



Influenza and Pneumococcal Disease

*Use of Standing Orders Programs to
Improve Vaccination Rates*



Vaccine Preventable Disease in Context

United States

- **The vast majority of vaccine preventable disease deaths occur in adults (approximately 99%)**
- **Deaths due to influenza and pneumococcal disease far exceed the number of deaths due to all other vaccine preventable diseases combined**

MMWR 2001; 48 (RR-53)

Thompson et al. *JAMA* 2003; 289: 179

Feikin DR, et al. *Am J Public Health* 2000; 90: 223-9.



Reality of vaccination in the public health setting.....

In public health clinics across the nation, nurses on a daily basis screen and safely vaccinate children and adults using physician-approved vaccination protocols. In most of these settings, there is no physician participation at the level of the individual patient when the vaccine is administered.

Presentation Outline

- **Vaccine preventable disease with a focus on influenza and pneumococcal disease**
- **Summary of available vaccines and recommendations for use**
- **The use of standing orders programs to improve vaccination rates in hospitals, nursing homes, clinics, and home health agencies**

Vaccine Preventable Disease



Influenza

- **Affects 5-20% of the population each year**
 - **Average of 36,000 deaths per year**
 - **Approximately 226,000 hospitalizations each year**
- **Uncomplicated Influenza**
 - **Symptoms**
 - **Fever, headache, fatigue, dry cough, sore throat, runny nose, myalgias, GI symptoms**
 - **Typically resolves in 3-7 days**

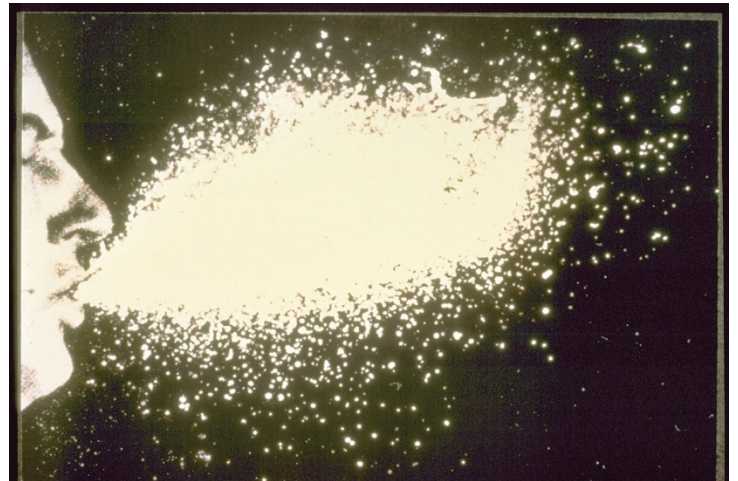


Complications of Influenza

- **Bacterial infections**
 - Pneumonia
 - Sinus and ear infections in children
- **Cerebrovascular and cardiac disease**
 - Increases risk of stroke
 - Increases AMI and HF admissions
- **Exacerbations of COPD or asthma**
- **Increases blood sugars in diabetics**
- **Respiratory failure**
- **Death**

Spread of Influenza

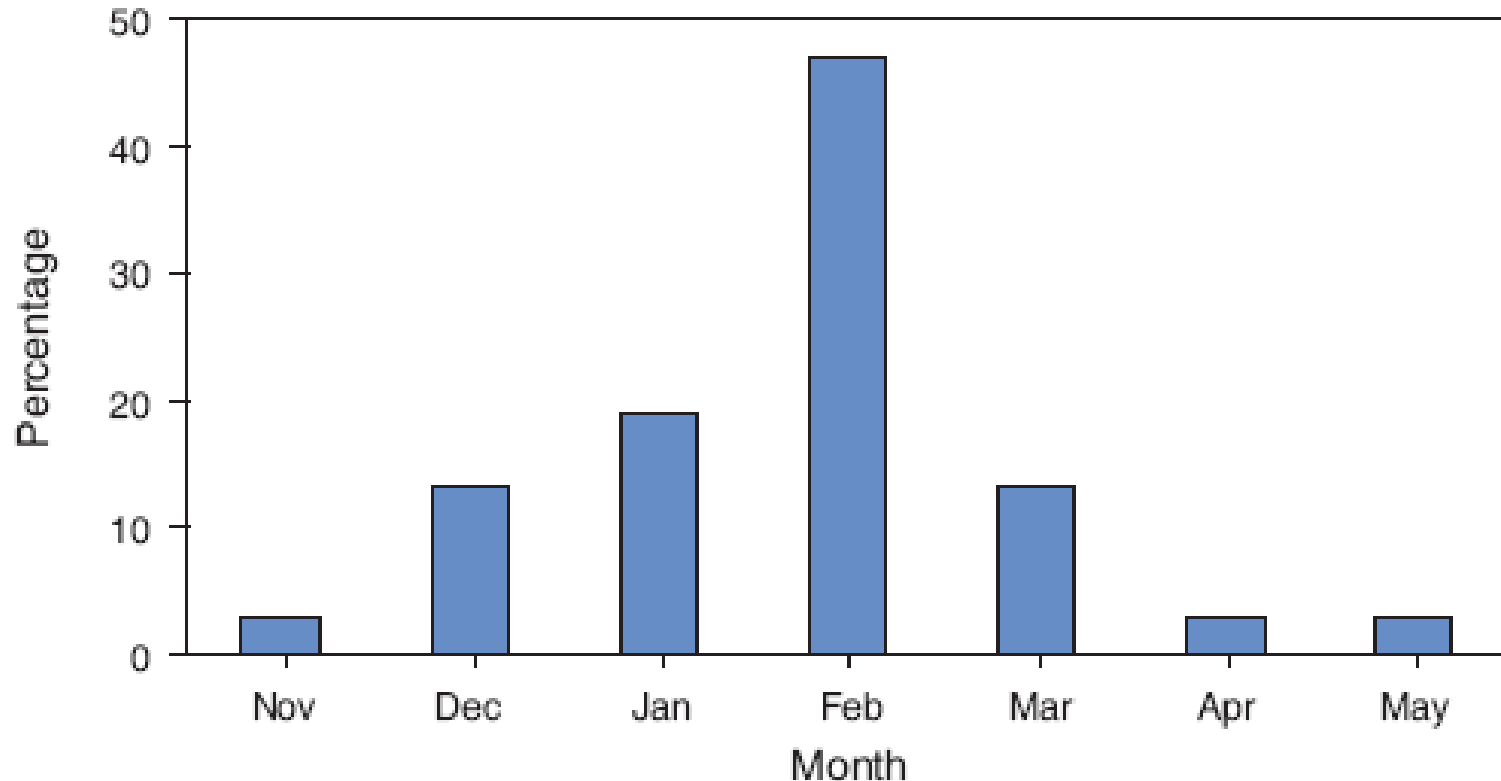
- Respiratory droplets
- Person-to-person
 - Contagious from one day prior to the onset of symptoms to up to 5-10 days after the onset of symptoms





Peak Months for Influenza Activity

FIGURE 1. Peak influenza activity, by month — United States, 1976–77 through 2007–08 influenza seasons



Vaccination needs to continue beyond December!



Pneumococcal Disease

Streptococcus pneumoniae

- **Gram-positive bacteria**
- **90 known serotypes**
- **Polysaccharide capsule important virulence factor**
- **Type-specific antibody is protective**
- **Resistance to antibiotics including penicillin has increased dramatically in the US**



Pneumococcal Pneumonia

Symptoms

- **Abrupt onset**
- **Fever**
- **Shaking chills (typically single rigor)**
- **Pleuritic chest pain**
- **Productive cough (rusty sputum)**
- **Dyspnea, tachypnea, hypoxia**



Pneumococcal Pneumonia

- **Estimated 175,000 hospitalized cases per year**
- **Up to 36% of adult community-acquired pneumonia and 50% of hospital-acquired pneumonia**
- **Common bacterial complication of influenza and measles**
- **Case-fatality rate 5%-7%, higher in elderly**



Pneumococcal Bacteremia

- **More than 50,000 cases per year in the United States**
- **Rates higher among elderly and very young infants**
- **Case fatality rate ~20%; up to 60% among the elderly**



Pneumococcal Meningitis

- **Estimated 3,000 - 6,000 cases per year in the United States**
- **Case-fatality rate ~30%, up to 80% in the elderly**
- **Neurologic sequelae common among survivors**



Pneumococcal Disease in Children

- **Bacteremia without known site of infection most common clinical presentation**
- ***S. pneumoniae* leading cause of bacterial meningitis among children younger than 5 years of age**
- **Highest rate of meningitis among children younger than 1 year of age**
- **Common cause of acute otitis media**



Annual Burden of Pneumococcal Disease in Children*

Syndrome	Cases
Bacteremia	13,000
Meningitis	700
Death	200
Otitis media	5,000,000

*Prior to routine use of pneumococcal conjugate vaccine.

Vaccines



Influenza vaccines

- **Inactivated subunit (TIV)**
 - Trivalent inactivated influenza vaccine
 - Intramuscular
- **Live attenuated vaccine (LAIV)**
 - Intranasal
 - Trivalent
 - Not recommended for persons ≥ 50 years of age
 - Not recommended in settings with immunocompromised patients



Benefits of Flu Shots in the Elderly

Pooled Estimates Over 6 Seasons

Outcome	Vaccine Effectiveness
Hospitalizations for	
Pneumonia & Influenza	39% (26% to 52%)
All Respiratory Conditions	32% (29% to 40%)
Congestive Heart Failure	27% (15% to 39%)
Deaths	50% (44% to 56%)
Cost Savings	\$73 per person

Data from MN HMO, 1990-91 thru 1995-96.
Nichol KL. Arch Intern Med 1998; 158: 1769.



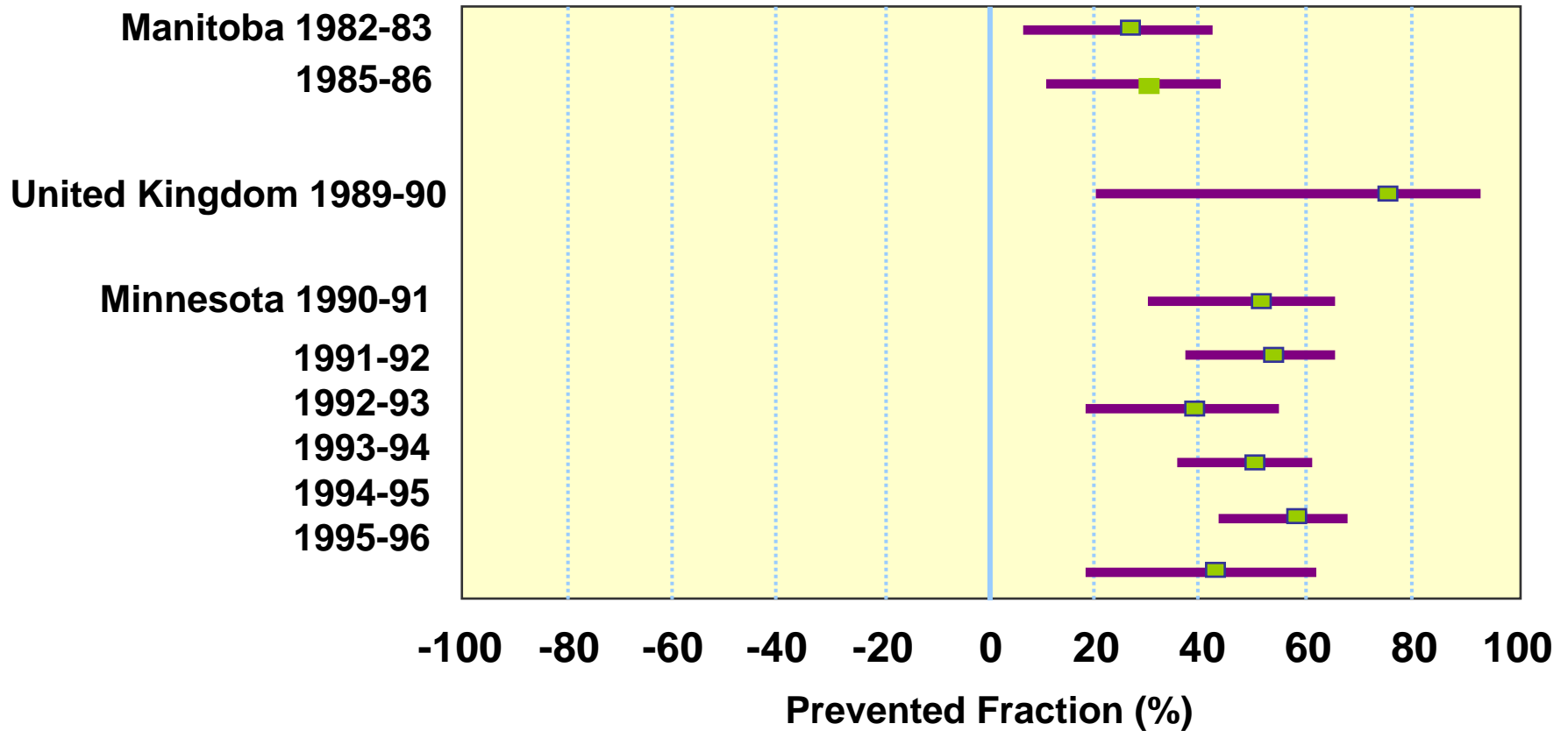
Influenza Vaccine

Reductions in Hospitalizations and Death

- **Comparing vaccinated to unvaccinated patients enrolled in an HMO:**
 - **32% relative reduction in hospitalization for pneumonia or influenza**
 - **19% relative reduction in hospitalization for cardiac causes**
 - **16% relative reduction in hospitalization for cerebrovascular causes**
 - **23% relative reduction in all-cause hospitalization**
 - **48% relative reduction in death**

Multiple Studies with Consistent Findings

Influenza Vaccine Relative Reduction in Risk of Death





Pneumococcal Vaccines

- 1977 **14-valent polysaccharide vaccine licensed**
- 1983 **23-valent polysaccharide vaccine licensed**
- 2000 **7-valent polysaccharide conjugate vaccine licensed for children**



Pneumococcal Polysaccharide Vaccine

- **Purified capsular polysaccharide antigen from 23 types of pneumococcus**
- **Those 23 strains of pneumococcus:**
 - **Account for 88% of bacteremic pneumococcal disease**
 - **Cross-react with types causing additional 8% of disease**



Pneumococcal Polysaccharide Vaccine (23-valent)

- **Not effective or indicated in children < 2 years of age**
- **60%-70% against invasive disease**
- **Less effective in preventing pneumococcal pneumonia**




Benefits of Pneumococcal Polysaccharide Vaccination

Group	Effectiveness / Cost Savings
All Elderly Persons ¹	
Bacteremias	75% (57% to 85%)
Cost savings	\$8.27 per person
Elderly w/ Chronic Lung Disease ²	
Hospitalizations for pneumonia	43% (16% to 62%)
Deaths	29% (9% to 44%)
Cost savings	\$294 per person

¹ Sisk J. JAMA 1997; 278: 1333.

² Nichol KL. Arch Intern Med 1999; 159: 2437.



Effectiveness of Pneumococcal Vaccination in Older Adults: *The VSD Cohort Study*

- **3 year cohort study of 47,365 members of Group Health Coop (Seattle)**
 - **PPV was associated with lower rates of bacteremia:**
 - **HR 0.56 (95% CI 0.33 – 0.93)**
 - **Rates of pneumonia were not decreased**

HR = hazard ratio.

Jackson LA, et al. NEJM 2003; 348: 1747.



Pneumococcal Vaccination Reduces Disease Severity

- **Prospective cohort of 11,241 patients \geq 65 years of age in Spain:**
 - ***“Pneumococcal vaccination did not alter the risk of hospitalisation from pneumoniaor overall pneumonia, but the vaccine was associated with considerable reductions of death risk from pneumonia (HR: 0.28; 95% CI: 0.09–0.83).”***



Pneumococcal Vaccination Reduces Disease Severity

- **62,918 consecutive adults (≥ 18 years) hospitalized with community-acquired pneumonia at 109 community and teaching hospitals in the United States:**
 - ***“Prior vaccination against pneumococcus is associated with improved survival, decreased chance of respiratory failure or other complications, and decreased length of stay among hospitalized patients with community-acquired pneumonia.”***



Pneumococcal Vaccination Reduces Disease Severity

- **Prospective study of 3,415 adults hospitalized in Canada with community-acquired pneumonia:**
 - ***“Patients with CAP who had prior PPV had about a 40% lower rate of mortality or ICU admission compared with those who were not vaccinated.”***



Pneumococcal Conjugate Vaccine

- **Highly immunogenic in infants and young children, including those with high-risk medical conditions**
- **97% effective against invasive disease caused by vaccine serotypes**
- **73% effective against pneumonia**
- **7% reduction in all episodes of acute otitis media**

Vaccination Recommendations



MMWRTM

Morbidity and Mortality Weekly Report

www.cdc.gov/mmwr

Early Release

July 17, 2008 / Vol. 57

Prevention and Control of Influenza

**Recommendations of the Advisory Committee
on Immunization Practices (ACIP), 2008**

Updated annually and available for free download at: www.cdc.gov/vaccines/



Recommendations for Influenza Vaccination*

- **Children ages 6 months to 18 years**
- **All persons aged ≥ 50 years**
- **Women who will be pregnant during the influenza season**
- **Adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological, or metabolic disorders (including diabetes mellitus)**
- **Adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV)**
- **Adults and children who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration**
- **Residents of nursing homes and other chronic-care facilities**
- **Persons who live with or care for persons at high risk for influenza-related complications (including healthcare personnel)**



April 4, 1997 / Vol. 46 / No. RR-8

MNWR[™]

*Recommendations
and
Reports*

MORBIDITY AND MORTALITY WEEKLY REPORT

Prevention of Pneumococcal Disease

**Recommendations of the Advisory Committee
on Immunization Practices (ACIP)**

Always refer to: www.cdc.gov/vaccines/ for latest updates to vaccine recommendations.



Recommendations for Pneumococcal Polysaccharide Vaccine Administration*

- **Immunocompetent persons**
 - Persons aged ≥ 65 years
 - Persons aged 2–64 years with chronic cardiovascular disease (including congestive heart failure and cardiomyopathies), chronic pulmonary disease (including chronic obstructive pulmonary disease and emphysema), or diabetes mellitus
 - Persons aged 2–64 years with alcoholism, chronic liver disease (including cirrhosis), or cerebrospinal fluid leaks
 - Persons aged 2–64 years with functional or anatomic asplenia (including sickle cell disease and splenectomy)
 - Persons aged 2–64 years living in special environments or social settings (including Alaskan Natives and certain American Indian populations).



Recommendations for Pneumococcal Polysaccharide Vaccine Administration

- **Immunocompromised persons**
 - Immunocompromised persons aged ≥ 2 years, including those with HIV infection, leukemia, lymphoma, Hodgkins disease, multiple myeloma, generalized malignancy, chronic renal failure, or nephritic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids); and those who have received an organ or bone marrow transplant.

If earlier vaccination status is unknown, patients in immunocompetent or immunocompromised groups should be administered pneumococcal polysaccharide vaccine



October 6, 2000 / Vol. 49 / No. RR-9

MMWRTM
MORBIDITY AND MORTALITY
WEEKLY REPORT

*Recommendations
and
Reports*

**Preventing Pneumococcal Disease
Among Infants and Young Children**

**Recommendations of the Advisory Committee on
Immunization Practices (ACIP)**

Always refer to: www.cdc.gov/vaccines/ for latest updates to vaccine recommendations.



Summary Recommendations for use of 7-valent Pneumococcal Conjugate Vaccine

- **All children \leq 23 months**
- **Children aged 24-59 months with**
 - **Sickle cell disease and other sickle cell hemoglobinopathies, congenital or acquired asplenia, or splenic dysfunction**
 - **Immunocompromising conditions**
 - **Congenital immunodeficiencies**
 - **Renal failure and nephrotic syndrome**
 - **Diseases associated with immunosuppressive therapy or radiation therapy**
 - **Chronic illness including chronic cardiac disease, chronic pulmonary disease, cerebrospinal fluid leaks, and diabetes mellitus**



ACIP Provisional Recommendations for Use of Pneumococcal Vaccines*

October 2008

- Proposed wording of the revised recommendation: *Persons aged 19 through 64 years who smoke cigarettes should receive a single dose of PPSV23 and smoking cessation counseling.*
- Proposed wording of the revised recommendation: *“Persons aged 19 through 64 years who have asthma should receive a single dose of PPSV23.”*
- Proposed wording for the revised recommendation: *“A second dose of PPSV23 is recommended 5 years after the first dose of PPSV23 for persons aged >2 years who are immunocompromised, have sickle cell disease, or functional or anatomic asplenia.”*



ACIP Provisional Recommendations for Use of Pneumococcal Vaccines*

October 2008

- **Revised recommendation for use of PPSV23 among American Indians and Alaska Natives**
 - a. **American Indian/Alaska Native children aged 24 through 59 months:**
 - ***Routine use of PPSV23 after PCV7 is not recommended for Alaska Native or American Indian children aged 24 through 59 months. However, in special situations, public health authorities may recommend the use of PPSV23 after PCV7 for Alaska Native or American Indian children aged 24 through 59 months who are living in areas in which risk of invasive pneumococcal disease is increased***
 - b. **American Indian/Alaska Native adults:**
 - ***Routine use of PPSV23 is not recommended for Alaska Native or American Indian persons younger than 65 years old unless they have underlying medical conditions that are PPSV23 indications. However, in special situations, public health authorities may recommend PPSV23 for Alaska Natives and American Indians aged 50 through 64 years who are living in areas in which the risk of invasive pneumococcal disease is increased.***

Use of Standing Orders Programs in Improve Vaccination Rates



Reality of Vaccination in the United States

- **Despite explicit guidelines for vaccination and policies that support requirements or payment for vaccination in many settings, rates of vaccination are suboptimal – particularly in adults**
 - **Many patients that are in healthcare settings are not screened for vaccination status or are not vaccinated (i.e., “missed opportunities”)**



Vaccination Myths

- **There are many “myths” about vaccination in healthcare settings that impede the delivery of vaccines:**
 - **Patients are “too sick”**
 - **Vaccination is not effective in patients receiving healthcare services (e.g., ED patients, hospitalized patients)**
 - **Vaccination is associated with frequent side effects**

In reality, many studies have demonstrated the safety and efficacy of vaccination in healthcare settings and significant side effects are exceedingly rare.



Standing Orders Programs

Standing orders programs authorize nurses or pharmacists to administer vaccinations according to an institution- or physician-approved protocol without a physician's examination*

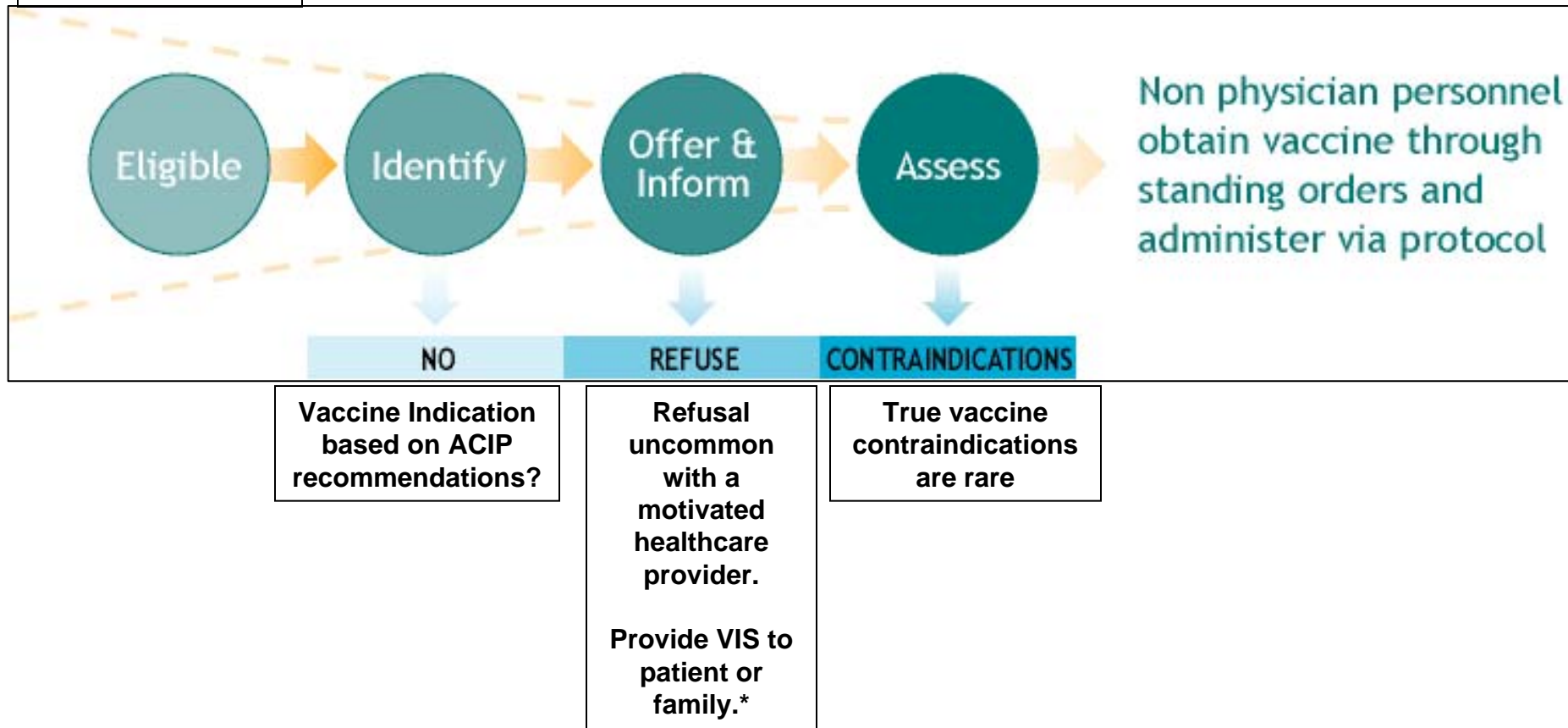
- Patients are screened for vaccination indication
- Patients are screened for the occasional contraindication to vaccination
- If there is an indication and no contraindication, the patient is vaccinated based on a protocol

*While standing orders programs are allowed in most states (indeed this is the mechanism by which most health departments provide vaccination) you should check state laws and regulations when implementing standing orders in various healthcare settings.

Standing Orders Program

Protocol for Implementation

Patient enters
healthcare setting



*Vaccine Information Statement. Available at: <http://www.cdc.gov/vaccines/pubs/vis/default.htm>



Use of Standing Orders Programs to Increase Adult Vaccination Rates

Recommendations of the Advisory
Committee on Immunization Practices

- **Standing orders programs recommended by the ACIP for:**
 - inpatient and outpatient facilities, long-term-care facilities, managed-care organizations, assisted living facilities, correctional facilities, pharmacies, adult workplaces, and home health-care agencies to vaccinate patient, client, resident, and employee populations.

“The Advisory Committee on Immunization Practices (ACIP) recommends standing orders for influenza and pneumococcal vaccinations.”



The Effectiveness of Standing Orders Programs

“Based on the scientific evidence of effectiveness in improving vaccination rates in institutions, the Task Force for Community Preventive Services and the Southern California Evidence-Based Practice Center–RAND recommend standing orders programs for the vaccination of adults in hospitals, clinics, and nursing homes. Standing orders policies are acceptable to most primary-care physicians and have resulted in higher vaccination rates than other vaccination delivery methods.”



The research is consistent...

- **Standing orders programs result in higher vaccination rates**
- **Can be safely implemented in a variety of healthcare settings**
- **Are cost effective**

Centers for Disease Control and Prevention. Adult immunization programs in nontraditional settings: quality standards and guidance for program evaluation—a report of the National Vaccine Advisory Committee and Use of standing orders programs to increase adult vaccination rates: recommendations of the Advisory Committee on Immunization Practices. *MMWR* 2000;49(No. RR-1):15-28.

Sokos DR, et al. Designing and implementing a hospital-based vaccine standing orders program. *Am J Health Syst Pharm* 2007; 64:1096-102.

Eckrode C, et al. Implementation and evaluation of a nursing assessment/standing orders-based inpatient pneumococcal vaccination program. *Am J Infect Control* 2007; 35:508-15.

Honecutt AA, et al. Cost-effectiveness of hospital vaccination programs in North Carolina. *Vaccine* 2007; 25:1484-96.

Middleton DB, et al. Economic evaluation of standing order programs for pneumococcal vaccination of hospitalized elderly patients. *Infect Control Hosp Epidemiol.* 2008; 29:385-94.

Standing Orders are Among the Most Effective Strategies to Improve Vaccination Rates

STANDING ORDER	
<p>Annual influenza immunization for all high-risk persons and other individuals who wish to reduce the likelihood of becoming ill with influenza is recommended by the Centers for Disease Control and Prevention and the Minnesota Coalition for Adult Immunization. A standing order to immunize high-risk patients, or patients not at high risk but requesting influenza immunization, and who are hospitalized or receiving services is provided below.</p>	
To Be Completed by Nurse/Pharmacist	
RISK CATEGORY: _____	
<input type="checkbox"/> Patient is "High Risk" due to:	
<input type="checkbox"/> Age 50 or older	
<input type="checkbox"/> History of heart disease, lung disease, diabetes, or other chronic medical condition	
<input type="checkbox"/> Patient is not "High Risk"	
COMPLETE IF PATIENT AT "HIGH RISK" or not high-risk but requests influenza immunization:	
<input type="checkbox"/> Influenza Vaccine not indicated for this patient due to:	
<input type="checkbox"/> Previous immunization this influenza season	
<input type="checkbox"/> Serious allergies to eggs	
<input type="checkbox"/> Previous severe reaction to influenza vaccine	
<input type="checkbox"/> Acute febrile illness	
<input type="checkbox"/> Refusal of vaccine by patient because he/she:	
<input type="checkbox"/> Believes not at risk for disease	
<input type="checkbox"/> Believes immunization doesn't work	
<input type="checkbox"/> Fear of adverse effects	
<input type="checkbox"/> Wants further advice (e.g. physician, family)	
<input type="checkbox"/> Would rather receive elsewhere	
<input type="checkbox"/> Other reason: _____	
<input type="checkbox"/> Not indicated for other reason (explain) _____	
<input type="checkbox"/> Influenza Vaccine Indicated. Give Influenza Vaccine Information Statement and Influenza Vaccine 0.5 mL IM if 13 years or older. (If patient is 12 years or younger, contact attending MD for order and refer to Pediatric Dosing Guidelines.)	
Information Collected by _____ Date _____	

- **Non-physicians offer and administer vaccinations without direct doctor involvement at the time of the visit**
- **Established through approved policies & protocols**
- **Locations: clinics, hospitals, home health agencies & nursing homes**



Standing Orders Supported in the Medicare *Conditions of Participation*

Federal Register, Vol. 67, No. 191 (October 2, 2002)

“All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under 482.12(c) *with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.*”

Removes the requirement for an individual physician signed order

Policy applies to hospitals, nursing homes, and home health agencies.

Summary

- **Vaccination rates for some of our most vulnerable patients are unacceptably low**
- **Vaccination in a variety of healthcare settings is safe and results in improved patient outcomes**
- **Standing orders programs represent one of the most effective interventions to increase vaccination rates**