Recommendations for Zoster Vaccine

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<tr>
<th>Category</th>
<th>Conflict of Interest</th>
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<td>Consultant</td>
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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.)

American College of Physicians
Guide to Adult Immunizations

Go to: Immunization Portal

www.acponline.org
http://immunization.acponline.org/

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:

1. Quality Improvement Principles in Immunization
2. Resources for Practical Application
3. Recommended Adult Vaccines and Their Indications
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 4.

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)
Immunization Action Coalition

www.immunize.org
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
Prevention of Herpes Zoster

Recommendations of the Advisory Committee on Immunization Practices (ACIP)

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:
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:
http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf
Zoster Vaccine Effectiveness

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

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

Context  Approximately 1 million episodes of herpes zoster occur annually in the United States. Although prelicensure data provided evidence that herpes zoster vaccine works in a selected population under idealized circumstances, the vaccine needs to be evaluated in field conditions.

Objective  To evaluate risk of herpes zoster after receipt of herpes zoster vaccine among individuals in usual clinical practice settings.

Design  Setting and Participants  A retrospective cohort study from January 1, 2007, through September 31, 2009, of individuals enrolled in the Kaiser Permanente Southern California health plan. Participants were immunocompetent community-dwelling adults age 50 years and older. 53,681 members who initiated zoster vaccine were analyzed.

Unvaccinated

Vaccinated

HERPES ZOSTER, COMMONLY known as shingles, is a painful rash caused by

• 55% effective against zoster
• NO decline with age
• Effective among those with chronic medical conditions
• 63% effective against ophthalmic zoster
• 65% effective against zoster hospitalizations

Source: Tseng 2011 JAMA;305(2):160
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)
- Case-centered study Vaccine Safety DataLink (n=190,083, Tseng)
- Both studies no difference in serious side effects - e.g., cerebrovascular, cardiovascular, 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

ACIP Recommendations for Zoster Vaccine

- On March 24, 2011 the FDA 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.

* Off-label use
CDC. MMWR 2008;57(RR-5):1-
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

* Off-label use
CDC. MMWR 2008;57(RR-5):1-
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

CDC. MMWR 2008;57(RR-5):1-
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
- Immunosuppressive therapy, including high-dose chemotherapy, or corticosteroid therapy of ≥ 20 mg/kg/day for ≥ 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

CDC. MMWR 2008;57(RR-5):1-
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

* Off-label use
CDC. MMWR 2008;57(RR-5):1-
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

* Off-label use

CDC. MMWR 2008;57(RR-5):1-
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)

CDC. MMWR 2008;57(RR-5):1-
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.

* Off-label use
CDC. MMWR 2008;57(RR-5):1- AND Ask the Experts
Zoster and PPSV Vaccines

- Tseng observational study of over 7,000 patients in a large HMO ≥ 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

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<th>Vaccination</th>
<th>Incidence (per 1,000 person years)</th>
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<tr>
<td>same day</td>
<td>4.55</td>
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<tr>
<td>different visits</td>
<td>4.51</td>
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Tseng. Vaccine 2011;29:3628-32
For More Information

- Massachusetts Immunization Program
  - 1-617-983-6800
  - 1-888-658-2850
  - Website [www.mass.gov/dph/imm](http://www.mass.gov/dph/imm)

- 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](http://www.cdc.gov/vaccines)