Standing Orders Protocols to Increase Adult Immunizations

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Massachusetts Adult Immunization Conference

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Disclosures - Tan

- I have received honoraria from Pfizer, Seqirus, Temptime Corp., TruMedSystems, and Sanofi Pasteur for service as a scientific consultant.
 - My honoraria is donated to the IAC
- I do NOT intend to discuss an unapproved or investigative use of a commercial product/device in my presentation.



Outline

- What are standing orders and who recommends them?
- Essential components of standing orders
- Do standing orders improve vaccination rates?
- How standing orders benefit medical practices
- Implementing standing orders
- Resources
- Q&As



Challenges to Adult Immunization

- Adult immunization rates are appallingly low
 - Maternal immunizations (influenza and Tdap) are a focus due to data showing protection not only of mother but also of newborn infant
- Patients aren't receiving their recommended vaccinations during office visits
- Clinicians must address acute and chronic medical issues first, resulting in lack of time for vaccinations and other preventive health issues
- Missed opportunities abound
- Patients are not protected from vaccine-preventable diseases



Standing Orders – A Solution

The goal of using standing orders is to increase vaccination coverage by:

- Reducing missed opportunities in your health care setting
- Routinizing vaccination by making it a program rather than relying on an individual clinician's order for each dose of vaccine
- Empowering nurses (or other legally qualified individuals) to manage your vaccination program
- Improving efficient use of clinician time by freeing clinicians from active roles in immunization



What are Standing Orders?



Standing Orders – What Are They?

Written protocols, approved by a physician or other authorized practitioner, that authorize nurses, pharmacists or other health care personnel (where allowed by state law) to:

- Assess a patient's need for vaccination
- Administer the vaccine without a clinician's direct involvement with the individual patient at the time of the interaction



Who Recommends Use of Standing Orders?

Community Preventive Services Task Force

Increasing Appropriate Vaccination: Standing Orders

Task Force Finding and Rationale Statement

Intervention Definition

Standing orders authorize nurses, pharmacists, and other healthcare personnel where allowed by state law, to assess a client's immunization status and administer vaccinations according to a protocol approved by an institution, physician, or other authorized provider. The protocol enables assessment and vaccination without the need for examination or direct order from the attending provider at the time of the interaction. Standing orders can be established for the administration of one or more specific vaccines to clients in health care settings such as clinics, hospitals, pharmacles, and long-term care facilities. In settings that require attending provider signatures for all orders, standing order protocols permit assessment and vaccination in advance of the provider signature.

Task Force Finding (March 2015)

The Community Preventive Services Task Force recommends standing orders for vaccinations on the basis of strong evidence of effectiveness in increasing vaccination rates among adults and children; when used alone or with additional interventions; and across a range of settings and populations.

Rationale

Basis of Finding

The Task Force finding is based on evidence from a Community Guide systematic review completed in 2009 (29 studies, search period 1997–2009) combined with more recent evidence (6 studies, search period 2009–February 2012). Based on the combined evidence, the Task Force reaffirms its recommendation based on strong evidence of effectiveness.

The Task Force considered evidence from 35 studies. Of these, 27 studies provided a common measurement of change in vaccination rates with a median increase of 24 percentage points (interquartile interval [IQI]: 12 to 35 percentage points). Nine studies that examined the impact of standing orders alone documented a median increase of 16 percentage points (IQI: 9 to 29 percentage points). Nineteen studies that evaluated standing orders when combined with additional interventions documented a median increase of 27 percentage points (IQI: 13 to 40 percentage points). Seven studies that did not provide a common measure of change for vaccination rates all reported favorable results after implementation of standing orders.

Applicability and Generalizability

The reviewed studies evaluated the effectiveness of standing orders across a wide range of clinical vaccination settings, health care personnel, and client populations. Standing orders were found to be effective in various settings including clinics, hospitals, and long-term care facilities. Interventions were effective when used with different vaccination providers including nurses and pharmacists. While most studies looked at adult populations, four examined intervention effectiveness among children and found a median absolute percent increase of 28 percentage points (range: 8 to 49). While no studies specifically evaluated the impact of standing orders for vaccination of adolescents, evidence from this review is likely applicable to this population. In addition, a subset of the included evidence suggests that standing orders may be more effective in improving vaccination rates in both inpatient and outpatient settings when compared to a provider reminder system. The *Community Preventive Services Task Force* recommends standing orders to increase vaccination coverage among adults and children on the basis of strong evidence of effectiveness.



Who Recommends Use of Standing Orders?



March 24, 2000 / Vol. 49 / No. RR-1

Recommendations and Reports

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

> U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Disease Control and Prevention (CDC) Atlanta. GA 30333



The Advisory Committee

 Immunization Practices
 (ACIP) recommends
 standing orders for influenza
 and pneumococcal
 vaccinations and several
 other adult vaccines.



Who Recommends Use of Standing Orders?

	RTMENT OF HEALTH & HUMAN SERVICES	
		7500 Security Boulevard Baltimore, MD 21244-1850
D . TT		Ref: S&C-03-02
DATE:	October 10, 2002	
FROM:	Director	
	Survey and Certification Group	
	Center for Medicaid and State Operations	
SUBJECT:	Change in requirement for signed physician's order for	r influenza and
	pneumonia vaccine	
TO:	Associate Regional Administrator, DMSO	
10.	State Survey Agency Directors	
	of this program memorandum is to provide information	
	tate survey agency personnel regarding a new regulation r requiring nursing home providers, home health agenci	
	igned physician's order for influenza and pneumococca	
	rocedures and Interpretive Guidelines for Long Term C	
	ies and Hospitals require physicians to sign and date al ows nursing home providers, home health agencies and	
	ncrease influenza and pneumonia vaccination rates such	
	proved protocols i.e., standing orders, that do not requir	
physician ord	ers. Accordingly, surveyors should not be citing provid	ers that have adopted
	rs for influenza and pneumococcal vaccinations for the	

 Centers for Medicare and Medicaid Services (CMS)



Use of Standing Orders

- In 2009, only 42% of physicians reported using standing orders for adult influenza vaccination
- Only 23% reported consistently using standing orders for both influenza vaccine and pneumococcal polysaccharide vaccine



Use of Standing Orders (cont.)

The most important factors associated with greater likelihood of a practice consistently using standing orders are:

- Being aware of the ACIP recommendations or Medicare regulations regarding adult immunizations
- Agreeing that standing orders are effective
- Having two or more clinical staff per physician



Use of Standing Orders (cont.)

Other important factors:

- Being a family physician
- Having an office staff that works well together and is open to innovation
- Having an electronic medical record (EMR)
- Having an immunization champion in the practice



Using Standing Orders (cont.)

Lack of standing orders implementation may be due to:

- Weak or no organizational support
- Small size of the clinical support staff relative to providers
- Concerns about legal ramifications

Our workshop experiences indicate that lack of resources is an often stated challenge



Barriers to the Use of Standing Orders

Table 2. Among Physicians with Differing Use of Standing Orders Programs (SOPs), Percent Reporting Various "Major Barriers" to Initiating or Maintaining SOPs for Adult Vaccinations ^a

		Category of SO	OP user	
Barrier	None, no Plans to Implement n = 273	None, Would Like to Implement n = 142	Uses Inconsistently n = 87	Uses Consistently n = 378
Insufficient care staff	22.6	22.6	12.2	4.8^{**}
Inadequate training of staff	14.0	5.3	3.7	2.1^{**}
Staff communication	6.7	5.3	11.0	3.3^{**}
Lack of reliable tracking system	15.4	19.5	15.7	4.5^{**}
Work flow pattern	21.9	20.0	12.2	5.4^{**}
Resources to change policy	26.0	26.5	15.9	6.0^{**}
Patient preference for physician management of care	15.1	8.9	4.9	2.4^{**}
Physician preference for management of care	25.7	5.2	4.9	2.4^{**}
Fear of malpractice	17.1	5.3	2.5	2.4^{**}
Frequently changing recommendations	8.7	10.5	4.9	2.7^{**}
Physicians do not support vaccination as a preventive measure	2.1	1.5	0.0	0.9^\dagger

Percent Who Report Major Barrier to SOPs for Influenza Vaccine

**p < .001 by χ^2 .

[†]Not significant.

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Yonas et al. J Healthcare Quality 2012;34:34-42

Vaccine Injury Compensation Program

- Established by National Childhood Vaccine Injury Act (1986)
- Provides no-fault compensation for specified injuries that are temporally related to specified vaccinations
- Program has greatly reduced the risk of litigation for both providers and vaccine manufacturers
- Covers all routinely recommended childhood vaccines, including those administered to adults



www.hrsa.gov/vaccinecompensation/index.html

What are the Components of a Standing Orders Protocol?



Standing orders for other vaccines are available at www.immunize.org/standing-orders. NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from IAC. As a courtey, please achrowledge IAC as its source.

STANDING ORDERS FOR Administering Influenza Vaccine to Adults

Purpose

To reduce morbidity and mortality from influenza by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

1 Assess Adults for Need of Vaccination against influenza

- All adults are recommended to receive influenza vaccination each year.
- People who do not recall whether they received influenza vaccine this year should be vaccinated.

2 Screen for Contraindications and Precautions

Contraindications for use of all influenza vaccines

Do not give influenza vaccine to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of the vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/ appendices/8/excipient-table-2.pdf.

Contraindications only for use of live attenuated influenza vaccine (LAIV; FluMist, nasal spray)

- Do not give live attenuated influenza vaccine (LAIV; nasal spray) to a person who:
- has a history of either an anaphylactic or non-anaphylactic allergy to eggs
- is pregnant
- has immunosuppression (including that caused by medications or HIV)
- is age 50 years or older
- received influenza antivirals (e.g., amantadine, rimantadine, zanamivir, or oseltamivir) within the previous 48 hours or will possibly receive them within 14 days after vaccination
- · provides care for a severely immunosuppressed person who requires a protective environment

Precautions for use of all influenza vaccines

- · Moderate or severe acute illness with or without fever
- · History of Guillain Barré syndrome within 6 weeks of a previous influenza vaccination

Precautions for use of LAIV only

- Asthma
- Other chronic medical conditions (e.g., other chronic lung diseases, chronic cardiovascular disease [excluding isolated hypertension], diabetes, chronic renal or hepatic disease, hematologic disease, neurologic disease, and metabolic disorders)

NOTE REGARDING PATIENTS WITH HIVES AFTER EATING EGGS: An egg-free recombinant hemagglutinin influenza vaccine (RIV3) may be used for people age 18 years and older with egg allergy of any severity. For people who experience onset of hives only (and not a more serious reaction) after ingesting eggs, health care providers should administer inactivated influenza vaccine (IIV) and observe the patient for at least 30 minutes after receipt of the vaccine for signs of a reaction.

3 Provide Vaccine Information Statements

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

Technical content reviewed by the Centers for Disease Control and Prevention

IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org www.immunize.org/catg.d/p3074.pdf • Item #P3074 (8/15)

(continued)	page 2 of 3

cularly, choose the needle gauge, needle length, and injection site

GE	NEEDLE LENGTH	INJECTION SITE
	5/8*-1*	Deltoid muscle of arm
	1"	Deltoid muscle of arm
	1-11/2"	Deltoid muscle of arm
	1-11/2"	Deltoid muscle of arm
	11/2"	Deltoid muscle of arm
	11/2"	Deltoid muscle of arm

30 lbs (<60 kg) for 1M injection in the deltoid muscle only if the ched, and the injection is made at a 90-degree angle to the skin.

lly or intradermally, prepare the vaccine according to directions in

the criteria and guidance in the table below:

	ROUTE	INSTRUCTIONS
	Intramuscular (IM)	Administer vaccine in deltoid muscle.
	Intradermal (ID)	Insert needle of the microinjection system at a 90 degree angle in the deltoid area.
	Intramuscular (IM)	Administer vaccine in deltoid muscle.
	Intramuscular (IM)	Administer vaccine in deltoid muscle.
. (0.1 mL ch nostril	Intranasal spray (NAS)	Spray half of vaccine into each nostril while the patient is in an upright position.

raccine, see "How to Administer Intramuscular, munize.org/catg.d/p2024.pdf.

n information and follow up in the following places:

was administered, the manufacturer and lot number, the vaccinaperson administering the vaccine. You must also document, in the ation date of the VIS and the date it was given to the patient. If f(s) for non-receipt of the vaccine (e.g., medical contraindication,

ate of vaccination and the name/location of the administering clinic.

stry": Report the vaccination to the appropriate state/local IIS,

-9009 • www.immunize.org • www.vaccineinformation.org www.immunize.org/catg.d/p3074.pdf • Item #P3074 (8/15)

> munize.org • www.vaccineinformation.org www.immunize.org/catg.d/p3074.pdf • Item #P3074 (8/15)



page 3 of 3

I to the administration of vaccine by having a written and medications. For IAC's "Medical Management of

d/p3082.pdf. To prevent syncope, vaccinate patients

enza vaccine to the federal Vaccine Adverse Event available on the website or by calling (800) 822-7967.

Effective date.

em for 15 minutes after receipt of the vaccine.

of the

Signature date

www.immunize.org/catg.d/p3074.pdf

ion tion

Components of a Standing Orders Protocol

A comprehensive standing order should include these elements:

- Who is targeted to receive the vaccine
- How to determine if a patient needs or should receive a particular vaccination (e.g., indications, contraindications and precautions)
- Provision of any federally required information (e.g., Vaccine Information Statement)
- Procedures for preparing and administering the vaccine (e.g., vaccine name, schedule for vaccination, appropriate needlemmunization size, vaccine dosage, route of administration)



Components of a Standing Orders Protocol

A comprehensive standing order should include these elements:

- How to document vaccination in the patient record
- A protocol for the management of any medical emergency related to the administration of the vaccine
- How to report possible adverse events occurring after vaccination
- Authorization by a physician or other authorized practitioner



Components of a Standing Orders Protocol (1)

Who is targeted to receive the vaccine – assessing the need

Procedure

- 1 Assess Adults for Need of Vaccination against influenza
 - All adults are recommended to receive influenza vaccination each year.
 - People who do not recall whether they received influenza vaccine this year should be vaccinated.



Components of a Standing Orders Protocol (2) How to determine if the patient can receive a particular vaccination (e.g., screen for contraindications and precautions)

2 Screen for Contraindications and Precautions

Contraindications for use of all influenza vaccines

Do not give influenza vaccine to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of the vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/ appendices/B/excipient-table-2.pdf.

Contraindications only for use of live attenuated influenza vaccine (LAIV; FluMist, nasal spray)

Do not give live attenuated influenza vaccine (LAIV; nasal spray) to a person who:

- has a history of either an anaphylactic or non-anaphylactic allergy to eggs
- is pregnant
- has immunosuppression (including that caused by medications or HIV)
- is age 50 years or older
- received influenza antivirals (e.g., amantadine, rimantadine, zanamivir, or oseltamivir) within the previous
 48 hours or will possibly receive them within 14 days after vaccination
- provides care for a severely immunosuppressed person who requires a protective environment

Precautions for use of all influenza vaccines

Moderate or severe acute illness with or without fever

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PATI	ENT	NAM	F	

DATE OF BIRTH______

to Inactivated Injectable Influenza Vaccination

Screening Checklist

for Contraindications

For patients (both children and adults) to be vaccinated: The following questions will help us determine if there is any reason we should not give you or your child inactivated injectable influenza vaccination today. If you answer "yes" to any question, it does not necessarily mean you (or your child) should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	yes	no	don't know
1. Is the person to be vaccinated sick today?			
2. Does the person to be vaccinated have an allergy to eggs or to a component of the vaccine?			
3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?			
4. Has the person to be vaccinated ever had Guillain-Barré syndrome?			
FORM COMPLETED BY	DAT	E	
FORM REVIEWED BY	DAT	E	

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www.immunize.org/catg.d/p4066.pdf • Item #P4066 (8/15)

Information for Healthcare Professionals about the Screening Checklist for Contraindications to Inactivated Injectable Influenza Vaccination (IIV or RIV)

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the sources listed at the bottom of this page.

1. Is the person to be vaccinated sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. People with a moderate or severe illness usually should not be vaccinated until their symptoms have improved. Minor illnesses with or without fever do not contraindicate use of influenza vaccine. Do not withhold vaccination if a person is taking antibiotics.

2. Does the person to be vaccinated have an allergy to a component of the vaccine?

All vaccines, including influenza vaccines, contain various components that might cause allergic and anaphylactic reactions. Not all such reactions are related to egg proteins. However, the possibility of a reaction to influenza vaccines in egg-allergic people might be of concern to both the person and vaccine providers.

An egg-free recombinant vaccine (RIV) is available for people age 18 years and older. ACIP does not state a preference for the use of RIV for egg-allergic people although some providers may choose to administer RIV to their severely egg-allergic patients.

Reviews of studies of IIV and LAIV indicate that severe allergic reactions to egg-based influenza vaccines in persons with egg allergy are unlikely. For the 2016–17 influenza season, ACIP recommends that persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine. Any licensed age-appropriate influenza vaccine (IIV or RIV) may be used. Providers should consider observing all patients for 15 minutes after vaccination to decrease the risk for injury should they experience syncope.

Persons who report having had reactions to egg involving symptoms other thinkes, such as angioedema, respiratory distress, lighthetaddness, or recurrent vomiting; or who required epinephrine or another emergency medical intervention, may also receive any age-appropriate influenza vaccine (IIV or RIV). The vaccine should be administered in a medical setting (e.g., a health department or physician office). Vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

Some inactivated influenza vaccines contain thimerosal as a preservative. Most people who had sensitivity to thimerosal when it was used in contact lens solution do not have reactions to thimerosal when it is used in vaccines. Check the package insert at www.immunize.org/packageinsents for a list of the vaccine components (i.e., excipients and culture media) used in the production of the vaccine, or go to www.cdc.gov/vaccines/pubs/ pinkbook/downloads/appendices/B/excipient.table2.pdf.

Some vaccines also contain latex in the prefilled syringe cap which may cause allergic reactions in latex-sensitive people.

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Check the package inserts at www.immunize.org/packageinserts for information on which vaccines are affected, or go to www. cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/ latex-table.pdf.

3. Has the person to be vaccinated ever had a serious reaction to influenza vaccine in the past?

Patients reporting a serious reaction to a previous dose of inactivated influenza vaccine should be asked to describe their symptoms. Immediate – presumably allergic – reactions are usually a contraindication to further vaccination against influenza.

Fever, malaise, myalgia, and other systemic symptoms most often affect people who are first-time vaccinees. These mildto-moderate local reactions are not a contraindication to future vaccination. Also, red eyes or mild upper facial swelling following vaccination with inactivated injectable influenza vaccine is most likely a coincidental event and not related to the vaccine. Similarly, oculorespiratory syndrome is not likely to be an allergic response to IIV. These people can receive injectable vaccine without further evaluation.

4. Has the person to be vaccinated ever had Guillain-Barré syndrome?

It is prudent to avoid vaccinating people who are not at high risk for severe influenza complications (see source 3) and who are known to have developed Guillain-Barré syndrome (GBS) within 6 weeks after receiving a previous influenza vaccination. As an alternative, physicians might consider using influenza antiviral chemoprophylaxis for these people. Although data are limited, the established benefits of influenza vaccination for the majority of people who have a history of GBS, and who are at high risk for severe complications from influenza, justify yearly vaccination.

SOURCES

- CDC. Epidemiology & Prevention of Vaccine-Preventable Diseases, Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. at www.cdc.gov/ vaccines/pubs/pinkbook/index.html.
- CDC. General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP) at www.cdc.gov/vaccines/hcp/acip-recs.
- CDC. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2016–17 Influenza Season at www.cdc.gov/mmwr/ volumes/65/rr/pdfs/rr6505.pdf, pages 1–56.

on on



Components of a Standing Orders Protocol (3)

Provision of federally required information: the Vaccine Information Statement

3 Provide Vaccine Information Statements

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")



VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know

Why get vaccinated?

Influenza ("flu") is a contagious disease that spreads around the United States every year, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:

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

Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk.

Each year thousands of people in the United States die from flu, and many more are hospitalized.

Flu vaccine can:

- keep you from getting flu,
- make flu less severe if you do get it, and
- keep you from spreading flu to your family and other people.

2 Inactivated and recombinant flu vaccines

A dose of flu vaccine is recommended every flu season. Children 6 months through 8 years of age may need two doses during the same flu season. Everyone else needs only one dose each flu season.

Some inactivated flu vaccines contain a very small amount of a mercury-based preservative called thimerosal. Studies have not shown thimerosal in vaccines to be harmful, but flu vaccines that do not contain thimerosal are available.

There is no live flu virus in flu shots. The the flu.

There are many flu viruses, and they are a changing. Each year a new flu vaccine is r against three or four viruses that are likely disease in the upcoming flu season. But es vaccine doesn't exactly match these viruse provide some protection.

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Flu vaccine cannot prevent:

- · flu that is caused by a virus not covered
- or
- illnesses that look like flu but are not.

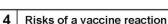
It takes about 2 weeks for protection to de vaccination, and protection lasts through t

3 Some people should this vaccine

- Tell the person who is giving you the vace • If you have any severe, life-threatenin If you ever had a life-threatening allergi after a dose of flu vaccine, or have a sev any part of this vaccine, you may be adv get vaccinated. Most, but not all, types c contain a small amount of egg protein.
- If you ever had Guillain-Barré Syndr called GBS).

Some people with a history of GBS shot vaccine. This should be discussed with y

- If you are not feeling well.
- It is usually okay to get flu vaccine when a mild illness, but you might be asked to when you feel better



With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get a flu shot do not have any problems with it.

Minor problems following a flu shot include:

- · soreness, redness, or swelling where the shot was
- given
- hoarseness
- sore, red or itchy eyescough
- fever
- · aches
- headache
- · itching
- fatigue

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

More serious problems following a flu shot can include the following:

- There may be a small increased risk of Guillain-Barré Syndrome (GBS) after inactivated flu vaccine. This risk has been estimated at 1 or 2 additional cases per million people vaccinated. This is much lower than the risk of severe complications from flu, which can be prevented by flu vaccine.
- Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure 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.

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: www.cdc.gov/vaccinesafety/

5 What if there is a serious reaction?

What should I look for?

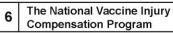
 Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get the person to the nearest hospital. Otherwise, call your doctor.
- Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not give medical advice.



The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

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. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider. He or she 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
- visit CDC's website at www.cuc.gov/iii

Vaccine Information Statement Inactivated Influenza Vaccine 08/07/2015 42 U.S.C. § 300aa-26



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Components of a Standing Orders Protocol (4) Prepare to administer the vaccine (e.g., by choosing appropriate vaccine product, needle size, and route of administration)

4 Prepare to Administer Vaccine

For vaccine that is to be administered intramuscularly, choose the needle gauge, needle length, and injection site according to the following chart:

NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
22–25	5/8*-1"	Deltoid muscle of arm
22–25	1"	Deltoid muscle of arm
22-25	1-11/2"	Deltoid muscle of arm
22–25	1-11/2"	Deltoid muscle of arm
22–25	11/2"	Deltoid muscle of arm
22–25	11/2"	Deltoid muscle of arm
	22–25 22–25 22–25 22–25 22–25 22–25	22-25 5/8*-1" 22-25 1" 22-25 1-11/2" 22-25 1-11/2" 22-25 1-11/2" 22-25 1-11/2"

* A ⁵/8" needle may be used in 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 to the skin.

For vaccine that is to be administered intranasally or intradermally, prepare the vaccine according to directions in the package insert.



Components of a Standing Orders Protocol (5)

Specific guidance for administration of the vaccine (e.g., right patient, right vaccine, right age group, right dose, right route and right site)

5	Administer Influenza	Vaccine according	g to the criteria and	d guidance in	the table below:
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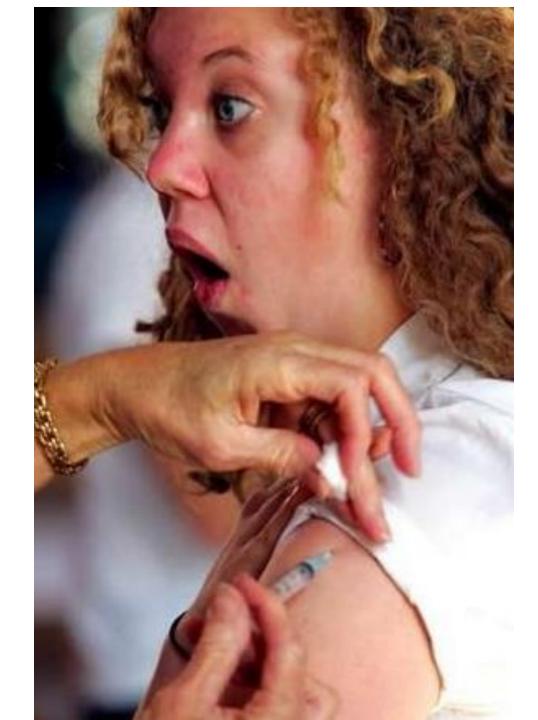
TYPE OF VACCINE	AGE GROUP	DOSE	ROUTE	INSTRUCTIONS†
Inactivated influenza vaccine (IIV)	All ages	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
IIV-intradermal	18 through 64 years	0.1 mL	Intradermal (ID)	Insert needle of the microinjection system at a 90 degree angle in the deltoid area.
IIV-high dose	65 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Recombinant influ- enza vaccine (RIV3)	18 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Intranasal influenza vaccine (LAIV)	Healthy, younger than age 50 years	0.2 mL (0.1 mL into each nostril	Intranasal spray (NAS)	Spray half of vaccine into each nostril while the patient is in an upright position.

† For complete instructions on how to administer influenza vaccine, see "How to Administer Intramuscular, Intradermal, and Intranasal Influenza Vaccines" at www.immunize.org/catg.d/p2024.pdf.



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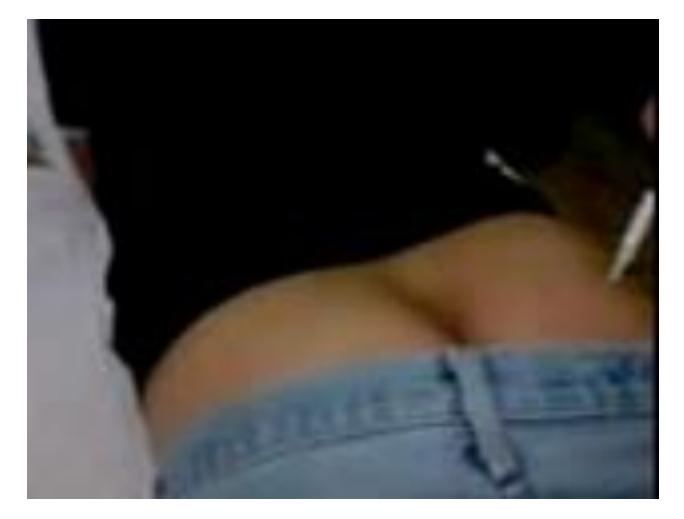
Wrong!



Wrong!



Wrong! Wrong





Correct locations for intramuscular vaccine injections (gloves not required)

Components of a Standing Orders Protocol (6)

How to document vaccination in the patient record

6 Document Vaccination

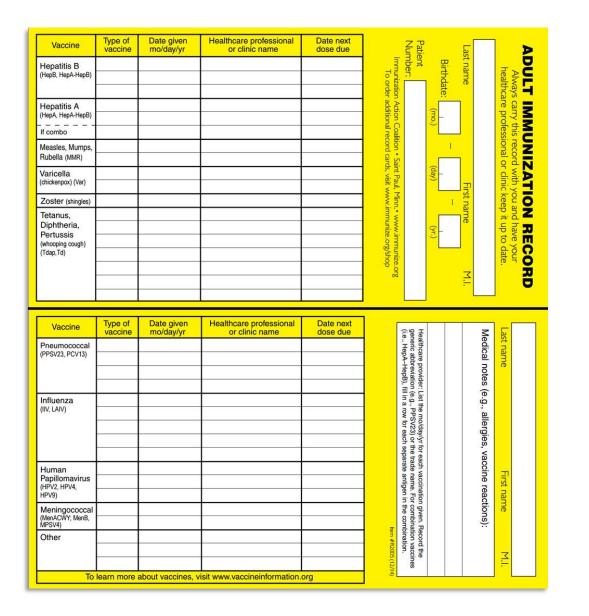
Document each patient's vaccine administration information and follow up in the following places:

Medical record: Document the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.







Available for purchase on www.immunize.org/shop

Components of a Standing Orders Protocol (7)

A protocol for the management of any medical emergency related to the administration of the vaccine

7 Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adults," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

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Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cau In order to minimize adverse reactio carefully screened for precautions and vaccine is administered. Even with ca may occur. These reactions can vary f ient (e.g., soreness, itching) to sever (e.g., anaphylaxis). If reactions occur, with procedures for their manageme describes procedures to follow if vari

REACTION	SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to Consider giving an analg antipruritic (anti-itch) me
1	Slight bleeding	Apply an adhesive compre
	Continuous bleeding	Place thick layer of gauze maintain direct and firm ing injection site (e.g., ar patient's heart.
Psychological fright and	Fright before injection is given	Have patient sit or lie do
syncope (fainting)	Extreme paleness, sweating, coldness of the hands and feet, nausea, light- headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit for several minutes. Loos and maintain an open ain cloths to patient's face an
	Fall, without loss of consciousness	Examine the patient to de present before attemptin Place patient flat on back
	Loss of consciousness	Check the patient to dete before attempting to mov patient flat on back with patient does not recover
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe broncho- spasm (wheezing); shortness of breath; shock; abdominal cramping; or cardio- vascular collapse.	See "Emergency Medical ment of Anaphylactic Rea next page for detailed ste anaphylaxis.

Medical Management of Vaccine Reactions in Adults (continued)

Needed medications for a community immunization clinic

FIRST-LINE medication

□ Epinophrine, aqueous 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen and Auvi-Q). If autoinjectors are stocked, at least three should be available.

- Optional medication: H, antihistamines Diphenhydramine (e.g., Benadryl)
- oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) or injectable (50 mg/mL solution).
- (10 mg/5 mL or 25 mg/5 mL liquid, 25 mg capsules). Needed supplies for a community
- immunization clinic □ Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 11/2", and 2") for epinephrine, diphenhydramine, or hydroxyzine. For ampules, use filtered needles. □ Alcohol wipes □ Tourniquet Adult airways (small, medium, and large) Adult size pocket mask with one-way valve Oxygen (if available) □ Stethoscope Sphygmomanometer (blood pressure measuring device) with adult-size and extra-large cuffs □ Tongue depressors □ Flashlight with extra batteries (for examination of the mouth and throat)
- ination of the mouth and throat)
 Uristwatch with a second hand or other
 timing device
- Cell phone or access to onsite phone

REFERENCES

Simons FE, Camargo CA. Anaphylaxis: Rapid recognition and treatment. In: UpToDate, Bochner BS (Ed). UpToDate: Waltham, MA, 2013.

Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID Sponsored Expert Panel. Allergy Clin Immunol 2010; 126(6): S1–SS7.



www.immunize.org/catg.d/p3082.pdf . Item #P3082 (9/14)

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Emergency medical protocol for management of anaphylactic

- Emergency medical protocol for management of anaphylactic reactions in adults
- If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- 2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the patient's physician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient.
- 3 DRUG DOSING INFORMATION: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO contraindications to epinephrine in the setting of anaphylaxis.
- a First-line treatment: Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).
- b Optional treatment: H₁ antihistamines for hives or itching; you may also administer diphenhydramine (either orally or by intramuscular injection; the standard dose is 1-2 mg/kg every 4-6 hrs, up to 50 mg maximum single dose) or hydroxyzine (standard oral dose is 0.5-1 mg/kg every 4-6 hrs up to 100 mg maximum single dose).
- 4 Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.
- 5 If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient's response.
- 6 Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
- 7 Notify the patient's primary care physician.

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www.immunize.org/catg.d/p3082.pdf

Components of a Standing Orders Protocol (8)

How to report possible adverse events occurring after vaccination

8 Report All Adverse Events to VAERS

Report all adverse events following the administration of influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov. Forms are available on the website or by calling (800) 822-7967.





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www.vaers.hhs.gov

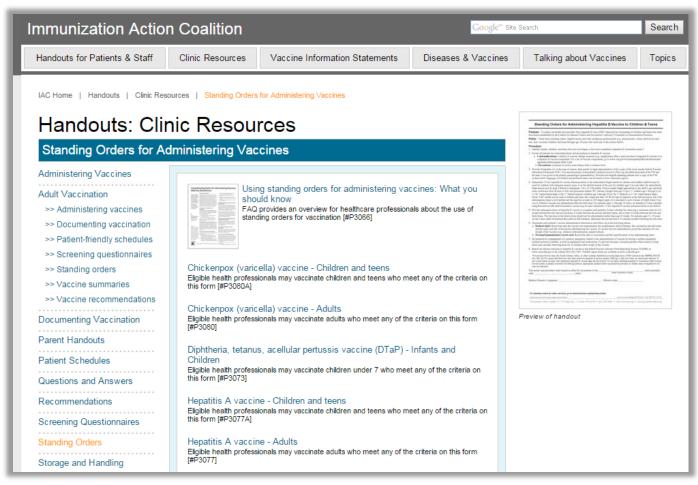
Components of a Standing Orders Protocol (9)

Authorization: In general, standing orders are approved by an institution, physician or authorized practitioner. State law or a regulatory agency might authorize other health care professionals to sign standing orders.

Standing C	Orders Authorization	
	This policy and procedure shall remain in effect for all patients of the	
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Standing Orders Templates for All Routine Vaccines are Available



www.immunize.org/standing-orders

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Do Standing Orders Improve Vaccination Rates?



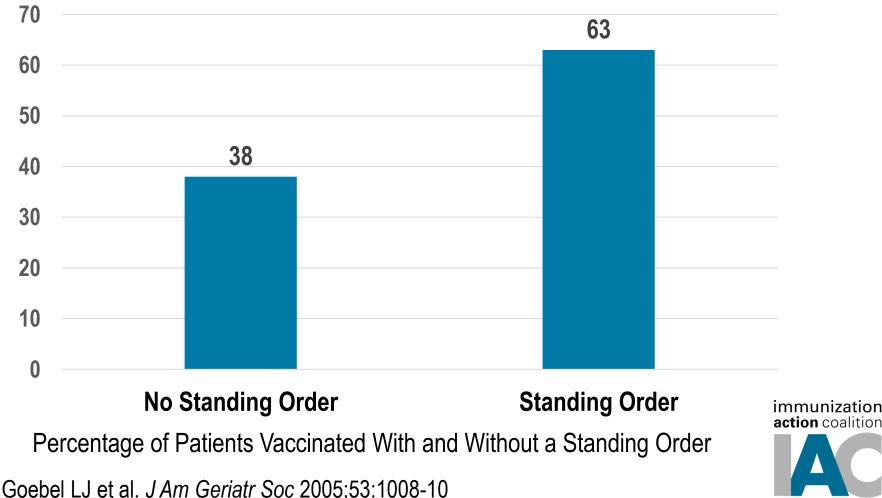
Are Standing Orders Effective?

- Based on a review of 29 studies (1997-2009) that examined standing orders either alone or combined with other activities, the Community Prevention Services Task Force found:
 - Used alone, standing orders increased adult vaccination coverage by a median of 17 percentage points (range: 13% to 30%)
 - Used in combination with other interventions,* standing orders increased adult vaccination coverage by a median of 31 percentage points (range: 13% to 43%)
- A study modeling influenza and pneumococcal vaccination in the over 65 population showed cost effectiveness — \$14,171 per quality lifeyear (QALY) gained¹
- * Such as expanding access in health care settings, client reminder and recall systems, clinic-based education, provider education, provider reminder and recall systems, or provider assessment plus feedback



1. Lin et al. Am J Manag Care. 2013;19(1):e30-e37

Example 1: Use of Standing Orders for Influenza Vaccine in an Ambulatory Care Setting



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Example 2: Impact of Standing Orders on Adolescent Vaccination Rates, Denver Health, 2013

Vaccine	National (2013)	Colorado (2013)	Denver Health (2013)
Tdap	86.0	87.1	95.9
MCV4	77.8	73.6	93.5
HPV – Females <u>></u> 1	57.3	58.2	89.0
HPV – Females <u>></u> 3	37.6	39.1	66.0
HPV – Males <u>></u> 1	34.6	33.5	89.3
HPV – Males <u>></u> 3	13.9	9.9	52.5

Kempe, A. 2015. National Foundation for Infectious Diseases Clinical Vaccinology Course Farmer, A.M. 2016. Pediatrics 138(5):e20152653.

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How Do Standing Orders Benefit Medical Practices?



Standing Orders in Clinical Practice

• Efficiency

 Clinician time is not required to assess vaccination needs and issue verbal or written orders to vaccinate

- Nurses (or others) take charge of vaccination program
- Increased number of patients seen = increased income stream
- Patient safety
 - Improved vaccine coverage, less vaccine-preventable disease
 - Decrease opportunities for VPD transmission in your health care setting



Implementing Standing Orders in Your System and/or Practice



10 Steps to Implementing Standing Orders for Immunization in Your Practice Setting

Introduction



Standing orders are written protocols approved by a physician or other authorized practitioner that allow qualified health care professionals (who are eligible to do so under state law, such as registered nurses or pharmacists) to assess the need for and administer vaccine to patients meeting certain criteria, such as age or underlying medical condition. The qualified health care professionals must also be eligible by state law to administer certain medications, such as epinephrine, under standing orders should a medical emergency (rare event) occur.

Having standing orders in place streamlines your practice workflow by eliminating the need to obtain an individual physician's order to vaccinate each patient. Standing orders carried out by nurses or other qualified health care professionals are the most consistently effective means for increasing vaccination rates and reducing missed opportunities for vaccination, which improves the quality of care for patients. While this guide focuses on implementing standing orders for influenza vaccination, the basic principles included can be used to implement standing orders for other vaccines and for any age group desired.

Standing orders are **straightforward to use**. The challenge is to integrate them into the practice setting so they can be used to their full potential. This process requires some preparation up front to assure everyone in the practice understands the reasons why standing orders are being implemented. Suggested steps to help you work through this process are shown below.

Phase 1: Get Ready - Build Support of Leadership

STEP 1 Discuss the benefits of implementing standing orders protocols with the leadership (medical director, clinicians, clinic manager, lead nurses) in your medical setting.

Standing orders will:

- Facilitate efficient assessment for and administration of influenza vaccine in your practice.
- Improve influenza vaccination rates in your practice.
- Protect more of your patients from influenza.
- Empower nurses and/or other eligible staff to use standing orders to protect more patients.
- Decrease opportunities for influenza transmission in your health care setting.

Technical content reviewed by the Centers for Disease Control and Prevention

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IAC's Standing Orders Implementation Guidance



- 1. Discuss the benefits of implementing standing orders protocols with the leadership
 - It is important to get buy-in from physician and nurse leadership from the start
 - Perform audit of current immunization rates
- 2. Identify the person who will take the lead of standing orders program
 - The lead person must be an influential leader who has medical knowledge, understands the standing orders protocols, and is able to answer questions about the from other staff members



- 3. Reach agreement about which vaccine(s) your practice will administer using standing orders
 - Start with flu if new to standing orders
 - Add other vaccines later
- 4. Create standing orders protocols for the vaccine(s) you want to administer
 - Don't reinvent the wheel use IAC's templates!
 - Get them signed by authorized provider



- 5. Hold a meeting to explain your new standing orders program to all staff members
 - Explain to all why you are starting standing orders; get everyone involved
 - IAC has helpful tips

Why are we starting a standing orders program?

- Disease should be prevented whenever possible, and vaccines can do this.
- Our patients are counting on us to keep them healthy.
- Adult vaccination rates in the United States are low and significant racial and ethnic disparities exist.
- Vaccination levels among adults are inadequate in most practices.

- Standing orders have been demonstrated to streamline the assessment and delivery of immunizations in medical practices.
- The burden of disease as a result of vaccine-preventable diseases is seen not only in increased morbidity and mortality, but also in increased costs to the health care system.



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- 6. Determine the role various staff members will play in implementing/using standing orders
 - Who does each activity? Eg. assessment, administering, etc
 - What is each person's role from receptionist to nurse?
 - Where is the vaccination being given? Where is it being documented?
- 7. Determine your standing orders operational strategy
 - Review your existing vaccination services logistics
 - Patient flow, operational flow?
 - Consider new approaches, eg walk-ins



- Identify ways to publicize your immunization program to your patients and others! EG. windows signs, participating in an online vaccine locator.
- 9. Start vaccinating!
 - Make sure the nursing and medical staff have all the tools they need
- 10. Review your progress
 - Consider whether you are ready to expand!



Conclusion

- Standing Orders Protocols
 - Improve vaccine coverage levels among adults in a variety of settings
 - Are endorsed by major vaccine policy-making institutions
 - Templates and 10 Steps for Implementing Standing Orders from IAC are ready to use and simplify process
 - Benefit medical practices



RESOURCES



IAC

- Immunization Action Coalition
 - www.immunize.org
 - Email questions: admin@immunize.org
- IAC Express free weekly emails

 www.immunize.org/subscribe
- Standing Orders Templates

 www.immunize.org/standing-orders
- Take A Stand™
 - www.standingorders.org



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QUESTIONS?

