



Recommendations for Zoster Vaccine

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1

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The speaker will discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration. But in accordance with ACIP recommendations

Objectives

- Shingles Vaccine Resources
- Shingles Vaccine Storage
- Shingles Vaccine Recommendations
 - Indications
 - Safety and Efficacy
 - Contraindications

ACIP recommendations

 "ACIP recommendations represent the standard of care for vaccination practice in the U.S. In general, to determine recommendations for use, one should follow the recommendations of ACIP rather than the information in the package insert."

Ask the Experts: http://www.immunize.org/askexperts/experts_per.asp



Recommendations of the Advisory Committee on Immunization Practices

www.cdc.gov/vaccines/recs/acip

Contraindications & Precautions

 Summary Table published annually by CDC with US adult
 schedule in MMWR.
 (CDC. MMWR 2013; Vol.62, No.1.)

http://www.cdc.gov/vaccines/sche dules/downloads/child/mmwr-0-18yrs-catchup-schedule.pdf

| Vaccine | Contraindications | Precautions |
|--|--|--|
| Influenza, inactivated vaccine (IIV) | Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine or to a vaccine component, including egg protein. | Moderate or severe acute illness with or without fever. History of Galifain-Barre Syndrome (GBS) within 6 weeks of previous influenza vaccimation. Persons who experience only hives with exposure to eggs sh receive IW with additional safety precautions. ² |
| Influenza, live attenuated (LAIV) ³ | Severe allergic reaction (e.g. anaphylaxis) after previous doe of any influenza vaccine or to a vaccine component, including egg protein. Conditions for which the Advisory Committee on immunization Practices (ACIP) recommends against use, but which are not contraindications in vaccine package insert: Immune suppression, certain chronic medical conditions such as asafma, diabetes, heart or kidney disease. and pregnancy. ⁴ | Moderate or severe acute illness with or without fever. History of GSS within 6 weeks of previous influenza vaccinat Beceipt of specific antivirals (i.e., amantadine, rimantadine, zamaritvir, or oselamitvir, 48 hours before vaccination. Avoid these antiviral drugs for 14 days after vaccination. |
| Tetanus, diphtheria, pertussis (Tdap); tetanus, diphtheria (Td) | Severe allergic reaction (e.g. anaphylaxis) after a previous dose or to a vaccine component. For pertussis-containing vaccines: encephalopathy (e.g. coma, decreased level of consciousness, or prolonged seizures) not attributable to another identifiable cause within 7 days of administration of a previous dose of Tdap or othinheria and tetanus toxoids and pertussis (IDP) or diphiheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. | Moderate or severe acute illness with or without fever. GBS within 6 weeks after a previous dose of tetanus toxoid- containing vacche. History of arthus-type hypersensitivity reactions after a prev dose of tetanus or dipthera toxoid-containing vacche, defe vaccination until al teast 10 years have elapsed since the last tetanus toxoid-containing vacches: progressive or unstable For pertussis-containing vacches: progressive encephalopathy until a treatment regimen has been establis and the condition has stabilized. |
| Varicella ² | Severe allergic reaction (e.g. anaphylaxis) after a previous doer to a vacatic component. Known severe immunodeficiency (e.g., from hematologic and solid tumous; receipt of chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy5 or patients with human immunodeficiency virus (HV) metchon who are severely immunocompromised). Pregnancy. | Recent (within 11 months) receipt of antibody-containing by product (specific interval depends on product), Network (specific interval depends on product), Receipt of specific antivirals (i.e. x-yclowf, famcidowf, or valacyclowf) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination. |
| Human papillomavirus (HPV) | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component. | Moderate or severe acute Illness with or without fever. Pregnancy. |
| Zöster | Severe allergic reaction (e.g., anaphylaxes) to a vaccine component. Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of diemotherapy, or fong-term immunosuppressive therapy ⁶ or patients with HW infection who are severely immunocompromised). Pregnancy. | Moderate or severe acute illness with or without fever. Beceipt of peorfice antibrial is a cyclorid, familiotori, or valacyclovit) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination. |
| Measles, mumps, rubella (MMR) ³ | Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccrine component. Known severe immunodeliciency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congential immunodeficiency, or long-term immunosuppressive therapy ⁶ or patients with HV infection who are severely immunocompromised). Pregnancy. | Moderate or severe acute illness with or without fever. Recent (within 11 months) receipt of antibody-containing bi product (specific interval depends on product)? History of thrombocytopenia or thrombocytopenic purpura Need for tuberculin skin testing. ⁸ |

MDPH 5-13 6

AMERICAN COLLEGE OF PHYSICIANS Immunization Portal

Download Full Guide:

High Resolution (60 MB) | Low Resolution (21.2 MB) (Updated: May 4)

SECTION Practice Improvement

Download Section 1 - Practice Improvement (51.9 MB)

Topics covered:

- · Immunization and the Chronic Care Model
- PDSA and Rapid Cycles of Change
- Measuring Change in Your Practice
- Incorporating Run Charts Into Daily Practice

SECTION 2 Practical Advice

Download Section 2 - Practical Advice (61 5 MB)

American College of

Physicians *Guide to Adult Immunizations*

Go to: Immunization Portal

www.acponline.org

http://immunization.acponline.

Welcome to the ACP Immunization Portal

ACP Guide to Adult Immunization

Produced by faculty of ACP's Quality Improvement Programs and members of the ACP Adult Immunization Advisory Board, the ACP Guide to Adult Immunization will help you develop systematic processes for incorporating immunization in your day-to-day practice.

The Guide is divided into four sections:

Section 1: Quality Improvement Principles in Immunization Section 2: Resources for Practical Application Section 3: Recommended Adult Vaccines and Their Indications Section 4: Special Populations (Pregnant Women, Immunocompromised, etc.)

Our intention is that this Guide will be read by and shared among the entire office team. You may find that Sections 1 and 2 are more beneficial to administrators and office staff, while physicians, physician assistants, nurse practitioners, and nurses may want to concentrate on Sections 3 and 4. Attending physicians and their residents will find residency clinic-specific information in Section 2.

Sections

- 1. Practice Improvement
- 2. Practical Advice
- 3. Vaccines and Their Indications (Zoster Vaccine too!)
- 4. Special Populations
 - Women who are Pregnant or Breastfeeding
 - Immunocompromised Persons
 - Patients with Anatomical or Functional Asplenia
 - Childhood Catch-up
 - Health Care Workers (HCWs)

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- 14. State Laws
- 15. ACIP Recommendations

and articles Read Reports

preventable diseases: compelling

personal testimonies, case reports,



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8

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IAC Resources Zoster Vaccine

Ask the Experts Zoster Vaccine

http://www.immunize.org/askexperts/experts_zos.asp

Screening Checklist Adults Vaccines http://www.immunize.org/catg.d/p4065.pdf

Standing Orders Zoster Vaccine

http://www.immunize.org/catg.d/p3092.pdf

| | tion and recommendations Administering vaccine |
|--|--|
| Disease-related issues | Vaccine storage and handling |
| Precautions & contraine | lications |
| | |
| | ation and recommendations |
| A single dose of zoster herpes zoster. Persons condition. For a copy of | vaccine is recommended for adults age 60 years and older whether or not they report a prior with chronic medical conditions may be vaccinated unless a contraindication or precaution er the ACIP recommendations on zoster vaccine, go to www.cdc.gov/mmwr/PDF/rr/rr57e0515.p |
| homes be tested to se Zoster vaccine can be a contraindication to vacc which they work and re | out giving zoster vaccine to nursing home patients? Should healthcare personnel in ie if they have had chickenpox before taking care of someone who has received zost diministered to anyone age 60 years and older regardless of where they reside, unless they h ination. All healthcare personnel should ensure they are immune to varicella regardless of the pardless of their patients' receipt of zoster vaccine. |
| ne new Zostavax va | ccine (Merck) package insert says that Zostavax should not be given simultaneously v ccharide vaccine (PPSV). What does ACIP say about this? |
| | Patient name: |
| | Screening Checklist for Contraindications to Vaccines for Adults |
| | For patients: The following questions will help us determine which wadnes you may be given today. If you snewer "yet" to any question, it does not necessarily mean you should not be wadnated. It just means utilitational question must be seled. If it question is not dany, place ask you healthane provider |
| | toepkinit. Don't Yer No Moor |
| | 1. Are you sidinto day? |
| | 2. Do youhave silengiest o medications, food, a vacaine component, or latest |
| | A. Have you even had a serious reaction after receiving a vacaination? |
| | Co you have a long term health problem with heart disease, lung disease, asthma, Iidney disease, metabolic disease (e.g., diabetel), anemà, or other blood disorder! |
| | 5. Do youhave cancer, leukenia, HIWADS, or any other innuune system problem? |
| | In the part 8 months, have you taken mediotisate that weaken your immune system, auch as contisme, predimisore, other stanistic, or anticancer dwags, or have you had addition treatment to |
| | 7. Have you had a seizure or a brain or other nervous system problem? |
| | During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antivinal drug? |
| | 9 For women: Are wouppement or is thereal chance you could become oriented |
| | Standing Orders for Administering Zoster Vaccine to Adults |
| | Purpore: To selvce mobility and montality from Jarper zorter (skingler) by voceinsking all solute the calatria setablished by the Centers for Disease Control and Parvendor's Advicey Committee on to in-Parcificate. Policy: Under the straining cellses, slightle ware and other headbacks place allowed by what has may are written as while the calatrial setabor. Proceedure 1. Listerity adder who can see 60 years or older and Jace to history of plan mosing of zorter wordin. |
| | 2. Scneen all patients for constraindications and presentions to zoster vaccine: a. Contraindications: * a bindray of a spations practice to a wave ine component, including goldain and neoryosin. For a list of v components, go to wave side govenessing/polyhpithoold/downloadshappendie of Blene joints table 2 r onique or a contraint insurred foritory in table? |
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| | programor og romshiftsy of programor vititis 4 vicele of scalefing varaine. Dre vide all y-alse vide i a copy of type most evanter fabrant. Vicents I futuration 5 varaines (VIIS) not requires the vide i a copy of type most evanues fabrant Vicents I futuration 5 varaines (VIIS) not requires the vide i a copy of type most evanues fabrant. Provide non-Bagdad in product gava fabrantism of type and the vide of the |
| | generon(g) for non-prospit of the vacuine (e.g., method contraindication, patient petient, education of the adm b. Personal immunization record card: Record the date of vaccination and the rame/location of the adm |
| | written emergency medical protocol available, as well as equipment and medications. |
| | 6. Be menored for management of a medical supercency related to the administration of maxime by h |

until zescinded or until _______ (date) (here of public or data)



CDC Shingles Website

http://www.cdc.gov/vaccines/vpd-vac/shingles/

Section for Healthcare Professionals

- Clinical Overview
- Diagnosis and Laboratory Testing
- Preventing Transmission in Health Care Settings
- Ask the Experts
- Vaccination Recommendations



http://www.cdc.gov/mmwr/PDF/rr/rr5705.pdf

Herpes Zoster Vaccine (Zostavax)



- Reduces the risk of subsequent development of zoster, postherpetic neuralgia, other complications
- Contains live varicella vaccine virus in much larger amount (14x) than standard varicella vaccine (Varivax)
- Reconstitute with diluent provided and administer 0.65 mL subcutaneously (SC)
- May be administered with other vaccines

Package Insert:

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM132831.pdf

Varicella Containing Vaccines Storage & Handling

- Store lyophilized vaccine in freezer between -58°F and +5°F (-50°C and -15°C) at all times
 - Protect from light by storing in original box
 - Vaccine should ideally be stored in a stand alone freezer unit, but a unit with separate refrigerator/freezer compartments with exterior doors is acceptable
- Store diluent at room temperature or refrigerate
- Discard if not used within 30 minutes of reconstitution
- CDC and the manufacturer do NOT recommend transporting varicella or zoster vaccine.
- If they must be transported, use a portable freezer that maintains temps as above. Do NOT use dry ice.

Source: CDC Vaccine Storage and Handling Toolkit at: <u>http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf</u>



Zoster Vaccine Effectiveness

Herpes Zoster Vaccine in Older Adults and the Risk of Subsequent Herpes Zoster Disease

Hung Fu Tseng, PhD, MPH Ning Smith, PhD Rafael Harpaz, MD, MPH Stephanie R. Bialek, MD, MPH Lina S. Sy, MPH Steven J. Jacobsen, MD, PhD

ERPES ZOSTER, COMMONLY known as shingles, is a pain-

55% effective against zoster

NO decline with age



- 63% effective against ophthalmic zoster
- 65% effective against zoster hospitalizations



Zoster Vaccine Follow-up Safety Studies

- Follow-up of subset of original Shingles Vaccine Study cohort selected for safety monitoring (n~ 6,600 → 3,000, Simberkoff)¹
- Case-centered study Vaccine Safety DataLink (n=190,083, Tseng)²
- Both studies no difference in serious side effects
 - e.g., cerebrovascular, cardiovasculuar, meningitis, encephalitis, Bell's Palsy, Ramsay-Hunt Syndrome, autoimmune, death, malignancy, etc.
- Simberkoff identifies herpes zoster in 7 vaccine recipients compared to 24 placebo
 - Specimens available from all but one
 - All 29 tested positive for wild-type virus
- Tseng identifies small risk nonserious allergic reactions

¹ Simberkoff. 2010 Annals;152(9):545. ² Tseng. 2012 J IntMed;271:510.

ACIP Recommendations for Zoster Vaccine



- On March 24, 2011 the FDA
- New!! approved a label change for zoster vaccine to include persons 50 through 59 years of age
 - ACIP declined to recommend vaccination of persons younger than 60 years because of inadequate supply and lower risk of zoster in this age group*
 - An ACIP recommendation is not necessary for clinicians to use a vaccine according to license

Zoster Vaccine Recommendations, cont.



 Adults 60 years and older should receive a single dose of zoster vaccine at the first available clinical encounter

- 5-8 encounters per year for this age group

 Offer to all eligible, including frail, > 80 years, nursing home residents and those with chronic medical conditions

- unless a contraindication or precaution exists

• Not intended for treatment of shingles

Zoster Vaccine Recommendations, cont.

- It is not necessary to inquire about chickenpox or test for varicella immunity before administering zoster vaccine
 - A negative test is more likely to indicate waning antibody level rather than true susceptibility
- Persons 60 years of age and older can be assumed to be immune regardless of their recollection of chickenpox
- Need for booster dose or doses not known at this time

Zoster Vaccine Contraindications

- Severe allergic reaction following a prior dose or to gelatin, neomycin or other vaccine component
- Pregnancy or planned pregnancy within 4 weeks
 - It is sufficient to ask a woman if she is pregnant
- Immunosuppression from any cause

Zoster Vaccine Contraindications Immunosuppression,(1)

- Leukemia, lymphoma or other malignant neoplasm affecting the bone marrow or lymphatic system
- Immunosupressive therapy, including high-dose chemotherapy, or corticosteroid therapy of <u>></u> 20 mg/kg/day for <u>></u> 2 weeks
- AIDS or other clinical manifestation of HIV infection
 - includes persons with CD4+ T-lymphocyte values less than 200 per mm3 or less than 15% of total lymphocytes
 - Asx. or mildly Sx. HIV is neither an indication or contraindication
- Clinical or laboratory evidence of other cellular immune deficiencies

Zoster Vaccine Contraindications Immunosuppression (2)

- •Hematopoietic cell transplant recipients*
 - experience is limited
 - assess the immune status of the recipient on a case-by-case basis
 - if a decision is made to vaccinate, the vaccine should be administered at least 24 months after transplantation



Zoster Vaccine Contraindications Immunosuppression (3)

- Recombinant human immune mediators and immune modulators*
 - Safety and efficacy of concurrently administering these is unknown
 - preferable to administer zoster vaccine before treatment
 - assess the immune status of the recipient on a case-by-case basis
 - vaccination should be deferred for at least 1 month after discontinuation of treatment



Zoster Vaccine May Be Administered to:

- Leukemia/lymphoma in remission, if no chemo or radiation for 3 mos.
- Short-term corticosteroids(<14 days); low to moderate dose (<20 mg/day of prednisone or equivalent); topical; intra-articular, bursal, or tendon injections; or long-term alternate day treatments with low to moderate doses of short-acting systemic corticosteroids.
- Low doses of methotrexate (<0.4 mg/kg/week), azathioprine (<0.3 mg/kg/day), or 6-mercaptopurine (<1.5mg.kg/day).
- Impaired humoral immunity (e.g., hypogammaglobulinemia or dysgammaglobulinemia)

Zoster Vaccine Precautions

- Moderate or severe acute illness
- Current treatment with an antiviral drug active against herpes viruses
 - discontinue at least 24 hours before administration of zoster vaccine
 - avoid use for at least 14 days after vaccination
- Recent receipt of a blood product is NOT a precaution

Zoster Vaccine Adverse Reactions

- Local reactions 34% (pain, erythema)
- Rash, including injection site lesions
- No increased risk of fever
- No serious adverse reactions identified
- No transmission of virus from zoster vaccine recipients

Zoster and Pneumococcal Polysaccharide (PPSV) Vaccines*

- In 2009, zoster package insert changed and advises that zoster and PPSV should not be administered concurrently
- Based on a study that showed the titer against VZV was lower in persons who received zoster and PPSV at the same visit compared to persons who received these vaccines 4 weeks apart
- CDC has not changed its recommendation for either vaccine
- Zoster and PPSV should be administered at the same visit if the person is eligible for both vaccines

Zoster and PPSV Vaccines

- Tseng observational study of over 7,000 patients in a large HMO <u>></u> 60 years
- Examined incidence of zoster among those who received zoster and PPSV vaccines on the same day or PPSV 30 to 365 days before zoster vaccine
- <u>Vaccination</u> <u>Incidence</u> (per 1,000 person years)
 same day 4.55
 different visits 4.51



For More Information

Massachusetts Immunization Program

- 1-617-983-6800
- 1-888-658-2850
- Website <u>www.mass.gov/dph/imm</u>
- Ordering MDPH materials

http://www.mass.gov/Eeohhs2/docs/dph/cdc/education al_materials_catalog.pdf

CDC/NIP

-1-800-232-4636 (1-800-CDC-INFO) for both English and Spanish

-1-888-232-6348 TTY (M-F 10 AM - 10 PM)

-Website http://www.cdc.gov/vaccines