenza campaign and to encourage Veterans to get vaccinated.
- Screensavers with messages to providers and staff regarding the phases of the influenza campaign – "get ready," "vaccinations being given date/time," "it's not too late for your patient to get vaccinated."
- Provide "I got my flu shot" stickers to all clinicians who vaccinate patients. Also ask them to wear IDPIO "flu buttons" during flu season.

Marketing Tools for Veterans

- "On hold" telephone recorded messages for callers
- Newsletters
- Posters
- Buttons
- Stickers
- Pens
- Cafeteria tray liners
- Table tents
- Phone calls, and/or mailed reminders to outpatients. Provide return envelope, card or tear off section of the letter, for Veterans to provide information if vaccinated at another location.
- Place reminder to let VA know if vaccinated at another location on the back of appointment letters or other informational letters sent.
- Include reminders with pharmacy refills.

Other Communication Tools

- Ask reason for patient's refusal of flu shot; discuss and dispel "flu shot myths."
- Use facility and VISN web sites to provide updates for number of Veterans, employees, and volunteers vaccinated.
- Use facility Facebook page, Twitter, or other social media resources.
- Put flu clinic notices in local newspaper and on local radio stations.
- Display posters in elevators and restrooms. Change the posters at regular intervals.

MESSAGES FOR VETERAN PATIENTS

- **Stay home when you are sick.** Don't go to work, visit friends, family or others to avoid spreading flu and other germs.
- **Keep your children at home when they are sick and away from others.**
- **Clean hands frequently with water and soap or with alcohol-based hand rubs.** Encourage those around you (friends, children, work colleagues) to practice hand hygiene especially after touching items such as doorknobs, computer keyboards, countertops and other surfaces. Clean hands after sneezing and coughing, or making contact with your own secretions. Place alcohol hand rub in convenient places at work and at home.
- **Exercise proper respiratory etiquette.** Cover coughs and sneezes and keep tissues in convenient places. Dispose of used tissues properly. Sneeze into your sleeves if you don't have tissues.
- **Keep surfaces clean within your home and your work place.**
- **Avoid/minimize contact with sick persons.**

ADDRESSING CONCERNS OF VETERAN PATIENTS (OR RESIDENTS IN LONG-TERM CARE FACILITIES)

"Why should I get my flu shot?"

There are several reasons to be vaccinated against influenza every year:

- Influenza vaccine is the still the best way to avoid getting sick from flu.
- They can acquire influenza infection and not have any symptoms, but still be able to transmit the disease to friends, family and work colleagues.
- The virus changes from year to year, requiring vaccination each fall.

"I'm healthy. I don't need to get vaccinated for flu."

Influenza can cause serious illness and death even in young, healthy people. It's not just a disease that affects the elderly. If you get influenza, you can spread it to your patients, putting them at risk for severe illness and complications from the influenza virus. Protect yourself, your co-workers, your family, your friends, and your patients—get vaccinated for flu. Ask Occupational Health about when and where to receive your vaccination.

"I don't want to get the vaccine because it has side effects."

Studies have shown that the influenza vaccine is not associated with higher rates of systemic symptoms than are seen with injections of placebos among healthy working adults. The most common side effects of influenza vaccination include: soreness, redness, or swelling at the injection site, mild or low-grade fever, and aches. The symptoms should only last a day or two. The most common side effects from the nasal influenza vaccine are a runny nose and nasal congestion. Allergic reactions (anaphylaxis) rarely occur (less than 1 in 1 million). Neurological reactions (Guillian Barré Syndrome) are also rare (1 in 1 million).

"I got the influenza vaccine before and I still got influenza, so why should I get it now?"

In years when there is a good match between the circulating viruses and the corresponding vaccine strains, vaccine efficacy for reducing illness has generally been between 70–90 percent. However, even when the viruses are not well matched, the vaccine can protect many people and prevent flu-related complications.

"I'm pregnant. Should I get the influenza vaccination?"

Yes. All pregnant women are at risk from influenza and its complications. It is important that pregnant health care personnel get the influenza vaccine to protect themselves and their babies. The influenza vaccine can be given any time during the pregnancy. However, pregnant women should NOT receive the nasal influenza vaccine.

"I don't like needles, so I don't want to get vaccinated."

Discuss with your provider. You may be a candidate for the nasal spray that delivers live attenuated influenza vaccine (LAIV). This is an option for healthy people up through age 49, especially when there is a shortage of inactivated influenza vaccine. There is also an intradermal vaccine available.

"I don't need the vaccine. If I get the flu, I'll just take an antiviral medication."

Antiviral medications do not eliminate flu symptoms. They do shorten the duration by about 3 days, so you will need to be off work. Like all medication, antivirals may have side effects. It's better to get the flu vaccine.

ADDRESSING CONCERNS OF VETERAN PATIENTS (OR RESIDENTS IN LONG-TERM CARE FACILITIES)

"I'm not in a high risk group."

CDC recommends influenza vaccination for all people over the age of 6 months. You may be at a high risk if you have a chronic health problem such as diabetes. Vaccination helps to protect the Veterans you care for, your co-workers and your family.

"I always get 'the flu' when I take the vaccine."

When you are vaccinated, you may develop a temporary mild body aches, soreness at the injection site, and/or low grade fever. Any of these indicate a healthy normal response that may result in some mild discomfort, but this is different from actually getting influenza.

"My immune system is working just fine, thank you" or "I never get the flu."

Remember, you can transmit influenza to others before you become symptomatic. You may transmit the flu virus to others before you develop any symptoms of the flu. To protect yourself, your friends, and family, you should get vaccinated.

Checklist of a Successful Influenza Vaccination Campaign

1. **Identify a facility champion as the flu coordinator. This person may want to work with the occupational health staff to combine resources and efforts to establish a facility-wide flu vaccination campaign for Veterans and staff.**
2. **Encourage top management to be active members of the influenza vaccination program.**
3. **Enlist peer vaccination champions to encourage influenza vaccination. Make sure they are trained and know how to properly document vaccination.**
4. **Sponsor a kickoff event. Make it fun.**
5. **Make the vaccine accessible by encouraging all staff to promote and vaccinate Veteran patients. Increase vaccination events and locations where vaccination is available, and taking the vaccine to clinics via mobile carts.**
7. **Advertise the dates, times, and locations of influenza vaccination in multiple message formats and multiple locations.**
8. **Provide training or educational materials on why it is important to get vaccinated.**
9. **Identify why individuals do not wish to get the influenza vaccine and develop targeted messages to address those concerns.**

Section Six 6

MITIGATION STRATEGIES: HAND HYGIENE RESPIRATORY ETIQUETTE

SECTION SIX

MITIGATION STRATEGIES: HAND HYGIENE

VHA is committed to reducing the spread of infections within its facilities and recognizes effective hand hygiene practices as an important component to infection prevention. Hand hygiene is a necessary complement to vaccinations and respiratory hygiene in stopping the spread of flu, healthcare associated infection (HAI), and other infection. While flu prevention primarily focuses on vaccination and respiratory hygiene, hand hygiene is essential in any comprehensive flu campaign, particularly in:

- Reducing the spread of flu from contaminated surface where the influenza virus can live for 2 to 8 hours.
- Protecting patients, families, and healthcare workers who are unable to receive a flu vaccine.

Healthcare associated infection (HAI) also called "nosocomial" or "hospital" infection, is an infection occurring in a patient during the process of care in a hospital or other health care setting which was not present at the time of admission. HAI can affect patients in any type of setting where they receive care and can also appear after discharge. They can also include occupational infections among staff. Infections from HAI result in long-term disability, increased resistance of microorganisms to antimicrobials, massive additional costs for health systems, high costs for patients and their family, and unnecessary deaths. Infections from influenza can result in prolonged illness, extended hospital stays, and even death. Effective hand hygiene practices can reduce the spread of these infections, reduce the need for additional care and services, and help minimize the monetary and physical burden to VA patients, staff, and the VA health care system.

Hand hygiene doesn't apply solely to health care personnel (HCP). Patients and visitors to VHA facilities have a recognized role in the transmission of infections, including influenza and HAI. Everyone has a personal responsibility to promote and practice effective hand hygiene. VHA has a commitment to advancing the culture of safety, with minimized risk of spreading or acquiring infection, throughout its health care system. HCP are expected to model effective hand hygiene behaviors and encourage the same among other HCP, patients, and visitors. Educate and demonstrate hand hygiene at various interactions as outlined in policies and guidelines. Fostering participation from patients and visitors will increase the success of reducing the spread of influenza, HAIs, and other infections.

HISTORY

The importance of hand hygiene was first introduced by Dr. Ignaz Semmelweis in 1847 before scientists had discovered bacteria and the role of germs in the spread of infection. He observed post-partum mortality rates were very different on two wards in Vienna General Hospital.

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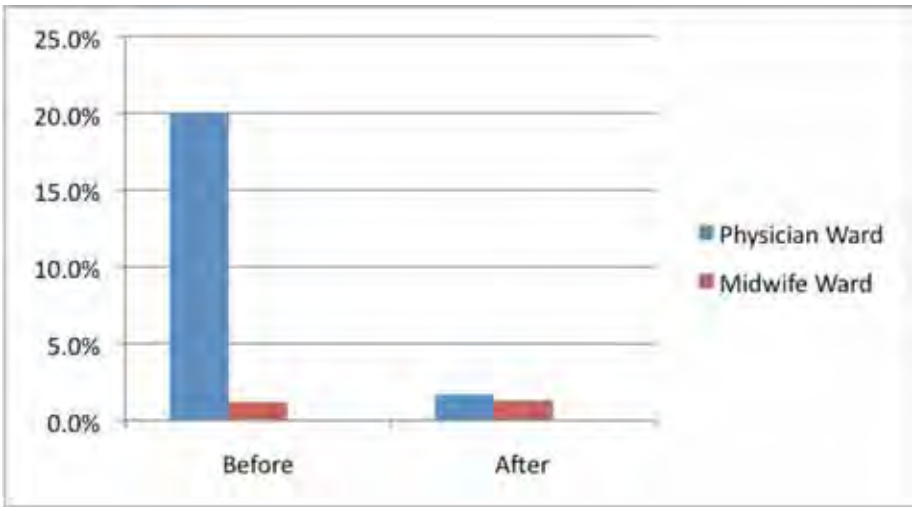
Encourage patients to ask their health care providers if they have cleaned their hands prior to touching them.

Figure 1: Dr. Ignaz Semmelweis' 1847 Chlorinated Lime Solution Experiement



Although both performed approximately 3,500 deliveries per year, *600-800* mothers died each year on wards overseen by physicians and medical students and *60* mothers died per year on wards overseen by midwives. This led to Dr. Semmelweis' groundbreaking experiment in which he required all physicians and medical student to rub their hands in chlorinated lime solution before every vaginal exam. The impact was dramatic. Before implementing his intervention, 13-18% of the mothers on the physician ward died, while 2% of mothers died on the midwife wards. After physicians began using the chlorinated lime solution, mortality rates dropped to 1.2% in physician wards.

ROLE OF HANDS IN TRANSMISSION OF INFLUENZA VIRUS

Evidence for the importance of hand hygiene has continued since Dr. Semmelweis' experiment. Multiple studies have shown decreases in overall hospital infection rates with hand hygiene compliance improvement.

Research studies also demonstrate hand hygiene can reduce the rate of transmission of flu and respiratory infections. A systematic review found that hand cleansing cut the risk of respiratory infection by 16%. Specifically, hands play a role in the transmission of the influenza virus when droplets carrying influenza virus contaminate animate and inanimate objects. It has been shown that a cough or sneeze from an infected person can spread the virus to surfaces 5-6 feet away. A noninfected person touching a contaminated surface can spread the virus to him or herself by then touching his or her eyes, nose, or mouth. The same transmission route may occur during patient care. Therefore, it is essential to follow hand hygiene guidelines regarding when to sanitize your hands in order to prevent the transmission of the influenza virus.

HEALTH CARE PERSONNEL (HCP): WHEN TO DISINFECT YOUR HANDS

VHA's Directive 2011-007, "Required Hand Hygiene Practices" provides guidance to facilities on structure and process of acceptable hand hygiene practices. This Directive incorporates The Joint Commission 2012 National Patient Safety Goal 07.01.01 as well as the World Health Organization's (WHO) guidelines and CDC recommendations on hand hygiene practices within medical facilities. The directive requires VHA healthcare workers to disinfect their hands at specific points during patients care. Those are listed below.

1. If hands are visibly dirty or soiled or exposure to *Clostridium difficile,* healthcare workers must wash their hands with soap and water.

In the remaining cases, alcohol-based hand rub may be used:

2. Before and after contact with a patient;

3. Before inserting an invasive device;

4. Before donning gloves and after removing gloves;

5. Moving from one contaminated body site to another on the same patient;

6. Before handling medication; and

7. After contact with inanimate surfaces and objects in the vicinity of the patient.

Multimodal programs for increasing hand hygiene compliance are recommended as the most reliable, evidence-based method for ensuring sustainable improvement.

THREE KEY STRATEGIES TO INCREASE HAND HYGIENE PRACTICE WITHIN VHA FACILITIES

1. Leverage Partnerships

The existing partnerships between VHA and labor leadership, Veterans Service Organizations (VSOs), and health care personnel (HCP) can provide an opportunity for improving our culture of safety. Coordinated communications from VHA, VSOs, and labor leadership set an expectation for hand hygiene for patients, visitors, and HCP in the spirit of a culture of safety. Whether seeking care or working within the VHA health care system, it understood that VHA, one of the nation's premier health care systems, expects a culture of safety. Framing hand hygiene as both an individual and community responsibility is essential to protect HCP's, patients, and others in VHA facilities.

2. Integrate Programs for a Comprehensive Approach

Hand hygiene is one part of a comprehensive, measurable program to improve safety by reducing the risk for an individual to develop unwanted infection and the risk for transmission of influenza and other infectious agents to others. Bundling hand hygiene with vaccination efforts and other important methods used to mitigate transmission (including respiratory etiquette and reducing the number of HCP who come to work while ill) is a proven disease prevention strategy. Linking hand hygiene, respiratory etiquette, and vaccination programs will strengthen VA's commitment to patient-centered care by building upon the energy, effort, and successes of our current infection control programs. Policy and operational strategy should be fully integrated to effectively target Veterans, visitors, and HCPs. Fully integrated programs include designate leads to address specific methodologies that advance a culture of safety.

3. Engage Resources

Seek ways to efficiently and effectively use facility HCP, information technology, and VACO program office resources to build a robust and successful hand hygiene campaign for HCP and the Veterans they serve. The *Infection: Don't Pass It On* (IDPIO) campaign continues to develop tools and resources to assist facilities in planning, implementing, and evaluating their influenza vaccination campaigns and hand hygiene compliance programs.

MEASURING HAND HYGIENE

The Joint Commission and other organizations agree that each health care setting is challenged to establish and select the measurement approaches that will best fit their needs. Following effective hand hygiene practices has long been recognized as the most important way to reduce the transmission of pathogens in health care settings. Many studies, however, have shown that adherence to hand hygiene recommendations remains low and that improvement efforts frequently lack sustainability. In 2004, The Joint Commission added a National Patient Safety Goal requiring that accredited health care organizations comply with hand hygiene guidelines. While most would agree that hand hygiene is of critical importance, many have found that measuring adherence to hand hygiene guidelines is not a simple task. Methods for measuring hand hygiene performance may include use of automated systems, direct observation, product use measurement, and surveys. Each has its own challenges and levels of validity. One method may prove effective in one environment but ineffective in another type of setting or clinic. For additional information about measurements and standards, visit the VHA Hand Hygiene Toolkit or The Joint Commission monograph: *MEASURING HAND HYGIENE ADHERENCE: OVERCOMING THE CHALLENGES* at www.jointcommission.org/Measuring_Hand_Hygiene_Adherence_Overcoming_the_Challenges_/.

Encourage Patients & Visitors to Clean Hands

- **Before eating**
- **Before touching a patient or someone sick**
- **Before entering the building/clinic or a patient room**
- **After using the restroom**
- **After sneezing or coughing**
- **After leaving the clinic or patient room**

VHA HAND HYGIENE TOOLKIT

VHA's *Infection: Don't Pass It On* (IDPIO) campaign, led by the Clinical Public Health, has developed an online toolkit on hand hygiene to provide relevant resources and tools for VHA facilities to use in promoting effective hand hygiene practices among all health care personnel, patients, and visitors.

Within the toolkit you'll find a myriad of resources. There are folders containing materials from different entities including the Centers for Disease Control and Prevention (CDC), the Joint Commission, the World Health Organization(WHO), and of course, the Veterans Health Administration (VHA). You'll find educational materials such as posters, brochures, and links to videos. Visit the reference folder to read the latest in research and literature on hand hygiene and related topics. A host of monitoring and evaluation systems are outlined, as well as guidance on promotion of effective hand hygiene policy and practice.

HAND HYGIENE RESOURCES

VHA Directive 2011-007: Required Hand Hygiene Practices outlines the hand hygiene policy in VHA
http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2367

Infection: Don't Pass It On Web Sites
http://www.publichealth.va.gov/InfectionDontPassItOn/

CDC Guideline for Hand Hygiene in Health-Care Settings
http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>

WHO "Clean Care is Safer Care" Patient Safety Challenge and Guideline on Hand Hygiene in Health Care
http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf

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SECTION SIX

MITIGATION STRATEGIES: RESPIRATORY ETIQUETTE

The primary mode of influenza transmission is thought to be the respiratory route through large, virus-laden particles called droplets. When an infected person coughs or sneezes they generate these particles that can travel up to 5 or 6 feet or more. These particles may then settle on the mucosal surfaces of another person's upper respiratory tract, thereby infecting that other person.

In addition to droplet transmission, influenza may also be transmitted through small, aerosol particles as well as through contaminated surfaces.

Influenza can spread within health care settings among patients, health care workers and visitors. Annual seasonal influenza vaccination is the most effective method of preventing influenza and everyone 6 months of age or older should receive an annual influenza vaccination. Even so, there will be people who decline the vaccine or cannot take the vaccine, requiring a multi-faceted approach to prevent the transmission of the influenza virus. The Centers for Disease Control and Prevention (CDC) have developed strategies for the prevention of seasonal influenza in all health care settings.

RESPIRATORY HYGIENE/ COUGH ETIQUETTE

Respiratory hygiene/cough etiquette involves measures to contain respiratory secretions and are recommended for all individuals with signs and symptoms of a respiratory infection (e.g. cough, sneeze, runny nose, fever). These practices are used to minimize influenza exposure, before arrival, upon arrival and throughout the visit to a health care setting.

- **Before Arrival** – During the influenza season, telephone discussions with patients should include instructions to tell a health care worker if they have any symptoms of a respiratory illness to ensure they are provided a mask to wear during their visit. Patients can also be offered a telephone consultation visit for mild respiratory illness to determine if they actually need to visit the facility or if their needs can be met without a face to face visit.
- **Upon Entry and During the Visit** – Processes should be in place to provide patients, visitors, and health care personnel (HCP) with the information and supplies to prevent transmission of influenza virus upon arrival to a health care facility.
  - Hang signs and posters at all facility entrances with instructions about respiratory hygiene and cough etiquette. Include all languages appropriate to the population served with instructions on:
    - How to use masks or tissues to cover nose and mouth when coughing or sneezing;

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Establish a culture of safety within your VHA facility. Encourage patients, visitors, and other staff to wear a mask if displaying symptoms of respiratory illness.

  - Disposal of contaminated items in a waste receptacle;
  - How and when to perform hand hygiene (soap and water, alcohol hand gel).
- Provide masks to patients/visitors with signs and symptoms of respiratory infection.
- Insure easy access to supplies to perform hand hygiene at entrances, waiting rooms and at patient check-in stations.
- Provide dedicated space and encourage persons with symptoms of respiratory infection to sit at least 3-6 feet from others.
- Establish dedicated triage stations, especially during periods of increase community influenza, to facilitate rapid screening of patients for symptoms of influenza and to separate from other patients.

HEALTH CARE PERSONNEL

- Facilities should establish and communicate sick leave guidance and practices that are non-punitive and encourage health care personnel to not report to work if they have a fever and symptoms of a respiratory infection.
- Facilities should advise health care personnel to follow respiratory hygiene and cough etiquette after returning to work, especially if coughing or sneezing persist, including wearing a facemask when performing patient-care activities.
- All HCP should perform frequent hand hygiene, especially before and after every patient contact and any contact with any respiratory secretions.
- All HCP, regardless of direct patient contact, should exclude from work until at least 24 hours after fever resolves, without the use of a fever-reducing medication.
- Sites should consider temporary reassignment or exclude from work for seven days for HCP working with high risk patients (hematopoietic stem cell transplant patients).

The Flu Team at the Lyons VA Medical Center in New Jersey.

ADHERENCE TO STANDARD PRECAUTIONS

- All health care personnel, patients and visitors should follow standard precautions which assume that every patient is potentially infected or colonized with a pathogen that can be transmitted. The elements of standard precautions that apply to patients with respiratory infections include:
  - **Hand Hygiene** – perform hand hygiene frequently, including before and after all patient contact, contact with potentially infectious material, before putting on and upon removal of personal protective equipment. Options for performing hand hygiene include alcohol-based hand rubs or soap and water (when hands are visibly soiled). Supplies should be readily available to HCP, patients, and visitors.
  - **Gloves** – should be worn for any contact with potentially infectious material, followed by hand hygiene. Gloves are for single patient use and should not be washed for the purpose of reuse.
  - **Gowns** – Gowns are worn when there is a potential for contact with blood, body fluids, secretions or excretions. Remove gown after use and perform hand hygiene. Gowns are for single patient use and should be changed between patients.

ADHERENCE TO DROPLET PRECAUTIONS

- Patients with suspected or confirmed influenza should be placed under droplet precautions for seven days after illness onset or until 24 hours after resolution of fever and respiratory symptoms, whichever is longer.
- Health care personnel should wear facemasks when entering the room of a patient under droplet precautions. The facemask is removed before leaving the room, disposed of in a waste container and hand hygiene performed.
- Patients under droplet precautions are provided a facemask if transport is necessary outside of room.
- Provide information to other departments providing care to patients with suspected or confirmed influenza infection to ensure they take measures to protect themselves and other patients.

USE CAUTION WHEN PERFORMING CERTAIN PROCEDURES

- Procedures such as bronchoscopy, sputum induction, elective intubation, extubation and autopsies may generate higher concentrations of infectious respiratory aerosols than coughing, sneezing, talking or breathing. The following precautions are recommended for patients with suspected or confirmed influenza:
  - Only perform these procedures if medically necessary.
  - Limit the number of health care personnel present.
  - Conduct the procedure in a negative pressure room with at least 12 air changes per hour.
  - Consider the use of a portable HEPA filtration unit.
  - Adhere to standard precautions, replacing a facemask with a fitted N95 mask.
  - Conduct a thorough environmental surface cleaning following the procedure.

Inform all visitors of procedures for standard or droplet precautions. Provide necessary supplies to promote compliance.

VISITORS OF PATIENTS WITH INFLUENZA OR SUSPECTED INFLUENZA

- Limit visitors to patients under droplet precautions for influenza to only persons necessary for emotional support. Visitors who have been in contact with the patient before and during hospitalization for influenza are a potential source of infection for other patients, visitors and staff.
- All visitors should follow respiratory hygiene and cough etiquette precautions when visiting patients with influenza/suspected influenza.
- Screen visitors for symptoms of acute respiratory illness before entering the hospital.
- Before visitors enter the patient's room, provide instruction on hand hygiene, limiting surfaces touched, and the use of gowns, gloves and masks per station policy.
- Caution visitors to limit their movement within the facility.
- Provide information on influenza vaccination.

Monitor Influenza and Other Respiratory Activity – to ensure prompt notification of increased activity in the community or outbreaks within the facility.

Environmental Controls – Standard cleaning and disinfection procedures are adequate for influenza virus control, including applying disinfectants to frequently touch surfaces/objects for the indicated contact times. Management of laundry, food service utensils and medical waste should follow standard procedures.

Engineering Controls – Use of physical barriers including partitions or the use of curtains to separate patients may help to reduce or eliminate exposures.

Training/Education for Health care Personnel – Information about influenza and other respiratory illnesses and their prevention should be provided to health care personnel. These include:

- Signs, symptoms, complications of influenza and other respiratory illnesses.
- Importance of the role of vaccination, respiratory hygiene and cough etiquette, sick leave policies and precautions during high risk procedures.
- Appropriate use of personal protective equipment, including respirator fit testing.
- Use of infection control practices and engineering controls to reduce exposure.

Use of Antiviral Treatment and Chemoprophylaxis of Patients and Health Care Personnel when Appropriate

- The most recent recommendations for the use of antiviral agents can be found in this manual and on the CDC website at http://www.cdc.gov/mmwr/pdf/rr/rr6001.pdf.

Patients and staff are reminded that persons continue to shed influenza virus while being treated with antiviral medications. Hand hygiene, respiratory hygiene, and cough etiquette should continue while undergoing treatment.

Health Care Personnel at Higher Risk for Complications of Influenza – pregnant women and women up to 2 weeks postpartum, persons aged 65 years and older, persons with chronic diseases including asthma, heart disease, diseases that suppress the immune system, other chronic medical conditions and morbid obesity are considered at high risk for complications of influenza. They should understand the importance of vaccination, early treatment with antiviral medication and avoidance of high-risk exposure scenarios to decrease the risk of hospitalization and death.

Some of the Flu Team having fun during their flu campaign at the Iowa City VA Medical Center.

SEVEN WAYS TO PROMOTE A CULTURE OF SAFETY WITHIN VHA HEALTH CARE SETTINGS

1. Get vaccinated against influenza.

2. Stay home when sick. Establish and discuss expectations with your supervisor based on VHA policy.

3. Cover your coughs and sneezes. Use a tissue or some other barrier (arm or sleeve) to cover your nose and mouth. Always clean your hands after.

4. Exercise and promote effective hand hygiene practice at work and at home. Encourage patients, visitors, and other HCP to do the same. Make friendly reminders a norm within your facility.

5. Make masks and tissues readily accessible to all.

6. Encourage patients and visitors to

- **a. wear masks if you hear them coughing frequently.**
- **b. cover their coughs and sneezes.**
- **c. comply with standard, droplet, or other posted respiratory precautions.**
- **d. clean their hands frequently.**

Use these occasions as teachable moments that define VHA commitment to maintaining a healthy and safe environment.

7. Encourage your colleagues and other HCP to wear masks or properly cover their mouths and noses if you hear them coughing or sneezing frequently or observe respiratory or flu-like symptoms. Make this behavior standard within your facility to demonstrate.

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OTHER SOURCES OF INFORMATION

VA Public Health website which offers a selection of posters for covering coughs/sneezes, etc. http://www.publichealth.va.gov/flu/materials/posters_respiratory_etiquette.asp.

VA Public Health website has a video about respiratory etiquette for patients http://www.publichealth.va.gov/flu/materials/videos.asp.

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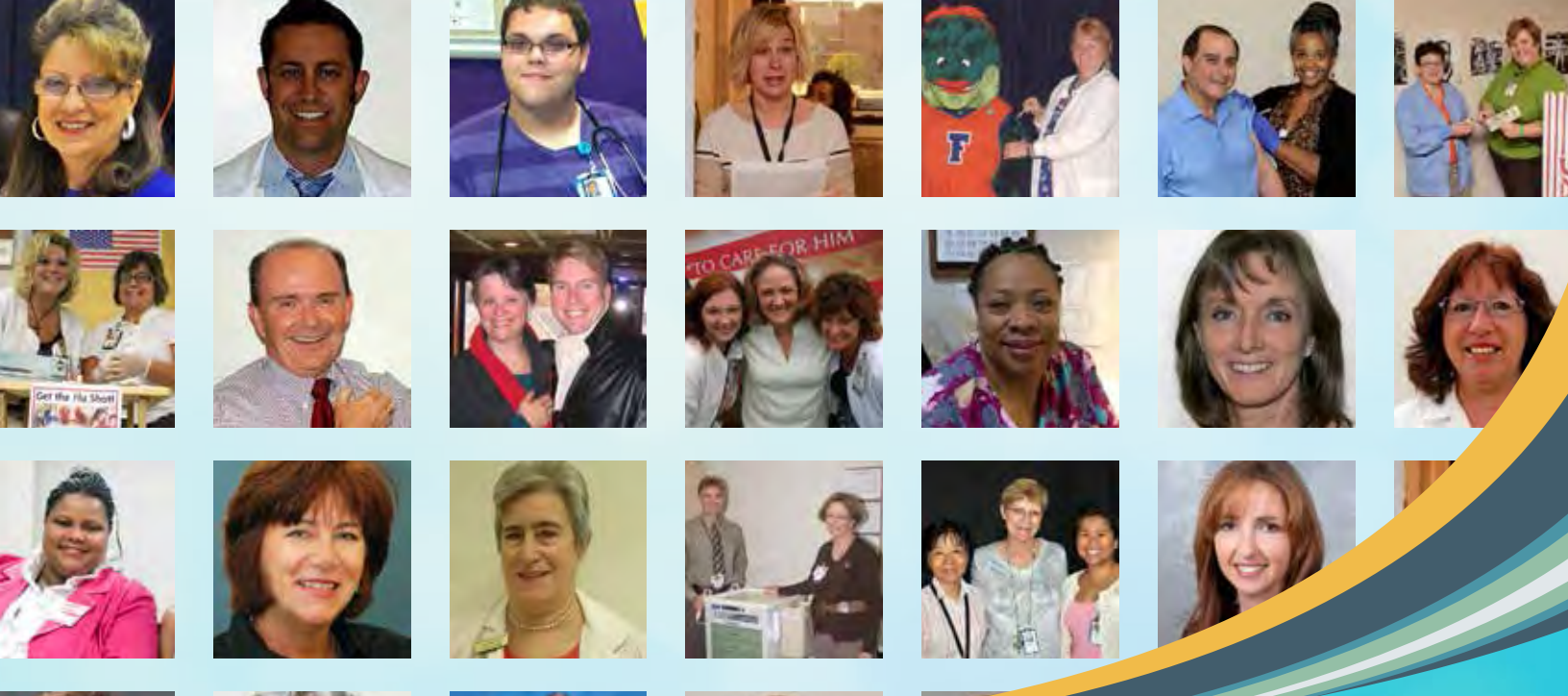
The Flu Team at the Erie, PA Medical Center.



Section Seven

DOCUMENTATION OF VACCINATION: CPRS: VETERAN PATIENTS OHRS: HEALTH CARE PERSONNEL

SECTION SEVEN

DOCUMENTATION OF VACCINATION: CPRS: VETERAN PATIENTS

Appropriate documentation of influenza vaccine administration is necessary to provide an accurate record of the patient's immunization history. Be sure to utilize one of the five CPT codes for each influenza vaccination administered. (See the documentation instructions and the CPT codes within this section.)

All influenza vaccinations should be documented in a way that results in the vaccination being entered on the patient's immunization list (i.e., entered in the V IMMUNIZATION file). This can be done in a number of different ways depending on your site and the location of the patient, but the maintenance of an accurate and up to date immunization list is critical.

The following list contains instructions about options for documenting influenza vaccinations in CPRS:

1. Vaccinations can be entered via a reminder dialog progress note template or a clinical reminder dialog. **This is the preferred method of documentation** since manufacturer name, lot numbers and expiration dates can be included in the dialog and the entry will populate the patient's immunization list in CPRS.
2. Direct entry of the vaccination into the Patient Care Encounter (PCE) can be made after administration of the vaccine.
3. IMPORTANT: Recording the administration of a vaccine dose in the Bar Code Medication Administration (BCMA) system on inpatients does not result in the entry of the vaccination on the patient's immunization list unless local programming has been accomplished to include this function. If no local programming exists to perform this function, then the site needs to implement one of the processes above to ensure that ALL vaccinations administered to patients are appropriately recorded on the immunization list.
4. PLEASE NOTE: Entry of the Current Procedural Terminology (CPT) code for a vaccination will result in the automatic update of the patient's immunization list ONLY IF THE PCE CODE MAPPING file contains a link from that CPT code to the correct immunization.

Utilizing these processes will assure entry of the correct CPT Codes for vaccine administration and the specific vaccine directly into the PCE VISIT files as well as the Immunization section of the encounter form. Completed documentation of the influenza vaccination can be viewed in the progress notes in CPRS with the actual immunizations and related CPT codes displayed in a window below the progress note.

Make the CPT code information below available to all who give flu vaccine at your site. Some sites communicate these codes during trainings, meetings, and/or emails. Accurate documentation of the influenza vaccination is essential for data tracking and measurement.

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Never only document flu vaccine administration directly in the progress notes. Flu vaccinations must be recorded using a method that enters appropriate CPT codes.

Documentation during mass influenza vaccination clinics can be a challenge, but a process should be in place to ensure it is complete, timely and accurate.

CPT Codes for Influenza Vaccine

- 90656 – **preservative free** standard dose vaccine – pre-filled syringes
- 90658 – standard dose vaccine – multi-dose vials
- 90660 – live attenuated (nasal) vaccine
- 90662 – high dose vaccine – pre-filled syringes
- 90654 – **preservative free** intradermal vaccine – pre-filled syringes

NOTE: The above vaccination codes should be entered into the medical record in addition to the code for the actual administration of the vaccine, 90471.

Clinical Reminder for Seasonal Flu Vaccination

There is NOT a national clinical reminder for staff to use in CPRS to document influenza vaccination. Individual facilities are encouraged to implement a locally developed influenza clinical reminder to help increase and track the rate of influenza vaccinations. There is a patient wellness reminder in My HealtheVet for use by in-person authenticated patients.

In April 2006, the National Clinical Reminders Group recommended each VA build a uniform health summary that included any local reminders for influenza vaccination. This health summary allows the user to view a record of all immunizations given at any VA site and can be accessed from the Reports Tab of CPRS under Health Summaries or in VistA Web. For assistance creating reminder dialogs and/or a health summary, contact your local facility's Office of Information Technology (OIT) staff. Members of the OIT staff are an important part of the team working on documentation of vaccine administration. Ideally, each facility/VISN would have a designated staff person to work on projects such as this.

SECTION SEVEN

DOCUMENTATION OF VACCINATION: OHRS: HEALTH CARE PERSONNEL

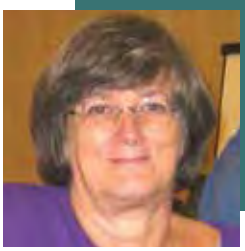
Appropriate documentation of influenza vaccine administration is necessary to provide an accurate record of VHA's staff (employees, volunteers, trainees, and other personnel) vaccination history. Documentation during mass influenza vaccination clinics can be a challenge, but a process should be in place to ensure it is complete and accurate.

Staff must document vaccination of health care personnel in the Occupational Health Record-Keeping System (OHRS) an electronic health record. The Occupational Health Record-keeping System is a Web based application. Only VHA staff who have been granted access to OHRS are able to document influenza vaccination administration. The person administering the vaccine must be the person who documents the administration of the influenza vaccination in OHRS. Remember to follow your facility's policy on timeliness of documenting vaccinations.

The following process is to be used to document influenza vaccinations in OHRS:

1. Individual vaccination

- **a)** Search and select the individual who is to receive the vaccine *Note: Search for volunteers using their last name. Search for employees using their last name, their full social security number or the first letter of their last name and the last four numbers of their social security number.*
- **b)** With the individual selected, click Create Encounter.
- **c)** From the **Category** drop-down list, select General Health.
- **d)** From the **Type** drop-down list, select Vaccination.
- **e)** Enter the **Purpose** for the vaccination encounter (free text).
- **f)** Click **Submit.**
- **g)** A list of vaccines displays. **Highlight** seasonal influenza vaccine. Click **Add.** *Note: If you are administering another vaccine at the same time highlight both vaccines and click Add.*
- **h)** Click **Submit.**
- **i)** A template appears.
- **j)** The template will display whether or not the individual has already received the vaccine if it was documented in OHRS. *Note: If the individual has already received the vaccine this season, click on cancel.*
- **k)** The template is divided into several sections: subjective, objective, assessment, plan and encounter codes. Only those sections with a "*" are required (plan and encounter codes).
- **l)** Click the plan tab and enter the required information. The template is dynamic and the required fields will change depending on what information is added.
  - The first question is was the vaccine received previously. If yes, document date received.
  - If no, additional information is required to document vaccination.



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Occupational Health
VA Central Office

VHA policy for using OHRS is outlined in VHA Directive 2012-012, Occupational Health Record-Keeping System, April 11, 2012 found in Appendix B of this flu manual.

The person administering the vaccine must be the person who documents the administration of the influenza vaccination in OHRS.

What's New:

- Identification of regular or high dose vaccine
- Drop down list of drug companies
- Preselected dose: 1.0 ml
- Preselected route: Intramuscular
- Vaccination Site: Most frequent injection sites are at the top of the list

You must still compete the lot number and expiration date.

m) Under the encounter codes tab, staff must select diagnostic and procedure codes. Default codes have been identified, but staff have the ability of searching and selecting another code, if applicable. The diagnosis code is the as when documenting influenza vaccination in CPRS for Veterans.

2. Quickload

Quickload allows occupational health staff to pre-load information about the vaccine being administered to a group of individuals (VIS, dose, route, manufacturer, lot number, and expiration date). Once the vaccine information is completed, staff search and select the individuals who received the vaccine.

What's New:

- Identification of regular or high dose vaccine
- Drop down list of drug companies
- Preselected dose: 1.0 ml
- Preselected route: Intramuscular
- Vaccination Site: Most frequent injection sites are at the top of the list

You must still compete the lot number and expiration date.

Staff may modify the injection site and time administered for each individual vaccinated, so that accurate information is collected. Once all the vaccination information is entered, the information is submitted. Documentation is now complete in all the selected records.

Occupational Health staff may generate summary and detailed reports on employee vaccination. Reports include: vaccination status, vaccination rate, vaccine administration, and immunity status.

HELPFUL HINTS

- Before loading several patient's vaccination information sign an encounter to make sure your electronic signature works.
- If the HCP's duty station is different from the person administering the vaccine, use Quickload to find him or her.
- Vaccination Status and Vaccination Rate Reports: There is a difference in who is included in the denominator in vaccination status and vaccination rate reports. Reports where the date includes "as of" will exclude all inactive patients. Reports where the date range is "from" and "to" include patients who were active any time during that date range.
- The vaccination administration report gives the number of doses of vaccine administered.

FREQUENTLY ASKED QUESTIONS

- **I logged in but I do not see the blue OHRS button.** If you do not see the blue OHRS button in the upper right corner of your screen, you have not been granted access to OHRS. Call your local administrator who is an occupational health physician, nurse practitioner, physician assistant or registered nurse.
- **I entered all of the encounter information, but I get an error message when I enter my VistA account information.** A VistA electronic signature (ESig) account is required for OHRS users to use their electronic signature when signing an encounter. Contact your local IMR staff who will verify that your VistA Esig user account is set up with at least one of the following:
  - The user must have the [XOBE ESIG USER] Broker option added to his or her secondary menu.
  - The [XOBE ESIG USER] Broker option must be added to the Common Menu [XUCOMMAND] in Kernel. (For IRM: this is the recommended option which enables all users on the system to have access to the ESig options so that the Broker option need not be assigned specifically to individual users).
- **My signature code is not working.** Check to make sure you are using the correct duty station (facility where you work). Make sure you are using the correct signature code (the same code you use to sign a clinical note in CPRS). If you continue to have problems contact your local Administrator: physician, nurse practitioner, physician assistant or registered nurse working in occupational health).
- **I need additional VHA staff trained and granted access to OHRS to document influenza vaccination administration.** Contact Cathy Morgan, Education Project Manager, Cleveland, OH at Cathy.Morgan@va.gov. She can provide the appropriate link and instructions to meet training requirements. Once completed and confirmed by Cathy, your occupational health staff can grant you access to OHRS.

Section Eight 8

VHA INFLUENZA AND EDUCATIONAL RESOURCES

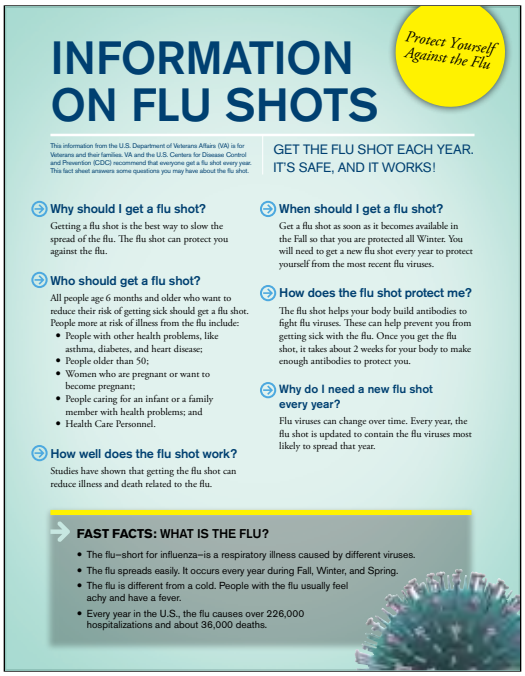
SECTION EIGHT

VHA INFLUENZA AND EDUCATIONAL RESOURCES

IDPIO CATALOG

The *Infection: Don't Pass It On* (IDPIO) campaign has developed resources to fcilitate the implementation of seasonal flu vaccination initiatives. Selected resources are available in print via TMS (instructions to follow). All IDPIO resources can be downloaded from the following website which features a compressive listing of all available resources. These materials can be viewed, downloaded, and printed on these four VA Web sites:

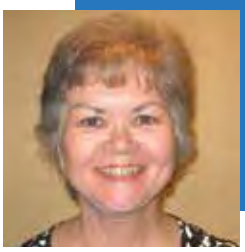
VA Internet
www.publichealth.va.gov/flu
www.publichealth.va.gov/InfectionDontPassItOn



Influenza Video Series

The IDPIO campaign has developed a total of seven videos, six of which are video clips approximately 2-3 minutes long.

- Four short clips are targeted toward a *general audience* (veteran patients, family, visitors and even VA staff) and focus on vaccination for seasonal flu, hand hygiene, respiratory etiquette, and how flu is spread. **These four clips are not for clinical instruction.**



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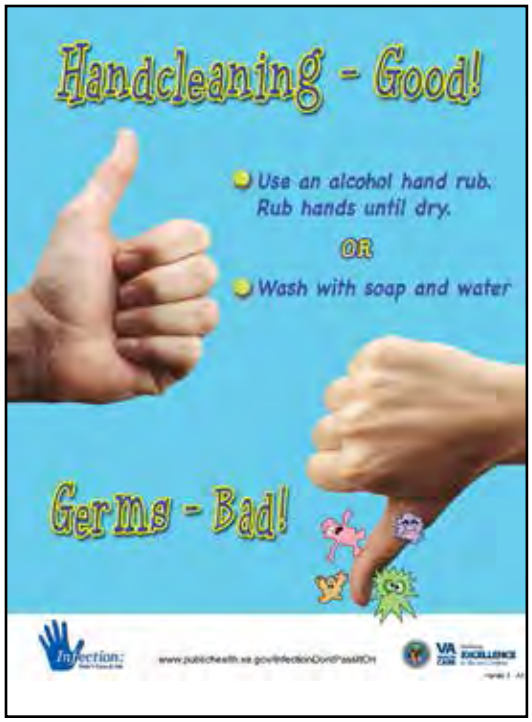
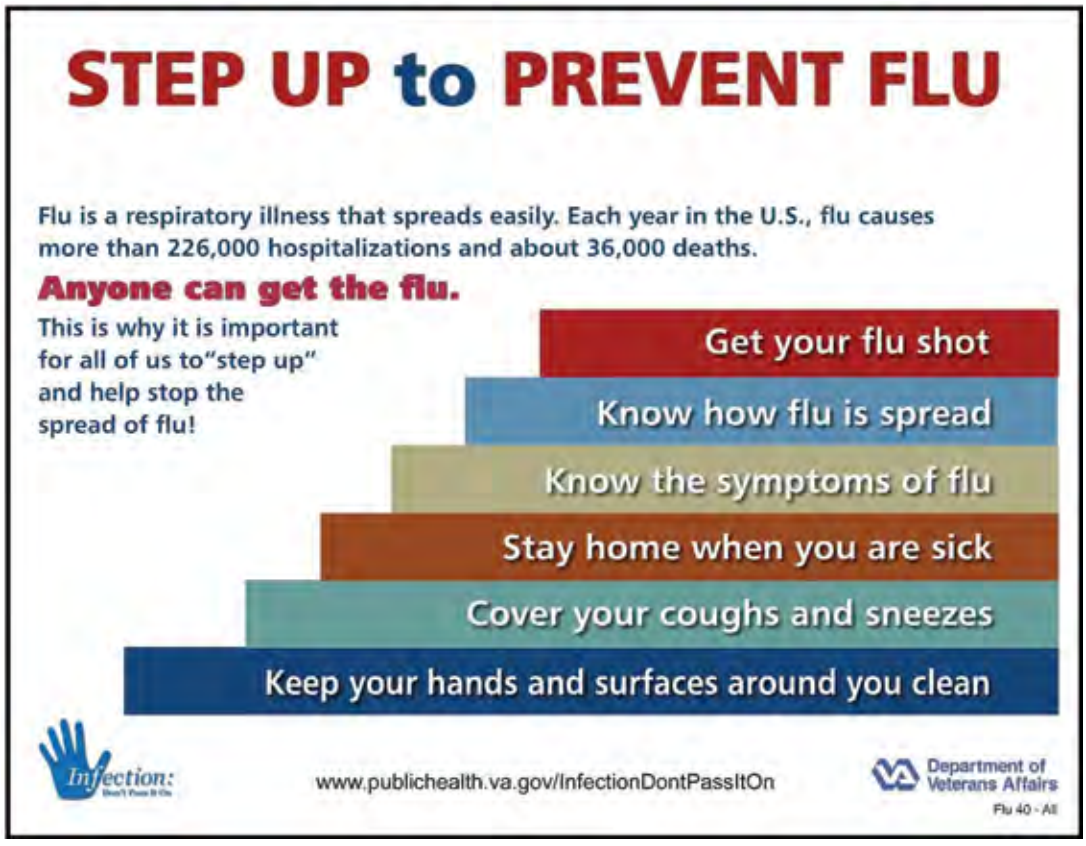
- Two short clips are intended for health care providers and others within the medical care setting. These focus on donning and doffing personal protective equipment (PPE) for combined airborne infection isolation and contact precautions.
- A 14-minute video on seasonal flu for a *general audience* is also included. It's "game show" format is both fun and informational for staff, patients and visitors.

All of the videos are posted for viewing at http://www.publichealth.va.gov/flu/materials/videos.asp.



Flu and Educational Resource Materials

1. **Flu Manual** – Each year the VA Influenza Manual is also available in electronic format in addition to print format.
2. **Posters/flyers** – These cover a myriad of topics that include flu, vaccination, hand cleaning, respiratory etiquette, and use



of personal protective equipment. Some posters have been designed for clinical audiences and other for general audiences. Hang them around clinics and facilities in appropriate areas.

3. **Buttons & Stickers** – Over the years, many buttons have been designed and distributed to facilities. Some templates are on the VA's Web sites and can be used if sites want to make their own buttons. Some buttons are available from our stock of IDPIO materials at the depot. Go to www.tms.va.gov and use keyword IDPIO.
4. **Brochures** – These cover topics ranging from seasonal flu and hand cleaning, to pandemic flu.
5. **Cafeteria tray liners** – Several designs are available if you want to work with your Canteen Service to have them printed and used during flu season.

Hand Hygiene Resource Materials

1. **Hand Hygiene Toolkit** – This online resource will continue to evolve with the emergence of new guidance, research, and science. Sources are the Centers for Disease Control and Prevention (CDC), the Joint Commission, the World Health Organization (WHO), and Veterans Health Administration (VHA). There are folders on:

- Posters, brochures, and links to resources.
- The latest research and literature.
- Monitoring and evaluation systems.
- Guidance on promotion of effective hand hygiene policy and practice.

How can I get more IDPIO and flu resources?

Some resources are available for order (posters, brochures, buttons, stickers, etc) through the Talent Management System (TMS). See the following steps to order.

Selected buttons, stickers, etc. are printed and available to order via TMS. Other resources can be printed from your computer with a color printer (if desired).

Ordering Instructions

Infection: Don't Pass It On (IDPIO) Resources

1. Go to the VA Talent Management System (TMS) at www.tms.va.gov
2. Log into TMS
3. Search CATALOG by typing in "IDPIO" in the search catalog field at the top of page.
4. Select ***IDPIO: Infection Don't Pass It On*** from the search results.
5. Scroll down to RELATED DOCUMENTS and click (on the tiny blue arrow) to expand.
6. If you know the Order # (F #) of the products you want, then proceed to step 10. If you don't know the order number (F#), then continue to step 7.
7. Select "Link to Document Holder".
8. Select ***Handout: IDPIO Catalog.*** This document displays all printed posters, brochures and other IDPIO educational resources available for order. Note the product titles and EES order numbers for each. You may wish to print this document as you'll need all this information to complete your order.
9. Return to RELATED DOCUMENTS by minimizing the resources list and the locator screen.
10. Select the ORDER THIS PRODUCT button to place an order. This link is located directly under the link for ***Handout: IDPIO Catalog.***
11. Fill in all of the required IDPIO Order Form information. This information will be transmitted directly to the *EES Distribution* team via Outlook email for processing. List all product titles, order numbers and quantities separately for each product you order.
12. After the form has been completely filled, complete your product order by clicking on the SUBMIT FORM button.

Note: The EES Distribution team will not deliver to home addresses. The request must come from a VA e-mail address to be received and processed. Orders are shipped within 3-5 business days unless otherwise specified in the special instructions. For assistance, email publichealth@va.gov or call 202-461-1040.

Infection: Don't Pass It On (IDPIO) Resources

This listing below contains IDPIO resources that can be ordered for FREE to VA staff for use in facilities. Use the instructions above and visit www.tms.gov to order available resources.

BUTTONS		
Title		**Reorder #**
Button 1	Protect Us All (10 per pack)	F60681
Button 2	Ask Me About the Flu (10 per pack)	F60682
Button 3	Cover your Sneezes (10 per Pack)	F60856
Button 4	Clean Hands Protect Veterans (10 per pack)	F60857

STICKERS		
Title		**Reorder #**
Sticker 4	I Got My Flu Shot - Red (100 per roll)	F60550
Sticker 5	I Got My Flu Shot, Did You? – Green (100 per roll)	F60680

POSTERS		
Title		**Reorder #**
Flu 1	Stay Healthy	F60535
Flu 10	Infection Control Management	F60614
Flu 11	We're all in this together	F60613
Flu 12	Employees & Volunteers	F60544
Flu 13	Seasonal Flu vs Pandemic Flu	F60690
Flu 14	Cold vs Flu	F60692
Flu 15	Will you be PREGNANT	F60725
Flu 16	Chronic Health Condition	F60728
Flu 2	At 65 I'm Healthy	F60536
Flu 3	If you're 65	F60537
Flu 5	Ask for Flu Shot	F60539
Flu 6	Keep Veterans Healthy	F60540
Flu 7	Do Your Part to Keep Veterans Healthy	F60541
Flu 8	Are You Ready?	F60542
Flu 9	Confirmed Influenza	F60615
Hands 8	Clean Your Hands	F60626
Hands 11	All Hands to the Pump	F60625
Hands 12	Break the Germ Cycle	F60624

POSTERS		
Title		**Reorder #**
Hands 13	Stop Spreading Germs	F60623
Hands 27	A Quick Test	F60620
Hands 29	CDC Guidelines	F60619
Hands 30	What are the top 10 carriers?	F60618
Hands 32	When Should You Clean Your Hands?	F60617
Hands 37	Patients & Visitors: It's okay to ask…	F60616
Hands 37	Lg Patients & Visitors: It's okay to ask	F60687
Prevent 6	Germs Get Down poster	F60545
Prevent 8	Stop	F60611
Prevent 13	Health Alert	F60610
Prevent 14	Keep Veterans Healthy	F60609
Prevent 16	Germs……Beware	F60689
Prevent 17	Isolation vs. Quarantine	F60693
Prevent 18	Be Prepared for Pandemic Flu	F60694
PPE 1	Airborne Infection Isolation & Contact…	F60599
PPE 2	PPE Donning and Doffing	F60598
PPE 3	Airborne Infection Isolation & Contact…	F60597
Resident 2	Residents & Visitors	F60601
Resident 3	Residents: Stop Germs	F60600
Respiratory 1	Don't Kiss Me	F60612
Restroom 1	Bathroom Rules	F60604
Restroom 2	After Using the Bathroom	F60603
Restroom 4	What's the Rush	F60602
Wash 1	Where to Wash	F60608
Wash 6	Wash Your Hands	F60607
Wash 9	Patients & Visitors: Wash Your Hands	F60606
Wash 10	Patients & Visitors: Wash Your Hands	F60605

BROCHURES		
Title		**Reorder #**
Brochure 8	Seasonal Flu, What you need to know	F60814
Gen Aud 2	Symptoms of Flu and When to Seek…	F60641
Gen Aud 3	How to Control the Spread of Flu	F60640
Gen Aud 4	Home Care Guide for Flu	F60642
Gen Aud 5	Be Prepared for Pandemic Flu	F60679
Gen Aud 6	When to Return to Work or School	F60678
Gen Aud 7	Hand Hygiene: VA Wants You…	F60754
Gen Aud 9	Pandemic Influenza: General Info	F60643

SPANISH LANGUAGE RESOURCES		
Title		**Reorder #**
Gen Aud 1 Sp	Pandemic flu: General Information	F60683
Gen Aud 2Sp	Symptoms of Flu/When to Seek Care	F60707
Gen Aud 3 Sp	How to Control the Spread of Flu	F60684
Gen Aud 4 Sp	Home Care Guide for Flu	F60685
Gen Aud 5 Sp	Be Prepared for Pandemic Flu	F60686
Gen Aud 6 Sp	When to Return to Work or School	F60703
PPE 1Sp	Airborne Infection Isolation & Contact	F60591
PPE 3Sp	Airborne Infection Isolation & Contact…	F60590
Prevent 11	SP Prevent	F60594

Section Nine 9

PNEUMOCOCCAL DISEASE AND VACCINE INFORMATION

SECTION NINE

PNEUMOCOCCAL DISEASE AND VACCINE INFORMATION

PNEUMOCOCCAL DISEASE

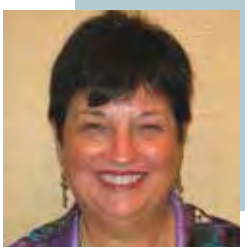
Pneumococcal disease is caused by Streptococcus pneumoniae, a bacterium that has more than 90 serotypes. Most serotypes cause disease, but only a few produce the majority of invasive pneumococcal disease. The 10 most common types cause 62% of invasive disease worldwide. The disease is spread from person to person by droplets in the air. The pneumococci bacteria are common inhabitants of the human respiratory tract. They may be isolated from the nasopharnyx of 5%-70% of normal, healthy adults.

There are two major clinical syndromes of invasive pneumococcal disease: bacteremia, and meningitis. They are both caused by infection with the same bacteria, but have different manifestations.

Pneumococcal pneumonia is the most common disease caused by pneumococcal infection. Pneumococcal pneumonia can occur in combination with bacteremia and/or meningitis, or it can occur alone. Isolated pneumococcal pneumonia is not considered invasive disease but it can be severe. It is estimated that 175,000 cases occur each year in the United States. The incubation period is short (1-3 days). Symptoms include abrupt onset of fever, shaking chills or rigors, chest pain, cough, shortness of breath, rapid breathing and heart rate, and weakness. The fatality rate is 5%-7% and may be much higher in the elderly. Pneumococcal bacteremia occurs in about 25%-30% of patients with pneumococcal pneumonia. More than 50,000 cases of pneumococcal bacteremia occur each year in the United States. Bacteremia is the most common clinical presentation among children less than two years, accounting for 70% of invasive disease in this group. Pneumococci cause 13%-19% of all cases of bacterial meningitis in the United States. There are 3,000-6,000 cases of pneumococcal meningitis each year. Symptoms and signs may include headache, tiredness, vomiting, irritability, fever, seizures, and coma. Children less than one year have the highest rate of pneumococcal meningitis, approximately 10 cases per 100,000 population. The mortality rate is high (30% overall, up to 80% in the elderly).

Pneumococcal disease is a serious disease that causes much sickness and death. In fact, pneumococcal disease kills more people in the United States each year than all other vaccine-preventable diseases combined.

More than 40,000 cases and more than 4,400 deaths from invasive pneumococcal diseases (bacteremia and meningitis) are estimated to have occurred in the United States in 2005. More than half of these cases occurred in adults who had an indication for pneumococcal polysaccharide vaccine. Young children and the elderly (younger than age five years and older than 65) have the highest incidence of serious disease. Case-fatality rates are highest for meningitis and bacteremia, and the highest mortality occurs among the elderly and patients who have underlying



Contributor:

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Ambulatory Care
Durham VAMC

Invasive disease from *Streptococcus pneumoniae* (pneumococcus) is a major cause of illness and death in the United States, with an estimated 43,500 cases and 5,000 deaths among persons of all ages in 2009.

medical conditions. Despite appropriate antimicrobial therapy and intensive medical care, the overall case-fatality rate for pneumococcal bacteremia is about 20% among adults. Among elderly patients, this rate may be as high as 60%.

PNEUMOCOCCAL VACCINE

Pneumococcal vaccine (Pneumococcal Polysaccharide Vaccine, PPSV 23) is used to decrease the risk of serious pneumococcal disease and its complications.

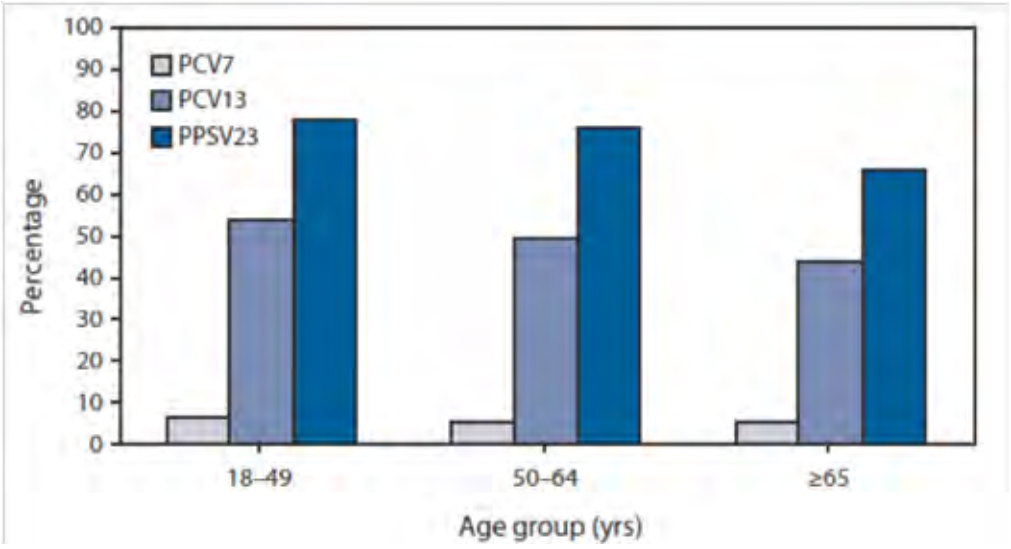
PPSV 23, Pneumovax®, is a 23-valent polysaccharide vaccine that includes 23 serotypes, has been shown to be 50-85% effective in preventing invasive disease caused by those 23 serotypes in adults with healthy immune systems. Observational studies have suggested effectiveness estimates ranging from approximately 50% to 80% for prevention of IPD among immunocompetent older adults and adults with various underlying illnesses, supporting the recommendations for using PPSV23 to prevent IPD.

At this time, two vaccines for prevention of pneumococcal disease are licensed for use in adults. The Advisory Committee on Immunization Practices (ACIP) currently recommends a single dose of PPSV23 for all persons aged 65 years and older. CDC published ACIP recommendations for PPSV23 and PCV13, in the October 12, 2012 issue of Morbidity and Mortality Weekly Report. Current recommendations for vaccination with PCV13 are listed below.

If **not already** vaccinated with PCV13 or PPSV23 a dose of PCV13 is recommended for adults aged 19 and older with:

- Immunocompromising conditions
- Functional asplenia
- Anatomic asplenia
- CSF leaks
- Cochlear implants

Figure: Percentage of invasive pneumococcal disease cases caused by serotypes covered in three different pneumococcal vaccine formulations (PCV7, PCV13, and PCV23) among adults aged ≥18 years, by age group—Active Bacterial Core surveillance, United States, 2008



Abbreviations: PCV7 = 7-valent pneumococcal conjugate vaccine. PCV13 = 13-valent pneumococcal conjugate vaccine. PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

This should be followed by a dose of PPSV23 no sooner than 8 weeks after initial vaccination. The current PPSV23 recommendations should then be followed for follow-up vaccination.

If **previously vaccinated** with PPSV23, adults aged 19 and older (conditions listed above), a dose of PCV13 should be administered when 1 year has elapsed from last dose of PPSV23. The MMWR outlines the schedule if additional doses of PVC13 or PPSV23 are required.

RECOMMENDATIONS FOR ADMINISTRATION OF PPSV 23 - "PNEUMOVAX"

PPSV 23 may be administered to adults any time during the year. It is recommended for the following adults: who meet any of the criteria or have conditions listed below:

Age 65 and older

Adults with long-term health problems:
- Heart disease including congestive heart failure and cardiomyopathies
- Lung disease including chronic obstructive pulmonary disease and asthma
- Sickle cell disease
- Diabetes
- Alcoholism
- Cirrhosis of the liver
- Cerebrospinal fluid leaks
- Cochlear implant

Adults who have a disease or condition that lowers the body's resistance to infection:
- HIV infection or AIDS
- Hodgkin's disease
- Lymphoma
- Leukemia
- Kidney failure
- Nephrotic syndrome
- Multiple myeloma
- Absent or damaged spleen
- Organ transplant

Adults who are receiving treatment that lowers the body's resistance to infection:
- Long-term steroids
- Certain cancer drugs
- Radiation therapy

Adults who smoke or have asthma.

If elective splenectomy or cochlear implant is being considered, the vaccine should be given at least 2 weeks prior to the procedure. If that is not feasible, vaccinate as soon as possible after surgery. For persons starting chemotherapy or other immunosuppressive therapy, if possible, vaccination should be administered at least 2 weeks prior to therapy.

Getting his flu shot - Secretary Eric Shinseki, U.S. Deptartment of Veterans Affairs.

FREQUENTLY ASKED QUESTIONS

1. How often should pneumococcal vaccine be given?

Most adults 65 and older only need one dose if they have not received an earlier dose. Those who need a second dose include:

- Adults age 65 years and older previously vaccinated should receive a second dose if five or more years have passed since the first dose and they were less than age 65 years at the time of the first dose.
- Adults at the highest risk of pneumococcal infections should receive a second dose five or more years after the first dose, regardless of the age at which the first dose was given. Adults at the highest risk include those with:
  - o HIV infection or AIDS
  - o Absent or damaged spleen
  - o Sickle cell disease
  - o Organ or bone marrow transplant,
  - o Nephrotic syndrome
  - o Cancer, leukemia, lymphoma, multiple myeloma
  - o Taking medication that lowers immunity, such as chemotherapy or long-term steroids
- Only two doses at most are given in a lifetime.

2. Should a dose be repeated if a patient is uncertain of having received it before?

ACIP does not recommend routine revaccination for most persons for whom PPSV23 is indicated. A second dose of PPSV23 is recommended 5 years after the first dose for persons aged 19–64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. ACIP does not recommend multiple revaccinations because of uncertainty regarding clinical benefit and safety.

If the patient's vaccination status is unknown, those in the recommended group should be administered pneumococcal vaccine. Consider supplying patients who have trouble remembering their vaccination history with a personal immunization card. Examples of cards are available at https://www.immunize.org/adultizcards/index.htm.

3. How is PPSV 23 administered?

- Pneumococcal polysaccharide vaccine may be given IM (intramuscularly) with a 22-25 g 1-1½-inch needle in the deltoid or SC (subcutaneously) in the fatty tissue over the triceps with a 23-25 g 5/8 inch needle.
- Pneumococcal polysaccharide vaccine can be administered at the same time as Influenza vaccine, using a different site.

Contraindications to vaccination include severe allergic reaction to one of the components to the vaccine, or following the first dose of vaccination. Vaccination should be delayed for persons with moderate or severe acute illness until their condition improves. Minor illnesses, for example a minor upper respiratory infection are not a contraindication.

Women who are at risk for pneumococcal disease and are candidates for vaccination should be vaccinated prior to pregnancy. See the vaccine information sheet (next page) or go to http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-ppv.pdf.

Pneumococcal vaccine should not be administered concurrently with Herpes Zoster (Shingles) vaccine. Please consult the change made to the vaccine labeling information regarding concurrent administration Pneumococcal and Zoster vaccines dated 12/18/09, available on the FDA website at http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm195993.htm.

4. What are the most common adverse reactions to PPSV 23, "Pneumovax"?

The most common adverse reactions, reported in >10% of subjects vaccinated with PNEUMOVAX 23 in clinical trials, were: injection-site pain/soreness/tenderness (60.0%), injection-site swelling/induration (20.3%), headache (17.6%), injection-site erythema (16.4%), asthenia and fatigue (13.2%), and myalgia (11.9%).

RESOURCES

CDC VIS for PPV here – http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-ppv.pdf.

Morbidity and Mortality Weekly Report October 12, 2012 – Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP) http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6140a4.htm.

Morbidity and Mortality Weekly Report September 3, 2010 – Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23) http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5934a3.htm.

PPSV 23 Package Insert: http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM257088.pdf.

Immunize.Org – Pneumococcal Disease: http://www.immunize.org/askexperts/experts_ppv.asp#disease.

Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/vaccines/vpd-vac/pneumo/dis-faqs.htm.

Licensure of 13-Valent Pneumococcal Conjugate Vaccine for Adults Aged 50 Years and Older

On December 30, 2011, FDA approved PCV13 for prevention of pneumonia and invasive disease caused by PCV13 serotypes among adults aged 50 years and older. For more information visit http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6121a3.htm.

Section Ten 10

APPENDICES

SECTION TEN
APPENDIX A
HOW TO ADMINISTER INFLUENZA VACCINES

INACTIVATED INFLUENZA VACCINE ADMINISTRATION

1. Understand concomitant vaccine administration. Usually, inactivated vaccines do not interfere with the immune response to other inactivated vaccines or to live vaccines.

2. Provide the vaccine recipient with the appropriate CDC Vaccine Information Statement (VIS). Document the date of the VIS and that it was given to the vaccine recipient. This must be a print copy that the patient may read and take home. Copies of the CDC influenza VIS's are included in Section 1 of this manual or on the Web at http://www.cdc.gov/vaccines/pubs/vis/default.htm. VA staff may also provide patients with other information or educational material in addition to the CDC VIS.

Inactivated influenza vaccine should never be frozen. Store between 2-8 C (35°-46° F). Refrigerator temp should be checked 2 x daily.

3. Ensure the patient has no known contraindications to receive the vaccine.

In some rare instances people receiving vaccine have had severe allergic reactions. The following precautions should be carefully noted:

a) People with known severe allergy to eggs SHOULD NOT receive the vaccine unless evaluated by their physician to help determine if vaccine should be administered. People may say they are allergic to eggs, yet they actually eat products made with eggs (e.g. bread, cake). Be sure the allergy to eggs is accurate information and not just personal food dislike/preference. People with hives only (majority of reactions) can safely receive the vaccine and should get it; very few adults are truly allergic to eggs (mostly occurs in childhood and is outgrown by adulthood). Skin testing prior to vaccine administration or dividing the dose are not necessary.

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b) People who have had a previous influenza vaccination and had a serious reaction to components of the vaccine should not receive influenza vaccine.

c) People with moderate or severe illness with a fever should delay getting vaccinated until after the acute phase of a febrile or respiratory illness (approximately 72 hours or until afebrile).

d) Persons who are not at high risk for severe influenza complications and who are known to have experienced Guillain Barre Syndrome (GBS) within 6 weeks of receipt of an influenza vaccine generally should not be vaccinated. As an alternative, physicians or non-physician providers might consider using influenza antiviral chemoprophylaxis for these persons. Although data are limited, the established benefits of influenza vaccination might outweigh the risks for many persons who have a history of GBS and who also are at high risk for severe complications from influenza.

e) Influenza vaccine is not approved for children less than 6 months of age.

4. Check manufacturer expiration date.

5. Practice injection safety: hand hygiene, glove use, and skin preparation and disinfection.

Injection safety is an important component of infection prevention. The concept of "standard precautions", with mandatory safe practices, applies to all healthcare settings. Every person in all healthcare settings is considered a potential source of infection.

a) Hand Hygiene – Perform hand hygiene (use soap and water or alcohol hand rub), and wash/rub carefully, including wrists and spaces between the fingers according to your health care system hand hygiene policy.

- Perform hand hygiene BEFORE:
  - starting an injection session (i.e. preparing injection material and giving injections);
  - coming into direct contact with patients for health-care related procedures;
  - putting on gloves (first make sure hands are dry).

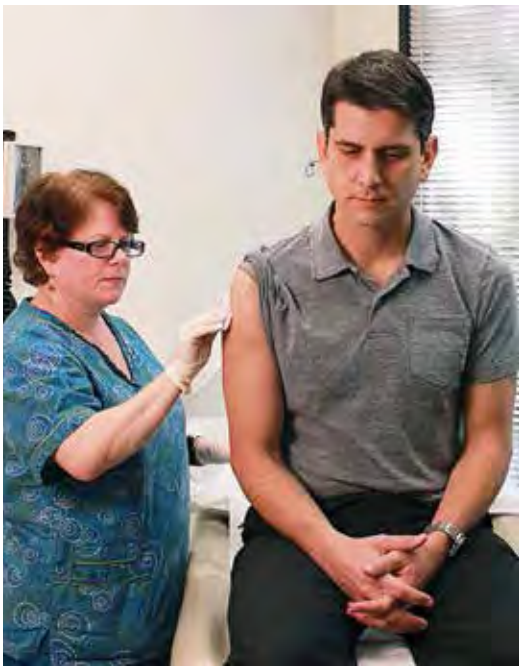
- Perform hand hygiene AFTER:
  - an injection session;
  - any direct contact with patients;
  - removing gloves.
- You may need to perform hand hygiene between injections in the same person. (if patient receives another vaccine at the same time as the flu vaccine), depending on the setting and whether there was contact with soil, blood or body fluids.
- Avoid giving injections if your skin integrity is compromised by local infection or other skin conditions (e.g. weeping dermatitis, skin lesions or cuts), and cover any small cuts.

b) Glove use

- Health workers should wear non-sterile, well-fitting single-use gloves when coming into contact with blood. Latex-free gloves are preferred.
- If wearing gloves, it may be helpful to open the individual bandage wrapper prior to applying gloves, to lessen the likelihood of the adhesive part of the bandage sticking to the gloves while applying the bandage to the vaccine recipient's skin.
- Follow steps for hand disinfection before donning and after removal of gloves.
- <u>Indications for glove use in injection practice are:</u>
  - when there is a likelihood of coming into direct contact with a patient's blood or other potentially infectious materials (e.g. body fluids, moist body substances, nonintact skin that may be adjacent to or near the injection site).
  - if the health worker's skin is NOT intact (e.g. through eczema, or cracked or dry skin)
  - if the patient's skin is NOT intact (e.g. through eczema, burns or skin infections).

c) Skin preparation and disinfection

- Apply a 60-70% alcohol-based solution (isopropyl alcohol or ethanol) on a single-use swab or cotton-wool ball. DO NOT use methanol or methyl-alcohol as these are not safe for human use.
- Wipe the area from the center of the injection site working outwards, without going over the same area.
- Apply the solution for 30 seconds then allow it to dry completely.
- ***DO NOT*** pre-soak cotton wool in a container – these become highly contaminated with hand and environmental bacteria.
- Have latex-free bandages ready to apply to the injection site immediately after the injection is complete. Bandages to the injection site are not required, but most vaccine recipients prefer them. It is a good idea to apply to the injection site, in the event the site bleeds after injection and to cover/protect the skin where the injection occurred.



InactivatedTrivalent Influenza Vaccine (TIV): In adults ≥50 years old, safety precautions and ensuring adequate immune response was indicated when Zoster vaccine and TIV were administered simultaneously or 4 weeks apart.

6. Administer the vaccine properly.

a) Clean or decontaminate your hands. See information above concerning glove use and hand hygiene.

b) Examine and prepare the vaccine: Always double check the vial or syringe label to make sure that you have the vaccine you want to administer and it is not past the expiration date.

i. For Multi-dose Vials: Shake the vial and visually inspect it for particulate matter. If you cannot shake the vaccine into a relatively even suspension, do not use it. After wiping the rubber stopper with an alcohol swab, load the syringe by injecting air into the vial, the same volume of air as the dose of vaccine to be drawn, pull plunger and draw vaccine into syringe. NOTE: Never reinsert a used needle into the vial.

ii. For Manufacturer Pre-filled (standard dose, high dose, or intradermal) syringes: Shake well before administration.

c) Can I pre-fill syringes for a flu shot clinic? If so, how long before the clinic can I pre-fill the syringes?

CDC does not recommend pre-filling syringes because of the potential for administration errors. The same person who draws vaccine should ideally be the person who administers it. Once the needle is placed on the syringe it should be used immediately.

d) Check vaccine expiration dates: Per the Joint Commission FAQ1, influenza vaccine is exempt from the new Joint Commission requirement on multi-dose vials being labeled with a revised expiration date once it has been opened or used. The **manufacturer expiration date** for influenza vaccines should be used for shelf life even after opening. The Joint Commission has clarified these multi-dose requirements. The requirements are addressed in their Medication Management standard MM.03.01.01 element of performance 7 which requires organizations to store all medications labeled with the expiration date.

e) Use the appropriate vaccine formulation: 2012-2013 Inactivated Trivalent Influenza Vaccine (TIV) vaccine has more than one formulation. The standard dose formulation is acceptable for use in all age groups >6 months of age. The high dose formulation is approved only for use in age groups 65 years old and older. The purpose of the high dose formulation is to get a better immune response in the older adult population. More data is needed to substantiate this theory. =TIV is now also available to be given under the skin using a microinjection system.

Concurrent Administration of Influenza Vaccine with Other Vaccines.

In the absence of specific data indicating interference, following ACIP's general recommendations for vaccination is prudent. Inactivated vaccines do not interfere with the immune response to other inactivated vaccines or to live vaccines. Inactivated or live vaccines can be administered simultaneously with LAIV. However, after administration of a live vaccine, at least 4 weeks should pass before another live vaccine is administered. (CDC General Recommendations on immunization, recommendations of the Advisory Committee on immunization Practices (ACIP) and the American Academy of Family Physicians).

What length of needle should we use to give IM influenza vaccinations to adults?

Adults 19 yrs or older:	Needle Length	Injection Site
Male or female less than 130 lbs	5/8-1 inch *	Deltoid muscle of arm
Female 130-200 lbs Male 130-260 lbs	1-1½ inch	Deltoid muscle of arm
Female 200+ lbs Male 260+ lbs	1½ inch	Deltoid muscle of arm

*A 5/8" needle may be used for patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

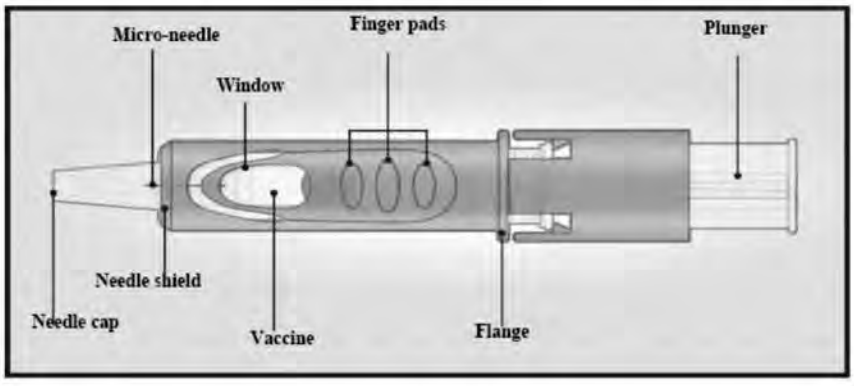
f) Use the appropriate site and needle for intramuscular (IM) injection.

The intramuscular route is recommended for TIV unless using intradermal preparation. When using IM route, adults and older children should be vaccinated in the deltoid muscle, below the shoulder on the upper arm. *Use a 22-25 gauge needle. Choose the injection site and needle length appropriate to the person's age and body mass.* Needles of less than 1 inch might be of insufficient length to penetrate muscle tissue in certain adults and older children. A 1 inch (25mm) to 1.5-inch (38 mm) needle should be used to give inactivated influenza vaccine intramuscularly to adults. The needle length must be able to ensure sufficient intramuscular injection.

g) Use the appropriate site for intradermal injection.

The preferred site for intradermal injection is over the deltoid area. Remove the needle cap from the microinjection system. Hold the unit by placing the thumb and middle finger only on the finger pads, leaving the index finger free. Do not place fingers on the windows. Insert the needle perpendicular to the skin over the deltoid muscle in a short, quick movement. Maintain light pressure on the unit over the skin and inject using the index finger to push the plunger. Do not aspirate. Remove the needle from the skin, direct the needle away from you and others, and push very firmly with the thumb on the plunger to activate the needle shield. You will hear a "click" when the shield extends to cover the needle. For vaccination with the intradermal vaccine, the specifically designed microinjector has a 3/50 inch needle.

Micro-Injection System



h) Document influenza vaccination: It is important to keep organized and accurate vaccination records. (Section 7 of this manual).

7. Dispose of the needle and syringe safely. Use a safety needle product and activate the safety mechanism before discarding syringe with needle into the sharps container. Activation of the safety needle should occur immediately after injection. If a non-safety needle must be used, do not recap the needle after use. Discard the uncapped used needle still attached to the syringe into a sharps container keeping your eyes on the needle continuously until it is inside the container. These disposal techniques apply to intramuscular and intradermal needles and syringes.

8. Prepare and watch for an allergic reaction (anaphylaxis). Acute anaphylactic reactions are very rare, occurring after approximately one out of every 500,000 doses of vaccine. When they occur, however, you must take immediate action. During walk-in immunization clinics, no vaccine should ever be administered unless epinephrine, diphenhydramine, adult airways, and blood pressure cuffs are close at hand. All providers administering influenza vaccine should be familiar with an anaphylaxis protocol and with cardiopulmonary resuscitation (CPR).

After you have administered a vaccine to the vaccine recipient, instruct the recipient to report any itching, redness (with or without hives), difficulty breathing, or abdominal pain within several minutes of injection. Having the vaccine recipient wait 15 minutes in a post-injection area is suggested but is not officially required.

Drive through clinics should advise vaccine recipients in the vehicle to report any itching, redness (with or without hives), difficulty breathing, or abdominal pain within several minutes of injection to VA staff working in the drive through clinic. Follow the facility protocol for drive through immunization clinic recommendations when advising the vaccine recipients (or their driver) what to do if this occurs.

Brenda McCall prepares to give a flu shot at the drive through flu clinic at the Marion, Illinois VA Medical Center.

VACCINE STORAGE AND HANDLING

Store Inactivated Trivalent Influenza Vaccine (TIV) properly: Store between 2-8 C (35º-46º F). Vaccine should never be frozen. Refrigerator temperature should be checked 2 times daily.

- The temperature in the refrigerator varies depending on if the item is stored in the vegetable bin, on the floor, next to the walls, in the door, etc., and may be a significant difference from the temperature in the body of the refrigerator away from these locations. Always store vaccines in their original packaging in the body of the refrigerator away from outlying locations. Place vaccine packages in such a way that air can circulate around the compartment. Never over pack the refrigerator compartment.
- Temperatures fluctuate throughout the day. Temperatures in the refrigerator should be checked at the beginning and end of the day to determine if the unit is getting too cold or too warm. Ideally, continuous monitoring thermometers that measure and record temperatures all day and all night are best. For vaccine storage only certified thermometers should be used. Recording the temperature of the room on the temperature log is a good idea in case there is a problem with the refrigerator/freezer temperatures. This information may be helpful to the vaccine company during a telephone consult to determine whether your vaccine can still be used if there has been a problem identified.

CONTENT FOR INACTIVATED INFLUENZA ADAPTED FROM:

1. U.S. Food and Drug Administration. (2011, July 5). *Vaccines, Blood and Biologicals: FluMist.* Retrieved August 5, 2011, from U.S. Department of Health and Human Services: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094047.htm.

2. Immunization Action Coalition. (January, 2004). *Adults Only Vaccination: A Step-by-Step Guide.* Retrieved August 2011, 2011, from http://www.immunize.org/guide/aovguide_all.pdf.

3. MMWR / August 17, 2012 / Vol. 61 / No. 33; Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm?s_cid=mm6132a3_x.

4. *Standard FAQ Details, Multi-dose vials, The Joint Commission, July 20, 2010,* http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=143&ProgramId=1.

5. Immunization Action Coalition. (2008, June). Don't Be Guilty of These Errors in *Vaccine Storage and Handling.* Retrieved August 5, 2011, from http://www.sanantonio.gov/health/pdf/immunizations/VFCforms/In%20Service%20Materials/Vaccine%20Storage%20%20Handling%20Errors.pdf.

6. Centers for Disease Control and Prevention. (2011, January 31). *Vaccine Storage and Handling.* Retrieved August 4, 2011, from http://www.cdc.gov/vaccines/recs/default.htm#storage.

7. "How to administer IM and SC injections to adults," available at http://www.immunize.org/catg.d/p2020A.pdf.

8. Immunization Action Coalition. (2009, February). *Administering Vaccines: Dose, Route, Site, and Needle Size.* Retrieved August 5, 2011, from http://www.immunize.org/catg.d/p3085.pdf.

9. For a detailed explanation and demonstration of immunization techniques, the 35-minute video "Immunization Techniques DVD" can be ordered through the IAC at http://www.immunize.org, using the "Shop IAC" link.

LIVE ATTENUATED INFLUENZA VACCINE ADMINISTRATION (LAIV)

1. Understand concomitant vaccine administration.

a. In the absence of specific data indicating interference, following ACIP's general recommendations for vaccination is prudent. Inactivated vaccines do not interfere with the immune response to other inactivated vaccines or to live vaccines. Inactivated or live vaccines can be administered simultaneously with LAIV. However, after administration of a live vaccine, at least 4 weeks should pass before another live vaccine is administered. (CDC General Recommendations on immunization, recommendations of the Advisory Committee on immunization Practices (ACIP) and the American Academy of Family Physicians).

b. LAIV administration with measles, mumps, rubella and varicella vaccine among children (12-15 months) has been studied and indicates immunity was achieved with all vaccines administered.

2. Provide the vaccine recipient with the appropriate CDC Vaccine Information Statement (VIS) and document it was given to the vaccine recipient. This must be a print copy that the patient may read and take home. A copy of the CDC influenza VISs are included in Section 1 of this manual or on the Web at http://www.cdc.gov/vaccines/pubs/vis/default.htm VA staff may also provide patients with other information or educational material in addition to the CDC VIS.

Though rare, as with any vaccine, post-vaccination reactions can occur.

Severely immunosuppressed persons: should not administer LAIV to patients. However, other persons at higher risk for influenza complications **can administer LAIV to patients.** These include persons with underlying medical conditions placing them at higher risk or who are likely to be at risk, including pregnant women, persons with asthma, and persons aged 50 years and older.

3. Ensure vaccine recipient meets criteria to receive LAIV. Healthy persons ages 2 years of age through 49 years of age and are not pregnant are eligible for this type of vaccination.

LAIV should NOT be given to:

a) Pregnant women

b) People who are 50 or over

c) Children under 2 years old because of an increased risk for hospitalization and wheezing observed in clinical trials

d) Anyone with history of hypersensitivity, or anaphylactic reaction, to any component of LAIV or any previous influenza vaccination

e) Those allergic to eggs or egg products, gentamicin, gelatin, or arginine

(**Note:** People with known severe allergy to eggs, SHOULD NOT receive the vaccine unless evaluated by their physician to help determine if vaccine should be administered. People may say they are allergic to eggs, yet they actually eat products made with eggs (e.g. bread, cake). Be sure the allergy to eggs is accurate information and not just personal food dislike/preference. People with hives only (majority of reactions) can safely receive the vaccine and should get it; very few adults are truly allergic to eggs (mostly occurs in childhood and is outgrown by adulthood). Skin testing prior to vaccine administration or dividing the dose are not necessary

f) Persons who:

- Have had a severe allergic reaction to previous influenza vaccinations (e.g. rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips, or tongue)
- Are children and adolescents (6 months to 18 years of age) receiving aspirin or aspirin-containing therapy (or another salicylate) (because of the association of Reye syndrome with wild-type influenza virus infection)
- Have asthma, or active wheezing, or children younger than 5 yrs with recurrent wheezing or a wheezing episode in the previous 12 months
- Have nasal congestion that impedes delivery of the vaccine to the nasopharyngeal mucosa (delay LAIV administration until resolved or offer TIV)
- Have a moderate or severe illness with or without fever
- Are a close contact of immunosuppressed persons who require a protected environment

(**Note:** The precaution regarding use of LAIV in protected environments is based upon a theoretic concern that the live attenuated vaccine virus could be transmitted to severely immunocompromised persons. However, no transmission of LAIV in health-care settings ever has been reported, and because these viruses are also cold-adapted (and cannot effectively replicate at normal body temperature) the risk for transmitting a vaccine virus to a severely immunocompromised person and causing severe infection appears to be extremely low. HCP working in environments such as neonatal intensive care, oncology, or labor and delivery units can receive LAIV without any restrictions

g) Persons who have:

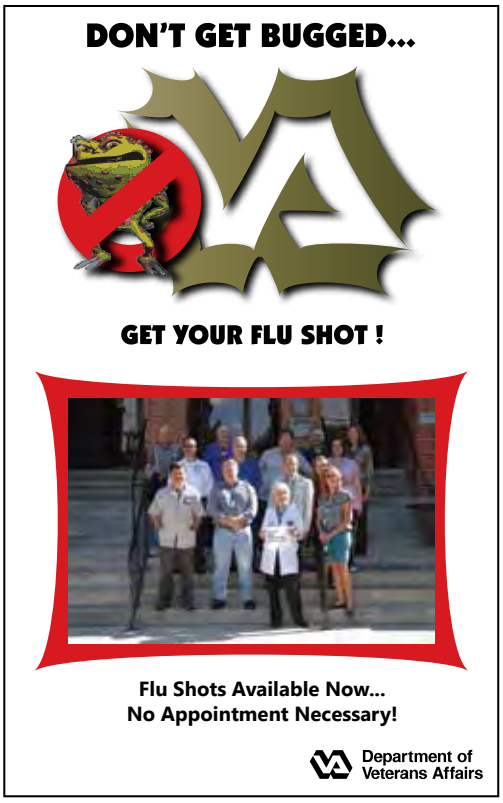
- Heart disease, except isolated high blood pressure
- Lung disease
- Kidney disease
- Liver disease
- Immunosuppression/ immunodeficiency disease
- Diabetes/metabolic disorders
- Anemia or other blood disorders
- Neurologic/neuromuscular disorders
- History of Guillain-Barré Syndrome

(**Note:** A moderate or severe illness with or without fever is a precaution for use of LAIV. Development of GBS within 6 weeks following a previous dose of influenza vaccine is considered to be a precaution for use of influenza vaccines.)

4. Check manufacturer expiration date.

5. Check the syringe to make sure it is LAIV. LAIV is intended for intranasal administration only and should not be administered by the intramuscular, intradermal, or intravenous route.

6. Administer vaccine intranasally; only one dose of 0.2 ml per season for adults. Remove the vaccine pre-filled single use sprayer from refrigerator. LAIV is supplied in a prefilled, single-use sprayer containing 0.2 mL of vaccine. While the recipient is in the upright position, insert tip of sprayer just inside the nose and rapidly depress the plunger until the dose-divider clip stops the plunger. Approximately 0.1 mL (i.e., half of the total sprayer contents) is sprayed into the first nostril while the recipient is in the upright position. Remove the dose-divider clip from the sprayer to administer the second half of the dose (approximately 0.1 ml) into the *other* nostril. If the vaccine recipient sneezes immediately after administration, the dose should not be repeated.



Mary Gillis and the flu team at the Boise, Idaho VA Medical Center.

Postpone administration of LAIV if:

- Patient is in the acute phase of a febrile or respiratory illness (other than asthma) and administration should be delayed approximately 72 hours or until afebrile.
- Nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa. Offer TIV or consider deferral of LAIV administration until resolution of the illness or condition causing the nasal congestion. No data exist about concomitant use of nasal corticosteroids or other intranasal medications.

7. Dispose of the sprayer properly. Once LAIV has been administered, the sprayer should be disposed of according to the standard procedures for medical waste.

8. Prepare and watch for an allergic reaction (anaphylaxis). Acute anaphylactic reactions are very rare, occurring after approximately one out of every 500,000 doses of vaccine. When they occur, however, you must take immediate action. During walk-in immunization clinics, no vaccine should ever be administered unless epinephrine, diphenhydramine, adult airways, and blood pressure cuffs are close at hand. Employees and volunteers should be familiar with an anaphylaxis protocol and with cardiopulmonary resuscitation (CPR).

After you have administered a vaccine to the vaccine recipient, instruct the recipient to report any itching, redness (with or without hives), difficulty breathing, or abdominal pain within several minutes of administration. Having the vaccine recipient wait 15 minutes in a post-injection area is suggested but is not officially required.

Note the live attenuated influenza vaccine (LAIV) should only be given to a healthy, non-pregnant population within a specific age group (2 to 49 years of age).

Vaccine prepared for a previous influenza season should not be administered to provide protection for any subsequent season

Important Notice about LAIV: LAIV should be stored in a refrigerator between 2-8 degrees Centigrade (35°-46°F) when received and used before the expiration date. **DO NOT FREEZE.**

VACCINE STORAGE AND HANDLING:

LAIV is shipped from the distributor to the receiving healthcare facility in a refrigerated state and should be refrigerated upon receipt and kept refrigerated until used. Refrigerated vaccine is good for use until expiration date. Do not freeze vaccine. Store vaccine between 2°-8° C (35°-46° F). Check refrigerator temp where vaccine is stored 2 times daily.

- The temperature in the refrigerator varies depending on if the item is stored in the vegetable bin, on the floor, next to the walls, in the door, etc., and may be a significant difference from the temperature in the body of the refrigerator away from these locations. Always store vaccines in their original packaging in the body of the refrigerator away from outlying locations. Place vaccine packages in such a way that air can circulate around the compartment. Never over pack refrigerator compartment.
- Temperatures fluctuate throughout the day. Temperatures in the refrigerator should be checked at the beginning and end of the day to determine if the unit is getting too cold or too warm. Ideally, continuous monitoring thermometers that measure and record temperatures all day and all night are best. For vaccine storage only certified thermometers should be used. Recording the temperature of the room on the temperature log is a good idea in case there is a problem with the refrigerator/ freezer temperatures. This information may be helpful to the vaccine company during a telephone consult to determine whether your vaccine can still be used if there has been a problem identified.

IDPIO members during a strategic planning session, Sept. 2012.

CONTENT FOR LIVE ATTENUATED INFLUENZA VACCINE (LAIV) ADAPTED FROM:

1. U.S. Food and Drug Administration. (2011, July 5). *Vaccines, Blood and Biologicals: FluMist.* Retrieved August 5, 2011, from U.S. Department of Health and Human Services: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094047.htm.

2. Immunization Action Coalition. (january, 2004). *Adults Only Vaccination: A Step-by-Step Guide.* Retrieved August 2011, 2011, from http://www.immunize.org/guide/aovguide_all.pdf.

3. MMWR / August 17, 2012 / Vol. 61 / No. 33; Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm?s_cid=mm6132a3_x.

4. Immunization Action Coalition. (2008, June). *Don't Be Guilty of These Errors in Vaccine Storage and Handling.* Retrieved August 5, 2011, from http://www.sanantonio.gov/health/pdf/immunizations/VFCforms/In%20Service%20Materials/Vaccine%20Storage%20%20Handling%20Errors.pdf.

5. Centers for Disease Control and Prevention. (2011, January 31). *Vaccine Storage and Handling.* Retrieved August 4, 2011, from http://www.cdc.gov/vaccines/recs/default.htm#storage.

6. Immunization Action Coalition. (2009, February). *Administering Vaccines: Dose, Route, Site, and Needle Size.* Retrieved August 5, 2011, from http://www.immunize.org/catg.d/p3085.pdf.

7. For a detailed explanation and demonstration of immunization techniques, the 35-minute video "Immunization Techniques DVD" can be ordered through the IAC at http://www.immunize.org, using the "Shop IAC" link.

RELATED RESOURCES

Instruction sheets on vaccine administration are also available from the Immunization Action Coalition (IAC):

1. "How to administer IM and SC injections to adults," available at: http://www.immunize.org/catg.d/p2020A.pdf.

2. "Administering vaccines to adults: Dose, route, site, needle size, and preparation," available at: http://www.immunize.org/catg.d/p3084.pdf.

3. "Administering Vaccines: Dose, Route, Site, and Needle Size", available at: http://www.immunize.org/catg.d/p3085.pdf.

4. Instructions for administration of LAIV http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123743.pdf. For a detailed explanation and demonstration of immunization techniques, the 35-minute video "Immunization Techniques: Safe, Effective, Caring," can be ordered through the IAC at http://www.immunize.org, click the link for Video: IZ Techniques.

SECTION TEN
APPENDIX B

VHA DIRECTIVE 2012-012: OCCUPATIONAL HEALTH RECORD-KEEPING SYSTEM (OHRS)

Description: This Veterans Health Administration (VHA) Directive provides policy for the implementation of the Occupational Health Record System (OHRS), a newly released electronic health record for employee occupational health records maintained in the Employee Medical File System Records and Employee Medical File System Records (Title 38).

Department of Veterans Affairs **VHA DIRECTIVE 2012-012**
Veterans Health Administration
Washington, DC 20420 **April 11, 2012**

OCCUPATIONAL HEALTH RECORD-KEEPING SYSTEM

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy for the implementation of the Occupational Health Record System (OHRS), a newly released electronic health record for employee occupational health records maintained in the Employee Medical File System Records and Employee Medical File System Records (Title 38).

2. BACKGROUND

a. Essential elements for the effective delivery of occupational health care include: documentation of administrative examinations, injury, and illness care; medical surveillance; and infectious disease program management. Core actions in managing healthy workplaces include: tracking vaccinations; screening employees who report to duty despite illness; managing outbreaks with follow-up investigations; and identifying individuals who occupational health clinicians recommend be placed off duty.

b. Systematic and efficient processes to manage employee occupational health records and protect privacy are an essential element of occupational health practice.

c. The confidentiality of occupational health care records of employees of the Federal government are protected by the Privacy Act of 1974, Title 5 United States Code (U.S.C.) section 552a; the Federal Employees' Compensation Act (FECA), 5 U.S.C. Chapter 81 and Title 20 Code of Federal Regulations (CFR) Part 10, Subpart A; Privacy Procedures for Personnel Records in 5 CFR Parts 293 and 297; and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 CFR Parts 160 and 164. The records are maintained in Employee Medical File System Records (OPM/GOVT-10) and Employee Medical File System Records (Title 38) VA (08VA05) Privacy Act Systems of Records, which authorizes various routine use disclosures without the employee's written release of information or authorization.

d. The Computerized Patient Record System (CPRS) does not provide adequate privacy protections for employee occupational health records. The development of the Text Integration Utility (TIU) and business rules provides the ability to restrict access to employee progress notes to only occupational health clinicians. No such protection exists for personal health information outside of progress notes.

e. FECA distinguishes between the use of health information for injury reporting and safety management, management of the clinical care of employees, and the administrative management of workers' compensation claims. The use of the information used in the filing of workers' compensation claims is restricted to the

THIS VHA DIRECTIVE EXPIRES APRIL 30, 2017

VHA DIRECTIVE 2012-012
April 11, 2012

employees filing the claims, their supervisors, and workers' compensation personnel. Although the health records of an employee who elects to obtain treatment in Occupational Health may be used by clinicians in the provision of medical care, this information may not be accessed by supervisors, human resources managers, or other individuals not designated as workers' compensation staff, unless the individual provides a written authorization for such use of the information.

f. As with FECA, the HIPAA Privacy Rule authorizes clinicians to use employees' occupational health records to provide medical treatment. The HIPAA Privacy Rule, however, prohibits the use of health records, including clinical information regarding an employee's immunization status or exposures, by supervisors, human resources managers, or others. Further, the HIPAA Privacy Rule requires the use of access controls to safeguard such protected health information against any unauthorized use or disclosure.

g. OHRS employee health records are currently unscheduled and cannot be destroyed until disposition instructions are approved by the National Archives and Records Administration (NARA) and published in Record Control System (RCS) 10-1. The OHRS records appraisal was submitted to NARA on July 16, 2010. Additionally, OHRS is used to protect employee health records under applicable regulations and laws while promoting efficiency in recordkeeping and data access for workforce management and occupational safety.

h. **Definitions**

(1) **Federal Employee Compensation Act (FECA).** FECA provides workers' compensation benefits to Federal employees for work-related injuries or illnesses, and to their eligible dependents if a work-related injury or illness results in the employee's death. Occupational health, if selected as the provider of choice will provide treatment to employees with work-related injuries and illnesses.

(2) **Privacy Act.** The Privacy Act governs the collection, maintenance, use and dissemination of personally identifiable information about living individuals that is maintained in systems of records by federal agencies.

(3) **Health Insurance Portability and Accountability Act (HIPAA).** HIPAA provides standards and requirements for the electronic transmission, privacy, and security of certain health information.

(4) **Role-based Access.** Role-based access is an approach to restricting system access to authorized users. It determines what information a person may have the right to access.

(5) **Functionality.** Functionality refers to the set of functions or capabilities associated with computer software or hardware or an electronic device. OHRS functionality includes documentation of care and report generation.

VHA DIRECTIVE 2012-012
April 11, 2012

3. POLICY: It is VHA policy that health records of staff members, whether paid, voluntary or workers without compensation (WOC) created or maintained by occupational health is recorded in OHRS.

4. ACTION

a. **Director, Occupational Health Program, Occupational Health Strategic Health Care Group, Office of Public Health.** The Director, Occupational Health Program, is responsible for:

(1) Ensuring that occupational health staff are made aware of new OHRS functionality as it becomes available;

(2) Ensuring OHRS training is available and that new training modules are developed and deployed when new OHRS functionality is available;

(3) Granting role-based access to potential OHRS users; and

(4) Conducting audits of access to OHRS every 3 months to ensure users have appropriate role-based access.

b. **Veterans Integrated Service Network (VISN) Director.** The VISN Director, or designee, is responsible for:

(1) Designating a primary and alternate administrator in the VISN from the list of facility administrators in their VISN to manage role-based access to OHRS. These administrators must be either a registered nurse, physician assistant, nurse practitioner, or physician who is assigned to Occupational Health.

(2) Notifying the Director, Occupational Health Program of any changes in VISN OHRS administrators on quarterly basis.

c. **Facility Director.** Each facility Director, or designee, is responsible for:

(1) Ensuring that staff responsible for data-entry into the OHRS are trained in the use of OHRS. ***NOTE:*** *The extent of training depends on the individual's role-based access.*

(2) Ensuring that health care provided to staff is recorded in OHRS where such functionality exists. ***NOTE:*** *Additional functionality will be available every 3 to 6 months as it is developed, tested and deployed. All functionality is expected to be completed within the next 5 years.*

(3) Ensuring that new releases of OHRS are installed within 30 days after their release.

VHA DIRECTIVE 2012-012
April 11, 2012

(4) Designating a primary and alternate administrator at the facility to manage role-based access to OHRS. These administrators must be a registered nurse, physician assistant, nurse practitioner, or physician who is assigned to Occupational Health.

(5) Ensuring that individuals assigned access to OHRS are given the correct role-based access.

(6) Notifying the Director, Occupational Health Program, of any changes in local OHRS administrators on a quarterly basis.

d. **OHRS Administrators.** The OHRS Administrator is responsible for**:**

(1) Completing OHRS training specific to the OHRS Administrator;

(2) Granting VHA staff appropriate role-based access to OHRS, reviewing this access every 3 months, and making necessary changes.

5. REFERENCES

a. Privacy Act of 1974, 5 U.S.C. 552a.

b. FECA, 5 U.S.C. Chapter. 81.

c. Occupational Health and Safety Act, 29 U.S.C. Chapter 15.

d. Personnel Records, 5 CFR Parts 293.

e. Privacy Procedures for Personnel Records, 5 CFR Part 297.

f. Claims for Compensation Under the Federal Employee' Compensation Act, 20 CFR Part 10.

g. Recording and Reporting Occupational Injuries and Illnesses, 29 CFR Part 1904.

h. HIPAA Privacy and Security Rules, 45 CFR Parts 160 and 164.

i. Employee Medical File System Records,. OPM/GOVT-10.

j. Employee Medical File System Records (Title 38)-VA,08VA05.

k. Public Printing and Documents, Federal agency responsibilities, 44 U.S.C. 3506.

l. Electronic Records Management, 36 CFR 1236, Subpart C.

m. Recordkeeping and Reporting Requirements 29 CFR Part 1960, (Subpart I).

VHA DIRECTIVE 2012-012
April 11, 2012

n. VA Directive and Handbook 7701.

6. FOLLOW-UP RESPONSIBILITY: The Director, Occupational Health Program in the Occupational Health, Safety and Prevention Strategic Health Care Group (10P3D) in the Office of Public Health is responsible for the contents of this Directive. Questions may be addressed to Director, Occupational Health, at (202) 461-1042.

7. RESCISSIONS: None. This VHA Directive expires April 30, 2017.

Robert A. Petzel, M.D.
Under Secretary for Health

DISTRIBUTION: E-mailed to the VHA Publications Distribution List 4/12/2012

SECTION TEN
APPENDIX C

CDC MMWR: PREVENTION AND CONTROL OF INFLUENZA WITH VACCINES

PREVENTION AND CONTROL OF INFLUENZA WITH VACCINES: RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

2012 MMWR
Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2012. MMWR/ August 17, 2012 / Vol. 61 / No. 33; found at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6132a3.htm?s_cid=mm6132a3_x.

Description: This document provides updated guidance for the use of influenza vaccines in the United States for the 2012–13 influenza season.

2011 MMWR
Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011. MMWR / August 26, 2011 / Vol. 60 / No. 33. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6033a3.htm?s_cid=mm6033a3_w.

2010 MMWR
Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. MMWR August 6, 2010 / Vol. 59 / No. RR–8. Available at http://www.cdc.gov/mmwr/pdf/rr/rr5908.pdf.

Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP) — United States, 2012–13 Influenza Season

In 2010, the Advisory Committee on Immunization Practices (ACIP) first recommended annual influenza vaccination for all persons aged ≥6 months in the United States (*1*). Annual influenza vaccination of all persons aged ≥6 months continues to be recommended. This document 1) describes influenza vaccine virus strains included in the U.S. seasonal influenza vaccine for 2012–13; 2) provides guidance for the use of influenza vaccines during the 2012–13 season, including an updated vaccination schedule for children aged 6 months through 8 years and a description of available vaccine products and indications; 3) discusses febrile seizures associated with administration of influenza and 13-valent pneumococcal conjugate (PCV-13) vaccines; 4) provides vaccination recommendations for persons with a history of egg allergy; and 5) discusses the development of quadrivalent influenza vaccines for use in future influenza seasons. Information regarding issues related to influenza vaccination that are not addressed in this update is available in CDC's *Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010* and associated updates (*1,2*).

Methodology for the formulation of the ACIP annual vaccine recommendations has been described previously (*1*). The ACIP Influenza Work Group meets every 2–4 weeks throughout the year. Work Group membership includes several voting members of ACIP and representatives of ACIP Liaison Organizations. Meetings are held by teleconference and include discussion of influenza-related issues, such as influenza surveillance, vaccine effectiveness and safety, coverage in groups recommended for vaccination, program feasibility, cost-effectiveness, and anticipated vaccine supply. Presentations are requested from invited experts, and published and unpublished data are discussed. CDC's Influenza Division provides data on influenza surveillance, antiviral resistance, and vaccine effectiveness. CDC's Immunization Safety Office provides information on vaccine safety, and CDC's Immunization Services Division provides information on vaccine distribution and coverage.

Recommendations for routine use of vaccines in children and adolescents are issued by CDC and are harmonized to the greatest extent possible with recommendations made by the American Academy of Pediatrics, the American Academy of Family Physicians (AAFP), and the American College of Obstetrics and Gynecology (ACOG). CDC recommendations for routine use of vaccines in adults are harmonized to the greatest extent possible with recommendations made by AAFP, ACOG, and the American College of Physicians. The Advisory Committee on Immunization Practices (ACIP) is chartered as a federal advisory committee to provide expert external advice and guidance to the Director of CDC on use of vaccines in the civilian population of the United States. ACIP members are named by the Secretary of the U.S. Department of Health and Human Services. ACIP recommendations become CDC policy once approved by the Director of CDC, on the date published by *MMWR*.

Vaccine Strains for the 2012–13 Influenza Season

U.S. influenza vaccines for 2012–13 will contain A/California/7/2009 (H1N1)-like, A/Victoria/361/2011 (H3N2)-like, and B/Wisconsin/1/2010-like (Yamagata lineage) antigens. The influenza A(H3N2) and B antigens differ from the respective 2010–11 and 2011–12 seasonal vaccine antigens (*3*). The influenza A(H1N1) vaccine virus strain is derived from an influenza A(H1N1)pdm09 (2009[H1N1]) virus and was included in the 2009(H1N1) monovalent pandemic vaccine as well as the 2010–11 and 2011–12 seasonal vaccines.

Recommendations for Vaccination

Routine annual influenza vaccination is recommended for all persons aged ≥6 months. To permit time for production of protective antibody levels (*4,5*), vaccination optimally should occur before onset of influenza activity in the community. Therefore, vaccination providers should offer vaccination as soon as vaccine is available. Vaccination should be offered throughout the influenza season (i.e., as long as influenza viruses are circulating in the community).

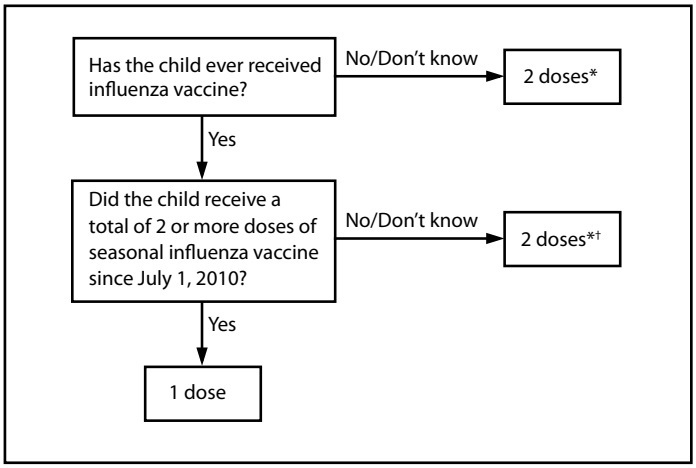
Vaccine Dose Considerations for Children Aged 6 Months Through 8 Years

Children aged 6 months through 8 years require 2 doses of influenza vaccine (administered a minimum of 4 weeks apart) during their first season of vaccination to optimize immune response. In a study of children aged 5 through 8 years receiving trivalent inactivated influenza vaccine (TIV) for the first time,

the proportion of children with protective antibody responses was significantly higher after 2 doses compared with a single dose (*6*). Several studies have indicated that the time interval between two initial doses (from 4 weeks up to 1 year) of the same antigen might not be critical (*7–9*). However, because of the antigenic novelty of the 2009(H1N1) pandemic virus, which is anticipated to continue circulating during 2012–13, exposure history to this antigen also must be considered. Children who last received seasonal (trivalent) influenza vaccine before the 2010–11 season but did not receive a vaccine containing 2009(H1N1) antigen (either seasonal vaccine since July 2010 or monovalent 2009[H1N1] vaccine) will not have received this antigen. These children are recommended to receive 2 doses this season, even if 2 doses of seasonal influenza vaccine were received before the 2010–11 season. This is illustrated in two approaches for determining the number of doses required for children aged 6 months through 8 years, both of which are acceptable (Figure 1).

1. The first approach takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010. This recommendation is harmonized with that of the American Academy of Pediatrics (*10*). This approach has the advantage of simplicity, particularly in settings in which ascertaining vaccination history before the 2010–11 season is difficult. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in 2012–13 if they received a total of 2 or more doses of seasonal vaccine since July 1, 2010. Children who did not receive a total of 2 or more doses of seasonal vaccine since July 1, 2010, require 2 doses in 2012–13.
2. In settings where adequate vaccination history from before the 2010–11 season is available, the second approach may be used. By this approach, if a child aged 6 months through 8 years is known to have received at least 2 seasonal influenza vaccines during any previous season, and at least 1 dose of a 2009(H1N1)-containing vaccine (i.e., either 2010–11 or 2011–12 seasonal vaccine or the monovalent 2009[H1N1] vaccine), then the child needs only 1 dose for 2012–13. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in 2012–13 if they have received any of the following:
   - 2 or more doses of seasonal influenza vaccine since July 1, 2010; or
   - 2 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of monovalent 2009(H1N1) vaccine; or
   - 1 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of seasonal influenza vaccine since July 1, 2010.

FIGURE 1. Influenza vaccine dosing algorithm for aged children 6 months through 8 years — Advisory Committee on Immunization Practices, United States, 2012–13 influenza season



* Doses should be administered at least 4 weeks apart.

† For simplicity, this algorithm takes into consideration only doses of seasonal influenza vaccine received since July 1, 2010. As an alternative approach in settings where vaccination history from before July 1, 2010, is available, if a child aged 6 months through 8 years is known to have received at least 2 seasonal influenza vaccines during any previous season, and at least 1 dose of a 2009(H1N1)-containing vaccine (i.e., either 2010–11 or 2011–12 seasonal vaccine or the monovalent 2009[H1N1] vaccine), then the child needs only 1 dose for 2012–13. Using this approach, children aged 6 months through 8 years need only 1 dose of vaccine in 2012–13 if they have received any of the following: 1) 2 or more doses of seasonal influenza vaccine since July 1, 2010; 2) 2 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of monovalent 2009(H1N1) vaccine; or 3) 1 or more doses of seasonal influenza vaccine before July 1, 2010, and 1 or more doses of seasonal influenza vaccine since July 1, 2010. Children for whom one of these conditions is not met require 2 doses in 2012–2013.

Children for whom one of these conditions is not met require 2 doses in 2012–13.

Available Vaccine Products and Indications

Multiple influenza vaccines (with the same antigenic composition) are expected to be available during the 2012–13 season (Table). Current package inserts should be consulted for updated information and description of additional components of various vaccine formulations, indications, contraindications, and precautions.

TIV preparations, with the exception of Fluzone Intradermal (Sanofi Pasteur), should be administered intramuscularly. For adults and older children, the deltoid is the preferred site. Infants and younger children should be vaccinated in the anterolateral thigh. Specific guidance regarding site and needle length for intramuscular administration can be found in ACIP's General Recommendations on Immunization (*11*). For intramuscular TIV preparations, children aged 6 through 35 months receive 0.25 mL per dose; persons aged ≥36 months receive 0.5 mL per dose (Table). Fluzone Intradermal is administered intradermally

TABLE. Influenza vaccine information, by age group — United States, 2012–13 influenza season*

Vaccine	Trade name	Manufacturer	Presentation	Mercury content (μg Hg per 0.5 mL dose)	Ovalbumin content (μg per 0.5mL dose)†	Age group	No. of doses	Route
TIV	Fluzone	Sanofi Pasteur	0.25 mL prefilled syringe	0.0	—§	6–35 mos	1 or 2¶	IM**
			0.5 mL prefilled syringe	0.0	—§	≥36 mos	1 or 2¶	IM**
			0.5 mL vial	0.0	—§	≥36 mos	1 or 2¶	IM**
			5.0 mL multidose vial	25.0	—§	≥6 mos	1 or 2¶	IM**
TIV	Agriflu	Novartis Vaccines	0.5 mL prefilled syringe	0	<0.4	≥18 yrs	1	IM**
TIV	Fluvirin	Novartis Vaccines	0.5 mL prefilled syringe	≤1	≤1	≥4 yrs	1 or 2¶	IM**
			5.0 mL multidose vial	25.0	≤1			
TIV	Fluarix	GlaxoSmithKline	0.5 mL prefilled syringe	0	≤0.05	≥3 yrs	1 or 2¶	IM**
TIV	FluLaval	ID Biomedical Corporation of Quebec (distributed by GlaxoSmithKline)	5.0 mL multidose vial	<25.0	≤0.3	≥18 yrs	1	IM**
TIV	Afluria	CSL Biotherapies (distributed by Merck)	0.5 mL prefilled syringe	0.0	≤1	≥9 yrs††	1	IM**
			5.0 mL multidose vial	24.5	≤1			
TIV high- dose§§	Fluzone High-Dose	Sanofi Pasteur	0.5 mL prefilled syringe	0.0	—§	≥65 yrs	1	IM**
TIV intradermal¶¶	Fluzone Intradermal	Sanofi Pasteur	0.1 mL prefilled microinjection system	0.0 (per 0.1 mL)	—§	18–64 yrs	1	ID
LAIV	FluMist***	MedImmune	0.2 mL prefilled intranasal sprayer	0.0 (per 0.2 mL)	<0.24 (per 0.2mL)†††	2–49 yrs§§§	1 or 2¶	IN

Abbreviations: TIV = trivalent inactivated vaccine; LAIV = live-attenuated influenza vaccine; IM = intramuscular; ID = intradermal; IN = intranasal.

* Vaccination providers should consult Food and Drug Administration–approved prescribing information for 2012–13 influenza vaccines for the most updated information, including indications, contraindications, and precautions.

† Data on maximum ovalbumin content is supplied in package inserts of certain vaccines. Persons with a history of mild allergy to egg (specifically, those who experience only hives) should receive TIV with additional precautions (Figure 2).

§ Information is not included in package insert but is available upon request from the manufacturer, Sanofi Pasteur, by contacting 1-800-822-2463 or mis.emails@sanofipasteur.com.

¶ Figure 1 describes two approaches for determining the number of doses needed for children aged 6 months through 8 years.

** For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh.

†† Age indication per package insert is ≥5 years; however, the Advisory Committee on Immunization Practices recommends that Afluria not be used in children aged 6 months through 8 years because of increased risk for febrile reactions noted in this age group with CSL's 2010 Southern Hemisphere TIV. If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5 through 8 years who has a medical condition that increases the child's risk for influenza complications, Afluria can be used; however, vaccination providers should discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria before administering this vaccine. Afluria may be used in persons aged ≥9 years.

§§ A 0.5-mL dose contains 60 μg of each vaccine antigen (180 μg total).

¶¶ A 0.1-mL dose contains 9 μg of each vaccine antigen (27 μg total).

*** A new quadrivalent formulation of FluMist was approved by the Food and Drug Administration in February 2012. It is anticipated that this formulation will replace the currently available seasonal trivalent LAIV formulation for the 2013–14 season. FluMist is shipped refrigerated and stored in the refrigerator at 35°F–46°F (2°C–8°C) after arrival in the vaccination clinic. The dose is 0.2 mL divided equally between each nostril. Health-care providers should consult the medical record, when available, to identify children aged 2 through 4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2 through 4 years should be asked, "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record within the past 12 months should not receive FluMist.

††† Insufficient data available for use of LAIV in egg-allergic persons.

§§§ Flumist is indicated for healthy, nonpregnant persons aged 2 through 49 years. Persons who care for severely immunosuppressed persons who require a protective environment should not receive FluMist given the theoretical risk for transmission of the live-attenuated vaccine virus.

via a single-dose, prefilled microinjection syringe. The preferred site for administration is over the deltoid muscle.

Age indications for the various TIV products differ. All TIV preparations contain the same quantity of hemagglutinin (15 μg per vaccine virus strain per 0.5 mL dose; 45 μg total), except Fluzone Intradermal and Fluzone High-Dose (Sanofi Pasteur). Fluzone Intradermal is indicated for persons aged 18 through 64 years and contains 9 μg of hemagglutinin per vaccine virus strain (27 μg total) in a 0.1 mL dose. Fluzone High-Dose is indicated for persons aged ≥65 years and contains 60 μg of hemagglutinin per vaccine virus strain (180 μg total) in a 0.5 mL dose. Within specified age indications, ACIP expresses no preference for any given TIV formulation over another.

The intranasally administered live-attenuated influenza vaccine (LAIV), FluMist (MedImmune), is indicated for healthy, nonpregnant persons aged 2 through 49 years. No preference is indicated for LAIV versus TIV in this age group

(*1*). Persons with a history of egg allergy should receive TIV rather than LAIV. Persons who care for severely immunosuppressed persons who require a protective environment should not receive LAIV given the theoretical risk for transmission of the live-attenuated vaccine virus.

Febrile Seizures Associated with TIV and PCV13

Febrile seizures are common in young children. At least one febrile seizure is experienced by 2%–5% of children, and nearly all children who have a febrile seizure recover quickly and are healthy afterwards (*12*). Before the 2010–11 influenza season, an increased risk for febrile seizures after TIV administration had not been observed in the United States (*13,14*). During the 2010–11 influenza season, CDC and the Food and Drug Administration (FDA) conducted enhanced monitoring for febrile seizures after influenza vaccination because of reports of an increased risk for fever and febrile seizures in young children in Australia associated with a 2010 Southern Hemisphere vaccine produced by CSL Biotherapies (up to nine febrile seizures per 1,000 doses) (*15*). Because of the findings in Australia, ACIP does not recommend the U.S.-licensed CSL Biotherapies' TIV, Afluria, for children aged <9 years (*2,16*) (Table).

Surveillance for U.S.-licensed influenza vaccines during the 2010–11 season subsequently detected safety signals for febrile seizures in young children after TIV administration (*17,18*). Further assessment determined that the increased risk was in children aged 6 months through 4 years on the day of vaccination to the day after (the 0–1 day risk window). The risk was higher when children received concomitant PCV13 (i.e., when the two vaccines are administered at the same health-care visit) and peaked at approximately age 16 months (*18*). No increased risk was observed in children aged ≥5 years after TIV or in children of any age after LAIV. The magnitude of the increased risk for febrile seizures in young children in the United States (<1 per 1,000 children vaccinated) was substantially lower than the risk observed in Australia in 2010 (*15*).

After evaluating the data on febrile seizures from the 2010–11 influenza season and taking into consideration benefits and risks of vaccination, no policy change was recommended for use of TIV or PCV13 for the 2011–12 season (*16,19,20*). Surveillance data on febrile seizures in young children after administration of influenza vaccine for the 2011–12 influenza season (same vaccine formulation as 2010–11) were consistent with those from the 2010–11 influenza season (CDC, unpublished data, 2012). No changes in the use of TIV or PCV13 are recommended for the 2012–13 influenza season. As stated previously, ACIP does not recommend the U.S.-licensed CSL Biotherapies' TIV, Afluria, for children aged <9 years (*2,16*) (Table).

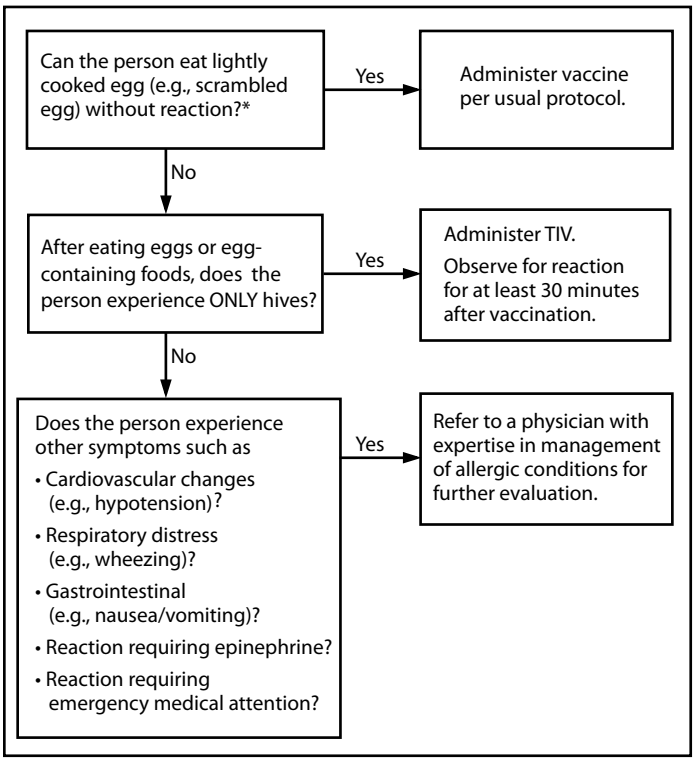
Influenza Vaccination of Persons with a History of Egg Allergy

Severe allergic and anaphylactic reactions can occur in response to a number of influenza vaccine components, but such reactions are rare. All currently available influenza vaccines are prepared by means of inoculation of virus into chicken eggs. The use of influenza vaccines for persons with a history of egg allergy has been reviewed recently by ACIP (*16*). For the 2011–12 influenza season, ACIP recommended that persons with egg allergy who report only hives after egg exposure should receive TIV, with several additional safety measures, as described in this document. Recent examination of VAERS data indicated no disproportionate reporting of allergy or anaphylaxis after influenza vaccination during the 2011–12 season (*21*). For the 2012–13 influenza season, ACIP recommends the following:

1. Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine, with the following additional safety measures (Figure 2):
   a) Because studies published to date involved use of TIV, TIV rather than LAIV should be used (*22*);
   b) Vaccine should be administered by a health-care provider who is familiar with the potential manifestations of egg allergy; and
   c) Vaccine recipients should be observed for at least 30 minutes for signs of a reaction after administration of each vaccine dose (*22*).

   Other measures, such as dividing and administering the vaccine by a two-step approach and skin testing with vaccine, are not necessary (*22*).
2. Persons who report having had reactions to egg involving such symptoms as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, particularly those that occurred immediately or within a short time (minutes to hours) after egg exposure, are more likely to have a serious systemic or anaphylactic reaction upon reexposure to egg proteins. Before receipt of vaccine, such persons should be referred to a physician with expertise in the management of allergic conditions for further risk assessment (Figure 2).

FIGURE 2. Recommendations regarding influenza vaccination for persons who report allergy to eggs — Advisory Committee on Immunization Practices, United States, 2012–13 influenza season



Abbreviation: TIV = trivalent inactivated vaccine.

* Persons with egg allergy might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy.

3. All vaccines should be administered in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available. ACIP recommends that all vaccination providers should be familiar with the office emergency plan (*11*).
4. Some persons who report allergy to egg might not be egg-allergic. Those who are able to eat lightly cooked egg (e.g., scrambled egg) without reaction are unlikely to be allergic. Egg-allergic persons might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy (*23*). Egg allergy can be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, plus skin and/or blood testing for immunoglobulin E antibodies to egg proteins.
5. A previous severe allergic reaction to influenza vaccine, regardless of the component suspected to be responsible for the reaction, is a contraindication to future receipt of the vaccine.

Quadrivalent Influenza Vaccines

All currently available influenza vaccines are trivalent and contain A(H1N1), A(H3N2), and B viral antigens. There are two antigenically distinct lineages of influenza B viruses referred to as Victoria and Yamagata lineages (*24*). Immunization against B virus strains of one lineage provides limited cross-protection against strains in the other lineage (*25*). Because of this and the difficulty of predicting which B virus lineage will predominate during a given season, inclusion of a second influenza B vaccine virus strain in seasonal influenza vaccines has been proposed. A recent analysis indicates that the impact of such a quadrivalent vaccine could result in a modest reduction in influenza-associated outcomes, depending upon adequate vaccine supply, coverage, effectiveness, and incidence of influenza associated with the two B lineages (*26*).

In February 2012, FDA approved a new seasonal quadrivalent LAIV, FluMist Quadrivalent (MedImmune). This vaccine currently is not anticipated to be available until the 2013–14 influenza season, at which time it is expected to replace the currently available seasonal trivalent FluMist formulation (Table). Inactivated quadrivalent influenza vaccines currently are in development. These vaccines will be addressed in the ACIP influenza statement as they are approved and become available commercially.

Reported by

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Acknowledgments

Members of the Advisory Committee on Immunization Practices; member roster for July 2011–June 2012 available at http://www.cdc.gov/vaccines/recs/acip/members-archive/07-2011-06-2012.htm.

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Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011

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This document provides updated guidance for the use of influenza vaccines in the United States for the 2011–12 influenza season. In 2010, the Advisory Committee on Immunization Practices (ACIP) first recommended annual influenza vaccination for all persons aged ≥6 months in the United States (*1,2*). Vaccination of all persons aged ≥6 months continues to be recommended. Information is presented in this report regarding vaccine strains for the 2011–12 influenza season, the vaccination schedule for children aged 6 months through 8 years, and considerations regarding vaccination of persons with egg allergy. Availability of a new Food and Drug Administration (FDA)–approved intradermally administered influenza vaccine formulation for adults aged 18 through 64 years is reported. For issues related to influenza vaccination that are not addressed in this update, refer to the 2010 ACIP statement on prevention and control of influenza with vaccines and associated updates (*1,2*).

Methodology for the formulation of the ACIP annual influenza statement has been described previously (*1*). The ACIP Influenza Work Group meets every 2–4 weeks throughout the year. Work Group membership includes several voting members of the ACIP, as well as representatives from ACIP Liaison Organizations. Meetings are held by teleconference and include discussion of influenza-related issues, such as vaccine effectiveness and safety, coverage in groups recommended for vaccination, feasibility, cost-effectiveness, and anticipated vaccine supply. Presentations are requested from invited experts, and published and unpublished data are discussed. CDC's Influenza Division provides influenza surveillance and antiviral resistance data, and the Immunization Safety Office and Immunization Services Division provide information on vaccine safety and distribution and coverage, respectively.

Vaccine Strains for the 2011–12 Influenza Season

The 2011–12 U.S. seasonal influenza vaccine virus strains are identical to those contained in the 2010–11 vaccine. These include A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens. The influenza A (H1N1) vaccine virus strain is derived from a 2009 pandemic influenza A (H1N1) virus (*3*).

Recommendations for Vaccination

Routine annual influenza vaccination is recommended for all persons aged ≥6 months (*1*). To permit time for production of protective antibody levels (*4,5*), vaccination should optimally occur before onset of influenza activity in the community, and providers should offer vaccination as soon as vaccine is available. Vaccination also should continue to be offered throughout the influenza season.

Although influenza vaccine strains for the 2011–12 season are unchanged from those of 2010–11, annual vaccination is recommended even for those who received the vaccine for the previous season. Although in one study of children vaccinated against A/Hong Kong/68 (H3N2) virus, vaccine efficacy remained high against this strain 3 years later, the estimated efficacy of vaccine decreased over the seasons studied (*6*). Moreover, several studies have demonstrated that postvaccination antibody titers decline over the course of a year (*7–10*). Thus, annual vaccination is recommended for optimal protection against influenza.

Vaccine Doses for Children Aged 6 Months Through 8 Years

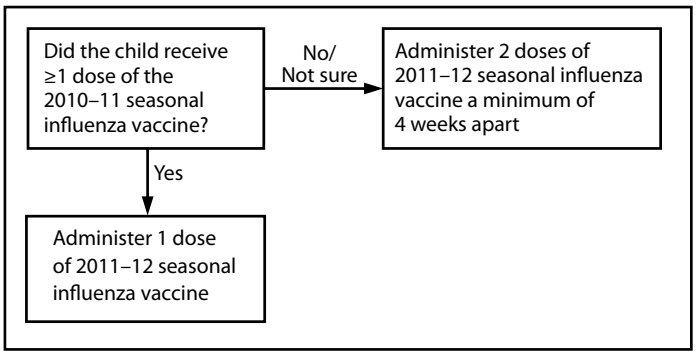
Children aged 6 months through 8 years require 2 doses of influenza vaccine (administered a minimum of 4 weeks apart) during their first season of vaccination to optimize immune response. In a study of children aged 5 through 8 years who received trivalent inactivated vaccine (TIV) for the first time, the proportion of children with protective antibody responses was significantly higher after 2 doses than after 1 dose (*11*).

The importance of vaccine priming might depend more on the similarity of the antigenic composition between the priming and second dose than the temporal interval between doses. From the 2003–04 to 2004–05 influenza seasons, the A(H1N1) virus antigen remained unchanged; however, the A(H3N2) virus antigen changed to a drifted strain, and the B virus antigen changed more substantially to a different lineage. In a study conducted over those two seasons, influenza-vaccine naïve children aged 6 through 23 months who received 1 dose of TIV in the spring of their first year of vaccination followed by a second dose in the fall were less likely to have protective antibody responses to the A(H3N2) and B virus antigens when compared with children who received 2 doses of identical vaccine in the fall (*12*). Response to the unchanged A(H1N1) virus antigen was comparable between the groups. In another study conducted over the same two seasons, unprimed children aged 10 through 24 months who received 1 dose of TIV during the fall of each season had similar responses to the unchanged A(H1N1) virus antigen as well as to the drifted A(H3N2) virus antigen when compared with children aged 6 through 24

months who received 2 doses of the same TIV during the latter season; however, the first group had significantly lower response to the B virus antigen (*13*). During two seasons in which all influenza vaccine virus antigens were identical, unprimed children aged 6 through 23 months had similar responses when they received 1 dose in the spring followed by a second dose in the fall, as compared with 2 doses received 1 month apart in the fall (*14*). Studies of inactivated monovalent pandemic 2009 (H1N1) vaccine in children aged <9 years also have demonstrated improved response to this antigen when 2 doses are administered (*15–17*).

Vaccination providers should note that, in previous seasons, children aged 6 months through 8 years who received only 1 dose of influenza vaccine in their first year of vaccination required 2 doses the following season. However, because the 2011–12 vaccine strains are unchanged from the 2010–11 season, children in this age group who received at least 1 dose of the 2010–11 seasonal vaccine will require only 1 dose of the 2011–12 vaccine. Children in this age group who did not receive at least 1 dose of the 2010–11 seasonal influenza vaccine, or for whom it is not certain whether the 2010–11 seasonal vaccine was received, should receive 2 doses of the 2011–12 seasonal influenza vaccine (Figure 1). Recommendations regarding the number of doses for this age group might change for the 2012–13 season if vaccine antigens change.

FIGURE 1. Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices (ACIP), 2011–12 influenza season



Available Vaccine Products and Indications

Multiple influenza vaccines are expected to be available during the 2011–12 season (Table). All contain the same antigenic composition. Package inserts should be consulted for information regarding additional components of various vaccine formulations.

TIV preparations, with the exception of Fluzone Intradermal (Sanofi Pasteur), should be administered intramuscularly. For adults and older children, the deltoid is the preferred site. Infants and younger children should be vaccinated in the anterolateral thigh. Specific guidance regarding site and needle length can be found in the ACIP's *General Recommendations on Immunization* (*18*).

A new intradermally administered TIV preparation, Fluzone Intradermal, was licensed in May 2011. This vaccine is indicated for persons aged 18 through 64 years and contains less antigen than intramuscular TIV preparations (9 μg rather than 15 μg of each strain per dose) in a smaller volume (0.1mL rather than 0.5 mL). The vaccine is administered intradermally via a single-dose, prefilled microinjection syringe. The preferred site for administration is over the deltoid muscle (*19*). The most common adverse reactions include injection-site erythema, induration, swelling, pain, and pruritus. With the exception of pain, these reactions occurred more frequently than with intramuscular vaccine, but generally resolved within 3–7 days. This vaccine is an alternative to other TIV preparations for those in the indicated age range, with no preferential recommendation.

As during the 2010–11 season, a vaccine containing 60 μg of hemagglutinin per vaccine strain (rather than 15 μg per strain as in other intramuscular TIV preparations), Fluzone High-Dose (Sanofi Pasteur), is available as an alternative TIV for persons aged ≥65 years. No preference is indicated for this TIV versus other TIV preparations (*1*).

The intranasally administered live attenuated influenza vaccine (LAIV), FluMist (MedImmune) is indicated for healthy, nonpregnant persons aged 2 through 49 years. Within the indicated groups specified for each vaccine in the package inserts, no preference is indicated for LAIV versus TIV (*1*).

Vaccination of Persons Reporting Allergy to Eggs

Allergy to eggs must be distinguished from allergy to influenza vaccine. Severe allergic and anaphylactic reactions can occur in response to a number of influenza vaccine components, but such reactions are rare. A review of reports to the Vaccine Adverse Events Reporting System (VAERS) of adverse events in adults noted four reports of death caused by anaphylaxis following influenza vaccine during 1990–2005; the vaccine components potentially responsible for these reactions were not reported (*20*). A prior severe allergic reaction to influenza vaccine, regardless of the component suspected to be responsible for the reaction, is a contraindication to receipt of influenza vaccine.

All currently available influenza vaccines are prepared by inoculation of virus into chicken eggs. Hypersensitivity to eggs has been listed as a contraindication to receipt of influenza vaccine on most package inserts. However, several recent studies have documented safe receipt of TIV in persons with egg allergy (*21–29*), and recent revisions of some TIV

TABLE. Influenza vaccine information, by age group — United States, 2011–12 influenza season*

Vaccine	Trade name	Manufacturer	Presentation	Mercury content (μg Hg/0.5 mL dose)	Ovalbumin content (μg /0.5mL dose)	Age group	No. of doses	Route
TIV	Fluzone	Sanofi Pasteur	0.25 mL prefilled syringe	0.0	—†	6–35 mos	1 or 2§	IM¶
			0.5 mL prefilled syringe	0.0	—†	≥36 mos	1 or 2§	IM¶
			0.5 mL vial	0.0	—†	≥36 mos	1 or 2§	IM¶
			5.0 mL multidose vial	25.0	—†	≥6 mos	1 or 2§	IM¶
TIV	Fluvirin	Novartis Vaccines	0.5 mL prefilled syringe	≤1	≤1	≥4 yrs	1 or 2§	IM¶
			5.0 mL multidose vial	25.0	≤1			
TIV	Fluarix	GlaxoSmithKline	0.5 mL prefilled syringe	0	≤0.05	≥3 yrs	1 or 2§	IM¶
TIV	FluLaval	ID Biomedical Corporation of Quebec (distributed by GlaxoSmithKline)	5.0 mL multidose vial	25.0	≤1	≥18 yrs	1	IM¶
TIV	Afluria	CSL Biotherapies (distributed by Merck)	0.5 mL prefilled syringe	0.0	≤1	≥9 yrs**	1	IM¶
			5.0 mL multidose vial	24.5	≤1			
TIV High-Dose††	Fluzone High-Dose	Sanofi Pasteur	0.5 mL prefilled syringe	0.0	—†	≥65 yrs	1	IM¶
TIV Intradermal	Fluzone Intradermal	Sanofi Pasteur	0.1 mL prefilled microinjection system	0.0	—†	18–64 yrs	1	ID
LAIV	FluMist§§	MedImmune	0.2 mL prefilled intranasal sprayer	0.0	—¶¶	2–49 yrs***	1 or 2§	IN

Abbreviations: TIV = trivalent inactivated vaccine; LAIV = live attenuated influenza vaccine; IM = intramuscular; ID = intradermal; IN = intranasal.

* Vaccination providers should check Food and Drug Administration–approved prescribing information for 2011–12 influenza vaccines for the most updated information.

† Information not included in package insert but is available upon request from the manufacturer, Sanofi Pasteur, by telephone, 1-800-822-2463, or e-mail, MIS.Emails@sanofipasteur.com.

§ Children aged 6 months through 8 years who did not receive seasonal influenza vaccine during the 2010–11 influenza season should receive 2 doses at least 4 weeks apart for the 2011–12 season. Those children aged 6 months through 8 years who received ≥1 dose of the 2010–11 seasonal vaccine require 1 dose for the 2011–12 season.

¶ For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh.

** Age indication per package insert is ≥5 years; however, the Advisory Committee on Immunization Practices recommends Afluria not be used in children aged 6 months through 8 years because of increased reports of febrile reactions in this age group. If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5–8 years who has a medical condition that increases the child's risk for influenza complications, Afluria can be used; however, providers should discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria before administering this vaccine. Afluria may be used in persons aged ≥9 years.

†† TIV high-dose: A 0.5-mL dose contains 60 μg each of A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens.

§§ FluMist is shipped refrigerated and stored in the refrigerator at 35°F–46°F (2°C–8°C) after arrival in the vaccination clinic. The dose is 0.2 mL divided equally between each nostril. Health-care providers should consult the medical record, when available, to identify children aged 2–4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2–4 years should be asked: "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record within the past 12 months should not receive FluMist.

¶¶ Insufficient data available for use of LAIV in egg-allergic persons.

*** FluMist is indicated for healthy, nonpregnant persons aged 2–49 years.

package inserts note that only a severe allergic reaction (e.g., anaphylaxis) to egg protein is a contraindication. In general, these studies include relatively fewer persons reporting a history of anaphylactic reaction to egg, compared with less severe reactions. Several documents providing guidance on use of influenza vaccine in persons with egg allergy have been published recently (*30–32*).

The quantity of egg protein in vaccine is expressed as the concentration of ovalbumin per dose or unit volume. Among studies in which the ovalbumin content of the administered vaccine was reported, up to 1.4 μg/mL (0.7 μg/0.5 mL dose) was tolerated without serious reactions (*22,23,25–29*); however, a safe maximum threshold of ovalbumin, below which no anaphylactic reactions would be expected, is not known.

Although ovalbumin content is not required to be disclosed on package inserts for vaccines used in the United States, manufacturers either report maximum albumin content in the package inserts or will provide this information on request. Ovalbumin concentration can vary from season to season and from lot to lot for a given vaccine. Independent assessments of

ovalbumin content of commercially available vaccines have noted lower concentrations than those listed on package inserts (*33,34*).

In several studies evaluating influenza vaccine in persons with egg allergy, additional safety measures have been taken, such as skin prick testing with vaccine (*21–24,26,28,29*) and administering the vaccine in 2 doses (e.g., 10% of the dose initially, followed by the remaining 90% if no reaction has occurred during a 30-minute observation period) (*22,24–29*). Skin prick testing with vaccine was poorly predictive of allergic reactions in these studies (*22–24,26*). In general, administration of both full doses and split doses have been well-tolerated without serious reactions, although systemic reactions (e.g., wheezing, eczema exacerbation, and hives on face/chest) were observed with the initial 10% dose among six (3.5%) of 171 participants in one study (*24*).

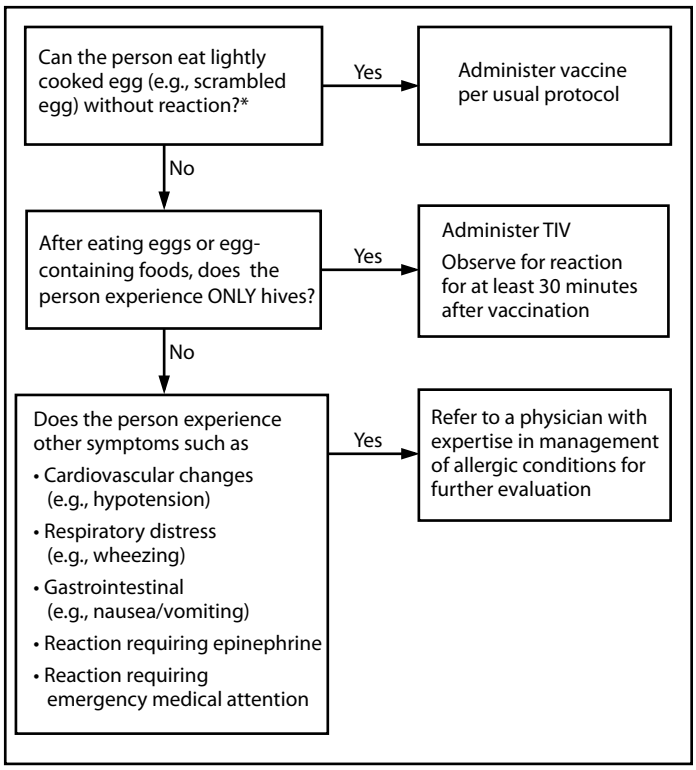
Recommendations Regarding Persons with Egg Allergy

Each of the following recommendations applies when considering influenza vaccination of persons who have or report a history of egg allergy.

1. Persons who have experienced only hives following exposure to egg should receive influenza vaccine with the following additional measures (Figure 2):
   a) Because studies published to date involved use of TIV, TIV rather than LAIV should be used.
   b) Vaccine should be administered by a health-care provider who is familiar with the potential manifestations of egg allergy.
   c) Vaccine recipients should be observed for at least 30 minutes for signs of a reaction following administration of each vaccine dose.

   Other measures, such as dividing and administering the vaccine by a two-step approach and skin testing with vaccine, are not necessary.
2. Persons who report having had reactions to egg involving angioedema, respiratory distress, lightheadedness, or recurrent emesis, or persons who required epinephrine or other emergency medical intervention, particularly those that occurred immediately or within minutes to hours after egg exposure are more likely to have a serious systemic or anaphylactic reaction upon reexposure to egg proteins. Before receipt of vaccine, such persons should be referred to a physician with expertise in the management of allergic conditions for further risk assessment (Figure 2).
3. All vaccines should be administered in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available. ACIP recommends that all vaccination providers be familiar with the office emergency plan (*18*).

FIGURE 2. Recommendations regarding influenza vaccination for persons who report allergy to eggs — Advisory Committee on Immunization Practices (ACIP), 2011–12 influenza season



* Persons with egg allergy might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy.

4. Some persons who report allergy to egg might not be egg allergic. Those who are able to eat lightly cooked egg (e.g., scrambled eggs) without reaction are unlikely to be allergic. Conversely, egg-allergic persons might tolerate egg in baked products (e.g., bread or cake); tolerance to egg-containing foods does not exclude the possibility of egg allergy (*35*). Egg allergy can be confirmed by a consistent medical history of adverse reactions to eggs and egg-containing foods, plus skin and/or blood testing for immunoglobulin E antibodies to egg proteins.
5. A previous severe allergic reaction to influenza vaccine, regardless of the component suspected to be responsible for the reaction, is a contraindication to receipt of influenza vaccine.

Reported by

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* Roster available at http://www.cdc.gov/vaccines/recs/acip/members-archive.htm.

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Prevention and Control of Influenza with Vaccines

Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010

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CONTENTS

Prevention and Control of Influenza with Vaccines

Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010

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Summary

This report updates the 2009 recommendations by CDC's Advisory Committee on Immunization Practices (ACIP) regarding the use of influenza vaccine for the prevention and control of influenza (CDC. Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 2009;58[No. RR-8] and CDC. Use of influenza A (H1N1) 2009 monovalent vaccine—recommendations of the Advisory Committee on Immunization Practices [ACIP], 2009. MMWR 2009;58:[No. RR-10]). The 2010 influenza recommendations include new and updated information. Highlights of the 2010 recommendations include 1) a recommendation that annual vaccination be administered to all persons aged ≥6 months for the 2010–11 influenza season; 2) a recommendation that children aged 6 months–8 years whose vaccination status is unknown or who have never received seasonal influenza vaccine before (or who received seasonal vaccine for the first time in 2009–10 but received only 1 dose in their first year of vaccination) as well as children who did not receive at least 1 dose of an influenza A (H1N1) 2009 monovalent vaccine regardless of previous influenza vaccine history should receive 2 doses of a 2010–11 seasonal influenza vaccine (minimum interval: 4 weeks) during the 2010–11 season; 3) a recommendation that vaccines containing the 2010–11 trivalent vaccine virus strains A/California/7/2009 (H1N1)-like (the same strain as was used for 2009 H1N1 monovalent vaccines), A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens be used; 4) information about Fluzone High-Dose, a newly approved vaccine for persons aged ≥65 years; and 5) information about other standard-dose newly approved influenza vaccines and previously approved vaccines with expanded age indications. Vaccination efforts should begin as soon as the 2010–11 seasonal influenza vaccine is available and continue through the influenza season. These recommendations also include a summary of safety data for U.S.-licensed influenza vaccines. These recommendations and other information are available at CDC's influenza website (http://www.cdc.gov/flu); any updates or supplements that might be required during the 2010–11 influenza season also will be available at this website. Recommendations for influenza diagnosis and antiviral use will be published before the start of the 2010–11 influenza season. Vaccination and health-care providers should be alert to announcements of recommendation updates and should check the CDC influenza website periodically for additional information.

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Introduction

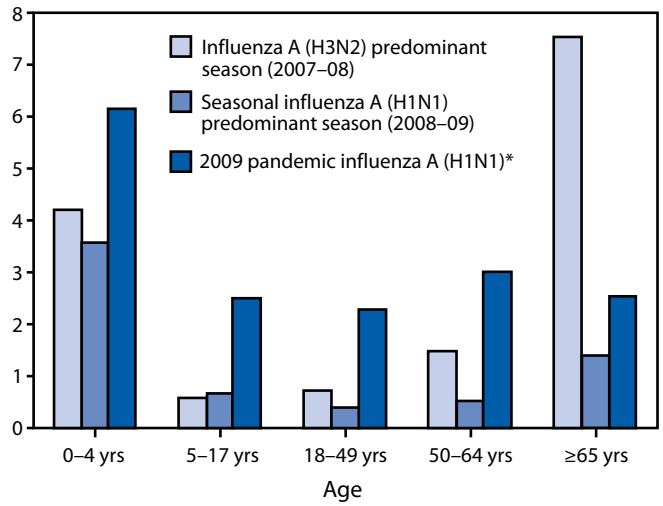
In the United States, annual epidemics of influenza occur typically during the late fall through early spring. Influenza viruses can cause disease among persons in any age group, but rates of infection are highest among children (*1–3*). During these annual epidemics, rates of serious illness and death are highest among persons aged ≥65 years, children aged <2 years, and persons of any age who have medical conditions that

place them at increased risk for complications from influenza (*1,4,5*). Influenza epidemics were associated with estimated annual averages of approximately 36,000 deaths during 1990–1999 and approximately 226,000 hospitalizations during 1979–2001 (*6,7*).

Influenza A subtypes that are generated by a major genetic reassortment (i.e., antigenic shift) or that are substantially different from viruses that have caused infections over the previous several decades have the potential to cause a pandemic (*8*). In April 2009, a novel influenza A (H1N1) virus, 2009 influenza A (H1N1), that is similar to but genetically and antigenically distinct from influenza A (H1N1) viruses previously identified in swine, was determined to be the cause of respiratory illnesses that spread across North America and were identified in many areas of the world by May 2009 (*9,10*). Influenza morbidity caused by 2009 pandemic influenza A (H1N1) remained above seasonal baselines throughout spring and summer 2009 and was the cause of the first pandemic since 1968. In the United States, the pandemic was characterized by a substantial increase in influenza activity, as measured by multiple influenza surveillance systems, that was well beyond historical norms in September 2009, peaking in late October 2009, and returning to seasonal baseline by January 2010 (Figures 1 and 2). During this time, >99% of viruses characterized were the 2009 pandemic influenza A (H1N1) virus (*11*). Data from epidemiologic studies conducted during the 2009 influenza A (H1N1) pandemic indicate that the risk for influenza complications among adults aged 19–64 years who had 2009 pandemic influenza A (H1N1) was greater than typically occurs for seasonal influenza (*12*). Influenza caused by 2009 pandemic influenza A (H1N1) virus is expected to continue to occur during future winter influenza seasons in the Northern and Southern Hemispheres, but whether 2009 pandemic influenza A (H1N1) viruses will replace or co-circulate with one or more of the two seasonal influenza A virus subtypes (seasonal H1N1 and H3N2) that have co-circulated since 1977 is unknown. Influenza viruses undergo frequent antigenic change as a result of point mutations and recombination events that occur during viral replication (i.e., antigenic drift). The extent of antigenic drift and evolution of 2009 pandemic influenza A (H1N1) virus strains in the future cannot be predicted.

Annual influenza vaccination is the most effective method for preventing influenza virus infection and its complications (*8*). Annual vaccination with the most up-to-date strains predicted on the basis of viral surveillance data is recommended. Influenza vaccine is recommended for all persons aged ≥6 months who do not have contraindications to vaccination.

FIGURE 1. Cumulative rate of hospitalizations during three influenza seasons, by age group — Emerging Infections Program, United States, 2007–2010

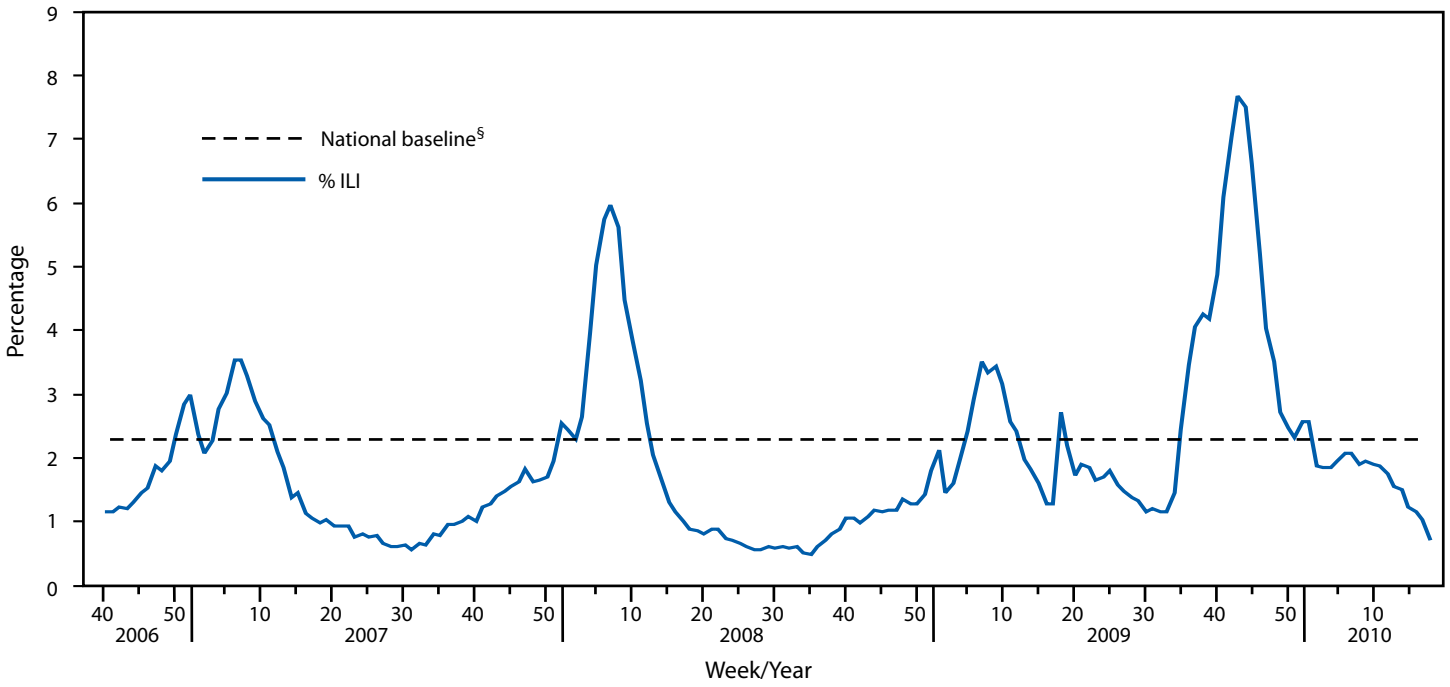


* 2009 Pandemic Influenza A(H1N1) hospitalization data from September 1, 2009–January 21, 2010.
† Per 10,000 population.

Trivalent inactivated influenza vaccine (TIV) can be used for any person aged ≥6 months, including those with high-risk conditions (Box). Live, attenuated influenza vaccine (LAIV) may be used for healthy nonpregnant persons aged 2–49 years. No preference is indicated for LAIV or TIV when considering vaccination of healthy nonpregnant persons aged 2–49 years. Because the safety or effectiveness of LAIV has not been established in persons with underlying medical conditions that confer a higher risk for influenza complications, these persons should be vaccinated only with TIV. Although vaccination coverage has increased in recent years for many groups recommended for routine vaccination, considerable room for improvement remains (*13*), and strategies to improve vaccination coverage in the medical home and in nonmedical settings should be implemented or expanded (*14*).

Antiviral medications are an adjunct to vaccination and are effective when administered as treatment and when used for chemoprophylaxis after an exposure to influenza virus. However, the emergence since 2005 of resistance to one or more of the four licensed antiviral agents (oseltamivir, zanamivir, amantadine, and rimantadine) among circulating strains has complicated antiviral treatment and chemoprophylaxis recommendations. CDC has revised recommendations for antiviral treatment and chemoprophylaxis of influenza periodically in response to new data on antiviral resistance patterns among circulating strains and risk factors for influenza complications (*15*). With few exceptions, 2009 pandemic influenza A (H1N1) virus strains that began circulating in April 2009 remained sensitive to oseltamivir (*16*).

FIGURE 2. Percentage of visits for influenza-like Illness (ILI)* reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet),† by surveillance week — United States, October 1, 2006–May 1, 2010



* ILI is defined as fever (temperature of ≥100°F [≥37.8°C) and a cough and/or a sore throat in the absence of a known cause other than influenza.
† ILINet consists of approximately 2,400 health-care providers in 50 states reporting approximately 16 million patient visits each year.
§ The mean percentage of visits for ILI during noninfluenza weeks for the previous three seasons plus two standard deviations. A noninfluenza week is a week during which <10% of specimens tested positive for influenza.

Methods

CDC's Advisory Committee on Immunization Practices (ACIP) provides annual recommendations for the prevention and control of influenza. The ACIP Influenza Work Group (the Work Group)* meets every 2–4 weeks throughout the year to discuss newly published studies, review current guidelines, and consider revisions to the recommendations. As the Work Group reviews the annual recommendations for consideration by the full ACIP, its members discuss a variety of issues, including the burden of influenza illness; vaccine effectiveness, vaccine safety, and coverage in groups recommended for vaccination; feasibility; cost-effectiveness; and anticipated vaccine supply. Work Group members also request periodic updates on vaccine and antiviral production, supply, safety, and efficacy from vaccinologists, epidemiologists, and manufacturers. State and local vaccination program representatives are consulted. CDC's Influenza Division (available at http://www.cdc.gov/flu) provides influenza surveillance and antiviral resistance data. The Vaccines and Related Biological Products Advisory Committee provides advice on vaccine strain selection to the Food and Drug Administration (FDA), which selects the viral strains to be used in the annual trivalent influenza vaccines.

Published, peer-reviewed studies are the primary source of data used by ACIP in making recommendations for the prevention and control of influenza, but unpublished data that are relevant to issues under discussion also are considered. Among studies discussed or cited, those of greatest scientific quality and those that measure influenza-specific outcomes are the most influential. For example, population-based estimates of influenza disease burden supported by laboratory-confirmed influenza virus infection outcomes contribute the most specific data. The best evidence for vaccine or antiviral efficacy comes from randomized controlled trials that assess laboratory-confirmed influenza infections as an outcome measure and consider factors such as timing and intensity of influenza viruses' circulation and degree of match between vaccine strains and wild circulating strains (*17,18*). However, randomized controlled trials cannot be performed ethically in populations for which vaccination already is recommended, and in this context, observational studies that assess outcomes associated with laboratory-confirmed influenza infection also can provide important vaccine or antiviral safety and effectiveness data. Evidence for vaccine or antiviral safety also is provided

* A list of the members appears on page 62 of this report.

BOX. Summary of influenza vaccination recommendations, 2010

- All persons aged ≥6 months should be vaccinated annually.
- Protection of persons at higher risk for influenza-related complications should continue to be a focus of vaccination efforts as providers and programs transition to routine vaccination of all persons aged ≥6 months.
- When vaccine supply is limited, vaccination efforts should focus on delivering vaccination to persons who:
  - are aged 6 months–4 years (59 months);
  - are aged ≥50 years;
  - have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus);
  - are immunosuppressed (including immunosuppression caused by medications or by human immunodeficiency virus);
  - are or will be pregnant during the influenza season;
  - are aged 6 months–18 years and receiving long-term aspirin therapy and who therefore might be at risk for experiencing Reye syndrome after influenza virus infection;
  - are residents of nursing homes and other chronic-care facilities;
  - are American Indians/Alaska Natives;
  - are morbidly obese (body-mass index ≥40);
  - are health-care personnel;
  - are household contacts and caregivers of children aged <5 years and adults aged ≥50 years, with particular emphasis on vaccinating contacts of children aged <6 months; and
  - are household contacts and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.

by randomized controlled studies; however, the number of subjects in these studies often is inadequate to detect associations between vaccine and rare adverse events. The best way to assess the frequency of rare adverse events after vaccination is by controlled studies after vaccines are used widely in the population. These studies often use electronic medical records from large linked clinical databases and medical charts of persons who are identified as having a vaccine adverse event (*19–21*). Vaccine coverage data from a nationally representative, randomly selected population that include verification of vaccination through health-care record review are superior to coverage data derived from limited population samples or from self-reported vaccination status; however, the former rarely is obtained in vaccination coverage data for children aged ≥5 years (*22*). Finally, studies that assess vaccination program practices that improve vaccination coverage are most influential in formulating recommendations if the study design includes a nonintervention comparison group. In cited studies that included statistical comparisons, a difference was considered to be statistically significant if the p-value was <0.05 or the 95% confidence interval around an estimate of effect allowed rejection of the null hypothesis (i.e., no effect).

Data presented in this report were current as of June 29, 2010, and represent recommendations presented to the full ACIP and approved on February 24, 2010, and June 24, 2010. Modifications were made to the ACIP statement during the subsequent review process at CDC to update and clarify wording in the document. Vaccine recommendations apply only to persons who do not have contraindications to vaccine use (see Contraindications and Precautions for Use of TIV and Contraindications and Precautions for Use of LAIV). Further updates, if needed, will be posted at CDC's influenza website (http://www.cdc.gov/flu).

Primary Changes and Updates in the Recommendations

The 2010 recommendations include five principal changes or updates:

- Routine influenza vaccination is recommended for all persons aged ≥6 months. This represents an expansion of the previous recommendations for annual vaccination of all adults aged 19—49 years and is supported by evidence that annual influenza vaccination is a safe and effective preventive health action with potential benefit in all age groups. By 2009, annual vaccination was already recommended for an estimated 85% of the U.S. population, on the basis of risk factors for influenza-related complications or having close contact with a person at higher risk for influenza-related complications. The only group remaining that was not recommended for routine vaccination was healthy nonpregnant adults aged 18–49 years who did not have an occupational risk for infection and who were not close contacts of persons at higher risk for influenza-related complications. However, some adults who have influenza-related complications have no previously identified risk factors for influenza complications. In addition, some adults who have medical conditions

or age-related increases in their risk for influenza-related complications or another indication for vaccination are unaware that they should be vaccinated. Further support for expansion of annual vaccination recommendations to include all adults is based on concerns that 2009 pandemic influenza A (H1N1)-like viruses will continue to circulate during the 2010–11 influenza season and that a substantial proportion of young adults might remain susceptible to infection with this virus. Data from epidemiologic studies conducted during the 2009 pandemic indicate that the risk for influenza complications among adults aged 19–49 years is greater than is seen typically for seasonal influenza (*12,23,27*).

- As in previous recommendations, all children aged 6 months–8 years who receive a seasonal influenza vaccine for the first time should receive 2 doses. Children who received only 1 dose of a seasonal influenza vaccine in the first influenza season that they received vaccine should receive 2 doses, rather than 1, in the following influenza season. In addition, for the 2010–11 influenza season, children aged 6 months–8 years who did not receive at least 1 dose of an influenza A (H1N1) 2009 monovalent vaccine should receive 2 doses of a 2010–11 seasonal influenza vaccine, regardless of previous influenza vaccination history. Children aged 6 months–8 years for whom the previous 2009–10 seasonal or influenza A (H1N1) 2009 monovalent vaccine history cannot be determined should receive 2 doses of a 2010–11 seasonal influenza vaccine.
- The 2010–11 trivalent vaccines will contain A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens. The influenza A (H1N1) vaccine virus is derived from a 2009 pandemic influenza A (H1N1) virus.
- A newly approved inactivated trivalent vaccine containing 60 mcg of hemagglutinin antigen per influenza vaccine virus strain (Fluzone High-Dose [sanofi pasteur]) is an alternative inactivated vaccine for persons aged ≥65 years. Persons aged ≥65 years can be administered any of the standard-dose TIV preparations or Fluzone High-Dose. Persons aged <65 years who receive inactivated influenza vaccine should be administered a standard-dose TIV preparation.
- Previously approved inactivated influenza vaccines that were approved for expanded age indications in 2009 include Fluarix (GlaxoSmithKline), which is now approved for use in persons aged ≥3 years, and Afluria (CSL Biotherapies), which is now approved for use in persons aged ≥6 months. A new inactivated influenza vaccine, Agriflu (Novartis), has been approved for persons aged ≥18 years.

Background and Epidemiology

Biology of Influenza

Influenza A and B are the two types of influenza viruses that cause epidemic human disease. Influenza A viruses are categorized into subtypes on the basis of two surface antigens: hemagglutinin and neuraminidase. During 1977–2010, influenza A (H1N1) viruses, influenza A (H3N2) viruses, and influenza B viruses have circulated globally. Influenza A subtypes and B viruses are separated further into groups on the basis of antigenic similarities. New influenza virus variants result from frequent antigenic change (i.e., antigenic drift) caused by point mutations and recombination events that occur during viral replication (*8*). Recent studies have explored the complex molecular evolution and epidemiologic dynamics of influenza A viruses (*28–30*).

New or substantially different influenza A subtypes have the potential to cause a pandemic when they are able to cause human illness and demonstrate efficient human-to-human transmission and when little or no previously existing immunity has been identified among humans (*8*). In April 2009, human infections with a novel influenza A (H1N1) virus were identified, and this virus subsequently caused a worldwide pandemic (*9*). The 2009 pandemic influenza A (H1N1) virus is derived from influenza A viruses that have circulated in swine during the past several decades and is antigenically distinct from human influenza A (H1N1) viruses in circulation since 1977. The 2009 pandemic influenza A (H1N) virus contains a combination of gene segments that had not been reported previously in animals or humans. The hemagglutination (HA) gene, which codes for the surface protein most important for immune response, is related most closely to the HA found in contemporary influenza viruses circulating among pigs. This HA gene apparently evolved from the avian-origin 1918 pandemic influenza H1N1 virus, which is thought to have entered human and swine populations at about the same time (*28*).

Currently circulating influenza B viruses are separated into two distinct genetic lineages (Yamagata and Victoria) but are not categorized into subtypes. Influenza B viruses undergo antigenic drift less rapidly than influenza A viruses. Influenza B viruses from both lineages have circulated in most recent influenza seasons (*31*).

Immunity to surface antigens, particularly hemagglutinin, reduces the likelihood of infection (*32*). Antibody against one influenza virus type or subtype confers limited or no protection against another type or subtype of influenza virus. Furthermore, antibody to one antigenic type or subtype of influenza virus might not protect against infection with a new antigenic variant of the same type or subtype (*33*). Frequent

emergence of antigenic variants through antigenic drift is the virologic basis for seasonal epidemics and is the reason for annually reassessing the need to change one or more of the recommended strains for influenza vaccines.

More dramatic changes, or antigenic shifts, occur less frequently. Antigenic shift occurs when a new subtype of influenza A virus appears and can result in the emergence of a novel influenza A virus with the potential to cause a pandemic. The 2009 pandemic influenza A (H1N1) virus is not a new subtype, but because most humans had no pre-existing antibody to key pandemic 2009 influenza A (H1N1) virus hemagglutinin epitopes, widespread transmission was possible (*28*).

Health-Care Use, Hospitalizations, and Deaths Attributed to Influenza

In the United States, annual epidemics of influenza typically occur during the fall or winter months, but the peak of influenza activity can occur as late as April or May. Influenza-related complications requiring urgent medical care, including hospitalizations or deaths, can result from the direct effects of influenza virus infection, from complications associated with age or pregnancy, or from complications of underlying cardiopulmonary conditions or other chronic diseases. Studies that have measured rates of a clinical outcome without a laboratory confirmation of influenza virus infection (e.g., respiratory illness requiring hospitalization during influenza season) to assess the effect of influenza can be difficult to interpret because of circulation of other respiratory pathogens (e.g., respiratory syncytial virus) during the same time as influenza viruses (*34–36*). However, increases in health-care provider visits for acute febrile respiratory illness occur each year during the time when influenza viruses circulate. Data from the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) demonstrate the annual increase in physician visits for influenza-like illness (ILI)[†] and for each influenza season; for 2009, these data also indicated the increase in respiratory illness associated with circulation of 2009 pandemic influenza A (H1N1) virus during Spring 2009 and the resurgence of cases in Fall 2009 (Figure 2) (*37,38*).

In typical winter influenza seasons, an increase in deaths and hospitalizations is observed during periods when influenza viruses are circulating. Some persons whose hospitalization is attributed to invasive pneumococcal pneumonia are likely to have influenza as a co-pathogen, based on correlation between influenza activity and seasonal variations in pneumococcal pneumonia (*39*). The number of deaths or hospitalizations attributable at least partly to influenza can be estimated by applying modeling techniques to viral surveillance and national mortality or hospitalizations data and includes deaths and hospitalizations for which influenza infection is likely a contributor to mortality but not necessarily the sole cause of death (*6,7,40,41*).

Excess deaths and hospitalizations during influenza season that are likely to be caused at least partly by influenza are derived from the broad category of pulmonary and circulatory deaths or hospitalizations. Estimates that include only outcomes attributed to pneumonia and influenza underestimate the proportion of severe illnesses that are attributable at least partly to influenza because such estimates exclude deaths caused by exacerbations of underlying cardiac and pulmonary conditions that are associated with influenza infection (*6,7,40–42*).

During seasonal influenza epidemics from 1979–1980 through 2000–2001, the estimated annual overall number of influenza-associated hospitalizations in the United States ranged from approximately 55,000 to 431,000 per annual epidemic (mean: 226,000) (*7*). In the United States, the estimated number of influenza-associated deaths increased during 1990–1999. This increase was attributed in part to the substantial increase in the number of persons aged ≥65 years, including many who were at higher risk for death from influenza complications (*6*). When mortality data that included deaths attributable to both the pneumonia and influenza as well as the respiratory and circulatory categories were used as a basis for estimating the influenza burden, an average of approximately 19,000 influenza-associated deaths per influenza season occurred during 1976–1990 compared with an average of approximately 36,000 deaths per season during 1990–1999 (*6*). On the basis of data from the pneumonia and influenza category alone, an estimated annual average of 8,000 influenza-related deaths occurred. In addition, influenza A (H3N2) viruses, which have been associated with higher mortality (*43*), predominated in 90% of influenza seasons during 1990–1999 compared with 57% of seasons during 1976–1990 (*6*). From the 1990–91 influenza season through the 1998–99 season, the estimated annual number of deaths attributed to influenza ranged from 17,000 to 51,000 per epidemic (*6*). Estimates of mortality using a variety of different modeling techniques generally have been similar, although estimates for more recent years, when influenza A (H1N1) viruses have predominated more often, have been somewhat lower (*40*).

Influenza viruses cause disease among persons in all age groups (*1–5*). Rates of infection are highest among children, but the risks for complications, hospitalizations, and deaths from seasonal influenza are higher among adults aged ≥65 years, children aged <5 years, and persons of any age who

[†] ILI is defined as fever (temperature of ≥100°F [≥37.8°C) and a cough and/or a sore throat in the absence of a known cause other than influenza.

have medical conditions that place them at increased risk for complications from influenza (*1,4,5,44–47*). Estimated rates of influenza-associated hospitalizations and deaths varied substantially by age group in studies conducted during different seasonal influenza epidemics. During 1990–1999, estimated average rates of influenza-associated pulmonary and circulatory deaths per 100,000 persons were 0.4–0.6 among persons aged 0–49 years, 7.5 among persons aged 50–64 years, and 98.3 among persons aged ≥65 years (*6*).

During the 2009 influenza A (H1N1) pandemic, epidemiologic studies in multiple countries indicated that hospitalization rates and deaths among children and adults aged <65 years exceeded those observed during typical winter seasonal influenza epidemics (*12,23,25,48,49*). In one analysis, the mean age among persons who died in the United States during May–December 2009 and who had laboratory-confirmed influenza was 37 years. In contrast, the estimated mean age among persons who died from seasonal influenza during 1979–2001 was 76 years (*50*). The estimated number of hospitalizations and deaths among adults aged ≥65 years was below that observed in most seasonal epidemics. This difference was attributed to a lower risk for infection (*51*) associated with a higher prevalence of partial or full immunity among older persons, presumably as a result of exposures to antigenically similar influenza A viruses that circulated in the early-mid 20th century. One indication of some degree of preexisting immunity was the presence of cross-reacting antibody present among approximately one third of older adults (*52*), which has been attributed to similarities in the structure of the hemagglutinin protein among the 2009 H1N1 virus and those that circulated earlier in the 20th century (*53*).

Children

Among children aged <5 years, influenza-related illness is a common cause of visits to medical practices and emergency departments (EDs). During two influenza seasons (2002–03 and 2003–04), the percentage of visits among children aged <5 years with acute respiratory illness or fever caused by laboratory-confirmed influenza ranged from 10%–19% of medical office visits to 6%–29% of ED visits. On the basis of these data, the rate of visits to medical clinics for influenza was estimated to be 50–95 visits per 1,000 children, and the rate of visits to EDs was estimated to be 6–27 visits per 1,000 children (*54*). In a multiyear study in New York City that used viral surveillance data to estimate influenza strain-specific illness rates among ED visits, in addition to the expected variation by season and age group, influenza B epidemics were determined to be an important cause of illness among school-aged children in several seasons, and annual epidemics of both influenza A and B peaked among school-aged children before other age groups (*55*). Retrospective studies using medical records data have demonstrated similar rates of illness among children aged <5 years during other influenza seasons (*45,56,57*). During an influenza season, seven to 12 additional outpatient visits and five to seven additional antibiotic prescriptions per 100 children aged <15 years have been estimated compared with periods when influenza viruses are not circulating, with rates decreasing with increasing age of the child (*57*). During 1993–2004 in the Boston area, the rate of ED visits for respiratory illnesses that were attributed to influenza virus on the basis of viral surveillance data among children aged ≤7 years during the winter respiratory illness season ranged from 22.0 per 1,000 children aged 6–23 months to 5.4 per 1,000 children aged 5–7 years (*58*).

Estimates of rates of influenza-associated hospitalization are substantially higher among infants and children aged <2 years compared with older children and are similar to rates for other groups considered at higher risk for influenza-related complications (*59–64*), including persons aged ≥65 years (*57,61*). During 1979–2001, the estimated rate of influenza-associated hospitalizations among children aged <5 years in the United States was 108 hospitalizations per 100,000 person-years, based on data from a national sample of hospital discharges of influenza-associated hospitalizations (*7*). Recent population-based studies that measured hospitalization rates for laboratory-confirmed influenza in young children have documented hospitalization rates that are similar to or higher than rates derived from studies that analyzed hospital discharge data (*54,56,63,65,66*). Annual hospitalization rates for laboratory-confirmed influenza decrease with increasing age, ranging from 240–720 per 100,000 children aged <6 months to approximately 20 per 100,000 children aged 2–5 years (*54*). Hospitalization rates for children aged <5 years with high-risk medical conditions are approximately 250–500 per 100,000 children (*45,47,67*).

Influenza-associated deaths are uncommon among children. An estimated annual average of 92 influenza-associated deaths (0.4 deaths per 100,000 persons) occurred among children aged <5 years during the 1990s compared with 32,651 deaths (98.3 per 100,000 persons) among adults aged ≥65 years (*6*). Of 153 laboratory-confirmed influenza-related pediatric deaths reported during the 2003–04 influenza season, 96 (63%) deaths occurred among children aged <5 years and 61 (40%) among children aged <2 years. Among the 149 children who died and for whom information on underlying health status was available, 100 (67%) did not have an underlying medical condition that was an indication for vaccination at that time (*68*). In California during the 2003–04 and 2004–05 influenza seasons, 51% of children aged <18 years with laboratory-confirmed influenza who died and 40% of those who required

admission to an intensive care unit had no underlying medical conditions (*69*). These data indicate that although children with risk factors for influenza complications are at higher risk for death, the majority of pediatric deaths occur among children with no known high-risk conditions.

Since 2004, death associated with laboratory-confirmed influenza virus infection among children (defined as persons aged <18 years) has been a nationally reportable condition. During 2004–2005, the annual number of seasonal influenza-associated deaths among children aged <18 years reported to CDC ranged from 47 during 2004–05 to 88 during 2007–08 (*70*). During April 2009–March 2010, over 300 deaths attributable to laboratory-confirmed 2009 H1N1 influenza among children, the majority of whom had one or more underlying medical conditions, were reported to CDC in the United States, and over 1,000 deaths are estimated to have occurred (*71*; CDC, unpublished data, 2010).

Deaths among children that have been attributed to co-infection with influenza and *Staphylococcus aureus*, particularly methicillin-resistant *S. aureus* (MRSA), have increased (*38,72*), and illness severity of co-infection is increased compared with influenza alone (*73*). The reason for this increase in co-infections has not been established but might reflect an increasing prevalence within the general population of colonization with MRSA strains, some of which carry certain virulence factors (*74,75*).

Adults

Among healthy younger adults, illness caused by seasonal influenza is typically not severe and rarely results in hospitalization, compared with children aged <5 years, adults aged ≥65 years, pregnant women, or persons with chronic medical conditions. However, illness burden among healthy adults aged 19–49 years is an important cause of outpatient medical visits and worker absenteeism. The impact of influenza varies considerably by season, making estimates of the attack rate in healthy younger adults difficult. In most studies, attack rates have varied from 2% to 10% annually, and influenza has been estimated to cause 0.6–2.5 workdays lost per illness (*76–80*). In one economic analysis, the average annual burden of seasonal influenza among adults aged 18–49 years who did not have a medical condition that conferred a higher risk for influenza complications was estimated to include approximately 5 million illnesses, 2.4 million outpatient visits, 32,000 hospitalizations, and 680 deaths (*78*).

Hospitalization rates during typical influenza seasons are substantially increased for persons aged ≥65 years compared with younger age groups. One retrospective analysis based on data from managed-care organizations collected during 1996–2000 estimated that the risk during influenza season among persons aged ≥65 years with underlying conditions that put them at risk for influenza-related complications (i.e., one or more of the conditions listed as indications for vaccination) was approximately 560 influenza-associated hospitalizations per 100,000 persons compared with approximately 190 per 100,000 healthy persons aged ≥65 years. Persons aged 50–64 years who have underlying medical conditions also were at substantially increased risk for hospitalizations during influenza season compared with healthy adults aged 50–64 years (*44*).

Influenza is an important contributor to the annual increase in deaths attributed to pneumonia and influenza that is observed during the winter months. During 1976–2001, an estimated yearly average of 32,651 (90%) influenza-related deaths occurred among adults aged ≥65 years, with the risk for an influenza-related death highest in the oldest age groups (*6*). Persons aged ≥85 years were 16 times more likely to die from an influenza-related illness compared with persons aged 65–69 years (*6*).

During the 2009 H1N1 pandemic, adults aged <65 years were at higher risk for influenza-related complications (*23,81,82*), particularly those aged 50–64 years who had underlying medical conditions, compared with typical influenza seasons. The distribution of hospitalizations by age group differed from usual seasonal influenza patterns during 2009–10, with more hospitalizations among younger age groups and fewer among adults aged ≥65 years (Figure 1). Hospitalization rates exceeded those seen in any recent influenza season among adults aged ≤65 years (*26*). Pneumonia with evidence of invasive bacterial co-infection has been reported in approximately one third of fatal cases in autopsy studies (*83*). In one study of critically ill adults who required mechanical ventilation, *Streptococcus pneumoniae* pneumonia at admission was an independent risk factor for death (*84*). In addition, obesity (body-mass index [BMI] ≥30) and particularly morbid obesity (BMI ≥40) appeared to be risk factors for hospitalization and death in some studies (*23,24,81,85,86*). Additional studies are needed to determine whether obesity is a risk factor specific to the 2009 H1N1-like influenza viruses or a previously unrecognized risk factor for influenza-related complications caused by other influenza viruses. Other epidemiologic features of the 2009 H1N1 pandemic underscored racial and ethnic disparities in the risk for influenza-related complications among adults, including higher rates of hospitalization for blacks and a disproportionate number of deaths among American Indians/Alaska Natives and indigenous populations in other countries (*87–91*). These disparities might be attributable in part to the higher prevalence of underlying medical conditions or disparities in medical care among these racial/ethnic groups (*92,93*).

The duration of influenza symptoms is prolonged and the severity of influenza illness increased among persons with

human immunodeficiency virus (HIV) infection (*94–98*). A retrospective study of women aged 15–64 years enrolled in Tennessee's Medicaid program determined that the attributable risk for cardiopulmonary hospitalizations among women with HIV infection was higher during influenza seasons than it was either before or after influenza was circulating. The risk for hospitalization was higher for HIV-infected women than it was for women with other underlying medical conditions (*99*). Another study estimated that the risk for influenza-related death was 94–146 deaths per 100,000 persons with acquired immune deficiency syndrome (AIDS) compared with 0.9–1.0 deaths per 100,000 persons aged 25–54 years and 64–70 deaths per 100,000 persons aged ≥65 years in the general population (*100*).

Influenza-related excess deaths among pregnant women were reported during the pandemics of 1918–1919, 1957–1958, and 2009–2010 (*48,101–106*). Severe infections among postpartum women (those delivered within the previous 2 weeks) also were observed in the 2009–10 pandemic (*48,107,108*). Case reports and several epidemiologic studies also indicate that pregnancy increases the risk for seasonal influenza complications for the mother (*109–114*). The majority of studies that have attempted to assess the effect of influenza on pregnant women have measured changes in excess hospitalizations for respiratory illness during influenza season but not laboratory-confirmed influenza hospitalizations. Pregnant women have an increased number of medical visits for respiratory illnesses during influenza season compared with nonpregnant women (*115*). Hospitalized pregnant women with respiratory illness during influenza season have increased lengths of stay compared with hospitalized pregnant women without respiratory illness. Rates of hospitalization for respiratory illness were twice as common during influenza season (*116*). A retrospective cohort study of approximately 134,000 pregnant women conducted in Nova Scotia during 1990–2002 compared medical record data for pregnant women to data from the same women during the year before pregnancy. Among pregnant women, 0.4% were hospitalized, and 25% visited a clinician during pregnancy for a respiratory illness. The rate of third-trimester hospital admissions during the influenza season was five times higher than the rate during the influenza season in the year before pregnancy and more than twice as high as the rate during the noninfluenza season. An excess of 1,210 hospital admissions in the third trimester per 100,000 pregnant women with comorbidities and of 68 admissions per 100,000 women without comorbidities was reported (*117*). In one study, pregnant women with hospitalizations for respiratory symptoms did not have an increase in adverse perinatal outcomes or delivery complications (*118*); another study indicated an increase in delivery complications, including fetal distress, preterm labor, and cesarean delivery. However, infants born to women with laboratory-confirmed influenza during pregnancy do not have higher rates of low birth weight, congenital abnormalities, or lower Apgar scores compared with infants born to uninfected women (*109,119*).

In a case series conducted during the 2009 H1N1 pandemic, 56 deaths were reported among 280 women admitted to intensive care units (*120*). Among the deaths, 36 (64%) occurred in the third trimester. Pregnant women who received treatment >4 days after symptom onset were more likely than those treated within 2 days after symptom onset to be admitted to an intensive care unit (57% and 9%, respectively; relative risk [RR]: 6.0; 95% CI = 3.5–10.6) (*120*).

Options for Controlling Influenza

The most effective strategy for preventing influenza is annual vaccination. Strategies that focus on providing routine vaccination to persons at higher risk for influenza complications have long been recommended, although coverage among the majority of these groups remains low. Routine vaccination of certain persons (e.g., children, contacts of persons at risk for influenza complications, and health-care personnel [HCP]) who serve as a source of influenza virus transmission might provide additional protection to persons at risk for influenza complications and reduce the overall influenza burden. However, coverage levels among these persons need to be increased before effects on transmission can be measured reliably. Antiviral medications can be used for chemoprophylaxis and have been demonstrated to prevent influenza illness. When used for treatment, antiviral medications have been demonstrated to reduce the severity and duration of illness, particularly if used within the first 48 hours after illness onset. However, antiviral medications are adjuncts to vaccine in the prevention and control of influenza, and primary prevention through annual vaccination is the most effective and efficient prevention strategy. Despite recommendations to use antiviral medications to treat hospitalized patients with suspected influenza, antiviral drugs are underused (*121*).

Reductions in detectable influenza A viruses on hands after handwashing have been demonstrated, and handwashing has been demonstrated to reduce the overall incidence of respiratory diseases (*122–124*). Nonpharmacologic interventions (e.g., frequent handwashing and improved respiratory hygiene) are reasonable and inexpensive. However, the impact of hygiene interventions such as handwashing on influenza virus transmission is not well understood, and hygiene measures should not be advocated as a replacement or alternative to specific prevention measures such as vaccination. Few data are available to assess the effects of community-level respiratory

disease mitigation strategies (e.g., closing schools, avoiding mass gatherings, or using respiratory protection) on reducing influenza virus transmission during typical seasonal influenza epidemics (*125–127*). An interventional trial among university students indicated that students living in dormitories who were asked to use surgical face masks, given an alcohol-based hand sanitizer, and provided with education about mask use and hand hygiene during influenza season had substantially lower rates of ILI compared with students in dormitories for whom no intervention was recommended. However, neither face mask nor hand sanitizer use alone was associated with statistically significant reduction in ILI (*128*). During the 2009 pandemic, one study indicated that having members of households in which an influenza case was identified discuss ways to avoid transmission was associated with a significant reduction in the frequency of additional cases after one household member became ill, suggesting that education measures might be an effective way to reduce secondary transmission (*129*). Limited data suggest that transmission of seasonal influenza or ILI among household members can be reduced if household contacts use a surgical face mask or implement hand washing early in the course of an ill index case patient's illness (*130,131*). However, these interventions might supplement use of vaccine as a means to reduce influenza transmission or provide some protection when vaccine is not available (*130–132*).

Influenza Vaccine Efficacy, Effectiveness, and Safety

Evaluating Influenza Vaccine Efficacy and Effectiveness Studies

The efficacy (i.e., prevention of illness among vaccinated persons in controlled trials) and effectiveness (i.e., prevention of illness in vaccinated populations) of influenza vaccines depend in part on the age and immunocompetence of the vaccine recipient, the degree of similarity between the viruses in the vaccine and those in circulation (see Effectiveness of Influenza Vaccination When Circulating Influenza Virus Strains Differ from Vaccine Strains), and the outcome being measured. Influenza vaccine efficacy and effectiveness studies have used multiple possible outcome measures, including the prevention of medically attended acute respiratory illness (MAARI), laboratory-confirmed influenza virus illness, influenza or pneumonia-associated hospitalizations or deaths, or seroconversion. Efficacy or effectiveness for more specific outcomes such as laboratory-confirmed influenza typically will be higher than for less specific outcomes such as MAARI because the causes of MAARI include infections with other pathogens that influenza vaccination would not be expected to prevent (*133*). Observational studies that compare less-specific outcomes among vaccinated populations to those among unvaccinated populations are subject to biases that are difficult to control for during analyses. For example, an observational study that determines that influenza vaccination reduces overall mortality might be biased if healthier persons in the study are more likely to be vaccinated (*134,135*). Randomized controlled trials that measure laboratory-confirmed influenza virus infections as the outcome are the most persuasive evidence of vaccine efficacy, but such trials cannot be conducted ethically among groups recommended to receive vaccine annually.

Influenza Vaccine Composition

Both LAIV and TIV contain strains of influenza viruses that are equivalent antigenically to the annually recommended strains: one influenza A (H3N2) virus, one influenza A (H1N1) virus, and one influenza B virus. Each year, one or more virus strains in the vaccine might be changed on the basis of global surveillance for influenza viruses and the emergence and spread of new strains. The 2010–11 trivalent vaccines will contain A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens. The A/California/7/2009 (H1N1)-like antigen is derived from a pandemic 2009 influenza A (H1N1) virus and is the same vaccine antigen used in the influenza A (H1N1) 2009 monovalent vaccines. The A/Perth/16/2009 (H3N2)-like antigen is different from the H3N2-like antigen recommended for the 2009–10 northern hemisphere seasonal influenza vaccine. The influenza B vaccine strain will remain B/Brisbane/16/2008 and is not changed compared with the 2009–10 northern hemisphere seasonal influenza vaccine (*136*). Viruses for currently licensed TIV and LAIV preparations are grown in chicken eggs. Either vaccine is administered annually to provide optimal protection against influenza virus infection (Table 1). Both TIV and LAIV are widely available in the United States. Although both types of vaccines are expected to be effective, the vaccines differ in several respects (Table 1). None of the influenza vaccines licensed in the United States contains an adjuvant.

Major Differences Between TIV and LAIV

TIV contains inactivated viruses and thus cannot cause influenza. LAIV contains live attenuated influenza viruses that have the potential to cause mild signs or symptoms related to vaccine virus infection (e.g., rhinorrhea, nasal congestion, fever, or sore throat). LAIV is administered intranasally by sprayer, whereas TIV is administered intramuscularly by injection. LAIV is licensed for use among nonpregnant persons aged

TABLE 1. Live, attenuated influenza vaccine (LAIV) compared with inactivated influenza vaccine (TIV) for seasonal influenza, U.S. formulations

Factor	LAIV	TIV
Route of administration	Intranasal spray	Intramuscular injection
Type of vaccine	Live virus	Killed virus
No. of included virus strains	3 (2 influenza A, 1 influenza B)	3 (2 influenza A, 1 influenza B)
Vaccine virus strains updated	Annually	Annually
Frequency of administration	Annually*	Annually*
Approved age	Persons aged 2–49 yrs†	Persons aged ≥6 mos§
Interval between 2 doses recommended for children aged ≥6 mos–8 yrs who are receiving influenza vaccine for the first time	≥4 wks	≥4 wks
Can be given to persons with medical risk factors for influenza-related complications†	No	Yes
Can be given to children with asthma or children aged 2–4 yrs with wheezing in the past yr¶	No	Yes
Can be administered to family members or close contacts of immunosuppressed persons not requiring a protected environment	Yes	Yes
Can be administered to family members or close contacts of immunosuppressed persons requiring a protected environment (e.g., hematopoietic stem cell transplant recipient)	No	Yes
Can be administered to family members or close contacts of persons at higher risk including pregnant women, but not severely immunosuppressed	Yes	Yes
Can be administered simultaneously with other vaccines	Yes**	Yes††
If not administered simultaneously, can be administered within 4 weeks of another live vaccine	Prudent to space ≥4 wks apart	Yes
If not administered simultaneously, can be administered within 4 wks of an inactivated vaccine	Yes	Yes

* Children aged ≥6 months–8 years who have never received a seasonal influenza vaccine before or who did not receive at least 1 dose of an influenza A (H1N1) 2009 monovalent vaccine should receive 2 doses, spaced ≥4 weeks apart. Those children aged 6 months–8 years who were vaccinated for the first time in the 2009–10 season with the seasonal 2009–10 vaccine but who received only 1 dose of seasonal influenza vaccine should receive 2 doses in the following year, spaced ≥4 wks apart.

† Persons at higher risk for complications of influenza infection because of underlying medical conditions should not receive LAIV. Such persons include those who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurologic, hematologic, or metabolic (including diabetes mellitus) disorders; those who are immunosuppressed (including immunosuppression caused by medications or by human immunodeficiency virus); those who are or will be pregnant during the influenza season; those aged 6 months–18 years and receiving long-term aspirin therapy and who therefore might be at risk for experiencing Reye syndrome after influenza virus infection; and residents of nursing homes and other chronic-care facilities.

§ Approval varies by formulation. Fluzone (sanofi pasteur) and Afluria (CSL Biotherapies) have been approved previously for use in children as young as age 6 months. Fluzone High-Dose is approved for use in persons aged ≥65 years. Immunization providers should check Food and Drug Administration–approved prescribing information for 2010–11 influenza vaccines for the most updated information.

¶ Clinicians and vaccination programs should screen for possible reactive airways diseases when considering use of LAIV for children aged 2–4 years and should avoid use of this vaccine in children with asthma or a recent wheezing episode. Health-care providers should consult the medical record, when available, to identify children aged 2–4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2–4 years should be asked: "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record within the preceding 12 months, should not receive LAIV.

** LAIV coadministration has been evaluated systematically only among children aged 12–15 months who received with measles, mumps and rubella vaccine or varicella vaccine.

†† Inactivated influenza vaccine coadministration has been evaluated systematically only among adults who received pneumococcal polysaccharide or zoster vaccine.

2–49 years; safety has not been established in persons with underlying medical conditions that confer a higher risk for influenza complications. TIV is licensed for use among persons aged ≥6 months, including those who are healthy and those with chronic medical conditions (Table 1). During the preparation of TIV, the vaccine viruses are made noninfectious (i.e., inactivated or killed) (*8*). Only subvirion and purified surface antigen preparations of TIV (often referred to as "split" and subunit vaccines, respectively) are available in the United States. Standard-dose TIV preparations contain 7.5 mcg HA antigen per vaccine strain (for children aged <36 months) or 15 mcg of HA antigen (for persons aged ≥36 months) per vaccine strain (i.e., 22.5 mcg or 45 mcg total HA antigen). A newly licensed higher dose TIV (60 mcg per vaccine strain or 180 mcg total HA antigen) was approved recently for persons aged ≥65 years (Fluzone High-Dose, Sanofi pasteur).

Correlates of Protection after Vaccination

Immune correlates of protection against influenza infection after vaccination include serum hemagglutination inhibition antibody and neutralizing antibody (*32,137*). Increased levels of antibody induced by vaccination decrease the risk for illness caused by strains that are similar antigenically to those strains of the same type or subtype included in the vaccine (*138–141*). The majority of healthy children and adults have high titers of antibody after vaccination (*139,142*). Although immune correlates such as achievement of certain antibody titers after vaccination correlate well with immunity on a population level, the significance of reaching or failing to reach a certain antibody threshold (typically defined as a hemagglutination titer of 1:32 or 1:40) is not well understood on the individual level. Other immunologic correlates of protection that might best indicate

clinical protection after receipt of an intranasal vaccine such as LAIV (e.g., mucosal antibody) are more difficult to measure (*143,144*). Laboratory measurements that correlate with protective immunity induced by LAIV have been described, including measurement of cell-mediated immunity with ELISPOT assays that measure gamma-interferon (*143*).

Duration of Immunity

The recommended composition of influenza vaccines changes in most seasons, with one or more vaccine strains replaced annually to provide better protection against wild-type viruses that are likely to circulate. However, evidence from clinical trials suggests that protection against viruses that are similar antigenically to those contained in the vaccine extends for at least 6–8 months. Three years after vaccination with the A/Hong Kong/68 vaccine, vaccine effectiveness was 67% for prevention of influenza caused by the A/Hong Kong/68 virus (*145*). In randomized trials conducted among healthy college students, immunization with TIV provided 92% and 100% efficacy against influenza H3N2 and H1N1 illnesses, respectively, during the first year, and a 68% reduction against H1N1 illness during the second year (when the predominant circulating virus was H1N1) without revaccination (*146*). In a similar study of young adults in 1986–1987, TIV reduced influenza A (H1N1) illness 75% in the first year, H3N2 illness 45% in the second year, and H1N1 illness 61% in the third year after immunization (*146*). Serum anti-influenza antibodies and nasal IgA elicited by vaccination remain detectable in children vaccinated with LAIV for more than 1 year (*147*). In one community-based nonrandomized open label trial, continued protection from MAARI during the 2000–01 influenza season was demonstrated in children who received only a single dose of LAIV during the 1999–2000 season (*148*).

Adults aged ≥65 years typically have a diminished immune response to influenza vaccination compared with young healthy adults, suggesting that immunity might be of shorter duration (although still extending through one influenza season) (*149,150*). However, a review of the published literature concluded that no clear evidence existed that immunity declined more rapidly in the elderly (*151*), and additional vaccine doses during the same season do not increase the antibody response. One study that measured the proportion of persons who retained seroprotective levels of anti-influenza antibody declined in all age groups, including those aged ≥65 years, within 1 year of vaccination. However, the proportion in each age group that retained seroprotective antibody levels remained above standards typically used for vaccine licensure for seasonal influenza A (H1N1) and influenza A (H3N2) in all age groups. In this study, anti-influenza B antibody levels declined more quickly, but remained elevated well above licensure threshold for at least 6 months in all age groups (*152*). The frequency of breakthrough infections is not known to be higher among those who were vaccinated early in the season. Infections among the vaccinated elderly might be more likely related to an age-related reduction in ability to respond to vaccination rather than reduced duration of immunity.

Immunogenicity, Efficacy, and Effectiveness of TIV

Children

Children aged ≥6 months typically have protective levels of anti-influenza antibody against specific influenza virus strains after receiving the recommended number of doses of seasonal inactivated influenza vaccine (*137,142,153–157).* Immunogenicity studies using the influenza A (H1N1) 2009 monovalent vaccine indicated that >90% of children aged ≥9 years responded to a single dose with anti-influenza antibody levels that are considered to be protective. Young children had inconsistent responses to a single dose of the influenza A (H1N1) 2009 monovalent vaccine across studies, with 20% of children aged 6–35 months responding to a single dose with protective anti-influenza antibody levels. However, in all studies, 80%–95% of vaccinated infants, children, and adolescents developed protective anti-influenza antibody levels to the 2009 H1N1 influenza virus after 2 doses (*158–160*; National Institutes of Health, unpublished data, 2010).

In most seasons, one or more seasonal vaccine antigens are changed compared with the previous season. In consecutive years when vaccine antigens change, children aged <9 years who received only 1 dose of vaccine in their first year of vaccination are less likely to have protective antibody responses when administered only a single dose during their second year of vaccination compared with children who received 2 doses in their first year of vaccination (*161–163*).

When the vaccine antigens do not change from one season to the next, priming children aged 6–23 months with a single dose of vaccine in the spring followed by a dose in the fall engenders similar antibody responses compared with a regimen of 2 doses in the fall (*164*). However, one study conducted during a season when the vaccine antigens did not change compared with the previous season estimated 62% effectiveness against ILI for healthy children who had received only 1 dose in the previous influenza season and only 1 dose in the study season compared with 82% for those who received 2 doses separated by ≥4 weeks during the study season (*165*).

The antibody response among children at higher risk for influenza-related complications (e.g., children with chronic

medical conditions) might be lower than those reported typically among healthy children (*166,167*). However, antibody responses among children with asthma are similar to those of healthy children and are not substantially altered during asthma exacerbations requiring short-term prednisone treatment (*168*).

Vaccine effectiveness studies also have indicated that 2 doses are needed to provide adequate protection during the first season that young children are vaccinated. Among children aged <5 years who have never received influenza vaccine previously or who received only 1 dose of influenza vaccine in their first year of vaccination, vaccine effectiveness is lower compared with children who received 2 doses in their first year of being vaccinated. Two large retrospective studies of young children who had received only 1 dose of TIV in their first year of being vaccinated determined that no decrease was observed in ILI-related office visits compared with unvaccinated children (*165,169*). Similar results were reported in a case-control study of children aged 6–59 months in which laboratory-confirmed influenza was the outcome measured (*170*). These results, along with the immunogenicity data indicating that antibody responses are substantially higher when young children are given 2 doses, are the basis for the recommendation that all children aged 6 months–8 years who are being vaccinated for the first time should receive 2 vaccine doses separated by ≥4 weeks.

Estimates of vaccine efficacy or effectiveness among children aged ≥6 months have varied by season and study design. In a randomized trial conducted during five influenza seasons (1985–1990) in the United States among children aged 1–15 years, annual vaccination reduced laboratory-confirmed influenza A substantially (77%–91%) (*139*). A limited 1-year placebo-controlled study reported vaccine efficacy against laboratory-confirmed influenza illness of 56% among healthy children aged 3–9 years and 100% among healthy children and adolescents aged 10–18 years (*171*). A randomized, double-blind, placebo-controlled trial conducted during two influenza seasons among children aged 6–24 months indicated that efficacy was 66% against culture-confirmed influenza illness during the 1999–00 influenza season but did not reduce culture-confirmed influenza illness substantially during the 2000–01 influenza season (*172*).

A case-control study conducted during the 2003–04 season indicated vaccine effectiveness of 49% against laboratory-confirmed influenza (*170*). An observational study among children aged 6–59 months with laboratory-confirmed influenza compared with children who tested negative for influenza reported vaccine effectiveness of 44% in the 2003–04 influenza season and 57% during the 2004–05 season (*173*). Partial vaccination (only 1 dose for children being vaccinated for the first time) was not effective in either study. During an influenza season (2003–04) with a suboptimal vaccine match, a retrospective cohort study conducted among approximately 30,000 children aged 6 months–8 years indicated vaccine effectiveness of 51% against medically attended, clinically diagnosed pneumonia or influenza (i.e., no laboratory confirmation of influenza) among fully vaccinated children and 49% among approximately 5,000 children aged 6–23 months (*169*). Another retrospective cohort study of similar size conducted during the same influenza season in Denver but limited to healthy children aged 6–21 months estimated clinical effectiveness of 2 TIV doses to be 87% against pneumonia or influenza-related office visits (*165*). Among children, TIV effectiveness might increase with age (*139,174*). A systematic review of published studies estimated vaccine effectiveness at 59% for children aged >2 years but concluded that additional evidence was needed to demonstrate effectiveness among children aged 6 months–2 years (*175*).

Because of the recognized influenza-related disease burden among children with other chronic diseases or immunosuppression and the long-standing recommendation for vaccination of these children, randomized placebo-controlled studies to study efficacy in these children have not been conducted. In a nonrandomized controlled trial among children aged 2–6 years and 7–14 years who had asthma, vaccine efficacy was 54% and 78% against laboratory-confirmed influenza type A infection and 22% and 60% against laboratory-confirmed influenza type B infection, respectively. Vaccinated children aged 2–6 years with asthma did not have substantially fewer type B influenza virus infections compared with the control group in this study (*176*). The association between vaccination and prevention of asthma exacerbations is unclear. Vaccination was demonstrated to provide protection against asthma exacerbations in some studies (*177,178*).

TIV has been demonstrated to reduce acute otitis media in some studies. Two studies have reported that TIV decreases the risk for influenza-related otitis media by approximately 30% among children with mean ages of 20 and 27 months, respectively (*179,180*). However, a large study conducted among children with a mean age of 14 months indicated that TIV was not effective against acute otitis media (*172*). Influenza vaccine effectiveness against a nonspecific clinical outcome such as acute otitis media, which is caused by a variety of pathogens and is not typically diagnosed using influenza virus culture, would be expected to be relatively low.

Adults Aged <65 Years

One dose of TIV is highly immunogenic in healthy adults aged <65 years. Limited or no increase in antibody response is reported among adults when a second dose is administered

during the same season (*181–183*). The influenza A (H1N1) 2009 monovalent vaccines were also highly immunogenic; >90% of adults developed levels of anti-influenza antibody considered to be protective (*160,184*). When the vaccine and circulating viruses are antigenically similar, TIV prevents laboratory-confirmed influenza illness among approximately 70%–90% of healthy adults aged <65 years in randomized controlled trials (*77,80,185–187*). Vaccination of healthy adults also has resulted in decreased work absenteeism and decreased use of health-care resources, including use of antibiotics, when the vaccine and circulating viruses are well-matched (*77,185,186*). Efficacy or effectiveness against laboratory-confirmed influenza illness was substantially lower in studies conducted during different influenza seasons when the vaccine strains were antigenically dissimilar to the majority of circulating strains (*77,80,180,182,185,186*). However, effectiveness among healthy adults against influenza-related hospitalization, measured in the most recent of these studies, was 90% (*188*).

In certain studies, persons with certain chronic diseases have lower serum antibody responses after vaccination compared with healthy young adults and can remain susceptible to influenza virus infection and influenza-related upper respiratory tract illness (*189–191*). Vaccine effectiveness among adults aged <65 years who are at higher risk for influenza complications typically is lower than that reported for healthy adults. In a case-control study conducted during the 2003–04 influenza season, when the vaccine was a suboptimal antigenic match to many circulating virus strains, effectiveness for prevention of laboratory-confirmed influenza illness among adults aged 50–64 years with high-risk conditions was 48% compared with 60% for healthy adults (*188*). Effectiveness against hospitalization among adults aged 50–64 years with high-risk conditions was 36% compared with 90% effectiveness among healthy adults in that age range (*188*). A randomized controlled trial among adults in Thailand with chronic obstructive pulmonary disease (median age: 68 years) indicated a vaccine effectiveness of 76% in preventing laboratory-confirmed influenza during a season when viruses were well-matched to vaccine viruses. Effectiveness did not decrease with increasing severity of underlying lung disease (*192*).

Few randomized controlled trials have studied the effect of influenza vaccination on noninfluenza outcomes. A controlled trial conducted in Argentina among 301 adults hospitalized with myocardial infarction or undergoing angioplasty for cardiovascular disease (56% of whom were aged ≥65 years) who were randomized to receive influenza vaccine or no vaccine indicated that a substantially lower percentage (6%) of cardiovascular deaths occurred among vaccinated persons at 1 year after vaccination compared with unvaccinated persons (17%) (*193*). A randomized, double-blind, placebo-controlled study conducted in Poland among 658 persons with coronary artery disease indicated that significantly fewer vaccinated persons had a cardiac ischemic event during the 9 months of follow up compared with unvaccinated persons ($p<0.05$) (*194*).

Observational studies that have measured clinical endpoints without laboratory confirmation of influenza virus infection typically have demonstrated substantial reductions in hospitalizations or deaths among adults with risk factors for influenza complications. For example, in a case-control study conducted during 1999–2000 in Denmark among adults aged <65 years with underlying medical conditions, vaccination reduced deaths attributable to any cause 78% and reduced hospitalizations attributable to respiratory infections or cardiopulmonary diseases 87% (*195*). A benefit was reported after the first vaccination and increased with subsequent vaccinations in subsequent years (*196*). Among patients with diabetes mellitus, vaccination was associated with a 56% reduction in any complication, a 54% reduction in hospitalizations, and a 58% reduction in deaths (*197*). Certain experts have noted that the substantial effects on morbidity and mortality among those who received influenza vaccination in these observational studies should be interpreted with caution because of the difficulties in ensuring that those who received vaccination had similar baseline health status as those who did not (*134,135*). One meta-analysis of published studies concluded that evidence was insufficient to demonstrate that persons with asthma benefit from vaccination (*198*). However, a meta-analysis that examined effectiveness among persons with chronic obstructive pulmonary disease identified evidence of benefit from vaccination (*199*).

Immunocompromised Persons

TIV produces adequate antibody concentrations against influenza among vaccinated HIV-infected persons who have no or minimal AIDS-related symptoms (*200–202*). Among persons who have advanced HIV disease and low CD4+ T-lymphocyte cell counts, TIV might not induce protective antibody titers (*202,203*); a second dose of vaccine does not improve the immune response in these persons (*203,204*). A randomized, placebo-controlled trial determined that TIV was highly effective in preventing symptomatic, laboratory-confirmed influenza virus infection among HIV-infected persons with a mean of 400 CD4+ T-lymphocyte cells/mm^3; however, a limited number of persons with CD4+ T-lymphocyte cell counts of <200 were included in that study (*204*). A nonrandomized study of HIV-infected persons determined that influenza vaccination was most effective among persons with >100 CD4+ cells and among those with <30,000 viral copies of HIV type-1/mL (*95*).

On the basis of certain limited studies, immunogenicity for persons with solid organ transplants varies according to transplant type. Among persons with kidney or heart transplants, the proportion who developed seroprotective antibody concentrations was similar or slightly reduced compared with healthy persons (*205–207*). However, a study among persons with liver transplants indicated reduced immunologic responses to influenza vaccination (*208–210*), especially if vaccination occurred within the 4 months after the transplant procedure (*208*).

Pregnant Women and Neonates

Pregnant women have protective levels of anti-influenza antibodies after vaccination (*211,212*). Passive transfer of anti-influenza antibodies that might provide protection from vaccinated women to neonates has been reported (*211,213–216*). One randomized controlled trial conducted in Bangladesh that provided vaccination to pregnant women during the third trimester demonstrated a 29% reduction in respiratory illness with fever among the mothers and a 36% reduction in respiratory illness with fever among their infants during the first 6 months of life. In addition, infants born to vaccinated women had a 63% reduction in laboratory-confirmed influenza illness during the first 6 months of life (*217*). All women in this trial breastfed their infants (mean duration: 14 weeks). However, a retrospective study conducted during 1997–2002 that used clinical records data did not indicate a reduction in ILI among vaccinated pregnant women or their infants (*218*). In another study conducted during 1995–2001, medical visits for respiratory illness among infants were not reduced substantially (*219*).

Adults Aged ≥65 Years

One prospective cohort study indicated that immunogenicity among hospitalized persons who either were aged ≥65 years or were aged 18–64 years and had one or more chronic medical conditions was similar compared with outpatients (*220*). Immunogenicity data from three studies among persons aged ≥65 years indicate that higher-dose preparations elicit substantially higher hemagglutinin inhibition (HI) titers compared with the standard dose (*221–223*). In one study, prespecified criteria for superiority (defined as when the lower bound of the two-sided confidence interval of a ratio of geometric mean HI titers is >1.5 and the difference in fourfold rise of HI titers is >10%) were demonstrated for influenza A (H1N1) and influenza A (H3N2) antigens among persons aged ≥65 years who received a TIV formulation (Fluzone High-Dose, sanofi pasteur) that contains four times the standard amount of HA antigen (180 mcg [60 mcg of each strain]) of influenza virus hemagglutinin per dose (*222,224*). Prespecified criteria for noninferiority to a standard-dose vaccine (Fluzone, sanofi pasteur) was demonstrated for the influenza B antigen (*222*).

The only randomized controlled trial among community-dwelling persons aged ≥60 years reported a vaccine efficacy of 58% (95% CI = 26%–77%) against laboratory-confirmed influenza illness during a season when the vaccine strains were considered to be well-matched to circulating strains (*225*). Additional information from this trial published separately indicated that efficacy among those aged ≥70 years was 57% (95% CI = -36%–87%), similar to younger persons. However, few persons aged >75 years participated in this study, and the wide confidence interval for the estimate of efficacy among participants aged ≥70 years could not exclude no effect (i.e., included 0) (*226*). Influenza vaccine effectiveness in preventing MAARI among the elderly in nursing homes has been estimated at 20%–40% (*227,228*), and reported outbreaks among well-vaccinated nursing home populations have suggested that vaccination might not have any significant effectiveness when circulating strains are drifted from vaccine strains (*229,230*). In contrast, some studies have indicated that vaccination can be up-to-80% effective in preventing influenza-related death (*227,231–233*). Among elderly persons not living in nursing homes or similar long-term–care facilities, influenza vaccine is 27%–70% effective in preventing hospitalization for pneumonia and influenza (*234–236*). Influenza vaccination reduces the frequency of secondary complications and reduces the risk for influenza-related hospitalization and death among community-dwelling adults aged ≥65 years with and without high-risk medical conditions (e.g., heart disease and diabetes) (*235–240*). However, studies demonstrating large reductions in hospitalizations and deaths among the vaccinated elderly have been conducted using medical record databases and have not measured reductions in laboratory-confirmed influenza illness. These studies have been challenged because of concerns that they have not controlled adequately for differences in the propensity for healthier persons to be more likely than less healthy persons to receive vaccination (*134,135,232,241–244*).

Immunogenicity of Inactivated 2009 Pandemic H1N1 Vaccines

The 2010–11 seasonal influenza vaccine will contain an influenza A (H1N1) California/7/2009-like strain, which was also the strain used for the 2009 pandemic H1N1 monovalent vaccines. Clinical studies of the 2009 H1N1 monovalent vaccines indicate that this vaccine antigen is immunogenic and response rates are similar to those observed after immunization with influenza A antigens found in typical seasonal influenza vaccines. Among children aged 6–35 months, 19%–92% responded with an HI titer ≥40 at ≥21 days after 1 dose, and >90% responded with an HI titer ≥40 after 2 doses separated

by ≥21 days (*159,160*; National Institutes of Health, unpublished data, 2010). Among children aged 3 –9 years, 44%–93% responded with an HI titer ≥40 at 21 or more days after 1 dose, and >90% responded with an HI titer ≥40 after 2 doses separated by ≥21 days (*158–160*; National Institutes of Health, unpublished data, 2010). Among older children and adults, response rates after 1 dose exceeded 90% (*160,184*) although geometric mean titers were substantially lower among adults aged ≥50 years in one study (*184*) and among adults aged ≥65 years (*160*). Additional data on 2009 H1N1 pandemic vaccine immunogenicity among persons with chronic medical conditions or pregnant women are not yet available, but results from studies in other groups suggest that immunogenicity is likely to be similar to that observed in studies of seasonal vaccine immunogenicity.

TIV Dosage, Administration, and Storage

The composition of TIV varies according to manufacturer, and package inserts should be consulted. TIV formulations in multidose vials contain the vaccine preservative thimerosal; preservative-free, single-dose preparations also are available. TIV should be stored at 35°F–46°F (2°C–8°C) and should not be frozen. TIV that has been frozen should be discarded. Dosage recommendations and schedules vary according to age group (Table 2). Vaccine prepared for a previous influenza season should not be administered to provide protection for any subsequent season.

The intramuscular route is recommended for TIV. Adults and older children should be vaccinated in the deltoid muscle. A needle length of ≥1 inch (≥25 mm) should be considered for persons in these age groups because needles of <1 inch might be of insufficient length to penetrate muscle tissue in certain adults and older children (*245*). When injecting into the deltoid muscle among children with adequate deltoid muscle mass, a needle length of ⅞–1¼ inches is recommended (*245*).

Infants and young children should be vaccinated in the anterolateral aspect of the thigh. A needle length of ⅞–1 inch should be used for children aged <12 months.

Adverse Events After Receipt of TIV

Children

Studies support the safety of annual TIV in children and adolescents. The largest published postlicensure population-based study assessed TIV safety in 251,600 children aged <18 years (including 8,476 vaccinations in children aged 6–23 months) who were enrolled in one of five health maintenance organizations within the Vaccine Safety Datalink (VSD) during 1993–1999. This study indicated no increase in clinically important medically attended events during the 2 weeks after inactivated influenza vaccination compared with control periods 3–4 weeks before and after vaccination (*246*). A retrospective cohort study using VSD medical records data from 45,356 children aged 6–23 months during 1991–2003 provided additional evidence supporting overall safety of TIV in this age group. During the 2 weeks after vaccination, TIV was not associated with statistically significant increases in any clinically important medically attended events other than gastritis/duodenitis, compared with 2-week control time periods before and after vaccination. Analysis also indicated that 13 diagnoses, including acute upper respiratory illness, otitis media, and asthma, were substantially less common during the 2 weeks after influenza vaccine. On chart review, most children with a diagnosis of gastritis/duodenitis had acute episodes of vomiting or diarrhea, which usually are self-limiting symptoms. The positive or negative associations between TIV and any of these diagnoses do not necessarily indicate a causal relationship (*247*). The study identified no increased risk for febrile seizure during the 3 days after vaccination. Similarly, no increased risk for febrile seizure was observed during the 14 days after TIV vaccination, after controlling for simultaneous receipt of measles-mumps-rubella (MMR) vaccine which has a known association with febrile seizures in the second week after MMR vaccination (*247*). Another analysis assessed risk for prespecified adverse events in the VSD, including seizures and Guillan-Barré Syndrome (GBS), after TIV during three influenza seasons (2005–06, 2006–07, and 2007–08). No elevated risk for adverse events was identified among 1,195,552 TIV doses administered to children aged <18 years (*248*).

In a study of 791 healthy children aged 1–15 years, postvaccination fever was noted among 12% of those aged 1–5 years, 5% among those aged 6–10 years, and 5% among those aged 11–15 years (*139*). Fever, malaise, myalgia, and other systemic symptoms that can occur after vaccination with inactivated vaccine most often affect persons who have had no previous exposure to the influenza virus antigens in the vaccine (e.g., young children) (*249*). These reactions begin 6–12 hours after vaccination and can persist for 1–2 days (*249*).

Data about potential adverse events among children after influenza vaccination are available from the Vaccine Adverse Event Reporting System (VAERS). Because of the limitations of passive reporting systems, determining causality for specific types of adverse events usually is not possible using VAERS data alone. Published reviews of VAERS reports submitted after administration of TIV to children aged 6–23 months indicated that the most frequently reported adverse events were fever, rash, injection-site reactions, and seizures; the majority of the limited number of reported seizures appeared

TABLE 2. Influenza vaccines for different age groups — United States, 2010–11 season*

Vaccine	Trade name	Manufacturer	Presentation	Mercury content (mcg Hg/0.5 mL dose)	Age group	No. of doses	Route
TIV†	Fluzone	sanofi pasteur	0.25 mL prefilled syringe	0.0	6–35 mos	1 or 2§	Intramuscular¶
			0.5 mL prefilled syringe	0.0	≥36 mos	1 or 2§	Intramuscular
			0.5 mL vial	0.0	≥36 mos	1 or 2§	Intramuscular
			5.0 mL multidose vial	25.0	≥6 mos	1 or 2§	Intramuscular
TIV	Fluvirin	Novartis Vaccine	5.0 mL multidose vial	24.5	≥4 yrs	1 or 2§	Intramuscular
			0.5 mL prefilled syringe	<1.0			
TIV	Fluarix	Glaxo SmithKline	0.5 mL prefilled syringe	0.0	≥3 yrs	1	Intramuscular
TIV	FluLaval	Glaxo SmithKline	5.0 mL multidose vial	25.0	≥18 yrs	1	Intramuscular
TIV	Afluria	CSL Biotherapies	0.5 mL prefilled syringe	0.0	≥6 mos	1	Intramuscular
			5.0 mL multidose vial	25.0			
TIV High Dose**	Fluzone High-Dose	sanofi pasteur	0.5 mL prefilled syringe	0.0	≥65 yrs	1	Intramuscular
LAIV††	FluMist§§	MedImmune	0.2 mL sprayer, divided dose	0.0	2–49 yrs	1 or 2§	Intranasal

* Immunization providers should check Food and Drug Administration–approved prescribing information for 2010–11 influenza vaccines for the most updated information.
† Trivalent inactivated vaccine.
§ Children aged 6 months–8 years who have never received a seasonal TIV before or who did not receive at least 1 dose of an influenza A (H1N1) 2009 monovalent vaccine should receive 2 doses, spaced ≥4 weeks apart. Those children aged 6 months–8 years who were vaccinated for the first time in the 2009–10 season with the seasonal 2009–10 seasonal vaccine but who received only 1 dose should receive 2 doses of the 2010–11 influenza vaccine formula, spaced ≥4 weeks apart.
¶ For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh.
** Trivalent inactivated vaccine high dose. A 0.5-mL dose contains 60 mcg each of A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens.
†† Live attenuated influenza vaccine.
§§ FluMist is shipped refrigerated and stored in the refrigerator at 36°F–46°F (2°C–8°C) after arrival in the vaccination clinic. The dose is 0.2 mL divided equally between each nostril. Health-care providers should consult the medical record, when available, to identify children aged 2–4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2–4 years should be asked: "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record within the past 12 months should not receive FluMist.

to be febrile (*250,251*). Seizure and fever were the leading serious adverse events (SAEs) reported to VAERS in these studies (*250,2511*); analysis of VSD data did not confirm an association with febrile seizures and influenza vaccination as observed in VAERS (*247*).

In April 2010, Australia's Therapeutic Goods Administration reported preliminary data indicating an elevated risk for febrile reactions, including febrile seizures, among young children in Australia who received the 2010 trivalent vaccine Fluvax Jr., the southern hemisphere inactivated trivalent vaccine for children manufactured by CSL Biotherapies. The risk for febrile seizures was estimated to be as high as five to nine cases per 1,000 vaccinated children aged <5 years, and most seizures occurred among children aged <3 years. Other influenza vaccines, including previous seasonal and pandemic influenza vaccines manufactured by CSL Biotherapies, have not been associated with an increased risk for febrile seizures among children in the United States or Australia. As of July 2010, no cause for the increased frequency of febrile reactions among young children who received the southern hemisphere CSL Biotherapies vaccine had been identified (*252*). ACIP will continue to monitor safety studies being conducted in Australia and might provide further guidance on use of Afluria, the northern hemisphere trivalent vaccine manufactured by CSL Biotherapies later in 2010. Immunization providers should consult updated information on use of the CSL vaccine from CDC (http://www.cdc.gov/flu) and FDA (http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/default.htm).

Adults

In placebo-controlled studies among adults, the most frequent side effect of vaccination was soreness at the vaccination site (affecting 10%–64% of patients) that lasted <2 days (*253,254*). These local reactions typically were mild and rarely interfered with the recipients' ability to conduct usual daily activities. Placebo-controlled trials demonstrated that among older persons and healthy young adults, administration of TIV is not associated with higher rates for systemic symptoms (e.g., fever, malaise, myalgia, and headache) when compared with

placebo injections (*77,198,253–255*). One prospective cohort study indicated that the rate of adverse events was similar among hospitalized persons who either were aged ≥65 years or were aged 18–64 years and had one or more chronic medical conditions compared with outpatients (*220*). Among adults vaccinated in consecutive years, reaction frequencies declined in the second year of vaccination (*256*). In clinical trials, SAEs were reported to occur after vaccination with TIV at a rate of <1%. Adverse events in adults aged ≥18 years reported to VAERS during 1990–2005 were analyzed. The most common adverse events reported to VAERS in adults included injection-site reactions, pain, fever, myalgia, and headache. The VAERS review identified no new safety concerns. Fourteen percent of the TIV VAERS reports in adults were classified as SAEs, similar to proportions seen overall in VAERS. The most common SAE reported after receipt of TIV in VAERS in adults was GBS (*257*). The potential association between TIV and GBS has been an area of ongoing research (see Guillain-Barré Syndrome and TIV). No elevated risk for prespecified events after TIV was identified among 4,773,956 adults in a VSD analysis (*249*).

Solicited injection-site reactions and systemic adverse events among persons aged ≥65 years were more frequent after vaccination with a vaccine containing 180 mcg of HA antigen (Fluzone High-Dose, sanofi pasteur) compared with a standard dose (45 mcg) (Fluzone, Sanofi pasteur vaccines) but were typically mild and transient. In the largest study, 915 (36%) of 2,572 persons who received Fluzone High-Dose reported injection-site pain, compared with 306 (24%) of the 1,260 subjects who received Fluzone. The pain was of mild intensity and resolved within 3 days in the majority of subjects. Among Fluzone High Dose recipients, 1.1% reported moderate to severe fever; this was substantially higher than the 0.3% of Fluzone recipients who reported this systemic adverse event (*222*). During the 6-month follow-up period, SAEs were reported in 6% of the High-Dose recipients and 7% of the Fluzone recipients (*222*).

Pregnant Women and Neonates

FDA has classified TIV as a "Pregnancy Category C" medication, indicating that adequate animal reproduction studies have not been conducted. Available data do not indicate that influenza vaccine causes fetal harm when administered to a pregnant woman. One study of approximately 2,000 pregnant women who received TIV during pregnancy demonstrated no adverse fetal effects and no adverse effects during infancy or early childhood (*258*). A matched case-control study of 252 pregnant women who received TIV within the 6 months before delivery determined no adverse events after vaccination among pregnant women and no difference in pregnancy outcomes compared with 826 pregnant women who were not vaccinated (*212*). During 2000–2003, an estimated 2 million pregnant women were vaccinated, and only 20 adverse events among women who received TIV were reported to VAERS during this time, including nine injection-site reactions and eight systemic reactions (e.g., fever, headache, and myalgias). In addition, three miscarriages were reported, but these were not known to be related causally to vaccination (*259*). Similar results have been reported in certain smaller studies (*211,213,260*), and a recent international review of data on the safety of TIV concluded that no evidence exists to suggest harm to the fetus (*261*). The rate of adverse events associated with TIV was similar to the rate of adverse events among pregnant women who received pneumococcal polysaccharide vaccine in one small randomized controlled trial in Bangladesh, and no severe adverse events were reported in any study group (*217*).

Persons with Chronic Medical Conditions

In a randomized cross-over study of children and adults with asthma, no increase in asthma exacerbations was reported for either age group (*262*), and two additional studies also have indicated no increase in wheezing among vaccinated asthmatic children (*177*) or adults (*195*). One study reported that 20%–28% of children aged 9 months–18 years with asthma had injection-site pain and swelling at the site of influenza vaccination (*167*), and another study reported that 23% of children aged 6 months–4 years with chronic heart or lung disease had injection-site reactions (*153*). A blinded, randomized, cross-over study of 1,952 adults and children with asthma demonstrated that only self-reported "body aches" were reported more frequently after receipt of TIV (25%) than placebo-injection (21%) (*262*). However, a placebo-controlled trial of TIV indicated no difference in injection-site reactions among 53 children aged 6 months–6 years with high-risk medical conditions or among 305 healthy children aged 3–12 years (*157*).

Among children with high-risk medical conditions, one study of 52 children aged 6 months–3 years reported fever among 27% and irritability and insomnia among 25% (*153*), and a study among 33 children aged 6–18 months reported that one child had irritability and one had a fever and seizure after vaccination (*263*). No placebo comparison group was used in these studies.

Immunocompromised Persons

Data demonstrating safety of TIV for HIV-infected persons are limited, but no evidence exists that vaccination has a clinically important impact on HIV infection or immunocompetence. One study demonstrated a transient (i.e., 2–4 week) increase in HIV RNA (ribonucleic acid) levels in one

HIV-infected person after influenza virus infection (*264*). Studies have demonstrated a transient increase in replication of HIV-1 in the plasma or peripheral blood mononuclear cells of HIV-infected persons after vaccine administration (*202,265*). However, more recent and better-designed studies have not documented a substantial increase in the replication of HIV (*266–269*). CD4+ T-lymphocyte cell counts or progression of HIV disease have not been reduced after influenza vaccination among HIV-infected persons compared with unvaccinated HIV-infected persons (*202,270*). Limited information is available about the effect of antiretroviral therapy on increases in HIV RNA levels after either natural influenza virus infection or influenza vaccination (*94,271*).

Data are similarly limited for persons with other immunocompromising conditions. In small studies, vaccination did not affect allograft function or cause rejection episodes in recipients of kidney transplants (*205,206*), heart transplants (*207*), or liver transplants (*208*).

Immediate Hypersensitivity Reactions After Receipt of Influenza Vaccines

Vaccine components rarely can cause allergic reactions, also called immediate hypersensitivity reactions, among certain recipients. Immediate hypersensitivity reactions are mediated by preformed immunoglobulin E (IgE) antibodies against a vaccine component and usually occur within minutes to hours of exposure (*272*). Symptoms of immediate hypersensitivity range from mild urticaria (hives) and angioedema to anaphylaxis. Anaphylaxis is a severe life-threatening reaction that involves multiple organ systems and can progress rapidly. Symptoms and signs of anaphylaxis can include but are not limited to generalized urticaria, wheezing, swelling of the mouth and throat, difficulty breathing, vomiting, hypotension, decreased level of consciousness, and shock. Minor symptoms such as red eyes or hoarse voice also might be present *(246,272–275)*.

Allergic reactions might be caused by the vaccine antigen, residual animal protein, antimicrobial agents, preservatives, stabilizers, or other vaccine components (*276*). Manufacturers use a variety of compounds to inactivate influenza viruses and add antibiotics to prevent bacterial growth. Package inserts for specific vaccines of interest should be consulted for additional information. ACIP has recommended that all vaccine providers should be familiar with the office emergency plan and be certified in cardiopulmonary resuscitation (*246*). The Clinical Immunization Safety Assessment (95% CISA) network, a collaboration between CDC and six medical research centers with expertise in vaccination safety, has developed an algorithm to guide evaluation and revaccination decisions for persons with suspected immediate hypersensitivity after vaccination (*272*).

Immediate hypersensitivity reaction after receipt of TIV and LAIV are rare. A VSD study of children aged <18 years in four health maintenance organizations during 1991–1997 estimated the overall risk for postvaccination anaphylaxis after childhood vaccine to be approximately 1.5 cases per 1 million doses administered, and in this study, no cases were identified in TIV recipients (*277*). Anaphylaxis occurring after receipt of TIV and LAIV in adults has been reported rarely to VAERS (*257*).

Some immediate hypersensitivity reactions after receipt of TIV or LAIV are caused by the presence of residual egg protein in the vaccines (*278*). Although influenza vaccines contain only a limited quantity of egg protein, this protein can induce immediate hypersensitivity reactions among persons who have severe egg allergy. Asking persons if they can eat eggs without adverse effects is a reasonable way to determine who might be at risk for allergic reactions from receiving influenza vaccines (*246*). Persons who have had symptoms such as hives or swelling of the lips or tongue or who have experienced acute respiratory distress after eating eggs should consult a physician for appropriate evaluation to help determine if future influenza vaccine should be administered. Persons who have documented IgE-mediated hypersensitivity to eggs, including those who have had occupational asthma related to egg exposure or other allergic responses to egg protein, also might be at increased risk for allergic reactions to influenza vaccine, and consultation with a physician before vaccination should be considered (*279–281*). A regimen has been developed for administering influenza vaccine to asthmatic children with severe disease and egg hypersensitivity (*280*).

Hypersensitivity reactions to other vaccine components also can occur rarely. Although exposure to vaccines containing thimerosal can lead to delayed-type (Type IV) hypersensitivity (*282*), the majority of patients do not have reactions to thimerosal when it is administered as a component of vaccines, even when patch or intradermal tests for thimerosal indicate hypersensitivity (*283,284*). When reported, hypersensitivity to thimerosal typically has consisted of local delayed hypersensitivity reactions (*283*).

Ocular and Respiratory Symptoms After Receipt of TIV

Ocular or respiratory symptoms have been reported occasionally within 24 hours after TIV administration, but these symptoms typically are mild and resolve quickly without specific treatment. In some trials conducted in the United States,

ocular or respiratory symptoms included red eyes (<1%–6%), cough (1%–7%), wheezing (1%), and chest tightness (1%–3%) (*274,275,285–287*). However, most of these trials were not placebo-controlled, and causality cannot be determined. In addition, ocular and respiratory symptoms are features of a variety of respiratory illnesses and seasonal allergies that would be expected to occur coincidentally among vaccine recipients unrelated to vaccination. A placebo-controlled vaccine effectiveness study among young adults indicated that 2% of persons who received the 2006–07 formulation of Fluzone (sanofi pasteur) reported red eyes compared with none of the controls (p=0.03) (*288*). A similar trial conducted during the 2005–06 influenza season indicated that 3% of Fluzone recipients reported red eyes compared with 1% of placebo recipients; however the difference was not statistically significant (*289*).

Oculorespiratory syndrome (ORS), an acute, self-limited reaction to TIV with prominent ocular and respiratory symptoms, was first described during the 2000–01 influenza season in Canada. The initial case-definition for ORS was the onset of one or more of the following within 2–24 hours after receiving TIV: bilateral red eyes and/or facial edema and/or respiratory symptoms (coughing, wheezing, chest tightness, difficulty breathing, sore throat, hoarseness or difficulty swallowing, cough, wheeze, chest tightness, difficulty breathing, sore throat, or facial swelling) (*290*). ORS was first described in Canada and strongly associated with one vaccine preparation (Fluviral S/F, Shire Biologics, Quebec, Canada) not available in the United States during the 2000–01 influenza season (*291*). Subsequent investigations identified persons with ocular or respiratory symptoms meeting an ORS case-definition in safety monitoring systems and trials that had been conducted before 2000 in Canada, the United States, and several European countries (*292–294*).

The cause of ORS has not been established; however, studies suggest that the reaction is not IgE-mediated (*295*). After changes in the manufacturing process of the vaccine preparation associated with ORS during 2000–01, the incidence of ORS in Canada was reduced greatly (*293*). In one placebo-controlled study, only hoarseness, cough, and itchy or sore eyes (but not red eyes) were strongly associated with a reformulated Fluviral preparation. These findings indicated that ORS symptoms following use of the reformulated vaccine were mild, resolved within 24 hours, and might not typically be of sufficient concern to cause vaccine recipients to seek medical care (*296*).

Ocular and respiratory symptoms reported after TIV administration, including ORS, have some similarities with immediate hypersensitivity reactions. One study indicated that the risk for ORS recurrence with subsequent vaccination is low, and persons with ocular or respiratory symptoms (e.g., bilateral red eyes, cough, sore throat, or hoarseness) after receipt of TIV that did not involve the lower respiratory tract have been revaccinated without reports of SAEs after subsequent exposure to TIV (*297*).

Revaccination in Persons Who Experienced Ocular or Respiratory Symptoms After Receipt of TIV

When assessing whether a patient who experienced ocular and respiratory symptoms should be revaccinated, providers should determine if concerning signs and symptoms of Ig-E mediated immediate hypersensitivity are present (see Immediate Hypersensitivity after Influenza Vaccines). Healthcare providers who are unsure whether symptoms reported or observed after receipt of TIV represent an IgE-mediated hypersensitivity immune response should seek advice from an allergist/immunologist. Persons with symptoms of possible IgE-mediated hypersensitivity after receipt of TIV should not receive influenza vaccination unless hypersensitivity is ruled out or revaccination is administered under close medical supervision (*272*).

Ocular or respiratory symptoms observed after receipt of TIV often are coincidental and unrelated to TIV administration, as observed among placebo recipients in some randomized controlled studies. Determining whether ocular or respiratory symptoms are coincidental or related to possible ORS might not be possible. Persons who have had red eyes, mild upper facial swelling, or mild respiratory symptoms (e.g., sore throat, cough, or hoarseness) after receipt of TIV without other concerning signs or symptoms of hypersensitivity can receive TIV in subsequent seasons without further evaluation. Two studies indicated that persons who had symptoms of ORS after receipt of TIV were at a higher risk for ORS after subsequent TIV administration; however, these events usually were milder than the first episode (*297,298*).

Contraindications and Precautions for Use of TIV

TIV is contraindicated and should not be administered to persons known to have anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine unless the recipient has been desensitized. Prophylactic use of antiviral agents is an option for preventing influenza among such persons. Information about vaccine components is located in package inserts from each manufacturer. Persons with moderate to severe acute febrile illness usually should not be vaccinated until their symptoms have abated. Moderate or severe acute illness with or without fever is a precaution for TIV. GBS within 6

weeks following a previous dose of influenza vaccine is considered to be a precaution for use of influenza vaccines.

Guillain-Barré Syndrome and TIV

The annual incidence of GBS is 10–20 cases per 1 million adults (*299*). Substantial evidence exists that multiple infectious illnesses, most notably *Campylobacter jejuni* gastrointestinal infections and upper respiratory tract infections, are associated with GBS (*300–302*). A recent study identified serologically confirmed influenza virus infection as a trigger of GBS, with time from onset of influenza illness to GBS of 3–30 days. The estimated frequency of influenza-related GBS was four to seven times higher than the frequency that has been estimated for influenza-vaccine–associated GBS (*303*).

The 1976 swine influenza vaccine was associated with an increased frequency of GBS, estimated at one additional case of GBS per 100,000 persons vaccinated (*304,305*). The risk for influenza-vaccine–associated GBS was higher among persons aged ≥25 years than among persons aged <25 years (*306*). However, obtaining epidemiologic evidence for a small increase in risk for a rare condition with multiple causes is difficult, and no evidence consistently exists for a causal relation between subsequent vaccines prepared from other influenza viruses and GBS.

None of the studies conducted using influenza vaccines other than the 1976 swine influenza vaccine has demonstrated an increase in GBS associated with influenza vaccines on the order of magnitude seen in 1976–77. During three of four influenza seasons studied during 1977–1991, the overall relative risk estimates for GBS after influenza vaccination were not statistically significant in any of these studies (*307–309*). However, in a study of the 1992–93 and 1993–94 seasons, the overall relative risk for GBS was 1.7 (95% CI = 1.0–2.8; p=0.04) during the 6 weeks after vaccination, representing approximately one additional case of GBS per 1 million persons vaccinated; the combined number of GBS cases peaked 2 weeks after vaccination (*305*). Results of a study that examined health-care data from Ontario, Canada, during 1992–2004 demonstrated a small but statistically significant temporal association between receiving influenza vaccination and subsequent hospital admission for GBS. However, no increase in cases of GBS at the population level was reported after introduction of a mass public influenza vaccination program in Ontario beginning in 2000 (*310*). Data from VAERS have documented decreased reporting of GBS occurring after vaccination across age groups over time, despite overall increased reporting of other non-GBS conditions occurring after administration of influenza vaccine (*304*). Published data from the United Kingdom's General Practice Research Database (GPRD) indicated that influenza vaccine was associated with a decreased risk for GBS, although whether this was associated with protection against influenza or confounding because of a "healthy vaccinee" effect (e.g., healthier persons might be more likely to be vaccinated and also be at lower risk for GBS) (*311*) is unclear. A separate GPRD analysis identified no association between vaccination and GBS for a 9-year period; only three cases of GBS occurred within 6 weeks after administration of influenza vaccine (*312*). A third GPRD analysis indicated that GBS was associated with recent ILI, but not influenza vaccination (*313,314*).

The estimated risk for GBS (on the basis of the few studies that have demonstrated an association between vaccination and GBS) is low (i.e., approximately one additional case per 1 million persons vaccinated). The potential benefits of influenza vaccination in preventing serious illness, hospitalization, and death substantially outweigh these estimates of risk for vaccine-associated GBS. No evidence indicates that the case-fatality ratio for GBS differs among vaccinated persons and those not vaccinated. Preliminary data from the systems monitoring influenza A (H1N1) 2009 monovalent vaccines suggest that if a risk exists for GBS after receiving inactivated vaccines, it is not substantially higher than that reported in some seasons for TIV (*315*); analyses are ongoing to quantify any potential GBS risk (*316*).

Use of TIV Among Patients with a History of GBS

The incidence of GBS among the general population is low, but persons with a history of GBS have a substantially greater likelihood of subsequently experiencing GBS than persons without such a history (*299*). Thus, the likelihood of coincidentally experiencing GBS after influenza vaccination is expected to be greater among persons with a history of GBS than among persons with no history of this syndrome. Whether influenza vaccination specifically might increase the risk for recurrence of GBS is unknown. Among 311 patients with GBS who responded to a survey, 11 (4%) reported some worsening of symptoms after influenza vaccination; however, some of these patients had received other vaccines at the same time, and recurring symptoms were generally mild (*317*). However, as a precaution, persons who are not at high risk for severe influenza complications and who are known to have experienced GBS within 6 weeks of receipt of an influenza vaccine generally should not be vaccinated. As an alternative, physicians might consider using influenza antiviral chemoprophylaxis for these persons. Although data are limited, the established benefits of influenza vaccination might outweigh the risks for many persons who have a history of GBS and who also are at high risk for severe complications from influenza.

Vaccine Preservative (Thimerosal) in Multidose Vials of TIV

Thimerosal, a mercury-containing antibacterial compound, has been used as a preservative in vaccines and other medications since the 1930s (*318*) and is used in multidose vial preparations of TIV to reduce the likelihood of bacterial growth. No scientific evidence indicates that thimerosal in vaccines, including influenza vaccines, is a cause of adverse events other than occasional local hypersensitivity reactions in vaccine recipients. In addition, no scientific evidence indicates that thimerosal-containing vaccines are a cause of adverse events among children born to women who received vaccine during pregnancy. The weight of accumulating evidence does not suggest an increased risk for neurodevelopment disorders from exposure to thimerosal-containing vaccines (*319–328*). The U.S. Public Health Service and other organizations have recommended that efforts be made to eliminate or reduce the thimerosal content in vaccines as part of a strategy to reduce mercury exposures from all sources (*319,320,329*). Also, continuing public concerns about exposure to mercury in vaccines has been viewed as a potential barrier to achieving higher vaccine coverage levels and reducing the burden of vaccine-preventable diseases, including influenza. Since mid-2001, vaccines routinely recommended for infants aged <6 months in the United States have been manufactured either without or with greatly reduced (trace) amounts of thimerosal. As a result, a substantial reduction in the total mercury exposure from vaccines for infants and children already has been achieved (*246*). ACIP and other federal agencies and professional medical organizations continue to support efforts to provide thimerosal-preservative–free vaccine options.

The U.S. vaccine supply for infants and pregnant women is in a period of transition as manufacturers expand the availability of thimerosal-reduced or thimerosal-free vaccine to reduce the cumulative exposure of infants to mercury. Other environmental sources of mercury exposure are more difficult or impossible to avoid or eliminate (*319*). The benefits of influenza vaccination for all recommended groups, including pregnant women and young children, outweigh concerns on the basis of a theoretic risk from thimerosal exposure through vaccination. The risks for severe illness from influenza virus infection are elevated among both young children and pregnant women, and vaccination has been demonstrated to reduce the risk for severe influenza illness and subsequent medical complications. In contrast, no harm from exposure to vaccine containing thimerosal preservative has been demonstrated. For these reasons, persons recommended to receive TIV may receive any age- and risk factor–appropriate vaccine preparation, depending on availability. An analysis of VAERS reports identified no difference in the safety profile of preservative-containing compared with preservative-free TIV vaccines in infants aged 6–23 months (*251*).

Nonetheless, some states have enacted legislation banning the administration of vaccines containing mercury; the provisions defining mercury content vary (*330*). LAIV and many of the single-dose vial or syringe preparations of TIV are thimerosal-free, and the number of influenza vaccine doses that do not contain thimerosal as a preservative is expected to increase (Table 2). However, these laws might present a barrier to vaccination unless influenza vaccines that do not contain thimerosal as a preservative are routinely available in those states.

Dosage, Administration, and Storage of LAIV

Each dose of LAIV contains the same three vaccine antigens used in TIV. However, the antigens are constituted as live, attenuated, cold-adapted, temperature-sensitive vaccine viruses. Providers should refer to the package insert, which contains additional information about the formulation of this vaccine and other vaccine components. LAIV does not contain thimerosal. LAIV is made from attenuated viruses that are able to replicate efficiently only at temperatures present in the nasal mucosa. LAIV recipients might experience nasal congestion or mild fever, which is probably a result of effects of intranasal vaccine administration or local viral replication. However, LAIV does not typically cause the more prominent systemic symptoms of influenza such as high fever, myalgia, and severe fatigue (*331*).

LAIV is intended for intranasal administration only and should not be administered by the intramuscular, intradermal, or intravenous route. LAIV is not licensed for vaccination of children aged <2 years or adults aged >49 years. LAIV is supplied in a prefilled, single-use sprayer containing 0.2 mL of vaccine. Approximately 0.1 mL (i.e., half of the total sprayer contents) is sprayed into the first nostril while the recipient is in the upright position. An attached dose-divider clip is removed from the sprayer to administer the second half of the dose into the other nostril. LAIV is shipped at 35°F–46°F (2°C–8°C). LAIV should be stored at 35°F–46°F (2°C–8°C) on receipt and can remain at that temperature until the expiration date is reached (*331*). Vaccine prepared for a previous influenza season should not be administered to provide protection for any subsequent season.

Shedding, Transmission, and Stability of LAIV Viruses

Available data indicate that both children and adults vaccinated with LAIV can shed vaccine viruses after vaccination, although in lower amounts than occur typically with shedding of wild-type influenza viruses. In rare instances, shed vaccine viruses can be transmitted from vaccine recipients to unvaccinated persons. However, serious illnesses have not been reported among unvaccinated persons who have been infected inadvertently with vaccine viruses.

One study of 197 children aged 8–36 months in a child care center assessed transmissibility of vaccine viruses from 98 vaccinated children to the other 99 unvaccinated children; 80% of vaccine recipients shed one or more virus strains (mean duration: 7.6 days). One influenza type B vaccine strain isolate was recovered from a placebo recipient and was confirmed to be vaccine-type virus. The type B isolate retained the cold-adapted, temperature-sensitive, attenuated phenotype, and it possessed the same genetic sequence as a virus shed from a vaccine recipient who was in the same play group. The placebo recipient from whom the influenza type B vaccine strain was isolated had symptoms of a mild upper respiratory illness but did not experience any serious clinical events. The estimated probability of acquiring vaccine virus after close contact with a single LAIV recipient in this child care population was 1%–2% (*332*).

Studies assessing whether vaccine viruses are shed have been based on viral cultures or polymerase chain reaction (PCR) detection of vaccine viruses in nasal aspirates from persons who have received LAIV. Among 345 subjects aged 5–49 years, 30% had detectable virus in nasal secretions obtained by nasal swabbing after receiving LAIV. The duration of virus shedding and the amount of virus shed was correlated inversely with age, and maximal shedding occurred within 2 days of vaccination. Symptoms reported after vaccination, including runny nose, headache, and sore throat, did not correlate with virus shedding (*333*). Other smaller studies have reported similar findings (*334,335*). Vaccine strain virus was detected from nasal secretions in one (2%) of 57 HIV-infected adults who received LAIV, none of 54 HIV-negative participants (*336*), and three (13%) of 23 HIV-infected children compared with seven (28%) of 25 children who were not HIV-infected (*337*). No participants in these studies had detectable virus beyond 10 days after receipt of LAIV. The possibility of person-to-person transmission of vaccine viruses was not assessed in these studies (*334–337*).

In clinical trials, viruses isolated from vaccine recipients have retained attenuated phenotypes. In one study, nasal and throat swab specimens were collected from 17 study participants for 2 weeks after vaccine receipt (*338*). Virus isolates were analyzed by multiple genetic techniques. All isolates retained the LAIV genotype after replication in the human host, and all retained the cold-adapted and temperature-sensitive phenotypes. A study conducted in a child care setting demonstrated that limited genetic change occurred in the LAIV strains following replication in the vaccine recipients (*339*).

Immunogenicity, Efficacy, and Effectiveness of LAIV

LAIV virus strains replicate primarily in nasopharyngeal epithelial cells. The protective mechanisms induced by vaccination with LAIV are not understood completely but appear to involve both serum and nasal secretory antibodies. The immunogenicity of the approved LAIV has been assessed in multiple studies conducted among children and adults (*147,340–345*).

Healthy Children

A randomized, double-blind, placebo-controlled trial among 1,602 healthy children aged 15–71 months assessed the efficacy of LAIV against culture-confirmed influenza during two seasons (*346,347*). This trial included a subset of children aged 60–71 months who received 2 doses in the first season. During the first season (1996–97), when vaccine and circulating virus strains were well-matched, efficacy against culture-confirmed influenza was 94% for participants who received 2 doses of LAIV separated by ≥6 weeks, and 89% for those who received 1 dose. During the second season (1997–98), when the A (H3N2) component in the vaccine was not well-matched with circulating virus strains, efficacy (1 dose) was 86%, for an overall efficacy for two influenza seasons of 92%. Receipt of LAIV also resulted in 21% fewer febrile illnesses and a significant decrease in acute otitis media requiring antibiotics (*346,348*). Other randomized, placebo-controlled trials demonstrating the efficacy of LAIV in young children against culture-confirmed influenza include a study conducted among children aged 6–35 months attending child care centers during consecutive influenza seasons (*349*) in which 85%–89% efficacy was observed, and a study conducted among children aged 12–36 months living in Asia during consecutive influenza seasons in which 64%–70% efficacy was documented (*350*). In one community-based, nonrandomized open-label study, reductions in MAARI were observed among children who received 1 dose of LAIV during the 1990–00 and 2000–01 influenza seasons even though antigenically drifted influenza A/H1N1 and B viruses were circulating during that season (*148*). LAIV efficacy in preventing laboratory-confirmed influenza also has been demonstrated in studies comparing the efficacy of LAIV with TIV rather than with a placebo (see Comparisons

of LAIV and TIV Efficacy or Effectiveness). In clinical trials, an increased risk for wheezing postvaccination was observed in LAIV recipients aged <24 months. An increase in hospitalizations also was observed in children aged <24 months after vaccination with LAIV (*331*).

Healthy Adults

A randomized, double-blind, placebo-controlled trial of LAIV effectiveness among 4,561 healthy working adults aged 18–64 years assessed multiple endpoints, including reductions in self-reported respiratory tract illness without laboratory confirmation, work loss, health-care visits, and medication use during influenza outbreak periods. The study was conducted during the 1997–98 influenza season, when the vaccine and circulating A (H3N2) strains were not well-matched. The frequency of febrile illnesses was not substantially decreased among LAIV recipients compared with those who received placebo. However, vaccine recipients had substantially fewer severe febrile illnesses (19% reduction) and febrile upper respiratory tract illnesses (24% reduction), and substantial reductions in days of illness, days of work lost, days with health-care–provider visits, and use of prescription antibiotics and over-the-counter medications (*351,352*). Efficacy against culture-confirmed influenza in a randomized, placebo-controlled study among young adults was 57% in the 2004–05 influenza season, 43% in the 2005–06 influenza season, and 51% in the 2007–08 influenza season, although efficacy in 2004–05 and 2005–06 was not demonstrated to be substantially greater than placebo (*187,288,289*).

Adverse Events After Receipt of LAIV

Healthy Children Aged 2–18 Years

In a subset of healthy children aged 60–71 months from one clinical trial, certain signs and symptoms were reported more often after the first dose among LAIV recipients (n = 214) than among placebo recipients (n = 95), including runny nose (48% and 44%, respectively); headache (18% and 12%, respectively); vomiting (5% and 3%, respectively); and myalgias (6% and 4%, respectively) (*346*). However, these differences were not statistically significant. In other trials, signs and symptoms reported after LAIV administration have included runny nose or nasal congestion (20%–75%), headache (2%–46%), fever (0–26%), vomiting (3%–13%), abdominal pain (2%), and myalgias (0–21%) (*340,342,343,349,353–356*). These symptoms were associated more often with the first dose and were self-limited. A placebo-controlled trial in 9,689 children aged 1–17 years assessed prespecified medically attended outcomes during the 42 days after vaccination (*355*). Following >1,500 statistical analyses in the 42 days after LAIV, elevated risks that were assessed to be biologically plausible were observed for asthma, upper respiratory infection, musculoskeletal pain, otitis media with effusion, and adenitis/adenopathy. The increased risk for wheezing events after LAIV was observed among children aged 18–35 months (RR: 4.06; 90% CI = 1.3–17.9). Of the 16 children with asthma-related events in this study, seven had a history of asthma on the basis of subsequent medical record review. None required hospitalization, and elevated risks for asthma were not observed in other age groups (*355*). In this study, the rate of SAEs was 0.2% in LAIV and placebo recipients; none of the SAEs was judged to be related to the vaccine by the study investigators (*355*).

In a randomized trial, LAIV and TIV were compared among children aged 6–59 months (*357*). Children with medically diagnosed or treated wheezing within 42 days before enrollment or with a history of severe asthma were excluded from this prelicensure study. Among children aged 24–59 months who received LAIV, the rate of medically significant wheezing, using a prespecified definition, was not greater compared with those who received TIV (*357*). Wheezing was observed more frequently among younger LAIV recipients aged 6–23 months in this study; LAIV is not licensed for this age group.

Another study was conducted among >11,000 children aged 18 months–18 years in which 18,780 doses of vaccine were administered over 4 years. For children aged 18 months–4 years, no increase was reported in asthma visits 0–15 days after vaccination compared with the prevaccination period. A significant increase in asthma events was reported 15–42 days after vaccination, but only in vaccine year 1 (*358*). A 4-year, open-label field trial study assessed LAIV safety of >2,000 doses administered to children aged 18 months–18 years with a history of intermittent wheeze who were otherwise healthy. Among these children, no increased risk was reported for medically attended acute respiratory illnesses, including acute asthma exacerbation, during the 0–14 or 0–42 days after LAIV compared with the pre- and postvaccination reference periods (*359*).

Initial data from VAERS during 2007–2008 and 2008–2009, following ACIP's recommendation for use of LAIV in healthy children aged 2–4 years, did not demonstrate an increased frequency of wheezing after administration of LAIV. However, data also indicate that uptake of LAIV among children aged 2–4 years was limited (CDC, unpublished data, 2010). Safety monitoring for wheezing events after LAIV is ongoing.

Adults Aged <50 Years

Among adults, runny nose or nasal congestion (28%–78%), headache (16%–44%), and sore throat (15%–27%) have been reported more often among vaccine recipients than placebo recipients (*346,360*). In one clinical trial among a subset of

healthy adults aged 18–49 years, signs and symptoms reported significantly more often ($p<0.05$) among LAIV recipients (n = 2,548) than placebo recipients (n = 1,290) within 7 days after each dose included cough (14% and 11%, respectively), runny nose (45% and 27%, respectively), sore throat (28% and 17%, respectively), chills (9% and 6%, respectively), and tiredness/weakness (26% and 22%, respectively) (*144*). A review of 460 reports to VAERS after distribution of approximately 2.5 million doses during the 2003–04 and 2004–05 influenza seasons did not indicate any new safety concerns (*361*). Few of the LAIV VAERS reports (9%) were SAEs; respiratory events (47%) were the most common conditions reported (*361*).

The 2010–11 seasonal live attenuated influenza vaccine will contain an influenza A (H1N1) California/7/2009-like strain, which was also the strain used for the 2009 pandemic H1N1 monovalent live attenuated vaccine. (See Safety Monitoring of Pandemic 2009 H1N1 Monovalent Vaccines for additional information about 2009 H1N1 monovalent vaccine safety data among children and adults.)

Persons at Higher Risk for Influenza-Related Complications

Limited data assessing the safety of LAIV use for certain groups at higher risk for influenza-related complications are available. In one study of 54 HIV-infected persons aged 18–58 years with CD4+ counts ≥200 cells/mm^3 who received LAIV, no SAEs were reported during a 1-month follow-up period (*336*). Similarly, one study demonstrated no significant difference in the frequency of adverse events or viral shedding among HIV-infected children aged 1–8 years on effective antiretroviral therapy who were administered LAIV compared with HIV-uninfected children receiving LAIV (*337*). LAIV was well-tolerated among adults aged ≥65 years with chronic medical conditions (*362*). These findings suggest that persons at risk for influenza complications who have inadvertent exposure to LAIV would not have significant adverse events or prolonged viral shedding and that persons who have contact with persons at higher risk for influenza-related complications may receive LAIV.

Safety Monitoring of Pandemic 2009 H1N1 Monovalent Vaccines

The 2010–11 seasonal influenza vaccine will contain an influenza A (H1N1) California/7/2009-like strain, which was also the strain used for the 2009 pandemic H1N1 monovalent vaccines. Clinical immunogenicity and safety studies of the 2009 H1N1 monovalent vaccines indicate that the reactogenicity profile in children and adults is similar to seasonal influenza vaccines (*158–160,184*). Ongoing comprehensive safety monitoring of the pandemic 2009 H1N1 vaccine was implemented as part of the pandemic immunization program (*363*). A nongovernment working group was established by the National Vaccine Advisory Committee to provide an independent review of safety data, with members representing other federal advisory committees as well as experts in internal medicine, pediatrics, immunology, and vaccine safety (*314*). Data from the first 2 months of implementation of H1N1 vaccination from VAERS and VSD suggested a similar safety profile for influenza A (H1N1) 2009 monovalent vaccines and seasonal influenza vaccines. As of July 2010, analysis and review of vaccine safety data from numerous systems were underway (*314,316*).

Comparisons of LAIV and TIV Efficacy or Effectiveness

Both TIV and LAIV have been demonstrated to be effective in children and adults. However, data directly comparing the efficacy or effectiveness of these two types of influenza vaccines are limited and insufficient to identify whether one vaccine might offer a clear advantage over the other in certain settings or populations. Studies comparing the efficacy of TIV to that of LAIV have been conducted in a variety of settings and populations using several different outcomes. One randomized, double-blind, placebo-controlled challenge study that was conducted among 92 healthy adults aged 18–41 years assessed the efficacy of both LAIV and TIV in preventing influenza infection when challenged with wild-type strains that were antigenically similar to vaccine strains (*364*). The overall efficacy in preventing laboratory-documented influenza from all three influenza strains combined was 85% and 71%, respectively, when challenged 28 days after vaccination by viruses to which study participants were susceptible before vaccination. The difference in efficacy between the two vaccines was not statistically significant in this limited study. No additional challenges were conducted to assess efficacy at time points later than 28 days (*364*). In a randomized, double-blind, placebo-controlled trial that was conducted among young adults during the 2004–05 influenza season, when the majority of circulating H3N2 viruses were antigenically drifted from that season's vaccine viruses, the efficacy of LAIV and TIV against culture-confirmed influenza was 57% and 77%, respectively. The difference in efficacy was not statistically significant and was attributable primarily to a difference in efficacy against influenza B (*289*). Similar studies conducted during the 2005–06 and 2007–08 influenza seasons identified no significant difference in vaccine efficacy in 2005–06 (*288*), but a 50% relative efficacy or TIV compared with LAIV in the 2007–08 season (*187*).

A randomized controlled clinical trial conducted among children aged 6–59 months during the 2004–05 influenza season demonstrated a 55% reduction in cases of culture-confirmed influenza among children who received LAIV compared with those who received TIV (*357*). In this study, LAIV efficacy was higher compared with TIV against antigenically drifted viruses and well-matched viruses (*357*). An open-label, nonrandomized, community-based influenza vaccine trial conducted during an influenza season when circulating H3N2 strains were poorly matched with strains contained in the vaccine also indicated that LAIV, but not TIV, was effective against antigenically drifted H3N2 strains during that influenza season. In this study, children aged 5–18 years who received LAIV had significant protection against laboratory-confirmed influenza (37%) and pneumonia and influenza events (50%) (*365*). An observational study conducted among military personnel aged 17–49 years over three influenza seasons indicated that persons who received TIV had a substantially lower incidence of health-care encounters resulting in diagnostic coding for pneumonia and influenza compared with those who received LAIV. However, among new recruits being vaccinated for the first time, the incidence of pneumonia- and influenza-coded health-care encounters among those received LAIV was similar to those receiving TIV (*366*).

Although LAIV is not licensed for use in persons with risk factors for influenza complications, certain studies have compared the efficacy of LAIV to TIV in these groups. LAIV provided 32% increased protection in preventing culture-confirmed influenza compared with TIV in one study conducted among children aged ≥6 years and adolescents with asthma (*367*) and 52% increased protection compared with TIV among children aged 6–71 months with recurrent respiratory tract infections (*368*).

Effectiveness of Vaccination for Decreasing Transmission to Contacts

Decreasing transmission of influenza from caregivers and household contacts to persons at high risk might reduce ILI and complications among persons at high risk. Influenza virus infection and ILI are common among HCP (*369–371*). Influenza outbreaks have been attributed to low vaccination rates among HCP in hospitals and long-term–care facilities (*372–374*). One serosurvey demonstrated that 23% of HCP had serologic evidence of influenza virus infection during a single influenza season; the majority had mild illness or subclinical infection (*369*). Observational studies have demonstrated that vaccination of HCP is associated with decreased deaths among nursing home patients (*375,376*). In one cluster-randomized controlled trial that included 2,604 residents of 44 nursing homes, significant decreases in mortality, ILI, and medical visits for ILI care were demonstrated among residents in nursing homes in which staff were offered influenza vaccination (coverage rate: 48%) compared with nursing homes in which staff were not provided with vaccination (coverage rate: 6%) (*377*). Another trial demonstrated substantially lower rates of ILI among residents and staff absences in nursing homes where staff were specifically targeted for vaccination (coverage rate: 70%) compared with nursing homes where no intervention was attempted (coverage rate: 32%) (*378*). A review concluded that vaccination of HCP in settings in which patients also were vaccinated provided significant reductions in deaths among elderly patients from all causes and deaths from pneumonia (*379*).

Epidemiologic studies of community outbreaks of influenza demonstrate that school-aged children typically have the highest influenza illness attack rates, suggesting routine universal vaccination of children might reduce transmission to their household contacts and possibly others in the community. Results from certain studies have indicated that the benefits of vaccinating children might extend to protection of their adult contacts and to persons at risk for influenza complications in the community. However, these data are limited, and most studies have not used laboratory-confirmed influenza as an outcome measure. A single-blinded, randomized controlled study conducted as part of a 1996–1997 vaccine effectiveness study demonstrated that vaccinating preschool-aged children with TIV reduced influenza-related morbidity among some household contacts (*380*). A randomized, placebo-controlled trial among children with recurrent respiratory tract infections demonstrated that members of families with children who had received a live attenuated virosomal vaccine formulation (not currently available in the United States) were substantially less likely to have respiratory tract infections and reported substantially fewer workdays lost compared with families with children who received placebo (*381*). One cluster randomized trial conducted among rural Hutterite communities in Canada compared laboratory confirmed influenza among unvaccinated persons in communities where children were administered influenza vaccine (coverage: 83%) among children aged 3–15 years with communities where children received hepatitis A vaccine. Influenza vaccine effectiveness for prevention of influenza among unvaccinated persons was 61% (95% CI = 8%–81%) (*382*)

In nonrandomized community-based studies, administration of LAIV has been demonstrated to reduce MAARI (*383,384*) and ILI-related economic and medical consequences (e.g., workdays lost and number of health-care provider visits) among contacts of vaccine recipients (*384*). Households with children attending schools in which school-based LAIV vac-

cination programs had been established reported less ILI and fewer physician visits during peak influenza season compared with households with children in schools in which no LAIV vaccination had been offered. However a decrease in the overall rate of school absenteeism was not reported in communities in which LAIV vaccination was offered (*384*). During an influenza outbreak during the 2005–06 influenza season, countywide school-based influenza vaccination was associated with reduced absenteeism among elementary and high school students in one county that implemented a school-based vaccination program compared with another county without such a program (*385*). These community-based studies have not used laboratory-confirmed influenza as an outcome.

Some studies also have documented reductions in influenza illness among persons living in communities where focused programs for vaccinating children have been conducted. A community-based observational study conducted during the 1968 pandemic using a univalent inactivated vaccine reported that a vaccination program targeting school-aged children (coverage rate: 86%) in one community reduced influenza rates within the community among all age groups compared with another community in which aggressive vaccination was not conducted among school-aged children (*386*). An observational study conducted in Russia demonstrated reductions in ILI among the community-dwelling elderly after implementation of a vaccination program using TIV for children aged 3–6 years (57% coverage achieved) and children and adolescents aged 7–17 years (72% coverage achieved) (*387*). In a nonrandomized community-based study conducted over three influenza seasons, 8%–18% reductions in the incidence of MAARI during the influenza season among adults aged ≥35 years were observed in communities in which LAIV was offered to all children aged ≥18 months (estimated coverage rate: 20%–25%) compared with communities that did not provide routine influenza vaccination programs for all children (*383*). In a subsequent influenza season, the same investigators documented a 9% reduction in MAARI rates during the influenza season among persons aged 35–44 years in intervention communities, where coverage was estimated at 31% among school children. However, MAARI rates among persons aged ≥45 years were lower in the intervention communities regardless of the presence of influenza in the community, suggesting that lower rates could not be attributed to vaccination of school children against influenza (*365*).

The largest study to examine the community effects of increasing overall vaccine coverage was an ecologic study that described the experience in Ontario, Canada, which is the only province to implement a universal influenza vaccination program beginning in 2000. On the basis of models developed from administrative and viral surveillance data, influenza-related mortality, hospitalizations, ED use, and physicians' office visits decreased substantially more in Ontario after program introduction than in other provinces, with the largest reductions observed in younger age groups (*388*). In addition, influenza-associated antibiotic prescriptions were substantially reduced compared with other provinces (*389*).

Efficacy and Effectiveness of Influenza Vaccination When Circulating Influenza Virus Strains Differ from Vaccine Strains

Vaccination can provide reduced but substantial cross-protection against drifted strains in some seasons, including reductions in severe outcomes such as hospitalization. Usually one or more circulating viruses with antigenic changes compared with the vaccine strains are identified in each influenza season. In addition, two distinct lineages of influenza B viruses have co-circulated in recent years, and limited cross-protection is observed against the lineage not represented in the vaccine (*70*). However, assessment of the clinical effectiveness of influenza vaccines cannot be determined solely by laboratory evaluation of the degree of antigenic match between vaccine and circulating strains. In some influenza seasons, circulating influenza viruses with significant antigenic differences predominate, and reductions in vaccine effectiveness sometimes are observed compared with seasons when vaccine and circulating strains are well-matched (*77,170,188,239,289,390*). However, even during years when vaccine strains were not antigenically well-matched to circulating strains (the result of antigenic drift), substantial protection has been observed against severe outcomes, presumably because of vaccine-induced cross-reacting antibodies (*77,188,289,352*). For example, in one study conducted during the 2003–04 influenza season, when the predominant circulating strain was an influenza A (H3N2) virus that was antigenically different from that season's vaccine strain, effectiveness against laboratory-confirmed influenza illness among persons aged 50–64 years was 60% among healthy persons and 48% among persons with medical conditions that increased the risk for influenza complications (*188*). An interim, within-season analysis during the 2007–08 influenza season indicated that vaccine effectiveness was 44% overall, 54% among healthy persons aged 5–49 years, and 58% against influenza A, despite the finding that viruses circulating in the study area were predominately a drifted influenza A (H3N2) and an influenza B strain from a different lineage compared with vaccine strains (*391*). Among children, both TIV and LAIV provide protection against infection even in seasons when vaccines and circulating strains are not well-matched. Vaccine effectiveness against ILI was 49%–69% in two observational

studies, and 49% against medically attended, laboratory-confirmed influenza in a case-control study conducted among young children during the 2003–04 influenza season, when a drifted influenza A (H3N2) strain predominated, based on viral surveillance data (*165,169*). However, the 2009–10 seasonal influenza vaccines provided no protection against medically attended illness caused by the pandemic 2009 influenza A (H1N1) virus, because of substantial changes in key viral antigens compared with recently circulating strains (*392*).

Continued improvements in collecting representative circulating viruses and use of surveillance data to forecast antigenic drift are needed. Manufacturing trivalent influenza virus vaccines is a challenging process that takes 6–8 months to complete. Shortening manufacturing time to increase the time to identify good vaccine candidate strains from among the most recent circulating strains also is important. Data from multiple seasons that are collected in a consistent manner are needed to better understand vaccine effectiveness during seasons when circulating and vaccine virus strains are not well-matched.

Cost-Effectiveness of Influenza Vaccination

Economic studies of influenza vaccination are difficult to compare because they have used different measures of both costs and benefits (e.g., cost-only, cost-effectiveness, cost-benefit, or cost-utility measures). However, most studies indicate that vaccination reduces or minimizes health care, societal, and individual costs and the productivity losses and absenteeism associated with influenza illness. One national study estimated the annual economic burden of seasonal influenza in the United States (using 2003 population and dollars) to be $87.1 billion, including $10.4 billion in direct medical costs (*78*).

Studies of influenza vaccination in the United States among persons aged ≥65 years have estimated substantial reductions in hospitalizations and deaths and overall societal cost savings (*234,235*). A study of a larger population comparing persons aged 50–64 years with those aged ≥65 years estimated the cost-effectiveness of influenza vaccination to be $28,000 per QALY saved (in 2000 dollars) in persons aged 50–64 years compared with $980 per QALY saved among persons aged ≥65 years (*393*).

Economic analyses among adults aged <65 years have reported mixed results regarding influenza vaccination. Two studies in the United States indicated that vaccination can reduce both direct medical costs and indirect costs from work absenteeism and reduced productivity (*79,394*). However, another U.S. study indicated no productivity and absentee savings in a strategy to vaccinate healthy working adults, although vaccination still was estimated to be cost-effective (*395*). In Ontario, Canada, where a universal influenza vaccination program was implemented beginning in 2000, costs were estimated to be approximately twice as much as a targeted vaccination program; however, the number of cases of influenza was reduced 61%, and influenza-related mortality declined 28%, saving an estimated 1,134 QALYs per season overall from a health-care payer perspective. Most cost savings were attributed to the avoidance of hospitalizations. The incremental cost-effectiveness ratio was estimated to be $10,797 Canadian per QALY gained (*396*).

Cost analyses have documented the considerable financial burden of illness among children. In a study of 727 children conducted at a medical center during 2000–2004, the mean total cost of hospitalization for influenza-related illness was $13,159 ($39,792 for patients admitted to an intensive care unit and $7,030 for patients cared for exclusively in the general wards) (*397*). A strategy that focuses on vaccinating children with medical conditions that confer a higher risk for influenza complications are more cost-effective than a strategy of vaccinating all children (*395*). An analysis that compared the costs of vaccinating children of varying ages with TIV and LAIV indicated that costs per QALY saved increased with age for both vaccines. In 2003 dollars per QALY saved, costs for routine vaccination using TIV were $12,000 for healthy children aged 6–23 months and $119,000 for healthy adolescents aged 12–17 years compared with $9,000 and $109,000, respectively, using LAIV (*398*). Economic evaluations of vaccinating children have demonstrated a wide range of cost estimates, but have generally found this strategy to be either cost saving or cost beneficial (*399–402*).

Economic analyses most influenced by the vaccination venue, with vaccination in medical-care settings incurring higher projected costs. In a published model, the mean cost (year 2004 values) of vaccination was lower in mass vaccination ($17.04) and pharmacy ($11.57) settings than in scheduled doctor's office visits ($28.67) (*403*). Vaccination in nonmedical settings was projected to be cost saving for healthy adults aged ≥50 years and for high-risk adults of all ages. For healthy adults aged 18–49 years, preventing an episode of influenza would cost $90 if vaccination were delivered in a pharmacy setting, $210 in a mass vaccination setting, and $870 during a scheduled doctor's office visit (*403*). Medicare and Vaccines for Children program reimbursement rates in recent years have been less than the costs associated with providing vaccination in a medical practice (*404,405*).

Vaccination Coverage Levels

Continued annual monitoring is needed to determine the effects on vaccination coverage of vaccine supply delays and

shortages, changes in influenza vaccination recommendations and target groups for vaccination, reimbursement rates for vaccine and vaccine administration, and other factors. One of the *Healthy People 2010* objectives (objective no. 14-29a) includes achieving an influenza vaccination coverage level of 90% for persons aged ≥65 years and among nursing home residents (*406,407*); new strategies to improve coverage are needed to achieve this objective (*408,409*).

On the basis of 2009 final data and 2010 early release data from the National Health Interview Survey (NHIS), estimated national influenza vaccine coverage during the 2007–08 and 2008–09 influenza seasons did not increase substantially among persons aged ≥65 years and those aged 50–64 years (Table 3) and are only slightly higher than coverage levels observed before the 2004–05 vaccine shortage year (*410–412*). In the 2007–08 and 2008–09 influenza seasons, estimated vaccination coverage levels (based on NHIS data) among adults with high-risk conditions aged 18–49 years were 30.4% and 33%, respectively, substantially lower than the *Healthy People 2000* and *Healthy People 2010* objectives of 60% (Table 3) (*406,407*). Among adults with asthma aged 18–49 years and 50–64 years, estimated coverage during the 2006–07 influenza season was 24% and 55% respectively; the national objective for coverage among adults with asthma is 60% (*413*). Epidemiologic studies conducted during the 2009 pandemic indicated that more hospitalizations and deaths were occurring among adults aged <65 years with high-risk conditions than among any other group, and these adults were among the initial target groups to receive the 2009 H1N1 vaccination while vaccine supply was limited (*414*). However, coverage among adults aged <65 years with medical conditions that confer a higher risk for influenza complications was <40% for the 2009 H1N1 monovalent vaccine (*415*).

During the 2009 influenza A (H1N1) pandemic, state-level estimates of seasonal vaccine coverage data for both seasonal influenza and the monovalent 2009 H1N1 vaccines were obtained via telephone surveys conducted by the Behavioral Risk Factor Surveillance System (BRFSS) and the National 2009 H1N1 Flu Survey. By January 31, 2010 estimated state seasonal influenza vaccination coverage among persons aged ≥6 months ranged from 30.3% to 54.5% (median: 40.6%). Median coverage was 41.2% for children aged 6 months–17 years, 38.3% for adults aged 18–49 years with high-risk conditions, 28.8% for adults aged 18–49 years without high-risk conditions, 45.5% for adults aged 50–64 years, and 69.3% for adults aged ≥65 years. These results, compared with the previous season, suggest large increases in coverage for children and a moderate increase for adults aged 18–49 years without high-risk compared with seasonal influenza vaccine coverage estimates in previous seasons (*415,416*). However, vaccine coverage estimates using BRFSS data typically have been higher than estimates derived from NHIS data (*416*).

Studies conducted among children and adults indicate that opportunities to vaccinate persons at risk for influenza complications (e.g., during hospitalizations for other causes) often are missed. In one study, 23% of children hospitalized with influenza and a comorbidity had a previous hospitalization during the preceding influenza vaccination season (*417*). In a study of hospitalized Medicare patients, only 31.6% were vaccinated before admission, 1.9% during admission, and 10.6% after admission (*418*). A study in New York City conducted during 2001–2005 among 7,063 children aged 6–23 months indicated that 2-dose vaccine coverage increased from 1.6% to 23.7% over time; however, although the average number of medical visits during which an opportunity to be vaccinated decreased during the course of the study from 2.9 to 2.0 per child, 55% of all visits during the final year of the study still represented a missed vaccination opportunity (*419*). Using standing orders in hospitals increases vaccination rates among hospitalized persons (*420*), and vaccination of hospitalized patients is safe and stimulates an appropriate immune response (*220*). In one survey, the strongest predictor of receiving vaccination was the survey respondent's belief that he or she was in a high-risk group, based on data from one survey; however, many persons in high-risk groups did not know that they were in a group recommended for vaccination (*421,422*). In one study, over half of adults who did not receive influenza vaccination reported that they would have received vaccine if this had been recommended by their health-care provider (*422*).

Reducing racial/ethnic health disparities, including disparities in influenza vaccination coverage, is an overarching national goal that is not being met (*407*). Estimated vaccination coverage levels in 2008 among persons aged ≥65 years were 70% for non-Hispanic whites, 52% for non-Hispanic blacks, and 52% for Hispanics (*423*). Among Medicare beneficiaries, other key factors that contribute to disparities in coverage include variations in the propensity of patients to actively seek vaccination and variations in the likelihood that providers recommend vaccination (*424,425*). One study estimated that eliminating these disparities in vaccination coverage would have an impact on mortality similar to the impact of eliminating deaths attributable to kidney disease among blacks or liver disease among Hispanics (*426*). Differences in coverage by race or ethnicity might be partly attributable to differences in beliefs about vaccine effectiveness and safety (*422*). Among nursing home patients, fewer blacks and Hispanics are offered vaccine or receive it compared with whites, and blacks refuse vaccination more frequently (*427*). Disparities in seasonal influenza vaccine coverage among adult whites (43%), blacks (31%), and Hispanics (31%) also were observed during 2009–2010 (*416*).

TABLE 3. Influenza vaccination* coverage levels for the 2006–07, 2007–08, and 2008–09 influenza seasons, among population groups — National Health Interview Survey (NHIS), United States, 2007–2009, and National Immunization Survey (NIS), 2006–2008.

Population Group	2006–07 season			2007–08 season			2008–09 season		
	Crude sample size†	Influenza vaccination level		Crude sample size	Influenza vaccination level		Crude sample size	Influenza vaccination level	
		%	(95% CI§)		%	(95% CI)		%	(95% CI)
Persons with an age indication									
Aged 6–23 mos (NIS¶)	9,710	31.8	(30.2–33.4)	11964	40.7	(39.1–42.2)	NA**	NA	NA
Aged 2–4 yrs	853	37.9	(34.2–41.7)	674	40.3	(35.8–45.0)	652	41.8)	(36.5–47.4)
Aged 50–64 yrs	3,746	36.0	(34.0–38.0)	3,258	38.4	(36.4–40.4)	3,136	40.1	(37.9–42.3)
Aged ≥65 yrs	3,086	65.6	(63.3–67.9)	2,658	66.3	(64.2–68.3)	2,455	65.5	(63.2–67.8)
Persons with high-risk conditions††									
Aged 5–17 yrs	387	33.0	(26.2–40.7)	262	36.2	(29.3–43.6)	273	34.7	(27.8–42.3)
Aged 18–49 yrs	1,186	25.5	(22.4–28.9)	1,049	30.4	(27.1–34.0)	1,087	33.0	(29.7–36.4)
Aged 50–64 yrs	1,117	46.1	(42.8–49.4)	1,001	48.4	(44.7–52.2)	1,048	51.3	(47.2–55.3)
Aged 18–64 yrs	2,303	35.3	(33.0–37.7)	2,050	38.8	(36.2–41.4)	2,135	42.0	(39.3–44.6)
Persons without high–risk conditions									
Aged 5–17 yrs	3,307	17.5	(15.9–19.2)	2,925	21.1	(19.3–23.1)	2,906	24.6	(22.4–26.9)
Aged 18–49 yrs	7,905	15.3	(14.2–16.4)	6,467	17.0	(15.7–18.3)	6,083	19.3	(18.1–20.7)
Aged 50–64 yrs	2,619	31.8	(29.5–34.1)	2,248	34.1	(31.7-36.6)	2,083	34.3	(31.8–36.9)
Pregnant women§§	177	13.4	(8.5–20.5)	113	24.2	(15.1–36.6)	177	11.3	(6.4–19.0)
Health-care workers¶¶	850	44.4	(40.2–48.7)	1,037	49.0	(45.1–52.8)	NA	NA	NA
Household contacts of persons at high risk, including children aged <5 years* **									
Aged 5–17 yrs	741	26.0	(21.5–31.1)	968	24.8	(21.4–28.6)	997	26.0	(23.6–30.3)
Aged 18–49 yrs	1,349	17.0	(15.0–19.4)	1,753	19.5	(17.1–22.1)	1,775	23.7	(21.4–26.2)

* Answered yes to this question, "During the past 12 months, have you had a flu shot (flu spray)," and answered the follow-up question "What was the month and year of your most recent shot (spray), which were asked during a face-to-face interview conducted any day during March through August.

† Population sizes by subgroups are available at http://www.cdc.gov/flu/professionals/vaccination/pdf/influenza_vaccine_target_populations.pdf.

§ 95% confidence interval.

¶ NIS uses provider-verified vaccination status to improve the accuracy of the estimate. The NIS estimate for the 2008–09 season will be available summer or fall 2010.

** Data not yet available.

†† Adults categorized as being at high risk for influenza-related complications self-reported one or more of the following: 1) ever being told by a physician they had diabetes, emphysema, coronary heart disease, angina, heart attack, or other heart condition; 2) having a diagnosis of cancer during the preaceding 12 months (excluding nonmelanoma skin cancer) or ever being told by a physician they have lymphoma, leukemia, or blood cancer during the previous 12 months (postcoding for a cancer diagnosis was not yet completed at the time of this publication so this diagnosis was not included in the 2006–07 season data.); 3) being told by a physician they have chronic bronchitis or weak or failing kidneys; or 4) reporting an asthma episode or attack during the preceding 12 months. For children aged <18 years, high-risk conditions included ever having been told by a physician of having diabetes, cystic fibrosis, sickle cell anemia, congenital heart disease, other heart disease, or neuromuscular conditions (seizures, cerebral palsy, and muscular dystrophy), or having an asthma episode or attack during the preceding 12 months.

§§ Aged 18–44 years, pregnant at the time of the survey, and without high-risk conditions.

¶¶ Adults were classified as health-care workers if they were currently employed in a health-care occupation or in a health-care–industry setting, on the basis of standard occupation and industry categories recoded in groups by CDC's National Center for Health Statistics.

*** Interviewed sample child or adult in each household containing at least one of the following: a child aged <5 years, an adult aged ≥65 years, or any person aged 5–17 years at high risk (as defined in previous footnote for adults at high risk). To obtain information on household composition and high-risk status of household members, the sampled adult, child, and person files from NHIS were merged. Interviewed adults who were health-care workers or who had high-risk conditions were excluded. Information could not be assessed regarding high-risk status of other adults aged 18–64 years in the household; therefore, certain adults aged 18–64 years who live with an adult aged 18–64 years at high risk were not included in the analysis. Also note that although the recommendation for children aged 2–4 years was not in place during the 2005–06 season, children aged 2–4 years were included in these calculations as if the recommendation already was in place to facilitate comparison of coverage data for subsequent years.

Reported vaccination levels are low among children at increased risk for influenza complications. Coverage among children aged 2–17 years with asthma was estimated to be 29% for the 2004–05 influenza season (*428*). During the 2007–08 influenza season, the fourth season for which ACIP recommended that all children aged 6–23 months receive vaccination, National Immunization Survey data demonstrated that 41% of children aged 6–23 months received at least 1 dose of influenza vaccine, and 23% were fully vaccinated (i.e., received 1 or 2 doses depending on previous vaccination history); however, results varied substantially among states (*429*). Data from the eight Immunization Information System sentinel sites during 2008–09 indicated that 48% of children aged 6–23 months had received at least 1 dose, and 29% were fully vaccinated (*430*). Coverage levels in these sites for older children were lower and declined with increasing age, ranging from 22% fully vaccinated among children aged 2–4 years to 9% among children aged 13–18 years (*430*). As has been reported for older adults, a physician recommendation for vaccination and the perception that having a child be vaccinated

"is a smart idea" were associated positively with likelihood of vaccination of children aged 6–23 months (*431*). Similarly, children with asthma were more likely to be vaccinated if their parents recalled a physician recommendation to be vaccinated or believed that the vaccine worked well (*432*). Implementation of a reminder/recall system in a pediatric clinic increased the percentage of children with asthma receiving vaccination from 5% to 32% (*433*). Reminder/recall systems might be particularly useful when limited vaccine availability requires targeted vaccination of children with high-risk conditions (*434*).

Although annual vaccination is recommended for HCP and is a high priority for reducing morbidity associated with influenza in health-care settings and for expanding influenza vaccine use (*435–437*), NHIS data demonstrated a vaccination coverage level of only 44.4% among HCP during the 2006–07 season, and 49% during the 2007–08 season (Table 3). Coverage levels during the 2009 pandemic were higher for seasonal vaccine, but remained low for the 2009 pandemic vaccine. By mid-January 2010, estimated vaccination coverage among HCP was 37% for 2009 pandemic influenza A (H1N1) and 62% for seasonal influenza, based on a RAND Corporation–conducted telephone survey that used a somewhat different methodology than NHIS (*438*). Overall, 64% received either of these influenza vaccines, higher coverage than any previous season, but only 35% of HCP reported receiving both vaccines (*438*). Vaccination of HCP has been associated with reduced work absenteeism (*370*) and with fewer deaths among nursing home patients (*375,377*) and elderly hospitalized patients (*379*). Factors associated with a higher rate of influenza vaccination among HCP include older age, being a hospital employee, having employer-provided health-care insurance, having had pneumococcal or hepatitis B vaccination in the past, or having visited a health-care professional during the preceding year. HCP who decline vaccination frequently express doubts about the risk for influenza and the need for vaccination, are concerned about vaccine effectiveness and side effects, and dislike injections (*439*).

Vaccine coverage among pregnant women increased during the 2007–08 influenza season, with 24% of pregnant women reporting vaccination, excluding pregnant women who reported diabetes, heart disease, lung disease, and other selected high-risk conditions; seasonal vaccine coverage estimates for 2008–09 were only 11%, however, which is closer to pre-2007 estimates and likely reflects variation in estimates caused by the small sample size rather than significant fluctuations in coverage (Table 3). The causes of persistent low coverage among pregnant women are not fully determined. However, in a study of influenza vaccination acceptance by pregnant women, 71% of those who were offered the vaccine chose to be vaccinated (*440*). However, a 1999 survey of obstetricians and gynecologists determined that only 39% administered influenza vaccine to obstetric patients in their practices, although 86% agreed that pregnant women's risk for influenza-related morbidity and mortality increases during the last two trimesters (*441*). Pregnancy was an important risk factor during the 2009 H1N1 pandemic (*106,120*), and because the 2009 H1N1 influenza virus is expected to continue circulation during 2010–11, improved vaccination coverage among pregnant women is needed.

Influenza vaccination coverage in all groups recommended for vaccination remains suboptimal. Despite the timing of the peak of influenza disease, administration of vaccine decreases substantially after November. According to results from NHIS, for the three most recent influenza seasons for which these data are available, approximately 84% of all influenza vaccinations were administered during September–November. Among persons aged ≥65 years, the percentage of September–November vaccinations was 92% (*442*). Because many persons recommended for vaccination remain unvaccinated at the end of November, CDC encourages public health partners and health-care providers to conduct vaccination clinics and other activities that promote seasonal influenza vaccination annually during National Influenza Vaccination Week (December 6–12, 2010) and throughout the remainder of the influenza season.

Self-report of influenza vaccination among adults compared with determining vaccination status from the medical record, is a sensitive and specific source of information (*443*). Patient self-reports should be accepted as evidence of influenza vaccination in clinical practice (*443*). However, information on the validity of parents' reports of pediatric influenza vaccination is not yet available.

Vaccination coverage estimates for the influenza A (H1N1) 2009 monovalent vaccines indicate that most doses were administered to the initial target groups, and that, by January 2, 2010 (approximately 90 days after vaccine first became available), an estimated 20% of the U.S. population (61 million persons) had been vaccinated, including 28% of persons in the initial target groups. An estimated 30% of U.S. children aged 6 months–18 years had been vaccinated, including 33% of children aged 6 months–4 years. Estimated coverage for specific initial target groups was 38% for pregnant women, 22% for HCP, and 12% for adults aged 25–64 years with medical conditions that confer a higher risk for influenza complications. Estimates of 2009 H1N1 vaccination coverage levels generally were higher among non-Hispanic whites than among non-Hispanic blacks (*438*). These coverage estimates were in the same approximate range as estimates for seasonal vaccination coverage, suggesting that concerns about the pandemic were not sufficient to overcome some barriers to influenza vaccination among persons at higher risk for influenza complications.

Recommendations for Using TIV and LAIV During the 2010–11 Influenza Season

Routine vaccination of all persons aged ≥6 months is recommended. During the 2009–10 influenza season, an estimated 85% of the U.S. population already had an indication for vaccination (*444*). A universal vaccination recommendation for all persons aged ≥6 months eliminates the need to determine whether each person has an indication for vaccination and emphasizes the importance of preventing influenza among person of all ages. The expansion of recommendations for annual vaccination to include all adults is supported by evidence that influenza vaccines are safe and effective. In addition, morbidity and mortality among adults aged <50 years, including adults who were previously healthy, occurs in every influenza season. Although most adults in this age group who develop influenza-related complications have medical risk factors, some have no previously identified risk factors for influenza complications, or have risk factors but are unaware that they should be vaccinated. Expansion of vaccination recommendations to all adults reflects the need to remove potential barriers to receipt of influenza vaccine, including lack of awareness about vaccine indications among persons at higher risk for influenza complications and their close contacts. Although the capacity now exists to produce sufficient influenza vaccines to meet the predicted increase in demand, the annual supply of influenza vaccine and timing of its distribution cannot be guaranteed in any year.

Further support for expansion of recommendations to include all adults is based on data from the 2009 pandemic experience. Data from epidemiologic studies conducted during the 2009 influenza A (H1N1) pandemic indicates that the risk for influenza complications among adults aged <50 years who had 2009 pandemic influenza A (H1N1) is greater than is typically seen for seasonal influenza (*12*). Explosive outbreaks of 2009 H1N1 influenza among young adults in settings such as college campuses (*445*) were part of the basis for prioritizing vaccination of all persons aged 6 months–24 years during the 2009 pandemic influenza response. Pandemic 2009 influenza A (H1N1)-like viruses are expected to continue to circulate during the 2010–11 influenza season, and a substantial proportion of young adults do not yet have immunity as a result of natural infection with this virus (*446*). In addition, severe infections were observed more frequently in some younger adults who did not have previously recognized risk factors for influenza-related complications, including obese persons, persons in certain racial and ethnic minority groups, and postpartum women (*24,48,85,86,90,447*).

Both TIV and LAIV prepared for the 2010–11 season will include A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens. The influenza B virus component of the 2010–11 vaccine is from the Victoria lineage (*448*). These viruses will be used because they are representative of influenza viruses that are predicted to be circulating in the United States during the 2010–11 influenza season and have favorable growth properties in eggs. The H1N1 strain recommended for the 2010–11 trivalent influenza vaccine is the same as the vaccine strain in the 2009 H1N1 monovalent vaccines given during the pandemic. The 2009 pandemic influenza virus-derived vaccine strain has replaced the seasonal influenza H1N1 vaccine strains that were present in the vaccine since 1977.

Healthy nonpregnant persons aged 2–49 years can choose to receive either TIV or LAIV. Some TIV formulations are FDA-licensed for use in persons as young as age 6 months (see Recommended Vaccines for Different Age Groups). Persons aged ≥65 years can be administered either standard-dose TIV 15 mcg per vaccine strain) or the newly licensed TIV containing 60 mcg HA antigen per vaccine strain (Sanofi pasteur). TIV is licensed for use in persons with high-risk conditions (Table 2). LAIV is FDA-licensed for use only for persons aged 2–49 years. In addition, FDA has indicated that the safety of LAIV has not been established in persons with underlying medical conditions that confer a higher risk for influenza complications.

All children aged 6 months–8 years who have not been vaccinated previously at any time with at least 1 dose of either LAIV (if appropriate) or TIV should receive 2 doses of age-appropriate vaccine in the same season, with a single dose during subsequent seasons. Persons who received a 2009 H1N1 monovalent vaccine should still be vaccinated with the 2010–11 formulation of TIV or LAIV to provide protection against influenza A (H3N2) and influenza B strains that are expected to circulate during the 2010–11 influenza season. In addition, the duration of protection after receipt of the 2009 H1N1 monovalent influenza vaccines is unknown and likely declines over time.

In addition, emphasis on providing routine vaccination annually to certain groups at higher risk for influenza infection or complications is advised, including all children aged 6 months–18 years, all persons aged ≥50 years, and other persons at risk for medical complications from influenza. These persons, their household and close contacts, and all HCP should continue to be a focus of vaccination efforts as providers and programs transition to routinely vaccinating all persons aged ≥6 months (Box). Despite a recommendation for vaccination for approximately 85% of the U.S. population over the past

two seasons, <50% of the U.S. population received a seasonal influenza vaccination in 2008–09 or 2009–10. Estimated vaccine coverage for the 2009 H1N1 monovalent vaccine coverage was <40% (*438*).

Rationale for Vaccination of Specific Populations

Children Aged 6 Months–18 Years

Annual vaccination for all children aged 6 months–18 years is recommended. Healthy children aged 2–18 years can receive either LAIV or TIV. Children aged 6–23 months, and those aged 2–4 years who have evidence of asthma, wheezing, or who have medical conditions that put them at higher risk for influenza complications should receive TIV (see Considerations When Using LAIV).

Recommendations to provide routine influenza vaccination to all children and adolescents aged 6 months–18 years are made on the basis of 1) accumulated evidence that influenza vaccine is effective and safe for children (see Influenza Vaccine Efficacy, Effectiveness, and Safety); 2) increased evidence that influenza has substantial adverse impacts among children and their contacts (e.g., school absenteeism, increased antibiotic use, medical care visits, and parental work loss) (see Health-Care Use, Hospitalizations, and Deaths Attributed to Influenza); and 3) an expectation that a simplified age-based influenza vaccine recommendation for all children and adolescents will improve vaccine coverage levels among children who already have a risk- or contact-based indication for annual influenza vaccination.

Children typically have the highest attack rates during community outbreaks of influenza and serve as a major source of transmission within communities (*1,2*). If sufficient vaccination coverage among children can be achieved, potential benefits include the indirect effect of reducing influenza among persons who have close contact with children and reducing overall transmission within communities (*449*). Achieving and sustaining community-level reductions in influenza will require mobilization of community resources and development of sustainable annual vaccination campaigns to assist health-care providers and vaccination programs in providing influenza vaccination services to children of all ages. In many areas, innovative community-based efforts, which might include mass vaccination programs in school or other community settings, will be needed to supplement vaccination services provided in health-care providers' offices or public health clinics. In nonrandomized community-based controlled trials, reductions in ILI-related symptoms and medical visits among household contacts have been demonstrated in communities where vaccination programs among school-aged children were established compared with communities without such vaccination programs (*365,386,387*).

All children aged 6 months–8 years who receive a seasonal influenza vaccine for the first time should be administered 2 doses. Children aged 6 months–8 years who received a seasonal vaccine for the first time during 2009–2010 but who received only 1 dose should receive 2 doses, rather than 1, during 2010–2011. In addition, for the 2010–11 influenza season, children aged 6 months–8 years who did not receive at least 1 dose of an influenza A (H1N1) 2009 monovalent vaccine should receive 2 doses of a 2010–11 seasonal influenza vaccine, regardless of previous influenza vaccination history (Figure 3). Children aged 6 months–8 years for whom the previous 2009–10 seasonal or influenza A (H1N1) 2009 monovalent vaccine history cannot be determined should receive 2 doses of a 2010–11 seasonal influenza vaccine. For all children, the second dose of a recommended 2-dose series should be administered ≥4 weeks after the initial dose.

The recommendation to administer 2 doses to children who did not receive an influenza A (H1N1) 2009 monovalent vaccine, regardless of previous seasonal influenza vaccine history, is new. This change in recommendations is made on the basis of data from several immunogenicity studies indicating that children aged <9 years have lower antibody levels and lower rates of protective response after receiving a single dose of vaccines containing the 2009 pandemic H1N1 antigen compared with older children and adults. However, >80% of infants and children aged <3 years and >90% of older children who receive 2 doses of a vaccine that contains the 2009 H1N1 antigen develop protective antibody levels (*158,160*; National Institutes of Health, unpublished data, 2010). Therefore, current immunogonicity data indicate that at least 2 doses of the 2009 H1N1 vaccine antigen are needed to produce protective antibody levels for the majority of young children. This recommendation includes children who have received at least 2 doses of a seasonal influenza vaccine in a previous season and who would normally be scheduled to only receive 1 seasonal vaccine dose in the 2010–11 season.

A second dose is not necessary for children being vaccinated for the first time who were aged 8 years at the time of the first dose but who are seen again after they have reached age 9 years. Children aged 6 months–8 years who had never received a seasonal influenza vaccine previously and who received only the 2009 H1N1 monovalent vaccine should receive 2 doses of the 2010–11 seasonal influenza vaccine, to provide adequate protection against influenza A (H3N2) and influenza B. If possible, children recommended for 2 doses of seasonal influenza

FIGURE 3. Number of 2010–2011 seasonal influenza vaccine doses recommended for children

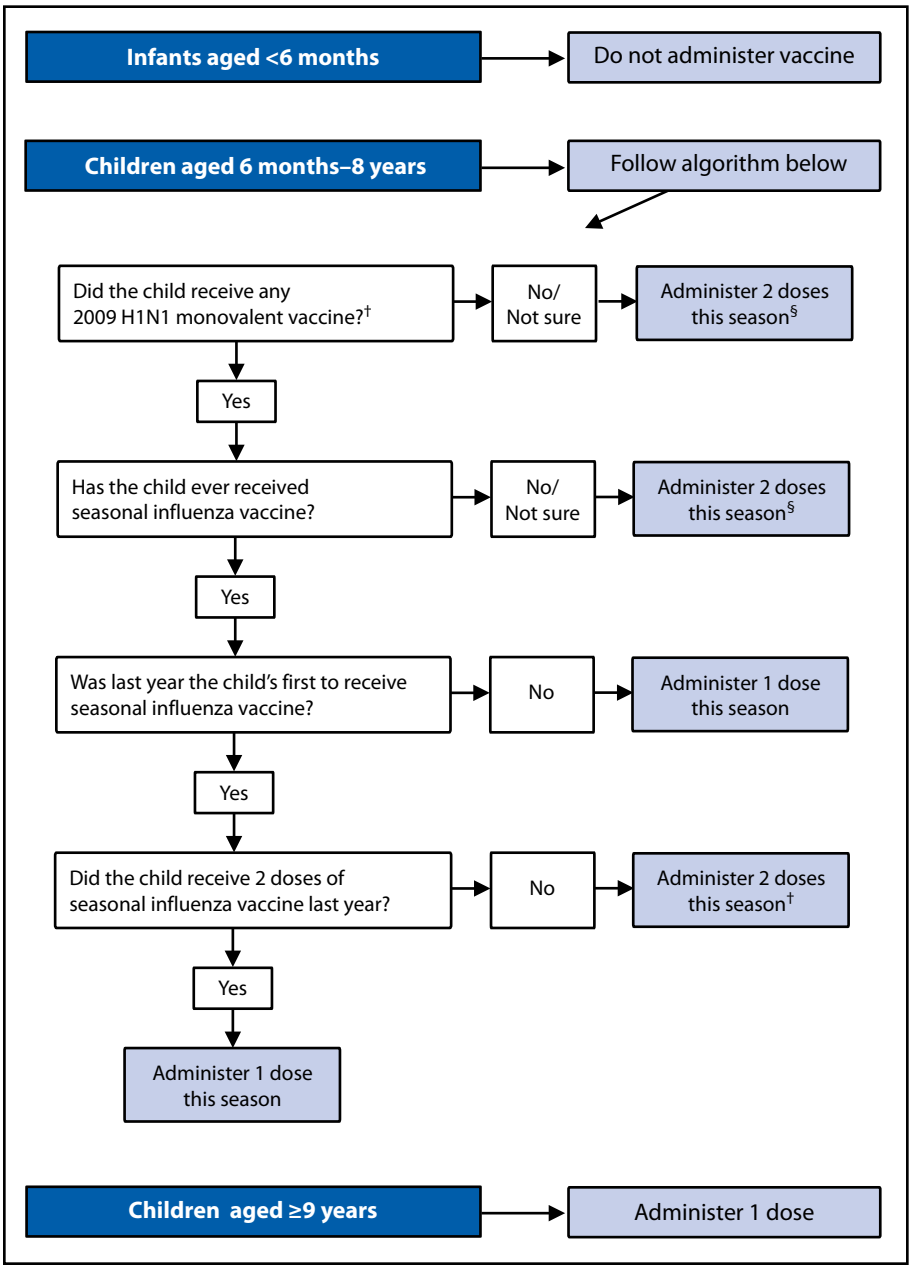


*Figure developed by CDC with the American Academy of Pediatrics, Committee on Infectious Diseases.

† Children who had a laboratory-confirmed 2009 pandemic H1N1 virus infection (e.g., reverse transcription–polymerase chain reaction or virus culture specific for 2009 pandemic influenza A(H1N1) virus) are likely to be immune to this virus. At provider discretion, these children can have a "Yes" entered at this box, and proceed down the path to the next box to determine whether two doses are indicated based on seasonal vaccine history. However, if no test result is available and no influenza A(H1N1) 2009 monovalent vaccine was administered, enter "no" here.

§ Interval between 2 doses is ≥4 weeks.

vaccine should receive them both before onset of influenza season. However, vaccination, including the second dose, is recommended even after influenza virus begins to circulate in a community.

Children who had a laboratory-confirmed 2009 pandemic influenza A (H1N1) virus infection (e.g., reverse transcription–PCR or virus culture specific for 2009 pandemic influenza A (H1N1) virus) are likely to be immune to this virus. There is no known harm in providing 2 doses of 2010–11 seasonal influenza vaccine to a child who has been infected previously with the 2009 pandemic influenza A (H1N1) virus. However, at immunization provider discretion, these children can receive the appropriate number of seasonal vaccine doses (1 or 2) without regard to previous receipt of the influenza A (H1N1) 2009 monovalent vaccine. However, most children did not receive specific diagnostic testing (i.e., were untested or received a rapid antigen test), and for others, evidence of laboratory confirmation using a diagnostic test specific for the 2009 H1N1 antigen is unavailable to immunization providers. If no test results are available and no influenza A (H1N1) 2009 monovalent vaccine had been administered, children who had a febrile respiratory illness during 2009–2010 cannot be assumed to have had influenza A (H1N1) virus infection, and these children should receive 2 doses of the 2010–11 seasonal vaccine. Providers who are determining the number of vaccine doses recommended for children with laboratory-confirmed 2009 pandemic influenza A (H1N1) virus infection (Figure 3) should also determine whether 2 doses are indicated on the basis of seasonal vaccine history.

Persons at Risk for Medical Complications

Vaccination to prevent influenza is particularly important for persons who are at increased risk for severe complications from influenza or at higher risk for influenza-related outpatient, ED, or hospital visits. When vaccine supply is limited, vaccination

efforts should focus on delivering vaccination to the following persons:

- all children aged 6 months–4 years (59 months);
- all persons aged ≥50 years;
- adults and children who have chronic pulmonary (including asthma) or cardiovascular (except isolated hypertension), renal, hepatic, neurological, hematologic, or metabolic disorders (including diabetes mellitus);
- persons who have immunosuppression (including immunosuppression caused by medications or by HIV);
- women who are or will be pregnant during the influenza season;
- children and adolescents (aged 6 months–18 years) who are receiving long-term aspirin therapy and who might be at risk for experiencing Reye syndrome after influenza virus infection;
- residents of nursing homes and other long-term–care facilities;
- American Indians/Alaska Natives;
- persons who are morbidly obese (BMI ≥40);
- HCP;
- household contacts and caregivers of children aged <5 years and adults aged ≥50 years, with particular emphasis on vaccinating contacts of children aged <6 months; and
- household contacts and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.

For children, the risk for severe complications from influenza is highest among those aged <2 years, who have much higher rates of hospitalization for influenza-related complications compared with older children (*7,54,61*). Medical care and ED visits attributable to influenza are increased among children aged <5 years compared with older children (*54*). Chronic neurologic conditions are thought to place persons at higher risk for influenza complications on the basis of the potential for compromised respiratory function or the handling of respiratory secretions, both of which can increase the risk for aspiration; such conditions include cognitive dysfunction, spinal cord injuries, seizure disorders, or neuromuscular disorders (*46*).

An observational study conducted during the 2009 H1N1 pandemic indicated that morbid obesity, and possibly obesity, might be a new or previously unrecognized risk factor for influenza-related complications (*85*). In another study, American Indians/Alaska Natives were demonstrated to have a higher risk for death from 2009 H1N1 influenza (*90*). These medical and race/ethnicity risk factors might reflect a higher prevalence of underlying chronic medical conditions, including conditions that are not known by the patient or provider. Other minority groups, including blacks, have been demonstrated to have higher incidence of hospitalizations as a result of laboratory-confirmed influenza compared with whites (CDC, unpublished data, 2010); additional study is needed to determine the reasons. Persons who have chronic medical conditions, who are pregnant, or who are at higher risk for 2009 H1N1 influenza-related complications should be encouraged to begin receiving a routine annual influenza vaccination as programs and practitioners transition to providing vaccination for all persons aged ≥6 months (Box).

Persons Who Live With or Care for Persons at Higher Risk for Influenza-Related Complications

All persons aged ≥6 months should be vaccinated annually. As providers and programs transition to providing annual vaccination to all persons, continued emphasis should be placed on vaccination of persons who live with or care for persons at higher risk for influenza-relate complications. When vaccine supply is limited, vaccination efforts should focus on delivering vaccination to persons at higher risk for influenza-related complications as well as these persons:

- HCP;
- household contacts (including children) and caregivers of children aged ≤59 months (i.e., aged <5 years) and adults aged ≥50 years; and
- household contacts (including children) and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.

Healthy persons who are infected with influenza virus, including those with subclinical infection, can transmit influenza virus to persons at higher risk for complications from influenza. In addition to HCP, groups that can transmit influenza to high-risk persons include:

- employees of assisted living and other residences for persons in groups at high risk;
- persons who provide home care to persons in groups at high risk; and
- household contacts of persons in groups at high risk, including contacts such as children or mothers of newborns.

In addition, because children aged <5 years are at increased risk for influenza-related hospitalization (*7,47,61,450,451*) compared with older children, vaccination is recommended for their household contacts and out-of-home caregivers. Because influenza vaccines have not been licensed by FDA for use among children aged <6 months, emphasis should be placed on vaccinating contacts of these children.

Healthy HCP and persons aged 2–49 years who are contacts of persons in these groups and who are not contacts of severely immunocompromised persons living in a protected

environment (see Close Contacts of Immunocompromised Persons) should receive either LAIV or TIV when indicated or requested. All other persons, including pregnant women, should receive TIV.

All HCP and persons in training for health-care professions should be vaccinated annually against influenza. Persons working in health-care settings who should be vaccinated include physicians, nurses, and other workers in both hospital and outpatient-care settings, medical emergency–response workers (e.g., paramedics and emergency medical technicians), employees of nursing home and long-term–care facilities who have contact with patients or residents, and students in these professions who will have contact with patients (*436,437,452*).

Facilities that employ HCP should provide vaccine to workers by using approaches that have been demonstrated to be effective in increasing vaccination coverage. The HCP influenza coverage goal should be vaccination of 100% of employees who do not have medical contraindications. Health-care administrators should consider the level of vaccination coverage among HCP to be one measure of a patient safety quality program and consider obtaining signed declinations from personnel who decline influenza vaccination for reasons other than medical contraindications (*437,453,454*). Influenza vaccination rates among HCP within facilities should be measured regularly and reported, and ward-, unit-, and specialty-specific coverage rates should be provided to staff and administration (*437*).

Policies that work best to achieve this coverage goal might vary among facilities. Studies have demonstrated that organized campaigns can attain higher rates of vaccination among HCP with moderate effort and by using strategies that increase vaccine acceptance (*435,437,455,456*). A mandatory influenza vaccination policy for HCP, exempting only those with a medical contraindication, has been demonstrated to be a highly effective approach to achieving high vaccine coverage among HCP (*456–458*). Hospitals and health-care systems that have mandated vaccination of HCP often have achieved coverage rates of >90%, and persons refusing vaccination who do not have a medical contraindication have been required to wear a surgical mask during influenza season in some programs (*458*). Efforts to increase vaccination coverage among HCP using mandatory vaccination policies are supported by various national accrediting and professional organizations, including the Infectious Diseases Society of America, and in certain states by statute (*457,459,460*). Worker objections, including legal challenges, are an important consideration for facilities considering mandates (*459,461*). Studies to assess the impact of mandatory HCP vaccination on patient outcomes are needed.

The Joint Commission on Accreditation of Health-Care Organizations has approved an infection-control standard that requires accredited organizations to offer influenza vaccinations to staff, including volunteers and licensed independent practitioners with close patient contact. The standard became an accreditation requirement beginning January 1, 2007 (*462*). Some states have regulations regarding vaccination of HCP in long-term–care facilities (*463*), require that health-care facilities offer influenza vaccination to HCP, or require that HCP either receive influenza vaccination or indicate a religious, medical, or philosophic reason for not being vaccinated (*464,465*).

Children aged <6 months are not recommended for vaccination, and antivirals are not licensed for use among infants. Protection of young infants, who have hospitalization rates similar to those observed among the elderly, depends on vaccination of the infants' close contacts. A recent study conducted in Bangladesh demonstrated that infants born to vaccinated women have significant protection from laboratory-confirmed influenza, either through transfer of influenza-specific maternal antibodies or by reducing the risk for exposure to influenza that might occur through vaccination of the mother (*217*). All household contacts, health-care and day care providers, and other close contacts of young infants should be vaccinated.

Immunocompromised persons are at risk for influenza complications but might have inadequate protection after vaccination. Vaccination of close contacts of immunocompromised persons, including HCP, might reduce the risk for influenza transmission. In 2006, a joint recommendation from ACIP and the Hospital Infection Control Practices Advisory Committee (HICPAC) recommended that TIV be used for vaccinating household members, HCP, and others who have close contact with severely immunosuppressed persons (e.g., patients with hematopoietic stem cell transplants) during those periods in which the immunosuppressed person requires care in a protective environment (typically defined as a specialized patient-care area with a positive airflow relative to the corridor, high-efficiency particulate air filtration, and frequent air changes) (*437,466*). To reduce the theoretic risk for vaccine virus transmission, ACIP/HICPAC recommended that HCP who receive LAIV should avoid providing care for severely immunosuppressed patients requiring a protected environment for 7 days after vaccination, and hospital visitors who have received LAIV should avoid contact with severely immunosuppressed persons in protected environments for 7 days after vaccination but should not be restricted from visiting less severely immunosuppressed patients. Healthy nonpregnant persons aged 2–49 years, including HCP, who have close contact with persons with lesser degrees of immunosuppression (e.g., persons with chronic immunocompromising conditions such as HIV infection, corticosteroid or chemotherapeutic medication use, or who are cared for in other hospital areas such as neonatal intensive care units) can receive TIV or LAIV.

The rationale for avoiding use of LAIV among HCP or other close contacts of severely immunocompromised patients is the theoretic risk that a live attenuated vaccine virus could be transmitted to the severely immunosuppressed person. However, instances of LAIV transmission from a recently vaccinated person to an immunocompromised contact in health-care settings have not been reported. In addition, the temperature-sensitive and attenuated viruses present in LAIV do not cause illness when administered to immunocompromised persons with HIV infection (*336*), children undergoing cancer treatment (*467*), or immunocompromised ferrets given dexamethasone and cytarabine (*468*). Concerns about the theoretic risk posed by transmission of live attenuated vaccine viruses contained in LAIV to patients should not be used to justify preferential use of TIV in health-care settings other than inpatient units that house severely immunocompromised patients requiring protected environments. Some health-care facilities might choose to not restrict use of LAIV in close contacts of severely immunocompromised persons, based on the lack of evidence for transmission in health-care settings since licensure in 2004.

Pregnant and Postpartum Women

Vaccination of pregnant women protects women and newborns. The American College of Obstetricians and Gynecologists and the American Academy of Family Physicians also have previously recommended routine vaccination of all pregnant women (*469*). Women who are postpartum are also at risk for influenza complications and should be vaccinated (*108*). No preference is indicated for use of TIV that does not contain thimerosal as a preservative (see Vaccine Preservative [Thimerosal] in Multidose Vials of TIV) for any group recommended for vaccination, including pregnant and postpartum women. LAIV is not licensed for use in pregnant women, but postpartum women can receive LAIV or TIV. Pregnant and postpartum women do not need to avoid contact with persons recently vaccinated with LAIV.

Breastfeeding Mothers

Breastfeeding does not affect the immune response adversely and is not a contraindication for vaccination (*246*). Unless contraindicated because of other medical conditions, women who are breastfeeding can receive either TIV or LAIV. In one randomized controlled trial conducted in Bangladesh, infants born to women vaccinated during pregnancy had a lower risk for laboratory-confirmed influenza. However, the contribution to protection from influenza of breastfeeding compared with passive transfer of maternal antibodies during pregnancy was not determined (*217*).

Travelers

The risk for exposure to influenza during travel depends on the time of year and destination. In the temperate regions of the Southern Hemisphere, influenza activity occurs typically during April–September. In temperate climate zones of the Northern and Southern Hemispheres, travelers also can be exposed to influenza during the summer, especially when traveling as part of large tourist groups (e.g., on cruise ships) that include persons from areas of the world in which influenza viruses are circulating (*470,471*). In the tropics, influenza occurs throughout the year. In a study among Swiss travelers to tropical and subtropical countries, influenza was the most frequently acquired vaccine-preventable disease (*472*).

Any traveler who wants to reduce the risk for influenza infection should consider influenza vaccination, preferably at least 2 weeks before departure. In particular, persons at high risk for complications of influenza and who were not vaccinated with influenza vaccine during the preceding fall or winter should consider receiving influenza vaccine before travel if they plan to travel:

- to the tropics,
- with organized tourist groups at any time of year, or
- to the Southern Hemisphere during April–September.

No information is available about the benefits of revaccinating persons before summer travel who already were vaccinated during the preceding fall, and revaccination is not recommended. Persons at high risk who receive the previous season's vaccine before travel should be receive the current vaccine the following fall or winter. Persons at higher risk for influenza complications should consult with their health-care practitioner to discuss the risk for influenza or other travel-related diseases before embarking on travel during the summer.

Recommended Vaccines for Different Age Groups

Each season, vaccination providers should check the latest information on FDA approval of the 2010–11 seasonal influenza vaccines and CDC recommendations for use of these vaccines to determine which vaccines are licensed for use in any particular age. Immunization providers should consult updated information on use of influenza vaccines from CDC (available at http://www.cdc.gov/flu) and FDA (available at http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/vaccinesafety/default.htm). The following information is based on approvals for the 2009–10 seasonal influenza vaccines.

When vaccinating children aged 6–35 months with TIV, health-care providers should use TIV that has been licensed by FDA for this age group (i.e., TIV manufactured by sanofi pasteur [FluZone] or CSL Biotherapies (Afluria) (*286*). TIV

from Novartis (Fluvirin) is FDA-approved in the United States for use among persons aged ≥4 years (*287*). One TIV preparation from GlaxoSmithKline (Fluarix) is licensed for use in children aged ≥3 years, and another preparation (FluLaval) is labeled for use in persons aged ≥18 years (*274,275,285*). LAIV from MedImmune (FluMist) is recommended for use by healthy nonpregnant persons aged 2–49 years (Table 2) (*360*). If a pediatric vaccine dose (0.25mL) is administered inadvertently to an adult, an additional pediatric dose (0.25 mL) should be given to provide a full adult dose (0.5mL). If the error is discovered later (after the patient has left the vaccination setting), an adult dose should be administered as soon as the patient can return. Vaccination with a formulation approved for adult use should be counted as a dose if inadvertently administered to a child.

An inactivated trivalent influenza vaccine (Fluzone High-Dose, sanofi pasteur.) that contains an increased amount of influenza virus antigen compared with other inactivated influenza vaccines was licensed in 2009. Fluzone High-Dose is available as single dose prefilled syringe formulation distinguished from Fluzone by a gray syringe plunger rod (*224*). As with other 2010–11 influenza vaccines, Fluzone High-Dose will contain the three recommended virus strains (A/California/7/2009 (H1N1)-like, A/Perth/16/2009 (H3N2)-like, and B/Brisbane/60/2008-like antigens) (*136*). ACIP recommends that all persons aged ≥65 years receive an inactivated 2010–11 seasonal influenza vaccination but has not expressed a preference for Fluzone High-Dose or any other inactivated influenza vaccine for use in persons aged ≥65 years (*473*). Whether or not the higher postvaccination immune responses observed among Fluzone High-Dose vaccine recipients (*221–223*) will result in greater protection against influenza illness is not known. High-dose vaccine should not be administered to persons aged <65 years. Several other new vaccine formulations are being evaluated in immunogenicity and efficacy trials; when licensed, these new products will increase the influenza vaccine supply and provide additional vaccine choices for practitioners and their patients. Providers should review the formulation and packaging before administering influenza vaccine to ensure the product used is appropriate for the age of the patient.

Influenza Vaccines and Use of Influenza Antiviral Medications

Administration of TIV to persons receiving influenza antivirals for treatment or chemoprophylaxis is acceptable. The effect on safety and effectiveness of LAIV coadministration with influenza antiviral medications has not been studied. However, because influenza antivirals reduce replication of influenza viruses, LAIV should not be administered until 48 hours after cessation of influenza antiviral therapy. If influenza antiviral medications are administered within 2 weeks after receipt of LAIV, the vaccine dose should be repeated 48 or more hours after the last dose of antiviral medication. Persons receiving antivirals within the period 2 days before to 14 days after vaccination with LAIV should be revaccinated at a later date with any approved vaccine formulation (*246,331*).

Considerations When Using LAIV

LAIV is an option for vaccination of healthy nonpregnant persons aged 2–49 years without contraindications, including HCP and other close contacts of high-risk persons (excepting severely immunocompromised hospitalized persons who require care in a protected environment). The precaution regarding use of LAIV in protected environments is based upon a theoretic concern that the live attenuated vaccine virus could be transmitted to severely immunocompromised persons. However, no transmission of LAIV in health-care settings ever has been reported, and because these viruses are also cold-adapted (and cannot effectively replicate at normal body temperature) the risk for transmitting a vaccine virus to a severely immunocompromised person and causing severe infection appears to be extremely low. HCP working in environments such as neonatal intensive care, oncology, or labor and delivery units can receive LAIV without any restrictions.

No preference is indicated for LAIV or TIV when considering vaccination of healthy nonpregnant persons aged 2–49 years. Possible advantages of LAIV include its potential to induce a broad mucosal and systemic immune response in children, its ease of administration, and the possibly increased acceptability of an intranasal rather than intramuscular route of administration.

If the vaccine recipient sneezes immediately after administration, the dose should not be repeated. However, if nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration should be considered until resolution of the illness, or TIV should be administered instead. No data exist about concomitant use of nasal corticosteroids or other intranasal medications (*331*).

Although FDA licensure of LAIV excludes children aged 2–4 years with a history of asthma or recurrent wheezing, the precise risk, if any, of wheezing caused by LAIV among these children is unknown because experience with LAIV among these young children is limited. Young children might not have a history of recurrent wheezing if their exposure to respiratory viruses has been limited because of their age. Certain children might have a history of wheezing with respiratory illnesses but have not had asthma diagnosed.

Clinicians and vaccination programs should screen for asthma or wheezing illness (or history of wheezing illness) when considering use of LAIV for children aged 2–4 years, and should avoid use of this vaccine in children with asthma or a wheezing episode within the previous 12 months. Health-care providers should consult the medical record, when available, to identify children aged 2–4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2–4 years should be asked: "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record during the preceding 12 months should not receive LAIV. TIV is available for use in children with asthma or wheezing (*474*). LAIV can be administered to persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if nasal congestion is present that might impede delivery of the vaccine to the nasopharyngeal mucosa, use of TIV, or deferral of administration should be considered until resolution of the illness, is recommended.LAIV is approved for use in persons aged 2–49 years. However, the effectiveness or safety of LAIV is not known or is of potential concern for certain persons, and LAIV is not recommended for these persons. Do not administer LAIV to the following groups:

- persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs;
- children aged <2 years, because of an increased risk for hospitalization and wheezing observed in clinical trials;
- children aged 2–4 years whose parents or caregivers report that a health-care provider has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 months;
- persons with asthma;
- persons aged ≥50 years;
- adults and children who have chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic/neuromuscular, hematologic, or metabolic disorders;
- adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV);
- children or adolescents aged 6 months–18 years receiving aspirin or other salicylates (because of the association of Reye syndrome with wild-type influenza virus infection); or
- pregnant women.

A moderate or severe illness with or without fever is a precaution for use of LAIV. Development of GBS within 6 weeks following a previous dose of influenza vaccine is considered to be a precaution for use of influenza vaccines. LAIV should not be administered to close contacts of immunosuppressed persons who require a protected environment.

Personnel Who Can Administer LAIV

Low-level introduction of vaccine viruses into the environment probably is unavoidable when administering LAIV, but no instances have been reported of illness or attenuated vaccine virus infections among inadvertently exposed HCP or immunocompromised patients. The risk for acquiring vaccine viruses from the environment is unknown but is probably low; in addition, vaccine viruses are cold-adapted and attenuated, and unlikely to cause symptomatic influenza. Severely immunosuppressed persons should not administer LAIV. However, other persons at higher risk for influenza complications can administer LAIV. These include persons with underlying medical conditions placing them at higher risk or who are likely to be at risk, including pregnant women, persons with asthma, and persons aged ≥50 years.

Concurrent Administration of Influenza Vaccine With Other Vaccines

Use of LAIV concurrently with measles, mumps, rubella (MMR) alone and MMR and varicella vaccine among children aged 12–15 months has been studied, and no interference with the immunogenicity to antigens in any of the vaccines was observed (*331,475*). Among adults aged ≥50 years, the safety and immunogenicity of zoster vaccine and TIV was similar whether administered simultaneously or spaced 4 weeks apart (*476*). In the absence of specific data indicating interference, following ACIP's general recommendations for vaccination is prudent (*246*). Inactivated vaccines do not interfere with the immune response to other inactivated vaccines or to live vaccines. Inactivated or live vaccines can be administered simultaneously with LAIV. However, after administration of a live vaccine, at least 4 weeks should pass before another live vaccine is administered.

Recommendations for Vaccination Administration and Vaccination Programs

Influenza vaccination levels increased substantially over the past 20 years, and a record proportion of children received seasonal or pandemic influenza A (H1N1) vaccines in 2009–10. However, a majority of persons in most groups recommended for vaccination do not receive an annual vaccine. Strategies to improve vaccination levels, including using reminder/recall systems and standing orders programs (*408,409,423*), should be implemented whenever feasible. Vaccination efforts should begin as soon as vaccine is available and continue through the influenza season, which typically extends through April. Vaccination coverage can be increased by administering vaccine before and during the influenza season to persons during hospitalizations or routine health-care visits. Vaccinations can be provided in alternative settings (e.g., schools, pharmacies, grocery stores, workplaces, or other locations in the community), thereby making special visits to physicians' offices or clinics unnecessary. Coordinated campaigns such as the National Influenza Vaccination Week (December 6–12, 2010) provide opportunities to refocus public attention on the benefits, safety, and availability of influenza vaccination throughout the influenza season. The 2009 pandemic provided opportunities for innovative programs to administer vaccine in a variety of settings, and lessons learned from this experience should be applied when developing routine influenza immunization programs.

Discussing Risk for Adverse Events after Vaccination

Concern about vaccine safety is often cited by persons who refuse vaccination, including health-care workers. When educating patients about adverse events, clinicians should provide Vaccine Information Statements (available at http://www.cdc.gov/vaccines/pubs/vis), and emphasize the risks and benefits of vaccination. Providers should inform patients or parents that 1) TIV contains noninfectious killed viruses and cannot cause influenza; 2) LAIV contains weakened influenza viruses that cannot replicate outside the upper respiratory tract and are unlikely to infect others; 3) many patients will experience no side effects and most known side effects are mild, transient, and manageable, such as injection-site pain after receipt of TIV or rhinorrhea after LAIV; and 4) concomitant symptoms or respiratory disease unrelated to vaccination with either TIV or LAIV can occur after vaccination.

Patients concerned about more severe adverse events might be reassured by discussing the many safety studies available, the safety monitoring systems currently in use, and the immunization provider or program's previous experience with influenza vaccines. Providers concerned about the risk for severe adverse events or who observe or report a severe adverse event after vaccination should keep in mind that relatively common events will occur by chance after vaccination. For example, one study used the background rate of spontaneous abortion to estimate that 397 per 1 million vaccinated pregnant women would be predicted to have a spontaneous abortion within 1 day of vaccination (*477*). Even rare events will be observed by chance after vaccination if large numbers of persons are vaccinated, as occurs with annual influenza immunization campaigns. For example, if a cohort of 10 million individuals was vaccinated, approximately 22 cases of GBS and six cases of sudden death would be expected to occur within 6 weeks of vaccination as coincident background cases unrelated to vaccination (*477*).

Information About the Vaccines for Children Program

The Vaccines for Children (VFC) program supplies vaccine to all states, territories, and the District of Columbia for use by participating providers. These vaccines are to be provided to eligible children without vaccine cost to the patient or the provider. Although the provider might charge a vaccine administration fee, vaccination will not be denied to parents who cannot pay an administration fee. All routine childhood vaccines recommended by ACIP are available through this program, including influenza vaccines. The program saves parents and providers out-of-pocket expenses for vaccine purchases and provides cost savings to states through CDC's vaccine contracts. The program results in lower vaccine prices and ensures that all states pay the same contract prices. Detailed information about the VFC program is available at http://www.cdc.gov/vaccines/programs/vfc/default.htm.

Influenza Vaccine Supply Considerations

The annual supply of influenza vaccine and the timing of its distribution cannot be guaranteed in any year. During the 2009–10 influenza season, 114 million doses of seasonal influenza vaccine were distributed in the United States. However, influenza vaccine distribution delays or vaccine shortages remain possible. One factor that affects production is the inherent critical time constraints in manufacturing the vaccine given the annual updating of the influenza vaccine strains. Multiple manufacturing and regulatory issues also might affect the production schedule.

If supplies of seasonal influenza vaccine are not adequate, vaccination should be carried out in accordance with local circumstances of supply and demand based on the judgment of state and local health officials and health-care providers. National guidance for tiered use of influenza vaccine during prolonged distribution delays or supply shortfalls will be based primarily on epidemiologic studies indicating that certain persons are at higher risk for influenza infection or influenza-related complications, as well as which vaccine formulations have limited supplies. When epidemiologic studies or other data that would guide tiered use are unavailable, persons previously demonstrated to be at higher risk for influenza or influenza-related complications should be among those targeted by immunization programs for receipt of limited supplies. Even if vaccine use is not restricted to certain persons known to be at higher risk for influenza complications, strategies employed by immunization programs and providers during periods of limited vaccine availability should emphasize outreach to persons at higher risk for influenza or influenza-related complications (Box), or who are part of populations that have limited access to medical care. During shortages of TIV, LAIV should be used preferentially when feasible for all healthy nonpregnant persons aged 2–49 years (including HCP) who desire or are recommended for vaccination to increase the availability of inactivated vaccine for persons at high risk.

Timing of Vaccination

Vaccination efforts should be structured to ensure the vaccination of as many persons as possible over the course of several months, with emphasis on vaccinating before influenza activity in the community begins. Even if vaccine distribution begins before October, distribution probably will not be completed until December or January. The following recommendations reflect this phased distribution of vaccine.

In any given year, the optimal time to vaccinate patients cannot be determined precisely because influenza seasons vary in their timing and duration, and more than one outbreak might occur in a single community in a single year. In the United States, localized outbreaks that indicate the start of seasonal influenza activity can occur as early as October. However, in >80% of influenza seasons since 1976, peak influenza activity (which often is close to the midpoint of influenza activity for the season) has not occurred until January or later, and in >60% of seasons, the peak was in February or later. In general, health-care providers should begin offering vaccination soon after vaccine becomes available and if possible by October. To avoid missed opportunities for vaccination, providers should offer vaccination during routine health-care visits or during hospitalizations whenever vaccine is available.

Vaccination efforts should continue throughout the season, because the duration of the influenza season varies and influenza might not appear in certain communities until February or March. Providers should offer influenza vaccine routinely, and organized vaccination campaigns should continue throughout the influenza season, including after influenza activity has begun in the community. Vaccine administered in December or later, even if influenza activity has already begun, is likely to be beneficial in the majority of influenza seasons. The majority of adults have antibody protection against influenza virus infection within 2 weeks after vaccination (*478,479*).

All children aged 6 months–8 years who are recommended for 2 doses should receive their first dose as soon after vaccine becomes available as is feasible and should receive the second dose ≥4 weeks later. This practice increases the opportunity for both doses to be administered before or shortly after the onset of influenza activity.

Planners are encouraged to develop the capacity and flexibility to schedule at least one vaccination clinic in December. Guidelines for planning large-scale vaccination clinics, including school-based clinics, are available at http://www.cdc.gov/flu/professionals/vaccination/vax_clinic.htm, http://www.cdc.gov/h1n1flu/vaccination/statelocal/settingupclinics.htm, and http://www.cdc.gov/h1n1flu/vaccination/slv.

During a vaccine shortage or delay, substantial proportions of TIV or LAIV doses might not be released and distributed until November and December or later. When the vaccines are substantially delayed or disease activity has not subsided, providers should consider offering vaccination clinics into January and beyond as long as vaccine supplies are available.

Strategies for Implementing Vaccination Recommendations

The expansion of the recommendations to all persons aged ≥6 months highlights the importance of making influenza vaccine readily accessible in a variety of settings. Many of the persons at highest risk for complications will likely continue to be vaccinated in health-care settings. However, vaccination in health-care settings must increasingly be complemented by vaccination in nonmedical settings that increase convenience and access. During the 2009–2010 H1N1 Vaccination Program, substantial efforts were made at the state and local level to direct vaccine to locations such as schools, pharmacies, workplaces, and health departments.

Health-Care Settings

Health-care settings remain a central component of an overall influenza vaccination strategy. Studies consistently show that provider recommendation is the strongest predictor of

vaccination (*425,480,481*). While nonmedical settings play an important role for those motivated to seek vaccination, health-care settings are critical for facilitating vaccination of all those who come into contact with the setting, including those who might not seek out vaccination.

Successful vaccination programs combine publicity and education for HCP and other potential vaccine recipients, use of reminder/recall systems, assessment of practice-level vaccination rates with feedback to staff, and efforts to remove administrative and financial barriers that prevent persons from receiving the vaccine, including use of standing orders programs (*409,482,483*). The use of standing orders programs by long-term–care facilities (e.g., nursing homes and skilled nursing facilities), hospitals, and home health agencies ensures that vaccination is offered. Standing orders programs for influenza vaccination should be conducted under the supervision of a licensed practitioner according to a physician-approved facility or agency policy by HCP trained to screen patients for contraindications to vaccination, administer vaccine, and monitor and report adverse events. The Centers for Medicare and Medicaid Services (CMS) has removed the physician signature requirement for the administration of influenza and pneumococcal vaccines to Medicare and Medicaid patients in hospitals, long-term–care facilities, and home health agencies (*484*). To the extent allowed by local and state law, these facilities and agencies can implement standing orders for influenza and pneumococcal vaccination of Medicare- and Medicaid-eligible patients. Payment for influenza vaccine under Medicare Part B is available (*485,486*). Other settings (e.g., outpatient facilities, managed-care organizations, assisted living facilities, correctional facilities, pharmacies, and adult workplaces) are encouraged to introduce standing orders programs (*487*). In addition, physician reminders (e.g., flagging charts) and patient reminders are recognized strategies for increasing rates of influenza vaccination (*483*).

Outpatient Facilities Providing Ongoing Care

Staff in facilities providing ongoing medical care (e.g., physicians' offices, public health clinics, employee health clinics, hemodialysis centers, hospital specialty-care clinics, and outpatient rehabilitation programs) should offer vaccine to all patients during visits throughout the influenza season. The offer of vaccination and its receipt or refusal should be documented in the medical record or immunization information system. Patients who do not have regularly scheduled visits during the fall should be reminded by mail, telephone, or other means of the need for vaccination.

Outpatient Facilities Providing Episodic or Acute Care

Acute health-care facilities (e.g., EDs and walk-in clinics) should offer vaccinations throughout the influenza season or provide written information regarding why, where, and how to obtain the vaccine. This written information should be provided in languages at literacy levels appropriate for the populations served by the facility.

Acute-Care Hospitals

Hospitals should serve as a key setting for identifying persons at increased risk for influenza complications. Unvaccinated persons without contraindications who are hospitalized at any time during the period when vaccine is available should be offered and strongly encouraged to receive influenza vaccine before they are discharged. Standing orders to offer influenza vaccination to all hospitalized persons should be considered.

Nursing Homes and Other Long-Term–Care Facilities

Vaccination should be provided routinely to all residents of long-term–care facilities. If possible, all residents should be vaccinated before influenza season. In the majority of seasons, TIV will become available to long-term–care facilities in October or November, and vaccination should commence as soon as vaccine is available. As soon as possible after admission to the facility, the benefits and risks of vaccination should be discussed and education materials provided (*488*). Informed consent is required, but this does not necessarily mean a signed consent must be present in order to implement a standing order for vaccination (*489*). Residents admitted after completion of the vaccination program at the facility should be vaccinated at the time of admission.

Lower rates of severe illness among older persons were observed during the 2009 pandemic, but outbreaks among residents of nursing homes and other long-term–care facilities still occurred (*490*). Although the influenza viruses that will circulate during the 2010–11 season are unknown, multiple influenza types and subtypes that often infect and cause severe infections among older adults (e.g., H3N2) circulate each winter influenza season. The 2010–11 influenza vaccine formulation should be administered to all residents and staff.

Since October 2005, CMS has required nursing homes participating in the Medicare and Medicaid programs to offer all residents influenza and pneumococcal vaccines and to document the results. According to the requirements, each resident is to be vaccinated unless contraindicated medically, the resident or a legal representative refuses vaccination, or the vaccine is not available because of shortage. This information is

to be reported as part of the CMS Minimum Data Set, which tracks nursing home health parameters (*486,491*).

Vaccination Provided by Visiting Nurses and Others Providing Home Care to Persons at High Risk

Vaccine should be administered in the home if necessary as soon as influenza vaccine is available and throughout the influenza season. Caregivers and other persons in the household (including children) should be referred for vaccination.

Vaccination for Health-Care Personnel

Health-care facilities should offer influenza vaccinations to all HCP, including night, weekend, and temporary staff. Particular emphasis should be placed on providing vaccinations to workers who provide direct care for persons at high risk for influenza complications. Efforts should be made to educate HCP regarding the benefits of vaccination and the potential health consequences of influenza illness for their patients, themselves, and their family members. All HCP should be provided convenient access to influenza vaccine at the work site, free of charge, as part of employee health programs (*437,455,462*).

Other Settings

Influenza vaccination has increasingly become available in nonmedical settings. In the 2009–2010 vaccination season, 33% of seasonal influenza vaccinations occurred in health departments, pharmacies or drug stores, workplaces, schools, or other nonmedical locations (CDC, unpublished data, 2009). The proportion of 2009 H1N1 vaccine administered in these settings was 45% (CDC, unpublished data, 2010). Availability of vaccine in a range of settings such as pharmacies and the workplace is especially important for persons who do not regularly accesss the health-care system. In addition, with the recent expansion of the influenza recommendations to include all persons aged ≥6 months, implementation of strategies that are sustainable beyond vaccination in provider offices are necessary. School-located vaccination provides an opportunity to address the challenges associated with large numbers of children to vaccinate, a short window of time for vaccination, and the need for annual revaccination. A number of states and immunization programs have effectively conducted school-located vaccination both for seasonal vaccination (*492,493*) and 2009 H1N1 vaccination (*494*). School-located vaccination does, however, present challenges from a resource perspective both for vaccine costs and program costs (*493*), because reimbursement practices might be different compared with those used in medical settings. In addition, documentation of vaccination must be provided to the vaccinated person's primary care provider and where appropriate state or local vaccine registries.

Nonmedical settings that should be considered to reach the elderly include assisted living housing, retirement communities, and recreation centers. Such facilities should offer unvaccinated residents, attendees, and staff annual on-site vaccination before the start of the influenza season. Continuing to offer vaccination throughout the fall and winter months is appropriate. Efforts to vaccinate newly admitted patients or new employees also should be continued, both to prevent illness and to avoid having these persons serve as a source of new influenza infections. Staff education should emphasize the benefits for self, staff and patients of protection from influenza through vaccination.

Future Directions for Research and Recommendations Related to Influenza Vaccine

Although available influenza vaccines are effective and safe, additional research is needed to improve prevention efforts. Most severe morbidity and mortality during typical influenza seasons occurs among persons aged ≥65 years of those who have chronic medical conditions (*6,7,24*). More immunogenic influenza vaccines are needed for persons at higher risk for influenza-related complications. Additional research also is needed to understand potential biases in estimating the benefits of vaccination among older adults in reducing hospitalizations and deaths (*134,241,495*). Additional studies of the relative cost-effectiveness and cost utility of influenza vaccination among children and adults, especially those aged <65 years, are needed and should be designed to account for year-to-year variations in influenza attack rates, illness severity, hospitalization costs and rates, and vaccine effectiveness when evaluating the long-term costs and benefits of annual vaccination (*496*). Additional data on indirect effects of vaccination also are needed to quantify the benefits of influenza vaccination of HCP in protecting their patients (*379*) and the impact of a universal vaccination recommendation on influenza epidemiology, particularly the impact on persons at higher risk for influenza complications. In addition, a better understanding is needed of how to motivate persons, particularly those at risk for influenza-related complications and their close contacts, to seek or accept annual influenza vaccination.

The expansion of annual vaccination recommendations to include all persons aged ≥6 months will require a substantial increase in resources for epidemiologic research to develop long-term studies capable of assessing the possible effects on community-level transmission. In Canada, a universal vac-

cination recommendation implemented in Ontario in 2000 has been compared with typical practice in other Canadian provinces. These studies have been challenging to conduct, but have indicated that a universal recommendation for annual vaccination is associated with overall reductions in influenza-related mortality, hospitalizations, ED use, physicians' office visits, and antibiotic use (*388,389,396*). However, differences between health-care systems in Canada and the United States limit the ability to generalize the findings in Ontario to the United States, and measures of the impact of a universal recommendation in the United States will likely require many years to evaluate. Additional planning to improve surveillance systems capable of monitoring effectiveness, safety and vaccine coverage, and further development of implementation strategies will be necessary. Vaccination programs capable of delivering annual influenza vaccination to a broad range of the population could potentially serve as a resilient and sustainable platform for delivering vaccines and monitoring outcomes for other urgently required public health interventions (e.g., vaccines for future influenza pandemics or medical countermeasures to prevent or treat illnesses caused by acts of terrorism).

Seasonal Influenza Vaccine and Influenza Viruses of Animal Origin

Human infection with novel or nonhuman influenza A virus strains, including influenza A viruses of animal origin, is a nationally notifiable disease in the United States (*497*). Human infections with nonhuman or novel human influenza A virus should be identified quickly and investigated to determine possible sources of exposure, identify additional cases, and evaluate the possibility of human-to-human transmission because transmission patterns could change over time with variations in these influenza A viruses.

Sporadic severe and fatal human cases of infection with highly pathogenic avian influenza A (H5N1) virus have been identified in Asia, Africa, Europe, and the Middle East, primarily among persons who have had direct or close unprotected contact with sick or dead birds associated with the ongoing H5N1 panzootic among birds (*498–506*). Severe lower respiratory illness with multiorgan failure has been reported in fatal H5N1 cases, and asymptomatic infection and clinically mild cases also have been reported (*507–510*). Limited, nonsustained human-to-human transmission of H5N1 virus has likely occurred in some case clusters (*508,511*). To date, there is no evidence of genetic reassortment between human influenza A and H5N1 viruses. However, influenza viruses derived from strains circulating among poultry (e.g., the H5N1 virus, which has caused outbreaks of avian influenza and occasionally have infected humans) have the potential to recombine with human influenza A viruses (*512,513*). To date, highly pathogenic H5N1 virus has not been identified in wild or domestic birds or in humans in the United States. Guidance for testing suspected cases of H5N1 virus infection among persons in the United States and follow-up of contacts is available (*514,515*). Human H5N1 cases have continued to occur in 2009 and 2010, including in the Middle East and Southeast Asia (*516*).

Human illness from infection with different avian influenza A subtype viruses also has been documented, including infections with low pathogenic and highly pathogenic viruses. A range of clinical illness has been reported for human infection with low pathogenic avian influenza viruses, including conjunctivitis with influenza A (H7N7) virus in the United Kingdom, lower respiratory tract disease and conjunctivitis with influenza A (H7N2) virus in the United Kingdom, and uncomplicated ILI with influenza A (H9N2) virus in Hong Kong and China (*517–523*). Two human cases of infection with low pathogenic influenza A (H7N2) have been reported in the United States (*520*). Although human infections with highly pathogenic A (H7N7) virus infections typically have ILI or conjunctivitis, severe infections, including one fatal case in the Netherlands, have been reported following exposure to poultry (*524–526*). Conjunctivitis also has been reported because of human infection with highly pathogenic influenza A (H7N3) virus in Canada and low pathogenic A (H7N3) in the United Kingdom (*517,525*). In contrast, sporadic infections with highly pathogenic avian influenza A (H5N1) virus have caused severe illness in many countries, with an overall case-fatality proportion of approximately 60% (*508,526*).

Swine influenza A (H1N1), A (H1N2), and A (H3N2) viruses, including reassortant viruses, are endemic among pig populations in the United States (*527*). Two clusters of influenza A (H2N3) virus infections among pigs have been reported recently (*528*). Outbreaks among pigs normally occur in colder weather months (late fall and winter) and sometimes with the introduction of new pigs into susceptible herds. An estimated 30% of the pig population in the United States has serologic evidence of having had swine influenza A (H1N1) virus infection. Sporadic human infections with a variety of swine influenza A viruses occur in the United States, but the incidence of these human infections is unknown (*529–534*). Persons infected with swine influenza A viruses typically report direct contact with ill pigs or places where pigs have been present (e.g., agricultural fairs or farms) and have symptoms that are clinically indistinguishable from infection with other respiratory viruses (*531,532,535,536*). Swine influenza virus infection has not been associated with household exposure to pork products or consumption of pork. Clinicians should consider

swine influenza A virus infection in the differential diagnosis of patients with ILI who have had recent contact with pigs. Sporadic cases among persons whose infections were linked to swine exposure have not resulted in sustained human-to-human transmission of swine influenza A viruses or community outbreaks (*9,536*). The 2009 pandemic influenza A (H1N1) virus contains some genes previously found in viruses currently circulating among swine, but the origin of the pandemic has not been definitively linked to swine exposures among humans. Although immunity to swine influenza A viruses appears to be low (<2%) in the overall human population, 10%–20% of persons with occupational exposure to pigs (e.g., pig farmers or pig veterinarians) have been documented in certain studies to have antibody evidence of prior swine influenza A (H1N1) virus infection (*529,537*).

Current seasonal influenza vaccines are not expected to provide protection against human infection with avian influenza A viruses, including influenza A (H5N1) viruses, or to provide protection against influenza A viruses currently circulating exclusively in swine (*318,448*). However, reducing seasonal influenza risk through influenza vaccination of persons who might be exposed to nonhuman influenza viruses (e.g., H5N1 virus) might reduce the theoretic risk for recombination of influenza A viruses of animal origin and human influenza A viruses by preventing seasonal influenza A virus infection within a human host.

CDC has recommended that persons who are charged with responding to avian influenza outbreaks among poultry receive seasonal influenza vaccination (*538,539*). As part of preparedness activities, the Occupational Safety and Health Administration (OSHA) has issued an advisory notice regarding poultry worker safety that is intended for implementation in the event of a suspected or confirmed avian influenza outbreak at a poultry facility in the United States. OSHA guidelines recommend that poultry workers in an involved facility receive vaccination against seasonal influenza; OSHA also has recommended that HCP involved in the care of patients with documented or suspected avian influenza should be vaccinated with the most recent seasonal human influenza vaccine to reduce the risk for co-infection with human influenza A viruses (*539*).

Recommendations for Using Antiviral Agents

Annual vaccination is the primary strategy for preventing complications of influenza virus infections. Antiviral medications with activity against influenza viruses are useful adjuncts in the prevention of influenza, and effective when used early in the course of illness for treatment. Four influenza antiviral agents are licensed in the United States: amantadine, rimantadine, zanamivir, and oseltamivir. Investigational antiviral medications, such as peramivir and intravenous formulations of zanamivir, might be available under investigational new drug protocols (*540*).

During the 2007–08 influenza season, influenza A (H1N1) viruses with a mutation that confers resistance to oseltamivir became more common in the United States and other countries (*541–543*). As of June 2010, in the United States, approximately 99% of seasonal influenza A (H1N1) viruses (i.e., H1N1 viruses not associated with the 2009 pandemic) tested have been resistant to oseltamivir. None of the influenza A (H3N2) or influenza B viruses tested were resistant to oseltamivir. However, few seasonal influenza viruses isolated after May 2009 are available for testing. As of June 2010, with few exceptions, 2009 pandemic influenza A (H1N1) virus strains that began circulating in April 2009 remained sensitive to oseltamivir, and all were sensitive to zanamivir (*16*). Sporadic cases of 2009 pandemic influenza A (H1N1) virus infection with an H275Y mutation in neuraminidase associated with oseltamivir resistance have been reported worldwide, but as of June 2010, no sustained community-wide transmission has been identified (*544*). Such oseltamivir-resistant virus infections have been identified in severely immunosuppressed patients, persons receiving oseltamivir chemoprophylaxis, and in some persons without oseltamivir exposure, including some influenza illness clusters (*544–549*). CDC's recommendations for use of influenza antiviral medications should be consulted for guidance on antiviral use (*15*). New guidance on clinical management of influenza, including use of antivirals, also is available from the Infectious Diseases Society of America and the World Health Organization (*550–552*). ACIP recommendations for antiviral use will be published separately later in 2010.

Sources of Information Regarding Influenza and its Surveillance

Information regarding influenza surveillance, prevention, detection, and control is available at http://www.cdc.gov/flu. During October–May, surveillance information is updated weekly. In addition, periodic updates regarding influenza are published in *MMWR* (http://www.cdc.gov/mmwr). Additional information regarding influenza vaccine can be obtained by calling 1-800-CDC-INFO (1-800-232-4636). State and local health departments should be consulted about availability of influenza vaccine, access to vaccination programs, information related to state or local influenza activity, reporting of influenza outbreaks and influenza-related pediatric deaths, and advice concerning outbreak control.

Vaccine Adverse Event Reporting System (VAERS)

Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) at http://vaers.hhs.gov/esub/index. Reports can be filed securely online, by mail, or by fax. A VAERS form can be downloaded from the VAERS website or requested by sending an e-mail message to info@vaers.org, by calling telephone 1-800-822-7967, or by sending a faxed request to 1-877-721-0366. Additional information on VAERS or vaccine safety is available at http://vaers.hhs.gov/about/index or by calling telephone 1-800-822-7967.

Reporting of Adverse Events that Occur After Administering Antiviral Medications (MedWatch)

Health-care professionals should report all serious adverse events (SAEs) after antiviral medication use promptly to MedWatch, FDA's adverse event reporting program for medications. SAEs are defined as medical events that involve hospitalization, death, life-threatening illness, disability, or certain other medically important conditions. SAEs that follow administration of medications should be reported at http://www.fda.gov/medwatch/report/hcp.htm.

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP), established by the National Childhood Vaccine Injury Act of 1986, as amended, provides a mechanism through which compensation can be paid on behalf of a person determined to have been injured or to have died as a result of receiving a vaccine covered by VICP. The Vaccine Injury Table lists the vaccines covered by VICP and the injuries and conditions (including death) for which compensation might be paid. If the injury or condition is not on the Table, or does not occur within the specified time period on the Table, persons must prove that the vaccine caused the injury or condition.

For a person to be eligible for compensation, the general filing deadlines for injuries require claims to be filed within 3 years after the first symptom of the vaccine injury; for a death, claims must be filed within 2 years of the vaccine-related death and not more than 4 years after the start of the first symptom of the vaccine-related injury from which the death occurred. When a new vaccine is covered by VICP or when a new injury/condition is added to the Table, claims that do not meet the general filing deadlines must be filed within 2 years from the date the vaccine or injury/condition is added to the Table for injuries or deaths that occurred up to 8 years before the Table change. Persons of all ages who receive a VICP-covered vaccine might be eligible to file a claim. Both the intranasal (LAIV) and injectable (TIV) trivalent influenza vaccines are covered under VICP. Additional information about VICP is available at http//www.hrsa.gov/vaccinecompensation or by calling 1-800-338-2382.

Additional Information Regarding Influenza Virus Infection Control Among Specific Populations

Each year, ACIP provides general, annually updated information regarding control and prevention of influenza. Other reports related to controlling and preventing influenza among specific populations (e.g., immunocompromised persons, HCP, hospital patients, pregnant women, children, and travelers) also are available in the following publications:

- CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Family Physicians (AAFP). MMWR 2006;55(No. RR-15).
- CDC. Influenza vaccination of health-care personnel: recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP). MMWR 2006;55(No. RR-2).
- CDC. Recommended immunization schedules for persons aged 0 through 18 years—United States, 2010. MMWR 2010;58:Q1–4.
- CDC. Guidelines for preventing health-care–associated pneumonia, 2003: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR 2004;53(No. RR-3).
- CDC. Respiratory hygiene/cough etiquette in health-care settings. Atlanta, GA: US Department of Health and Human Services, CDC; 2003. Available at http://www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm.
- CDC. Prevention and control of vaccine-preventable diseases in long-term–care facilities. Atlanta, GA: US Department of Health and Human Services, CDC; 2006. Available at http://www.cdc.gov/flu/professionals/infectioncontrol/longtermcare.htm.
- CDC. Vaccine safety. Atlanta, GA: US Department of Health and Human Services, CDC; 2009. Available at http://www.cdc.gov/vaccinesafety/index.htm.

- American College of Obstetricians and Gynecologists. Influenza vaccination and treatment during pregnancy. ACOG committee opinion no. 305. Obstet Gynecol 2004;104:1125–6.
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SECTION TEN
APPENDIX D
INFLUENZA VACCINATION COVERAGE AMONG HEALTH-CARE PERSONNEL AND PREGNANT WOMEN

Influenza Vaccination Coverage Among Health-Care Personnel — United States, 2011–12 Influenza Season, United States, MMWR; September 28, 2012 / 61(38);753-757. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6138a1.htm?s_cid=mm6138a1_w.

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Influenza Vaccination Coverage Among Health-Care Personnel — United States, 2010–11 Influenza Season

The Advisory Committee on Immunization Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee recommend that all U.S. health-care personnel (HCP) be vaccinated annually against influenza (*1*). Nonetheless, influenza vaccination coverage among HCP in the United States has increased slowly over the past decade (*2,3*); during the 2009–10 influenza season, 61.9% of HCP received seasonal influenza vaccination (*4*). To update data with estimates from the 2010–11 influenza season, CDC conducted an Internet-based survey of 1,931 HCP who participated in three online survey panels. This report summarizes the results of that survey, which indicated that overall influenza vaccination coverage among HCP was 63.5% during the 2010–11 influenza season, similar to coverage for the 2009–10 season. Among HCP who reported working at a facility where vaccination was required by their employer, 98.1% were vaccinated. Among HCP without such an employer requirement but who were offered vaccination onsite, greater coverage was associated with a personal reminder from the employer to get vaccinated (69.9%), vaccination availability at no cost (67.9%), and vaccination availability for >1 day (68.8%). Influenza vaccination of HCP is needed to protect patients from HCP-transmitted disease. Maximizing influenza vaccination for all HCP is an important part of any comprehensive infection-control program.

To monitor 2010–11 influenza vaccination coverage among HCP, during April 1–27, 2011, CDC conducted a web-based survey of eligible HCP participating in three online survey panels. A total of 1,150 self-identified HCP were recruited from an online research panel operated by Knowledge Networks, Inc.*; an additional 534 persons were sampled from a specialized research panel composed primarily of physician specialists recruited through sources such as the American Medical Association master file, and 247 self-identified HCP were sampled from a marketing research panel composed of persons recruited through web advertising who agreed to participate in exchange for small amounts of financial compensation (i.e., $10 or less per survey). The total sample of 1,931 from all three sources was weighted to be nationally representative of demographic and geographic characteristics of the U.S. population of HCP as reflected in the most recent Current Population Survey.† Statistical significance of weighted differences was determined by Wald chi-square tests ($p<0.05$). Factors associated with increased vaccination coverage were assessed in a multivariable logistic regression model. The survey measured self-reported influenza vaccination from August 2010 through approximately mid-April 2011.

Among the HCP, 63.5% reported receiving a 2010–11 influenza vaccination (Table 1).§ Vaccination coverage was higher among HCP working in hospitals (71.1%), compared with those working in ambulatory or outpatient centers (61.5%), patient homes (53.6%), and "other" health-care settings (46.7%). Vaccination coverage among physicians and dentists (84.2%) was similar to coverage among nurse practitioners and physician assistants (82.6%) and was significantly higher than for those working in all other occupational groups (Table 1).

* Additional information available at http://www.knowledgenetworks.com/ganp/docs/knowledgepanel(r)-design-summary-description.pdf.

† Available at http://www.census.gov/cps.

§ Responded "yes" to the question "Have you received an influenza vaccination this past influenza season (August 2010 through April 2011)?"

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Coverage also was significantly higher among persons aged ≥60 years (74.2%), compared with those aged 18–29 years (56.4%) and 30–44 years (57.8%). No significant differences in coverage were observed by race/ethnicity.

The prevalence of beliefs regarding influenza and influenza vaccination differed between vaccinated and unvaccinated HCP (Table 2). The greatest differences in prevalence were among HCP who believed getting vaccinated was worth the time and expense (vaccinated: 94.7%, unvaccinated: 45.8%), those who believed getting a vaccination would better protect persons around them (vaccinated: 89.1%, unvaccinated: 44.6%), those who believed vaccination could protect them from getting influenza (vaccinated: 92.7%, unvaccinated: 54.2%), and those who believed influenza to be a serious threat to their own health (vaccinated: 70.1%, unvaccinated: 34.2%). Among those vaccinated, 94.8% believed influenza vaccination was safe, compared with 66.2% of those not vaccinated who believed influenza vaccination was safe (Table 2).

Approximately 13% of HCP reported being required by their employers to be vaccinated for influenza. Among these persons, vaccination coverage was 98.1%, compared with 58.3% among those without an employer requirement (Table 1). Among HCP without an employer requirement who were offered vaccination onsite, greater coverage was associated with a personal reminder from the employer to get vaccinated (69.9% versus 59.5%), vaccination availability at no charge (67.9% versus 41.2%), and vaccination availability for >1 day (68.8% versus 41.4%) (Table 3). In all, 85.5% of HCP without an employer requirement were offered onsite vaccination at no charge on multiple days. Among HCP without onsite vaccination, neither a personal reminder from their employer to be vaccinated nor employers publicizing the risks and benefits of vaccination were associated with vaccination.

In a multivariable logistic regression model limited to HCP who did not have a vaccination requirement but were offered onsite vaccination, two incentives were associated with being vaccinated, after controlling for other incentives and demographic characteristics of HCP: a personal reminder to be vaccinated (odds ratio [OR] = 1.6; 95% confidence interval [CI] = 1.1–2.3) and vaccine availability at no cost and for >1 day (considered as a composite variable because of near complete overlap in the two occurrences) (OR = 2.8; CI = 1.7–4.5). Other incentives were not associated with being vaccinated in this model.

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TABLE 1. Influenza vaccination coverage among health-care personnel, by selected characteristics — United States, 2010–11 influenza season

Characteristic	Unweighted no. in sample	% vaccinated*	(95% CI)
Overall	**1,931**	**63.5**	**(60.2–66.8)**
Work setting			
Hospital	617	71.1	(66.0–76.3)
Ambulatory/Outpatient	658	61.5	(54.8–68.2)†
Dentist office	47	54.6	(35.6–73.6)
Retail pharmacy	102	64.1	(52.0–76.3)
Long-term care facility	220	64.4	(55.8–73.0)
Home health	156	53.6	(42.6–64.5)†
Other	131	46.7	(34.3–59.1)†
Occupation			
Physician or dentist	430	84.2	(80.4–88.0)
Nurse practitioner/ Physician assistant	72	82.6	(71.0–94.1)
Nurse	255	69.8	(62.6–77.0)§
Allied health professional	245	64.4	(56.5–72.3)§
Technician	236	64.0	(55.7–72.3)§
Nonclinical support	60	66.2	(48.7–83.8)§
Administrative	248	57.2	(49.0–65.3)§
Assistant/Aide	295	55.9	(47.8–64.0)§
Other	90	62.4	(49.2–75.5)§
Age group (yrs)			
18–29	276	56.4	(48.2–64.6)¶
30–44	564	57.8	(51.7–64.0)¶
45–59	844	69.0	(64.0–73.9)
≥60	246	74.2	(66.3–82.1)
Race/Ethnicity			
White, non-Hispanic	1,252	66.6	(63.0–70.1)
Black, non-Hispanic	257	61.1	(51.0–71.2)
Hispanic	289	57.6	(45.3–69.9)
Mixed race, non-Hispanic	37	38.9	(17.9–60.0)
Other, non-Hispanic	96	54.8	(38.8–70.8)
Required by employer to be vaccinated			
Yes	230	98.1	(96.5–99.7)
No	1,695	58.3	(54.8–61.9)**

Abbreviation: CI = confidence interval.
* Weighted estimate.
† Significantly different from those in hospital settings (p<0.05).
§ Significantly different from physicians or dentists (p<0.05).
¶ Significantly different from those aged ≥60 years (p<0.05).
** Significantly different from those subject to an employer requirement for vaccination (p<0.05).

Editorial Note

Vaccination of HCP against influenza has been shown to reduce illness and absenteeism and to reduce transmission of influenza to HCP, their families, and their patients (*1*). During the 2009–10 influenza season, influenza vaccination coverage among HCP reached peaks of 61.9% for the trivalent seasonal influenza vaccine and 64.3% for coverage with either the seasonal or pandemic monovalent 2009 H1N1 vaccine (*4*). Although increased attention to influenza resulting from the 2009 H1N1 pandemic was thought to have contributed to the increase in influenza vaccination coverage in 2009–10, comparable coverage was achieved during the 2010–11 season, with 63.5% of HCP in this analysis reporting receipt of influenza vaccination from August 2010 through mid-April 2011. However, to the extent that the coverage estimates derived from this survey are comparable to those from the National Health Interview Survey (NHIS), influenza vaccination coverage of HCP remains below the *Healthy People 2020* target of 90% (as tracked by NHIS) (*5*).

The results of this survey indicate that 66.2% of unvaccinated HCP believed that the influenza vaccine was safe. However, when compared with those vaccinated, significantly lower percentages of unvaccinated HCP expressed the beliefs that getting vaccinated was worth the time and expense and that influenza vaccination can protect them and the persons around them from disease. These results indicate that programs to educate HCP regarding the seriousness of influenza and the effectiveness of the vaccine in protecting HCP and their patients from illness should continue.

Consistent with reports from health-care institutions that have required annual influenza vaccination as a condition for employment (*6,7*), vaccination coverage of 98.1% was reported among respondents who had an employer requirement for vaccination. Approximately 13% of surveyed HCP worked at facilities with such requirements, compared with 11% during the 2009–10 season (*4*). In the absence of requirements for vaccination, significantly higher vaccination coverage was achieved among employees who were offered vaccination onsite and free of charge for >1 day.

The findings in the report are subject to at least four limitations. First, the sample is not necessarily representative of all HCP in the United States, and estimates might not be directly comparable to those made for the 2009–10

What is already known on this topic?

The Advisory Committee on Immunization Practices (ACIP) recommends annual influenza vaccination for all health-care personnel (HCP); however, overall coverage among HCP remains well below the *Healthy People 2020* target of 90% coverage.

What is added by this report?

Coverage for influenza vaccination among HCP was estimated at 63.5%. Coverage was 98.1% among HCP who had an employer requirement for vaccination. In the absence of requirements, increased vaccination coverage was associated with employers offering vaccination onsite, free of charge, for multiple days.

What are the implications for public health practice?

Health-care facilities should develop a comprehensive influenza vaccination strategy that uses a combination of approaches demonstrated to be effective in increasing vaccination coverage, such as education and accessible vaccination at no cost to HCP.

TABLE 2. Beliefs regarding influenza and vaccination among health-care personnel, by influenza vaccination status — United States, 2010–11 influenza season

Belief	Vaccinated (n = 1,334*)		Not vaccinated (n = 586*)	
	% agree/ strongly agree†	(95% CI)	% agree/ strongly agree†§	(95% CI)
I am at risk for getting influenza	85.6	(82.4–88.9)	60.6	(54.6–66.5)
People around me are at risk for getting influenza	91.8	(89.2–94.5)	71.1	(65.2–77.0)
Influenza is a serious threat to my health	70.1	(66.3–73.9)	34.2	(28.7–39.7)
Influenza is a serious threat to the health of people around me	88.9	(85.9–91.1)	59.9	(54.0–65.7)
Influenza vaccination can protect me from getting influenza	92.7	(90.4–95.1)	54.2	(48.4–60.1)
If I get an influenza vaccination, people around me will be better protected from influenza	89.1	(96.3–91.9)	44.6	(38.8–50.4)
Influenza vaccination is safe	94.8	(92.8–96.8)	66.2	(60.6–71.8)
Getting vaccinated for influenza is worth the time and expense	94.7	(92.8–96.6)	45.8	(40.0–51.7)
I know everything I need to know to make a good decision about getting vaccinated for influenza	91.1	(88.5–93.7)	82.5	(78.1–86.9)

Abbreviation: CI = confidence interval.
* Unweighted number in sample.
† Weighted estimate.
§ All estimates for those not vaccinated were significantly different from the estimates for those vaccinated (p<0.05).

TABLE 3. Influenza vaccination coverage among health-care personnel (HCP) not required by their employer to be vaccinated, by those with applicable employer incentives versus those without applicable employer incentives — United States, 2010–11 influenza season

Employer incentive	With applicable employer incentive			Without applicable employer incentive		
	Unweighted no. in sample	% vaccinated*	(95% CI)	Unweighted no. in sample	% vaccinated*	(95% CI)
Personally reminded by employer to get vaccinated						
Vaccination offered onsite	787	69.9	(65.0–74.7)	491	59.5	(52.1–66.8)†
Vaccination not offered onsite	42	38.6	(18.4–58.8)	363	38.5	(31.1–45.9)
Employer publicized risks and benefits of vaccination						
Vaccination offered onsite	919	67.5	(62.8–72.3)	357	62.8	(54.5–71.1)
Vaccination not offered onsite	79	49.5	(32.8–66.2)	323	35.6	(28.1–43.2)
Employer offered onsite vaccination						
Financial incentives or rewards to individuals§	45	42.8	(22.2–63.4)	1,238	67.2	(63.0–71.3)
Employer publicized coverage levels to employees§	208	70.3	(60.7–79.9)	1,072	65.3	(60.7–69.8)
Vaccination available at no cost	1,159	67.9	(63.7–72.1)	114	41.2	(26.2–55.7)†
Vaccination available during multiple shifts	1,059	67.8	(63.4–72.3)	208	55.7	(44.8–66.6)
Vaccination available for >1 day	1,168	68.8	(64.5–72.9)	102	41.4	(27.5–55.2)†
Vaccination available when requested by HCP	866	69.3	(64.4–74.2)	399	61.5	(54.2–68.8)
Vaccination available at direct work station	839	68.6	(63.6–73.6)	428	61.1	(53.9–68.5)
Vaccination available from mobile carts	330	64.5	(56.5–72.6)	930	66.5	(61.7–71.4)
Vaccination available from peer vaccinators	607	69.1	(63.2–75.0)	653	63.4	(57.5–69.2)
Vaccination available at special events	314	66.6	(58.0–75.3)	945	65.8	(61.0–70.6)

Abbreviation: CI = confidence interval.
* Weighted estimate.
† Significantly different when compared with employees with applicable employer incentive (p<0.05).
§ A small number (<10) of respondents whose employers did not offer onsite vaccination also reported these employer practices.

season, because the sample used for that survey was restricted to members of the Knowledge Networks panel and not supplemented with members from the opt-in panels. Second, all results are based on self-report and are not substantiated by employment records or employer interviews. Third, the survey is possibly subject to selection bias, if participation in the survey is correlated with receipt of vaccination or certain beliefs. Finally, the definition of HCP used in this survey might vary slightly from definitions used in previously published surveys of vaccination coverage. Despite these limitations, Internet panel surveys are a useful surveillance tool for timely midseason and postseason evaluation of influenza vaccination coverage and knowledge, attitude, practice, and barrier data not provided by other sources of HCP data.

Since July 2007, the Joint Commission has required accredited critical access hospitals, other hospitals, and long-term care centers to establish an annual influenza vaccination program that would, at minimum, offer onsite influenza vaccination, monitor vaccination coverage, and provide education to staff members and licensed independent practitioners. Since 2009, CDC's National Healthcare Safety Network has provided a web-based tool for surveillance of vaccination of HCP in voluntarily enrolled health-care facilities.¶ Beginning in 2013, the Centers for Medicaid & Medicare Services might require hospitals to report HCP influenza vaccination coverage as part of its Hospital Inpatient Quality Reporting Program (*8*). Tracking vaccination coverage among HCP is needed as a measure of patient safety and to mark progress toward reaching the *Healthy People 2020* target of 90%.

¶Additional information available at http://www.cdc.gov/nhsn/hps.html.

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Influenza Vaccination Coverage Among Pregnant Women — United States, 2010–11 Influenza Season

Women are at increased risk for morbidity and mortality from influenza during pregnancy (*1*). Vaccinating pregnant women for influenza can protect both the women and their infants, especially infants aged <6 months who are not old enough to receive influenza vaccination (*2–4*). Since 2004, the Advisory Committee on Immunization Practices and the American College of Obstetricians and Gynecologists have recommended inactivated influenza vaccine for all women who are pregnant during influenza season, regardless of trimester (*1,5*). Before 2009, estimated influenza vaccination coverage among pregnant women had been consistently low (approximately 15%) (*1,5*). However, vaccination levels increased substantially in response to the 2009 influenza A (H1N1) pandemic to nearly 50% (*6–7*). To estimate influenza vaccination coverage among pregnant women for the 2010–11 season, CDC analyzed data from an Internet panel survey conducted in April 2011 among women who were pregnant any time during October 2010–January 2011. Among 1,457 survey respondents, 49% reported that they had received influenza vaccination: 12% were vaccinated before pregnancy, 32% during pregnancy, and 5% after pregnancy. Women offered influenza vaccination by a health-care provider (62%) were more likely to be vaccinated (71%) than other women (14%) and were more likely to have positive attitudes about vaccine effectiveness and safety. These results indicate that the higher vaccination level achieved the previous season (2009–10) was sustained and emphasize the critical role of health-care providers in promoting influenza vaccination. Continued efforts are needed to encourage health-care providers to strongly recommend and offer influenza vaccination to pregnant patients to protect both the mothers and their infants.

CDC conducted an Internet panel survey during April 4–25, 2011, to provide end-of-season estimates of influenza vaccination coverage and information on knowledge, attitudes, and behaviors related to influenza vaccination among pregnant women. Women aged 18–49 years who were pregnant at any time since August 1, 2010, were recruited from the SurveySpot panel operated by Survey Sampling International.* Of all panel members contacted in April 2011, a total of 2,126 were determined to be eligible for the survey, and 1,937 (91%) completed the online survey. The sample was weighted to reflect the age and race/ethnicity distribution based on census region estimates from the U.S. population of pregnant women (*8*). To be consistent with a previous study (*6*), the study population was limited to 1,457 women reporting pregnancy at any time during the peak influenza vaccination period (October 2010–January 2011).

Survey respondents were asked if they had an influenza vaccination since August 1, 2010, and if yes, in which month and whether it was before, during, or after pregnancy. Pregnancy status questions included whether respondents were currently pregnant or pregnant at any time since August 1, 2010, and if so, what were the actual months of pregnancy. Respondents who were pregnant at the time of the survey were asked their expected delivery date. All respondents were asked if their doctor or other health professional had offered them influenza vaccination during an office visit and their attitudes toward influenza and influenza vaccination. Weighted analyses were conducted using statistical software. Confidence intervals were calculated, and chi-square tests were used to assess statistical significance of differences in vaccination coverage levels between subgroups.

*Additional information available at http://www.surveysampling.com. The SurveySpot panelists generally were recruited from Internet sites that host large and frequent numbers of visitors and diverse Internet traffic. Multiple methods of recruitment were used, including banner ads, direct invitations, pop-ups, and web intercepts. The panel represents approximately 1 million households, and new panelists are continually being recruited; existing panelists are removed from the panel if they have opted-out or have not responded to an invitation within a specified period. A minimum incentive is routinely used to maintain the panel but not for an inducement to participate in a particular survey. Pregnant women panelists in this report were recruited from the SurveySpot panel using two methods. First, a message advertising the survey was placed on the main panel website (http://www.surveyspot.com), inviting panelists to view the survey eligibility questions on the panel's requirements page. A total of 18,789 respondents were invited, and 1,705 (9.1%) viewed the first eligibility question. Second, an e-mail invitation was sent to a sample of 11,688 panelists whose panel profiles indicated that they were women aged 18–49 years living in the United States. Of these, 1,370 (11.7%) replied. As a result of the two methods, a total of 3,075 panelists recruited went to the survey website and answered the first eligibility question.

Of the 1,457 women pregnant at any time during October 2010–January 2011, 49% reported influenza vaccination for the 2010–11 season: 12% were vaccinated before pregnancy, 32% during pregnancy, and 5% after pregnancy. Vaccination after pregnancy was more prevalent for women delivering early in the vaccination period, and vaccination before pregnancy was more prevalent among women who were in earlier stages of pregnancy later in the vaccination period (Figure). Younger women (aged 18–24 years) were less likely to be vaccinated than older women (aged 25–49 years) (44% versus 52%) (Table 1). College graduates were more likely to be vaccinated than those with less education. Women with health insurance coverage also were more likely to report influenza vaccination compared with those who were not insured.

Overall, 62% of women reported that they were offered influenza vaccination by their health-care providers; among those offered vaccination, 71% received influenza vaccination, substantially higher than the 14% vaccination level among women whose health-care providers did not offer vaccination (Table 1). Forty-five percent of women reported influenza vaccination in a previous influenza season, and these women were four times as likely to report 2010–11 vaccination as women without previous vaccination (84% versus 21%).

Compared with women whose health-care provider did not offer vaccination, women who received a health-care provider offer were more likely to have positive attitudes about the effectiveness of influenza vaccination (82% versus 54%), safety of influenza vaccination for pregnant women (78% versus 53%), and safety of vaccination for their infants (75% versus 47%) (Table 2). In addition, women who received a health-care provider offer consistently had higher vaccination levels than those who did not receive a health-care provider offer, regardless of their perceptions of vaccination safety or effectiveness expressed in April 2011. Moreover, women with a negative attitude toward vaccination who had received a health-care provider offer of vaccination were more likely to be vaccinated than women who had a positive attitude without a health-care provider offer.

The top five "main" reasons for not receiving influenza vaccination were "I am concerned about possible safety risks to my baby if I got vaccinated" (20%), "I am concerned that the vaccination would give me the flu" (17%), "I don't think the vaccination is effective in preventing flu" (14%), "I am concerned about possible safety risk to myself if I got vaccinated" (11%), and either "I don't think I would get very sick if I got the flu" or "I think if I get the flu, I will just get some medication to treat it" (14%).

The majority of women who were vaccinated during pregnancy received vaccination at their obstetrician/gynecologist or midwife's office (61%), followed by another doctor's office or another medical-related place (22%), a pharmacy or grocery store (8%), health department (5%), and their workplace or school (5%). Among women vaccinated either before or after pregnancy, 18% were vaccinated in an obstetrician/gynecologist or midwife's office, and 61% in another doctor's office or another medical-related place.

FIGURE. Percentage of women aged 18–49 years pregnant at any time during October 2010–January 2011 (N = 1,457) who received influenza vaccination before, during, or after pregnancy for the 2010–11 influenza season, by month of delivery or expected month of delivery — United States, Internet panel survey, April 2011

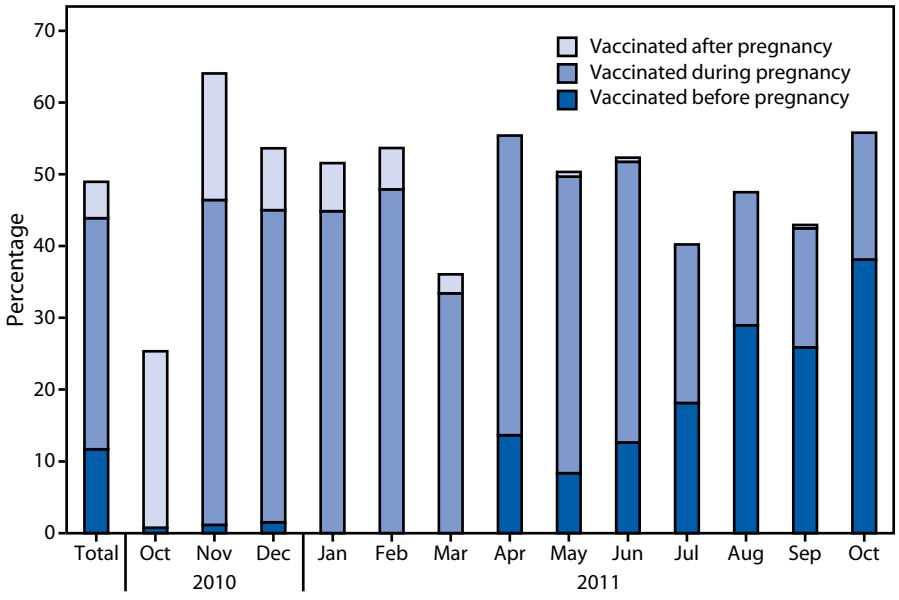

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TABLE 1. Percentage of women aged 18–49 years pregnant at any time during October 2010–January 2011 (N = 1,457) who received influenza vaccination before, during, or after pregnancy for the 2010–11 influenza season, by selected characteristics — United States, Internet panel survey, April 2011

Characteristic	Sample			Vaccination coverage*	
	No.	%†	(95% CI§)	%	(95% CI)
Overall	**1,457**	—	—	**49.0**	**(±2.8)**
Age group (yrs)					
18–24	504	34.5	(±2.6)	43.6	(±4.6)
≥25	953	65.5	(±2.6)	51.8	(±3.5)
Race/Ethnicity					
Hispanic	195	21.7	(±2.7)	53.2	(±7.3)
White, non-Hispanic	977	56.3	(±2.9)	46.5	(±3.3)
Black, non-Hispanic	200	16.5	(±2.1)	47.1	(±7.2)
Other	84	5.5	(±1.2)	63.8	(±10.9)
Education					
<College graduation	890	63.3	(±2.7)	43.4	(±3.6)
College graduate	441	30.2	(±2.6)	54.9	(±5.1)
>College graduation	93	6.5	(±1.4)	66.9	(±10.7)
Marital status					
Married	567	40.9	(±2.8)	53.6	(±3.6)
Not married	890	59.1	(±2.7)	42.3	(±4.4)
Working status¶					
Working	830	56.6	(±2.8)	54.6	(±4.2)
Not working	625	43.4	(±2.7)	44.6	(±3.7)
Health insurance coverage (at interview)					
Any public	656	46.2	(±2.8)	46.2	(±4.1)
Private/military	688	46.1	(±2.8)	54.1	(±4.1)
None	113	7.8	(±1.5)	35.0	(±9.4)
Had influenza vaccination in previous season					
Yes	644	44.8	(±2.8)	83.5	(±3.0)
No	813	55.2	(±2.7)	20.9	(±3.0)
Other high-risk conditions**					
Yes	354	26.3	(±2.5)	58.2	(±5.6)
No	1,103	73.7	(±2.5)	45.7	(±3.2)
Offered influenza vaccination††					
Yes	836	61.7	(±2.8)	70.8	(±3.3)
No	512	38.3	(±2.8)	14.4	(±3.1)

* Chi-square test of association between influenza vaccination and each characteristic was statistically significant (p<0.05).
† Weighted percentage.
§ Confidence interval.
¶ Those who were employed for wages and the self-employed were grouped as working; those who were out of work, homemakers, students, retired, or unable to work were grouped as not working.
** Conditions associated with increased risk for serious medical complications from influenza, including chronic asthma, a lung condition other than asthma, a heart condition, diabetes, a kidney condition, a liver condition, or a weakened immune system caused by a chronic illness or by medicines taken for a chronic illness.
†† Based on response to the question, "During your visits to the doctor/medical professional, did your doctor or other health professional offer the flu vaccination to you?"

What is already known on this topic?

Pregnant women are recommended by the American College of Obstetricians and Gynecologists and the Advisory Committee on Immunization Practices to receive influenza vaccination regardless of trimester. Vaccination coverage among pregnant women was approximately 50% for the 2009–10 season, much higher than coverage reported for previous influenza seasons. Health-care provider recommendation is strongly associated with vaccination among pregnant women.

What is added by this report?

Approximately 49% of pregnant women in an Internet panel survey were vaccinated for influenza for the 2010–11 influenza season; 32% were vaccinated during pregnancy, and 17% before pregnancy or after delivery. Among the 62% of pregnant women who received a health-care provider offer for influenza vaccination, nearly three quarters were vaccinated, which was five times the coverage among those who didn't receive a health-care provider offer.

What are the implications for public health practice?

Continued efforts are needed to 1) encourage health-care providers to strongly recommend and offer inactivated influenza vaccination to their pregnant patients and 2) remove barriers for health-care providers to administer influenza vaccination as part of routine practice. Messages to pregnant women from health-care providers and others should emphasize the safety and effectiveness of maternal influenza vaccination to maximize protection of pregnant patients and their infants.

Editorial Note

Results from this survey indicate that the record high influenza vaccination levels among pregnant women reported for the previous influenza season (2009–10) were sustained during the 2010–11 season. During 2009–10, pregnant women were included in the initial target groups to receive the inactivated 2009 H1N1 pandemic vaccine, and CDC worked closely with key partners, especially the American College of Obstetricians and Gynecologists, to increase awareness that pregnant women were at increased risk for severe illness from influenza and were recommended for influenza vaccination to protect themselves and their infants (*9*). However, vaccination levels are still below the *Healthy People 2020* target of 80% influenza vaccination coverage for pregnant women.†

This study found that women who received a health-care provider offer were more likely to believe influenza vaccination was effective, protective, and safe for themselves and their infants, and were nearly five times more likely to report receipt of vaccination compared with those who visited a doctor

† Additional information about *Healthy People 2020* objectives for influenza vaccination is available at http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23.

TABLE 2. Attitudes and vaccination coverage for the 2010–11 influenza season among women aged 18–49 years pregnant at any time during October 2010–January 2011 (N = 1,457), by receipt of a health-care provider offer of influenza vaccination — United States, Internet panel survey, April 2011

	Sample distribution						Vaccination coverage*			
	Offer† (n = 836)			No offer (n = 512)			Offer (n = 836)		No offer (n = 512)	
Response	No.	%§	(95% CI¶)	No.	%	(95% CI)	%	(95% CI)	%	(95% CI)
Flu vaccine is somewhat/very effective in preventing flu										
Yes	576	81.9	(±3.1)	168	53.8	(±6.0)	86.7**	(±3.0)	36.1**	(±7.6)
No	132	18.1	(±3.1)	147	46.2	(±5.9)	46.2	(±9.4)	4.5	(±3.4)
Agree/strongly agree that if a pregnant woman receives the flu vaccination, it will protect the baby from getting the flu after it is born										
Yes	431	52.5	(±3.7)	146	29.0	(±4.3)	81.1**	(±3.9)	24.7**	(±7.4)
No	404	47.5	(±3.7)	364	71.0	(±4.2)	59.6	(±5.3)	10.4	(±3.2)
Flu vaccination is somewhat/very/completely safe for most adult women										
Yes	774	92.6	(±1.9)	428	83.2	(±3.5)	73.6**	(±3.3)	16.1**	(±3.6)
No	61	7.4	(±2.0)	82	16.8	(±3.5)	39.0	(±13.3)	6.7	(±6.0)
Flu vaccination is somewhat/very/completely safe for pregnant women										
Yes	645	77.8	(±3.1)	272	52.7	(±4.6)	80.6**	(±3.2)	21.9**	(±5.1)
No	190	22.2	(±3.0)	240	47.3	(±4.7)	37.7	(±7.4)	6.1	(±3.1)
Flu vaccination that a pregnant woman receives is somewhat/very/completely safe for her baby										
Yes	618	75.1	(±3.2)	241	47.0	(±4.6)	81.7**	(±3.2)	23.3**	(±5.6)
No	217	24.9	(±3.1)	270	53.0	(±4.7)	38.9	(±7.0)	6.7	(±3.0)
Somewhat/very worried about getting sick from this season's flu vaccination										
Yes	397	47.9	(±3.7)	194	37.2	(±4.4)	74.2	(±4.6)	13.4	(±5.0)
No	438	52.1	(±3.7)	317	62.8	(±4.5)	68.1	(±4.6)	15.1	(±4.0)
If a pregnant women gets the flu, it is somewhat/very likely to harm the baby										
Yes	445	60.1	(±3.8)	258	61.7	(±5.0)	70.8	(±4.4)	17.1	(±4.8)
No	299	39.9	(±3.8)	171	38.3	(±4.9)	72.0	(±5.5)	15.0	(±5.6)

* The difference in vaccination coverage between those who received a health-care provider offer compared with those who did not receive a provider offer was statistically significant ($p<0.05$ by chi-square test) for each level (Yes or No) of each attitude.
† Based on response to the question, "During your visits to the doctor/medical professional, did your doctor or other health professional offer the flu vaccination to you?"
§ Weighted percentage.
¶ Confidence interval.
** The difference in vaccination coverage between those classified as "Yes" response to the attitude question compared with those classified as "No" response to the attitude questions was statistically significant ($p<0.05$ by chi-square test).

but did not receive an offer of vaccination. Pregnant women who had previously received influenza vaccination were four times more likely to receive influenza vaccination compared with those without a prior history of influenza vaccination. Because influenza vaccination is now recommended for all persons aged ≥6 months (*1*), further implementation of the universal vaccination recommendation among women of childbearing age might help to increase the likelihood of influenza vaccination before and during pregnancy.

Pregnant women who receive regular prenatal care have many more opportunities for a health-care provider offer of influenza vaccination than nonpregnant women. However, nearly four out of 10 women in this survey did not receive an offer of vaccination even though they visited a health-care provider at least one time. Barriers to providing influenza vaccination in health-care providers' offices identified by previous studies include lack of infrastructure for vaccine storage, lack of training for nurses to administer vaccines, and concern about safety and related lawsuits for vaccinating first trimester women (*10*). Another finding of this study was that women still reported safety risk to their infant as the most common main reason for refusing influenza vaccination, even though influenza vaccination during pregnancy can protect women and their infants (*2–4*). This study also indicated that a substantial proportion of women who delivered early in the influenza season received their vaccination after delivery. Vaccination of members of households with an infant aged <6 months is important for minimizing influenza risk for the upcoming influenza season.

The findings in this report are subject to at least two limitations. First, selection bias might remain after weighting adjustments, given the exclusion of women with no Internet access and the self-selection processes for entry into the panel and participation in the survey. However, influenza vaccination coverage estimated from this study, restricted to women who were pregnant at any time during December 2010 (48%), was similar to the coverage estimates based on December 2010 Behavioral Risk Factor Surveillance System (BRFSS) interviews of women who were pregnant at that time (51%) (CDC, unpublished data, 2011). BRFSS is a telephone survey and also might be subject to selection bias because of exclusion of households without landline telephone service. Pregnant women account for only 1% of the general population, and conducting a random-digit–dialing survey or a mail survey large enough to obtain an adequate sample size would be costly and time-consuming. The similar estimate from BRFSS provides more evidence to support the use of Internet panels as useful surveillance data sources for timely midseason and postseason evaluation of influenza vaccination among pregnant women. Second, the survey was self-administered, and because pregnancy and vaccination status were not validated by medical record review, all responses are subject to recall and reporting error.

This study found that the higher vaccination level achieved during the 2009–10 influenza season (the fall wave of 2009 H1N1 virus activity) among pregnant women was repeated the following season, and identified key elements highly associated with pregnant women's acceptance of influenza vaccination, such as the health-care provider offer of vaccination and past receipt of influenza vaccination. Continued efforts are needed to encourage health-care providers to strongly recommend and offer influenza vaccination to their pregnant patients. Additional efforts are needed to remove barriers for health-care providers to administer influenza vaccination as part of routine practice. Messages to pregnant women from health-care providers and others should emphasize the safety and effectiveness of maternal influenza vaccination to maximize protection of pregnant patients and their infants.

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SECTION TEN
APPENDIX E

A PROVIDERS' GUIDE TO DISCUSSING FLU VACCINATION

TALKING TIPS TO USE WITH THOSE WHO ARE RELUCTANT TO GET VACCINATED FOR SEASONAL INFLUENZA.

Each flu season Veterans and VA health care personnel are encouraged to get vaccinated for seasonal influenza (flu). However, misinformation, myths, and personal experience can influence those who choose not to get the flu vaccine. Given the many reasons people offer about why they don't get the flu vaccine, it can be a challenge to respond to these concerns.

Review the topics and consider using them to address concerns and questions regarding flu vaccination from Veteran patients and VA staff. These responses can assist you as a guide to structure your conversation by responding with facts, respect, encouragement, and empathy.

The reasons and their accompanying messages fall into four common categories: 1) safety, effectiveness, and fear; 2) vaccination timing; 3) confusion about appropriate vaccine and "risk groups"; and 4) overconfidence in one's own health.

1. Safety, Effectiveness, and Fear

What people say:

"I don't want to get the flu shot because…"

"I hear there are side effects."
"The flu shot will give me the flu."
"I don't know what's in the vaccine, so I won't take it."
"I don't like putting things in my body, especially when no one knows if it is safe."
"I got the flu last year even though I had been vaccinated. So, what's the point?"
"How do I know the vaccine really works?"
"I'm very afraid of needles."
"I can't get the flu shot because I'm allergic to eggs."
"I'm pregnant so getting the flu shot is scary to me."

Points to share with Veterans and health care personnel with regard to safety, effectiveness, and fear:

- The most effective way to protect yourself from the flu is by getting an annual flu vaccination. Studies show that both the flu shot and the nasal spray vaccine are effective in preventing the flu.
- You cannot get the flu from the flu shot or the nasal spray flu vaccine. The vaccine used in your arm is not made from a live virus and cannot infect you with the flu. Although the nasal spray vaccine is made with live, weakened flu viruses, it also does not cause the flu.
- Some people who get the flu shot can still get the flu. However, it is not caused by the vaccine. Sometimes you can already be exposed to the flu a few days before you received the vaccine, but you just didn't develop symptoms until around the same time you got vaccinated. Also, sometimes flu develops when there is a mismatch of the flu vaccine to the flu viruses that are circulating that year. Today's flu vaccines are safer and better than ever. They cause fewer side effects than those used in the past. Flu vaccines have been in use since the 1940s and have continuously been tested for safety and updated to improve their effectiveness.
- The U.S. Food and Drug Administration (FDA) ensures that vaccines undergo a rigorous and extensive development program. After a vaccine is approved by the FDA, its safety is continuously monitored. Ingredients used during the manufacture of flu vaccines include substances to help:
  - o prevent contamination,
  - o inactivate or "kill" the viruses, and
  - o stabilize the vaccine from changing.

VA health care personnel and Veterans can learn more about the composition of the seasonal flu vaccine at http://www.cdc.gov/flu/professionals/vaccination/virusqa.htm.

- One mild side effect from the flu shot is tenderness at the site of the shot (injection) that can last for several days. There may be soreness, redness, or swelling that can be relieved by putting ice on the injection site. Moving the arm to keep the muscle loose may also help.
- Some people who get the injection may have a slight fever, chills, headache, tiredness, or muscle ache within the first 48 hours of getting the shot. These reactions may begin 6 to 12 hours after the shot, can last for one to two days, and are more likely to happen in people who have never received a flu vaccine. Two days of discomfort are better than getting the flu and its related complications, which can last for many days or even weeks.
- The flu vaccine is changed each year to match the type of flu currently circulating. Each year the vaccine is formulated to provide a close match to the known circulating strains of flu virus in the most recent flu season. In years when there is a good match between the circulating viruses and the corresponding vaccine strains, the vaccine's effectiveness in reducing illness can be as high as 70–90 percent. In years where the match is not close, the chances of getting the flu without getting a flu shot is still going to be higher.
- Being afraid of needles means you are normal! If you are afraid of needles you may be a candidate for the nasal spray vaccine (FluMist®). The most common side effects from this delivery method are a runny nose and nasal congestion. If you are age 49 or under, healthy, and not pregnant, the nasal vaccine may be right for you. Discuss the nasal spray with your health care provider to see if it is an option for you.
- It is recommended that all pregnant women, including those that are Veterans or VA staff, get the flu vaccine to protect themselves and their babies. All pregnant women are at risk from influenza and its complications. The flu shot can be safely given any time during the pregnancy. However, pregnant women should NOT receive the nasal spray flu vaccine (FluMist®).

2. Vaccination Timing

What people say:

"I don't want to get the flu shot because…"

"I got the seasonal flu shot last year. I've heard that once is enough."
"It's past October, I waited too late to get the flu shot. I'll just get it next year."
"The flu is not circulating in my community."
"I don't have time to get my flu shot. I'm just too busy!"

Points to share with Veterans and VA staff with regard to timing:

- The flu vaccine is effective in your body for about one flu season. Therefore, the flu vaccine is recommended EVERY year to get the latest protection.
- The circulating flu virus strains usually change from year to year. The components of the flu vaccine are updated every year in response to the most common circulating strains of flu virus, so you need an annual shot to get the latest protection for the current flu season. Even if the vaccine and the circulating strains are not an exact match, the vaccine can reduce the severity of the illness and help prevent influenza-related complications.
- Adults need only ONE seasonal flu vaccination each year.
- The flu vaccine stimulates production of antibodies by your body that provide protection against the flu viruses. The greater your antibody response the greater your protection against flu. Usually it takes about two weeks after your vaccination for your body to build enough antibodies to provide protection from flu.
- It is never too late to get the flu shot. Flu viruses begin circulating in the U.S. in the fall and continue into spring. VA encourages flu vaccination as soon as the vaccine is available, but you can get a flu vaccination at any time during flu season and be protected after that.

- Even if you think the flu is not circulating in your community, it can show up anytime. So it's best to be ready and get vaccinated before flu shows up in your community.
- Because it's sometimes hard to find the time to get the flu vaccine, the VA offers the flu vaccine at no charge to enrolled Veterans at VA health facilities throughout the country. Getting vaccinated will protect you and help prevent the spread of flu to your family, fellow Veterans, VA health care personnel, and others.
- VA offers the flu vaccine at no charge to its staff at VA health care facilities across the country. Getting vaccinated will protect you, and reduce your chances of infecting your family, the Veterans you serve, your co-workers, and others.

3. Confusion about Vaccination and "Risk Groups"

What people say:

"I'm not going to get the flu shot because…"

"The rules keep changing about who should get vaccinated. I keep hearing mixed messages."

"I hear that older people are supposed to get the flu shot. I'm too young to need a flu shot."

"I'm not in a high-risk group."

"I don't like shots and wanted to get the flu nose spray but I was told I couldn't get it because I was too old. I am only 52 and the nurse said no one over 49 could get the nose spray for flu. Why is that?"

"I'm over 65 and I'm not sure whether I should get the regular flu shot or the high dose one?"

"I hear that now even young people are supposed to get the flu shot. The government can't seem to make up their minds on this. I'm at no more risk for flu than I was last year."

Points to share with Veterans and VA staff to clear up confusion and hesitation with regard to the flu vaccine:

- Yearly flu vaccination is now recommended for all persons age 6 months and older. The age range is expanded from previous recommendations, and is supported by evidence that annual flu vaccination is a safe and effective preventive health action with potential benefit for all people 6 months and older.
- People younger than age 65 should be administered a standard dose of flu vaccine.
- People age 65 years or older may be eligible for either the standard dose or the high dose flu vaccine. Both vaccines are made up of the three flu strains most likely to cause illness this flu season. The high dose vaccine, made available in 2010, contains four times the amount of antigen (the part of the vaccine that prompts the body to make antibody) than in regular flu shot. Because human immune defenses become weaker with age the high dose vaccine is intended for people age 65 and older. The additional antigen in the high-dose vaccine is intended to create a better immune response (more antibodies) in the person getting the vaccine. Thus, people age 65 and older now have another option - the high-dose flu vaccine. Your health care provider can help you decide if you should get the high dose OR the standard dose vaccine. You only need one, never both. It is estimated that 90 percent of the 36,000 annual deaths in the U.S. that are attributed to influenza and its complications are in people age 65 years and older so it is especially important that older Veterans and staff get vaccinated against the flu. As with the regular flu shot, the high dose formulation is not recommended for people with a severe allergy to chicken eggs, or people who have had a severe reaction to a flu vaccine in the past.
- Even if you are not at high risk, you should get a flu vaccination to protect yourself, and help reduce your chances of spreading the flu to your family, other Veterans, VA health care personnel, friends, and others.
- The nasal spray is not for everyone. It contains a live, weakened flu virus. It is approved for use only in people who are between the ages of 2 and 49. It should not be given to pregnant women or people who have severe allergy to eggs.

4. Overconfidence in One's Own Health

What people say:

"I don't want to get the flu shot because…"

"I'm healthy. I've always been healthy. I don't need to get vaccinated for flu."
"I have a strong immune system, so I am willing to risk getting the flu."
"I don't need the flu shot. If I get the flu, I'll just take an antiviral medication."
"If I get the flu, I'll just take an antibiotic."
"My immune system is working just fine, thank you. I never get sick!"
"I've been around a long time and probably been exposed to all kinds of flu. In fact, because I'm 70, I probably have some immunity to it."

Points to share with Veterans and VA staff with regard to feeling overconfident about their own health:

- Influenza can cause serious illness and death even in the healthiest of people. The flu is not a disease that affects just the elderly. The flu can infect any person of any age. If you get the flu, you can spread it to your family, other Veterans, VA health care personnel and other staff, co-workers, and others. This puts everyone at risk for severe illness and complications from the influenza virus. Getting vaccinated protects you, your family, other Veterans, VA staff, and others.
- The flu virus changes almost every year, so even if you were immune one year, you may not be immune to the strains of flu virus spreading the next year. It's better to be protected by getting vaccinated against flu each year.
- Antiviral medications do not eliminate flu symptoms. They do shorten the duration by about three days, but you'll feel sick, miss out on your daily activities for several days, and/or need to be out of work. There is a cost associated with these antivirals and they must be taken very early during your illness to be effective in reducing the symptoms of flu.
- The flu is a virus. Antibiotics only work against bacteria and, therefore, cannot help treat the flu.
- Remember, you can spread flu to others before you have symptoms. To protect yourself, your family, other Veterans, VA health care personnel and other staff, your coworkers, and others, you should get vaccinated.
- Most people who get the flu experience the full effect of its symptoms. There are some people who get flu without noticeable symptoms. These people can still spread the flu to others even before realizing they are ill.

For More Information

- Department of Veterans Affairs (VA) flu site: www.publichealth.va.gov/flu
- Centers for Disease Control and Prevention (CDC) flu site: www.cdc.gov/flu/
- U.S. Government flu site: www.flu.gov

SECTION TEN
APPENDIX F

RESOURCES, REFERENCES AND WEB SITES

RESOURCES

- This VA Influenza Manual 2012-2013 is available on the VA Internet sites www.publichealth.va.gov/flu and www.publichealth.va.gov/InfectionDontPassItOn

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www.vaccines.gov
Vaccines.gov is a Federal government website that brings together the best in federal resources on vaccine and immunizations. It provides easy-to-understand health information specifically designed for consumers. The site includes content about vaccine recommendations, the diseases that vaccines prevent, important information for getting vaccinated, and tips on travel health. It also links consumers with resources in their states to learn about vaccine requirements for school or child care entry and local community information.

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http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-flu-largetype.pdf (large type)

Live, Intranasal Influenza
http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-flulive.pdf
Pneumococcal Polysaccharide (PPV23)
http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-ppv.pdf

Flu Vaccine Package Inserts

FluMist:
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094047.htm

Fluzone and Fluzone HD
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm112854.htm

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HAND HYGIENE AND RESPIRATORY/COUGH ETIQUETTE

Videos

Veterans Health Administration (VHA) – Infection: Don't Pass It On
Target Audience: General (patients, Veterans and their families, colleagues, all VA staff, friends, family and community partners and organizations) http://www.publichealth.va.gov/flu/materials/videos.asp

2009 Detroit VAMC Hand Hygiene Video
"Germ-X" (spoof of 1950's science fiction B-movies) tells the story of how one employee learns the importance of hand hygiene. This production was done by the Medical Media Production Services @ John D. Dingell VA Medical Center.

CDC Patient Admission Video
This video, available in English and Spanish, teaches two key points to hospital patients and visitors to help prevent infections: the importance of practicing hand hygiene while in the hospital, and that it is appropriate to ask or remind their healthcare providers to practice hand hygiene as well.http://www.cdc.gov/handhygiene/Patient_materials.html

The Joint Commission Center for Transforming Healthcare
These Joint Commission videos from the Hand Hygiene Project focuses on improving and sustaining hand hygiene compliance. http://www.centerfortransforminghealthcare.org/projects/detail.aspx?Project=3

World Health Organization (WHO)
These videos focus on a myriad of topics related to hand hygiene. http://www.who.int/gpsc/5may/video/en/index.html

The New England Journal of Medicine
The New England Journal of Medicine website offers this video as a comprehensive resource that addresses equipment, indications, hand hygiene technique, appropriate use of gloves, jewelry and fingernails, skin irritation, fire hazard and religious issues. http://www.nejm.org/doi/full/10.1056/NEJMvcm0903599#figure=preview.jpg

Posters and Flyers

Veteran Health Administration (VHA)
These posters provide information on hand hygiene for target audiences throughout the VA health care system. See Section 8 for ordering information. http://www.publichealth.va.gov/flu/materials/posters.asp

Salt Lake City VA Medical Center, "Blue Hands Group"
The Salt Lake City VA Medical Center recruited their leadership team to support their hand hygiene campaign. Life size posters of their leaders wearing blue gloves with messages that encourage hand hygiene are strategically place throughout their medical center. http://www.saltlakecity.va.gov/SALTLAKECITY/pressreleases/bluehandgroup2010.asp

Centers for Disease Prevention and Control (CDC)
These posters will further emphasize the concepts and techniques to increase hand hygiene at your facility. http://www.cdc.gov/handhygiene/training/interactiveEducation/index2.htm

- These posters demonstrate hand hygiene techniques using traditional soap and water and alcohol-based hand sanitizer. http://www.cdc.gov/handhygiene/Basics.html
- This CDC poster focuses on hand hygiene for patients and visitors. http://www.cdc.gov/handhygiene/PDF/CDC_HandHygienePoster.pdf
- Provides posters and flyers in multiple languages on "stop the spread of germs" for health care settings as well as community and public settings like schools and child care facilities. http://www.cdc.gov/flu/protect/covercough.htm/

U.S. Department of Health and Human Services (DHHS)
The **"WAVE" campaign** is a new campaign launched by the DHHS asks patients and their family members to **w**ash hands, **a**sk questions, **v**accinate and **e**nsure safety. The campaign provides several free tools including a wallet card, brochure and posters which organizations and hospitals can use to support their infection prevention efforts. http://www.healthcare.gov/compare/partnership-for-patients/resources/conditions.html#wave

The Association for Professionals in Infection Control and Epidemiology (APIC)
This informative one-page flyer, Infection Control Tips for Hand Hygiene, provides helpful tips for healthcare professionals and is ideal for staff education for hand hygiene. http://www.apic.org/Resource_/EducationalBrochureForm/35946419-b224-4635-a5b6-07d666118531/File/Infection-Control-Tips-Handwashing-Brochure.pdf

Hand Hygiene Resource Center (HHRC)
The HHRC has tools that can help you promote good hand hygiene in your organization or institution. Educational presentations and other materials to help educate your physicians, clinicians, nurses and other staff about hand hygiene are provided. http://www.handhygiene.org/educational_tools.asp

The Ambulatory Surgical Center (ASC) Quality Collaborative
The ASC Quality Collaboration has assembled a variety of resources and information that may be used to supplement your current processes to improve hand hygiene practices.
The BASIC Hand Hygiene Toolkit includes four essential resources: Hand Hygiene: What CMS Surveyors Are Looking For; How to Handwash Poster; How to Handrub Poster; Hand Hygiene Policy and Procedure Template. The EXPANDED Hand Hygiene Toolkit contains both essential resources and a broader array of materials including: Assessment Tools, Implementation Aids, Training Materials, Monitoring Tools, Workplace Reminders, and Guidelines from Leading Authorities. http://www.ascquality.org/handhygienetoolkit.cfm

World Health Organization (WHO)
This site contains useful resources to promote and improve hand hygiene practices within health care facilities. http://www.who.int/gpsc/5may/tools/workplace_reminders/en/index.html

- **Your 5 Moments for Hand Hygiene Poster**
  A poster explaining the My 5 Moments for Hand Hygiene approach to display at your health-care facility. http://www.who.int/gpsc/5may/tools/workplace_reminders/Your_5_Moments_For_Hand_Hygiene_Poster_Chair.pdf
- **How to use Hand Rub**
  A poster with step-by-step instructions on how to properly use hand rubs to clean and decontaminate hand. http://www.who.int/gpsc/5may/How_To_HandRub_Poster.pdf
- **How to Wash Hands**
  A poster with step-by-step instructions on how to properly wash hands using soap and water. http://www.who.int/gpsc/5may/How_To_HandWash_Poster.pdf

Brochures & Pamphlets

Veterans Health Administration (VHA)
This brochure targeting a general audience (patients, veterans, and visitors) addresses hand washing and using alcohol hand rubs. See Section 5, Appendix for ordering information. http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1927

Association for Professionals in Infection Control and Epidemiology (APIC)
Hand Hygiene for Consumers explains when and how to wash your hands and when and how to use alcohol handrubs. The brochure also offers information about the skin, an important barrier against harmful irritants and germs, and how to protect it from dryness. http://www.apic.org/Resource_/EducationalBrochureForm/fa13a1c7-1fda-4987-a0be-118bbbee09cd/File/Hand-Hygiene-Consumers-Brochure.pdf

Association for Professionals in Infection Control and Epidemiology (APIC)
Improved adherence to hand hygiene practices and skin wellness may significantly impact patient outcomes and occupational health. http://www.apic.org/Resource_/EducationalBrochureForm/067506c0-c605-48de-9d6c-e236f0ed5c54/File/APIC-Healthy-Skin.pdf

World Health Organization (WHO)
WHO's summary of the why, how and when of hand hygiene for health care personnel. http://www.who.int/gpsc/5may/Hand_Hygiene_Why_How_and_When_Brochure.pdf

WEB SITES

Influenza and Immunization Web Sites

Department of Veterans Affairs

http://www.publichealth.va.gov/flu/ – Influenza Web sites for the Department of Veterans Affairs. These include links on the influenza virus and influenza vaccine, VA policy and guidance on influenza, and VA resources for implementation of seasonal influenza vaccination campaigns.

http://www.publichealth.va.gov/InfectionDontPassItOn – Web sites for the VA public health campaign "Infection: Don't Pass It On," which focuses on prevention of infection within the VA medical system through hand and respiratory hygiene, resources for infection emergencies and vaccination against influenza and pneumonia.

Federal Government

http://flu.gov – this site is the new official Federal website that provides information on seasonal and pandemic influenza information.

http://www.cdc.gov/vaccines – This is the Web site for the National Immunization Program of the Centers for Disease Control and Prevention (CDC) and has a great deal of information for the public and health care providers on all immunization topics.

http://www.cdc.gov/vaccines/recs/acip/default.htm – This page on the NIP site lists all recommendations of the ACIP (Advisory Committee for Immunization Practices).

http://www.cdc.gov/vaccines/schedules/index.html – This page includes easy-to-read. printable schedules of adult immunization recommendations, an interactive tool to download, and an adult vaccination screening form.

http://www.cdc.gov/flu/weekly/fluactivitysurv.htm This page provides weekly updated reports about national and international influenza activity and has fundamental information concerning influenza surveillance methods.

http://www.cdc.gov/vaccines/recs/rate-strategies/adultstrat.htm – This page includes Strategies for Increasing Adult Vaccination Rates (NIP), Updated June 2010.

http://www.cdc.gov/flu/ – This is the main influenza Web page of the CDC. It includes extensive information about influenza and its prevention and control for patients and health care professionals.

http://www.healthfinder.gov/nho/augtoolkit.aspx – A toolkit to use for National Immunization Awareness Month (August), including sample tweets and e-cards.

http://www.fda.gov/cder/drug/antivirals/influenza/ – This web page from the Food and Drug Administration has links for influenza vaccine information and antiviral drug information.

http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm110288.htm – FDA Web Page on Influenza Vaccine Safety & Availability.

http://www.cdc.gov/flu/about/qa/vaccine-selection.htm Information about 2012-2013 Influenza Vaccine Component Selection.

http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm310644.htm – List of strains included in the 2012-2013 Influenza Vaccine.

http://www.nlm.nih.gov/medlineplus/influenza.html – This is the influenza Web page of Medline Plus, a service of the National Library of Medicine, National Institutes of Health (NIH). It includes sections on news, diagnosis, treatment, prevention, disease management, clinical trials and other research, and information focused on audiences ranging from children to the elderly.

Non Federal Government

http://www.immunize.org – This is the Web site for the Immunization Action Coalition (IAC) with a wide variety of information about immunizations, including Vaccine Information Statements in many languages. The Directory of Immunization Resources is full of useful information on organizations, Web sites, hotlines, and agencies that are immunization resources.

http://www.vaccineinformation.org/ – This page from the IAC is comprehensive, organized, and easy to access. For each vaccine-preventable disease, there are answers to many questions about the disease and the vaccine, as well as sections containing photos, case histories, recommendations, references, and links to useful resources. Also included is material about vaccine safety, travel, bioterrorism, state laws – and much more. Has information in Spanish.

http://www.acponline.org/aii – This site from the American College of Physicians provides resources and tools to support physicians in their immunization efforts, with the goal of improving adult immunization rates. It includes physician education, patient education, and practice management tools for immunization and reimbursement.

http://www.nfid.org/ – This is the Web site for the National Foundation for Infectious Diseases and contains a call to action and strategies for increasing influenza immunization among employees, trainees, and volunteers.

http://www.vaccines.org – This Web site provides access to up-to-the-minute news about vaccines and an annotated database of vaccine resources on the Internet.

http://www.ImmunizationEd.org – This is a Web page from the Group on Immunization Education of the Society of Teachers of Family Medicine. On this site you will find news and reports to keep family physicians up-to-date on vaccines for children and adults, links to the most current immunization schedules and vaccine information, downloadable slide presentations and photographs of diseases.

http://www.atpm.org/ – This Web site of the Association of Teachers of Preventive Medicine has several educational resources available for download or purchase for training health care professionals and students about immunization issues.

http://www.naccho.org/ – This is the Web site of the National Association of County and City Health Officials and has links to toolboxes for influenza and immunizations as well as links to training and resources pages.

http://www.mayoclinic.com/invoke.cfm?objectid=5CB89570-8B46-4961-8BFE66D06D5BDD1B – This is the Mayo Clinic patient information page on influenza.

http://www.health.state.mn.us/divs/idepc/diseases/flu/index.html – This is the influenza section of the Minnesota Department of Health.

http://www.medscape.com/resource/influenza – On this site you will find comprehensive clinical information and educational tools for clinicians and other healthcare professionals.

PANDEMIC & 2009 H1N1 INFLUENZA WEB SITES

Department of Veterans Affairs

VA Pandemic Influenza Information http://www.pandemicflu.va.gov/ – These sites contains VA Pandemic Influenza Plan and links to other documents, including information on use of the antiviral drug oseltamivir, respiratory infectious disease emergency plan for facilities, hand and respiratory hygiene, personal protective equipment.

Federal Government

Federal Government Information http://www.flu.gov/professional/federal/index.html – this site contains links to national strategy, federal agency activities, and information for federal employees.

World Health Organization

International Pandemic Influenza Information http://www.who.int/csr/disease/swineflu/en/index.html This site contains links to advice for travelers, world regional 2009 H1N1 influenza information, country activities, outbreak news and timeline planning; business, school, health care, and community planning; influenza watch and meeting update.

Hand Hygiene and Respiratory/ Cough Etiquette Web Sites

Department of Veterans Affairs

www.publichealth.va.gov/InfectionDontPassItOn. *Infection: Don't Pass It On* (IDPIO) campaign. IDPIO is an ongoing public health campaign to involve VA staff, Veterans, their families, and visitors in preventing the transmission of infection.

http://www.va.gov/VAI2/FundedInnovations_VHA.asp This site gives a short description of the selected employee innovation initiatives, including hands free bathrooms (Louisville, KY) and a standardized tool to monitor hand hygiene compliance (Boston, MA).

Federal Government

http://www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm Provides guidance on infection control measures that can be implemented at the first point of contact with a potentially infected person.

Non Federal Government

http://www.who.int/csr/resources/publications/EPR_AM2_E7.pdf Provides a Memory Aid with checklist for Standard Precautions including Respiratory Etiquette.

http://www.apic.org/Resource_/EducationalBrochureForm/e1498a81-9326-4877-b857-9234445e22d4/File/APIC-Respiratory-Etiquette.pdf Brochure for healthcare personnel on promoting respiratory etiquette and decreasing respiratory illnesses in the workplace. (2003) Association for Professionals in Infection Control and Epidemiology, Inc.

State Governments

http://www.vdh.virginia.gov/epidemiology/surveillance/hai/documents/pdf/RespiratoryHygieneCoughEtiquette_FAQ.pdf Virginia Department of Health's Fall 2011 Informational poster/pamphlet with "Frequently Asked Questions" about Respiratory Hygiene/Cough Etiquette.

http://www.health.state.mn.us/divs/idepc/diseases/flu/avian/hcp/standard.pdf provides key elements of the Minnesota Department of Health's guidance on concepts of respiratory hygiene and cough etiquette using source control measures to prevent patients with respiratory infections from transmitting infection.

http://www.arkhospitals.org/disasterpdf/Germs%20-%20Recommended%20Guidelines.pdf Arkansas Hospital Association's recommended guidelines for Respiratory Hygiene/Cough Etiquette Strategy for Health Care Facilities.

SECTION TEN
APPENDIX G

ACKNOWLEDGEMENTS

This manual is developed by the *Infection: Don't Pass It On* (IDPIO) campaign. IDPIO is an ongoing public health campaign to involve VA staff, Veterans, their families and visitors in preventing the transmission of infection. The campaign develops and distributes education and communication resources for the VA community to promote:

- hand hygiene and respiratory etiquette
- annual seasonal influenza vaccination, preparedness and response
- correct and appropriate use of personal protective equipment, and
- basic public health measures to prevent transmission of infection.

The VA *Infection: Don't Pass It On* team, September 2012.

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CPH Clinical Public Health

PUBLIC HEALTH

INFECTION: DON'T PASS IT ON CAMPAIGN

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INTERNET SITES

www.publichealth.va.gov/flu
www.publichealth.va.gov/InfectionDontPassItOn
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