Varicella (Chickenpox) and Herpes Zoster (Shingles): Overview of VZV Disease and Vaccination for Healthcare Professionals

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Varicella-Zoster Virus (VZV)

- Human alpha-herpesvirus
- Causes varicella (chickenpox) and herpes zoster (shingles)
- Primary VZV infection leads to varicella
- VZV establishes latency in dorsal root ganglia after primary infection
- VZV can reactivate at a later time, causing herpes zoster
- There are 3 licensed vaccines to prevent varicella (Varivax[®], Proquad[®]) and herpes zoster (Zostavax[®]) in the US:
 - Varivax[®] (licensed 1995)
 - Proquad[®] (licensed 2005)
 - Zostavax[®] (licensed 2006)



VARICELLA: CLINICAL DESCRIPTION

Varicella: Clinical Features in Unvaccinated Cases

- Persons with varicella may develop prodrome of fever, malaise, headache, and abdominal pain 1-2 days before rash
- Rash involves 3 or more successive crops over several days; each crop usually progresses within less than 24 h from macules to papules, vesicles, pustules and crusts so that on any part of the body there are lesions in different stages of development
- Rash usually starts on face and trunk, then spreads to extremities
- Rash usually involves 250-500 lesions that are pruritic
- Lesions are typically crusted 4-7 days after rash onset

CDC. Prevention of Varicella. *MMWR* 2007; 56(No. RR-4); Arvin *Clin Microb Rev* 1996; *Vaccine* 5th Edition

Varicella: Clinical Features in Vaccinated Persons ("breakthrough varicella")

- Breakthrough varicella is defined as infection with wild-type varicella disease occurring > 42 days after vaccination
- Approximately 15-20% of 1-dose vaccinated persons may develop varicella if exposed to VZV
- Usually milder clinical presentation than varicella in unvaccinated cases
 - Usually low or no fever
 - Develop < 50 lesions</p>
 - Experience shorter duration of illness
 - Rash predominantly maculopapular rather than vesicular
- 25-30% of breakthrough varicella cases are not mild and have clinical features more similar to varicella in unvaccinated persons

Chaves J Infect Dis 2008; Arvin Clin Microb Rev 1996; CDC. Prevention of Varicella. MMWR 2007; 56(No. RR-4)



Varicella: Complications

- Secondary bacterial infection of skin lesions
- Central nervous system manifestations (meningoencephalitis, cerebelllar ataxia)
- Pneumonia (viral or bacterial)
- Hepatitis, hemorrhagic complications, thrombocytopenia, nephritis occur less frequently
- Certain groups at increased risk for complications
 - Adults
 - Immunocompromised persons
 - Pregnant Women
 - Newborns

Varicella: Transmission

- Transmitted person to person by direct contact, inhalation of aerosols from vesicular fluid of skin lesions of acute varicella or zoster, or aerosolized respiratory tract secretions
- Average incubation period: 14-16 days after exposure to rash (range: 10-21 days)
- Period of contagiousness: 1-2 days before rash onset until all lesions crusted or disappear if maculopapular rash (typically 4-7 days)
- Varicella in unvaccinated persons is highly contagious (61-100% secondary household attack rate)
- Varicella in 1 dose-vaccinated persons half as contagious as unvaccinated cases
 - One study indicated that varicella in 1-dose vaccinees with < 50 lesions was 1/3 as contagious as unvaccinated persons although contagiousness in vaccinees with ≥ 50 lesions was similar to unvaccinated persons

CDC. Prevention of Varicella. *MMWR* 2007; 56(No. RR-4); Arvin *Clin Microb Rev* 1996; Seward *JAMA* 2004; *Vaccines*, 5th edition

VARICELLA: EPIDEMIOLOGY AND IMPACT OF THE VARICELLA VACCINATION PROGRAM Varicella Disease Burden in the United States Before Introduction of Varicella Vaccine in 1995

- 4 million cases/year
- 11,0000 13,500 hospitalizations/year
- 100 150 deaths/year
- Greatest disease burden in children
 - >90% cases
 - 70% hospitalizations
 - 50% deaths



Wharton Infect Dis Clin North Am 1996; Galil Pediatr Infect Dis J 2002; Davis Pediatrics 2004; Meyer J Infect Dis 2000; Nguyen NEMJ 2005

Experience with 1-dose Varicella Vaccination Program

- 1-dose varicella vaccination coverage in 19-35 montholds increased from 26% to 91% from 1997 to 2008
- Varicella disease incidence declined by 90% in two varicella active surveillance sites by 2005 as compared to 1995
- Varicella hospitalizations declined 88% during 1994-2002
- Varicella mortality rate declined 93% from 1990-1994 to 2005-2006 in persons aged <50 years

National Immunization Survey (<u>www.cdc.gov/vaccines/stat-surv/default.htm#nis</u>); Guris J Infect Dis 2008; Marin Pediatrics 2008; Zhou JAMA 2005; National Center for Health Statistics Varicella and Measles Vaccine Coverage (1+ doses)*, Children 19-35 Months National Immunization Survey, 1997-2008



1997 1998 1999 2000 2001 2002 2003 2004 2005 2

*National Immunization Survey (NIS), coverage available at http://www.cdc.gov/vaccines/stats-surv/default.htm#nis

Year

Varicella Cases and 1-Dose Vaccine Coverage Varicella Active Surveillance Project Sites, 1995-2005



West Philadelphia



90% decline in varicella incidence in both sites Guris J Infect Dis 2008

Varicella-Related Hospitalization Rates U.S., 1994-2002



Zhou et al, JAMA, 2005

Reduction in Varicella Health Care Costs

- Total estimated direct medical expenditures for varicella hospitalizations and ambulatory visits
 - 1994-1995 \$85 million
 - 2002 \$22 million
 - 74% decline in total estimated direct medical expenditures for varicella hospitalizations and ambulatory visits from 85 to 22 million

Decline in Reported Varicella Deaths <50 years of age, US, 1990-2006



Impressive Achievements with the 1-Dose Varicella Vaccination Program But Challenges to Varicella Control Remained...

 15-20% of children vaccinated with 1 dose remain at risk for varicella due to lack of immune response or partial protection

Concern about accumulation of susceptible individuals

- Vaccinated persons with breakthrough varicella disease are contagious
- Outbreaks continued during the 1-dose program

VARICELLA: VACCINE INFORMATION

Varicella Vaccines

- Two live attenuated varicella virus vaccines licensed for use in US: Varivax[®] and Proquad[®]
- Both vaccines may be used for first and second doses of varicella vaccine
- Varivax [®] (1,400 pfu) is the single-antigen varicella vaccine licensed in 1995 for use among healthy persons aged ≥ 12 months
- Proquad[®] or MMRV (9,800 pfu) is a combination measles, mumps, rubella, and varicella vaccine licensed in 2005 for use among healthy children aged 12 months-12 years

Current Varicella Vaccination Policy in the United States

- Implemented routine 2-dose childhood varicella vaccination program in 2006
 - 1st dose at age 12-15 months
 - 2nd dose at age 4-6 years
 - Catch-up vaccination of children and adolescents who had previously received one dose
 - 2 doses for all adolescents and adults without evidence of immunity
 - Pre-natal screening and post-partum vaccination

CDC. Prevention of Varicella. MMWR 2007; 56(No. RR-4)



Prevention of Varicella Recommendations of the Advisory Committee

on Immunization Practices (ACIP)



Criteria for Determining Persons Who Can Be Considered Immune to Varicella

- Documentation of age-appropriate vaccination with varicella vaccine
- Laboratory evidence of immunity⁺ or laboratory confirmation of disease
- Birth in the US before 1980[§]
- Diagnosis or verification of history of varicella disease by a health-care provider
- Diagnosis or verification of history of herpes zoster by a health-care provider

⁺Commercial assays may lack sensitivity for detecting vaccine-induced immunity §For healthcare personnel, pregnant women, and immunocompromised persons, birth before 1980 should not be considered evidence of immunity

CDC. Prevention of Varicella. MMWR 2007; 56(No. RR-4)

Rationale for Timing of 2nd Dose of Varicella Vaccination at 4-6 Years of Age

- Varicella epidemiology during 1-dose program
 - Low incidence among 1-4 year old children
 - Outbreaks in elementary and middle schools
- Similar immune response to 2nd dose with intervals 3 months or 3-4 years after 1st dose
- Programmatic harmonization with MMR vaccine and availability of MMRV vaccine

Post-licensure One-Dose Vaccine Effectiveness in US*

- 17 studies with 20 estimates
 - Study designs: case-control, cohort (outbreaks, other), household contact
- Prevention all varicella
 - Median 85% (range 44% 100%)
 Mean 81%
- Prevention of combined moderate and severe varicella
 - Median 97% (range 86% 100%)
 Mean 96%
- Prevention of severe varicella*
 - Median 100% (range 97% to 100%) Mean 99%

*Definition 1) Varicella with > 500 lesions or a complication requiring physician visit
 2) disease severity scale used in clinical trails: # lesions, fever, systemic signs and subjective assessment of illness

VARIVAX[®] Merck and Co. Inc; Seward J Infect Dis 2008

Pre-licensure 2-Dose Varicella Vaccine Efficacy and Immune Response

2 Dose Vaccine Efficacy	
-Any disease	98%
-Severe disease	100%

Immune Response children aged 12 months-12 years, single antigen varicella vaccine*

*Measured as Geometric Mean Titer by VZV IgG gpELISA in units of μ /ml

-6 weeks after 1 dose	12.5
-6 weeks after dose 2 at age 4-6	212.4
years	

CDC. Prevention of Varicella. MMWR 2007; 56(No. RR-4)

Simultaneous Administration of Vaccines

- Varicella vaccine, either Varivax[®] or combination MMRV may be administered simultaneously with other vaccines recommended for children 12-15 months and children 4-6 years
- If varicella vaccine is not administered on the same day as MMR or live attenuated influenza vaccine, the vaccines should be separated by at least 4 weeks
- If separated by less than 4 weeks the vaccine given second should be repeated

Contra-indications and Precautions for Varicella Vaccination

- Severe allergic reaction to vaccine component or following a prior dose
- Immunosuppression
- Pregnancy
- Moderate or severe acute illness
- Recent blood product (due to potential inhibition of response to varicella vaccination)

Varicella Vaccination in Certain Groups of Immunocompromised Persons

- Varicella vaccine may be administered to persons with isolated humoral immunodeficiency
- Patients with leukemia, lymphoma, or other malignancies whose disease is in remission and those chemotherapy have been terminated ≥ 3 months can receive live-virus vaccines
- Consider varicella vaccination for HIV-infected children with CD4+ T-lymphocyte percentage of 15% or higher
 - Eligible children should receive 2 doses of single-antigen varicella vaccine 3 months apart
- Data on use of varicella vaccine in HIV-infected adolescents and adults lacking, but safety is likely to be similar to response in HIVinfected children. Vaccination may be considered for HIV-infected persons with CD4+T-lymphocyte count ≥ 200 cells/µl

CDC. Prevention of Varicella. MMWR 2007; 56(No. RR-4)

Post-exposure Prophylaxis

- Varicella vaccine recommended for use in healthy persons without evidence of immunity within 3-5 days after exposure to varicella
 - 290% effective in preventing varicella if vaccinated within 3 days of exposure and ~ 70% effective in preventing varicella and ~100% effective in modifying severe disease if given within 5 days
 - Vaccination still recommended for those with no other evidence of immunity even after 5 days of exposure because it will help provide protection against future exposures
- Varicella Zoster Immune Globulin (available product, VariZIG[™]) recommended for certain groups at high risk for severe disease AFTER EXPOSURE TO THE VARICELLA-ZOSTER VIRUS AND within 10 days of exposure.

CDC. Prevention of Varicella. *MMWR* 2007; 56(No. RR-4) <u>CDC. Updated Recommendations for Use of VariZIG — United States, 2013. MMWR 2013;62:574-576</u>²⁹

Varicella Vaccine Storage and Handling

<u>Varivax</u>

- Store frozen at 5°F (-15°
 C) or colder at all times
- May be stored up to 72 hours at 35-46°F (2-8°C), but discard unused vaccine after 72 hours at this temperature
- Discard if not used within 30 min of reconstitution
- Store diluent at room temp or in refrigerator

<u>MMRV</u>

- Store frozen at 5°F (-15°
 C) or colder at all times
- May <u>NOT</u> be stored at refrigerator temperature AT ANY TIME
- Discard if not used within 30 min of reconstitution
- Store diluent at room temp or in refrigerator

Freezer Requirements for Varicella Vaccine Storage

- Acceptable Freezer Units:
 - Stand-alone freezers
 - Freezer compartments of refrigerator-freezer combinations, provided that the freezer compartment has its own separate, sealed, and insulated exterior door
- Unacceptable Freezer Units:
 - Units with an internal freezer door that is unsealed and un-insulated (e.g., small, dormitory-style refrigerators)
- Temperatures should be documented at beginning and end of each day

Varicella Vaccine Adverse Events

- Non-serious adverse events
 - Rash, Fever
 Injection site reactions
 - Possible vaccine failure

- Serious adverse events are rare
 - Encephalitis Ataxia
 - Pneumonia
 - Hepatitis

- Arthritis
- Vasculitis

Thrombocytopenia

Reporting a Vaccine Adverse Event

- Complete VAERS form (next slide) for vaccine adverse events and if feasible, collect specimen for testing
 - CDC laboratory can conduct VZV PCR testing and genotyping
 - Genotyping may help to distinguish outcomes caused by wild-type versus vaccine strain VZV
- Additional Info: <u>http://vaers.hhs.gov/index/</u>; 1-800-822-7967

Vaccine Adverse Events Reporting System (VAERS)

VACCINE ADVERSE EVENT REPORTING SYSTEM 24 Hour Toll-Free Information 1-800-822-7867 P.O. Box 1100, Rockville, MD 20849-1100 PATIENT IDENTITY KEPT CONFIDENTIAL		For CDQFDA Use Only VABRS Number Date Received		
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VARICELLA: VARICELLA VACCINATION OF HEALTHCARE PERSONNEL

Varicella Vaccination of Healthcare Personnel

- To prevent disease and nosocomial spread of VZV, healthcare institutions should ensure that all HCP have evidence of immunity to varicella
 - Evidence of immunity = (1) laboratory evidence of immunity, (2) history of clinician diagnosed or verified varicella or zoster, (3) Documentation of age-appropriate vaccination
- Pre-vaccination serologic probably cost-effective
- Routine testing for varicella immunity after 2 doses of vaccine not recommended
 - Sensitive tests indicate 94-99% adults develop antibodies after second dose
 - VZV-specific cell-mediated immunity affords protection to vaccinated adults, even in the absence of detectable antibody response.
 - Available commercial assays may not be able to detect vaccine-induced immunity
- CDC. Prevention of Varicella. MMWR 2007; 56(No. RR-4)

HERPES ZOSTER

HERPES ZOSTER: CLINICAL DESCRIPTION

Herpes Zoster (Shingles)

- Following initial infection (varicella), VZV establishes permanent latent infection in dorsal root and cranial nerve ganglia
- Years to decades later VZV reactivates and spreads to skin through peripheral nerves causing pain and a unilateral vesicular rash in a dermatomal distribution
- ~1 million cases in the U.S. annually
- Lifetime risk of developing zoster: about 30%

Clinical Features of Herpes Zoster

Prodrome: headache, photophobia, malaise, fever, abnormal skin sensations and pain

Rash:

- Unilateral, involving 1-3 adjacent dermatomes
- Thoracic , cervical, ophthalmic involvement most common
- Initially erythematous, maculopapular
- Vesicles form over several days, then crust over
- Full resolution in 2-4 weeks
- Occasionally, rash never develops (zoster sine herpete)

Complications of Herpes Zoster

- Postherpetic Neuralgia (PHN)
 - -Pain ≥ 30 days occurs in 18-30% of zoster cases
 - -Mild to excruciating pain after resolution of rash
 - Constant, intermittent, or triggered by trivial stimuli
 - -May persist weeks, months or occasionally years
 - Can disrupt sleep, mood, work, and activities of daily living and lead to social withdrawal and depression
 - Risk factors for PHN include age ≥ 50, severe pain before or after onset of rash, extensive rash, and trigeminal or ophthalmic distribution of rash

Complications of Herpes Zoster

- Herpes Zoster Ophthalmicus
 - ~15% of HZ cases
 - Can occur when ophthalmic division of trigeminal nerve is involved
 - Untreated, 50-70% develop acute ocular complications
 - Can lead to chronic ocular complications, reduced vision, even blindness
- Neurologic complications
 - Myelitis, encephalitis, ventriculitis, meningoencephalitis, cranial nerve palsies, ischemic stroke syndrome
- VZV viremia
 - Cutaneous dissemination, pneumonia, hepatitis, disseminated intravascular coagulation
- Dermatologic complications
 - Secondary infections of rash
 - Permanent scarring and changes in pigmentation

VZV Transmission from Zoster

- VZV can be transmitted from persons with zoster to persons with no history of varicella disease or vaccine and cause varicella
 - Risk of VZV transmission from zoster is much lower than from varicella
 - Transmission is mainly through direct contact with zoster lesions, although airborne transmission has been reported in healthcare settings
 - Localized zoster is only contagious after the rash erupts and until the lesions crust
 - Transmission from localized zoster can be decreased by covering the lesions

HERPES ZOSTER: EPIDEMIOLOGY

Risk Factors for Herpes Zoster

- Increasing age
- Immunosuppression
 - Bone marrow and solid organ transplantation
 - Patients with hematological malignancies and solid tumors
 - HIV
 - Immunosuppressive medications
- Gender: Increased risk in females
- Race: Risk in blacks less than half that in whites
- Trauma or surgery in affected dermatome
- Early varicella (in utero, infancy): Increased risk of pediatric zoster

Age-specific Incidence of Herpes Zoster and Postherpetic Neuralgia: U.K., 1947-1972



Hope-Simpson J R Coll Gen Pract 1975.

Herpes Zoster Vaccination Coverage: U.S., Age 60 or Older, 2007-2009



1 Lu PJ, Euler G, Jumaan A, Harpaz R. Herpes zoster vaccination among adults aged 60 years or older in the United States, 2007: Uptake of the first new vaccine to target seniors. Vaccine. 2009; 27: 882-7

 2 (2008) Lu PJ, Euler GL, Harpaz R. Herpes zoster vaccination among adults aged 60 years and older, in the U.S., 2008. Am J Prev Med. 2011 Feb;40(2):e1-6
 2 (2009) Greby S, Lu PJ, Euler G, Williams W, Singleton J. 2009 Adult Vaccination Coverage, The National Health Interview Survey. Available from: http://www.cdc.gov/vaccines/stats-surv/nhis/2009-nhis.htm

3 Hales C, Harpaz R, Bialek S. Herpes Zoster In the Health and Retirement Study. Poster Session Presented at: Infectious Diseases Society of America; 2010 October 21-24; Vancouver, BC. Available at: http://idsa.confex.com/idsa/2010/webprogram/Paper4825.html

4 Lindley M, Harpaz R, Bialek S. Awareness and Uptake of Zoster Vaccine among U.S. Adults ≥60 Years. Presented at National Immunization Conference; 2010 April 19 – 22; Atlanta, GA. Available at: http://cdc.confex.com/cdc/nic2010/recordingredirect.cgi/id/6765

Am J Prev Med. 2011 Feb;40(2):e1-6

5 Joesoef R, Harpaz R, Bialek S. Herpes Zoster (HZ) Vaccination Among Elderly in the United States, 2007: Costs and Geographic Variation. Poster Session Presented at: Infectious Diseases Society of America; 2010 October 21-24; Vancouver, BC. Available at:

http://idsa.confex.com/idsa/2010/webprogram/Paper2756.html

HERPES ZOSTER: VACCINE INFORMATION

Herpes Zoster Vaccine

- Licensed in 1996
- Live, attenuated VZV
- Same strain used in the varicella vaccine, but 14x more potent
- Administered subcutaneously in deltoid region

Herpes Zoster Vaccine Efficacy

- Decreased zoster incidence by 51%
- Decreased risk of post-herpetic neuralgia in all participants by 67%
- Decreased burden of illness (severity x duration) in all participants by 61%

ACIP Recommendations for Zoster Vaccine

- In October 2008, the Advisory Committee on Immunization Practices (ACIP) recommended a dose of the herpes zoster vaccine (HZV) for all adults ≥60 years of age unless they have contraindications
- HZV should be offered at the patient's first available clinical encounter

ACIP Recommendations for Zoster Vaccine

- HZV can be administered simultaneously with influenza and pneumococcal vaccines
- HZV is recommended whether or not the patient reports a prior episode of zoster
- It is not necessary to check varicella history or titers before administering HZV
- HZV should be offered to eligible persons including those >80 y.o., frail, or with chronic illnesses

Contraindications for Zoster Vaccine

- Immunosuppression (high-dose steroids, biological response modifiers, chemotherapy, AIDS) is a contraindication for HZV
- HIV-positive status alone is not an contraindication
- Persons ≥60 y.o. anticipating immunodeficiency due to initiation of treatments or progression of illness should be offered HZV
- HZV is not recommended for persons ≥60 y.o. who have received the varicella vaccine

Zoster Vaccine Storage and Handing

- Must be stored at 5° F (-15° C) or colder AT ALL TIMES until reconstitution
- Protect from light
- Administer within 30 minutes of reconstitution

VZV LABORATORY TESTING

VZV Laboratory Testing

- Objectives of VZV Laboratory Testing
 - Confirm clinical diagnosis of varicella or herpes zoster with atypical presentation, such as varicella disease in vaccinated persons or shingles in immunosuppressed persons
 - Assess a person's susceptibility to varicella
 - Distinguish between vaccine and wild-type strains of the virus
- Available Testing Facilities
 - Contact your local health department to check if they offer VZV testing
 - CDC's National VZV Laboratory offers a range of VZV testing services. Please contact your local health department to determine the policy for sending specimens to CDC

Contact Information and Additional Resources

Contact Information:

- Nipinfo@cdc.gov
- 800.CDC.INFO

National VZV Laboratory:

- vzvlab@cdc.gov
- http://www.cdc.gov/shingles/lab-testing/index.html

Additional Resources:

- CDC Chickenpox (Varicella) Website: http://www.cdc.gov/chickenpox/index.html
- CDC Varicella Vaccine Webpage: <u>http://www.cdc.gov/vaccines/vpd-vac/varicella/</u>
- CDC Herpes Zoster Disease and Vaccine Webpages: http://www.cdc.gov/shingles/index.html http://www.cdc.gov/vaccines/vpd-vac/shingles/