## Immunization: Varicella, Zoster, Hepatitis A and Hepatitis B Vaccines

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# **Presentation Outline**

- Adult Immunization Schedule review
- Specific vaccines: limited disease epidemiology in adults, and vaccine recommendations

- Varicella vaccine

Zoster vaccine

- Hepatitis A vaccine
- Hepatitis B vaccine

#### Recommended Adult Immunization Schedule United States - 2014

The 2014 ACIP Adult Immunization Schedule was approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), the American College of Obstetricians and Gynecologists (ACOG), and the American College of Nurse-Midwives (ACNM). On February 3, 2014, the adult immunization schedule and a summary of changes from 2013 were published in Annals of Internal Medicine, and a summary of changes was published in the MMWR on February 7, 2014.

All clinically significant postvaccination reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Additional details regarding ACIP recommendations for each of the vaccines listed in the schedule can be found at: http://www.cdc.gov/vaccines/hcp/acip-recs/index.html

American Academy of Family Physicians (AAFP) http://www.aafp.org/home.html American College of Physicians (ACP) http://www.acponline.org/ American College of Obstetricians and Gynecologists (ACOG) http://www.acog.org/ American College of Nurse-Midwives (ACNM)

http://www.midwife.org/



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

#### **Recommended Adult Immunization Schedule—United States - 2014**

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group<sup>1</sup>

VACCINE ▼ AGE GROUP ►	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years			
Influenza <sup>2,*</sup>	1 dose annually								
Tetanus, diphtheria, pertussis (Td/Tdap) <sup>3,*</sup>	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs								
Varicella <sup>4,*</sup>	2 doses								
Human papillomavirus (HPV) Female <sup>s,*</sup>	3 d	oses							
Human papillomavirus (HPV) Male <sup>5,*</sup>	3 d	oses							
Zoster <sup>6</sup>									
Measles, mumps, rubella (MMR) <sup>7,*</sup>		1 or 2 do:	ses						
Pneumococcal 13-valent conjugate (PCV13) <sup>&amp;,*</sup>		1 dose							
Pneumococcal polysaccharide (PPSV23) <sup>9,10</sup>			1 or 2 doses	1		1 dose			
Meningococcal <sup>11,*</sup>	1 or more doses								
Hepatitis A <sup>12,*</sup>		······································	2 d	oses					
Hepatitis B 13,*	3 doses								
Haemophilus influenzae type b (Hib) <sup>14,*</sup>			1 or 3	doses					

\*Covered by the Vaccine Injury Compensation Program



For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indication)

No recommendation

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at <a href="http://www.cdc.gov/vaccines.or">www.cdc.gov/vaccines.or</a> from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).

#### Figure 2. Vaccines that might be indicated for adults based on medical and other indications<sup>1</sup>

		lmmuno- compromising conditions	HIV in CD4+T ly count	fection mphocyte 4,6,7,8,15	Men who	Kidney failure,	Heart disease, chronic	Asplenia (including elective splenectomy and persistent			
VACCINE  VAC	Pregnancy	(excluding human immunodeficiency virus [HIV]) <sup>46,7,8,15</sup>	< 200 cells/µL	≥ 200 cells/µL	have sex with men (MSM)	end-stage renal disease, receipt of hemodialysis	lung disease, chronic alcoholism	complement component deficiencies) <sup>8,14</sup>	Chronic liver disease	Diabetes	Health care personnel
Influenza <sup>2,*</sup>		1 dose IIV ann	ually		1 dose IIV or LAIV annually		1 dos	e IIV annually			1 dose IN or LAIV annually
Tetanus, diphtheria, pertussis (Td/Tdap) <sup>3,*</sup>	<mark>1 dose Tdap each pregnancy</mark>	Si	ubstitut	e 1-time	e dose of	Tdap for Td b	ooster; the	<mark>n boost with Td</mark> e	every 1	0 yrs	
Varicella <sup>4,*</sup>	c	ontraindicated					2 d	oses		,	
Human papillomavirus (HPV) Female <sup>s,*</sup>		3 doses throu	igh age	26 yrs			3 dos	es through age 2	26 yrs		
Human papillomavirus (HPV) Male <sup>5,*</sup>		3 doses t	hrough	age 26	yrs		3 dos	es through age 2	21 yrs		
Zoster <sup>6</sup>	c	ontraindicated						1 dose			
Measles, mumps, rubella (MMR) <sup>7,*</sup>	c	ontraindicated				1	1 or 2	doses		1	
Pneumococcal 13-valent conjugate (PCV13) <sup>&amp;*</sup>						1 d	ose			г	
Pneumococcal polysaccharide (PPSV23) <sup>9,10</sup>						1 or 2 dos	es				
Meningococcal <sup>11,*</sup>						1 or more do	oses			1	
Hepatitis A <sup>12,*</sup>						2 doses					
Hepatitis B <sup>13,*</sup>		r		• •		3 doses					
Haemophilus influenzae type b (Hib) <sup>14,*</sup>		post-HSCT recipients only				1 or 3 dos	es		2		
*Covered by the Vaccine For all p	ersons in this	category who meet t	he age reg	• uirements a	and who	Recor	mmended if som	• e other risk factor		No recor	nmendation

Injury Compensation Program

🔜 lack documentation of vaccination or have no evidence of previous infection; 🛽 🛽 zoster vaccine recommended regardless of prior episode of zoster

is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

**U.S. Department of Health and Human Services Centers for Disease Control and Prevention** 

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of February 1, 2014. For all vaccines being recommended on the Adult Immunization Schedule: a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/hcp/acip-recs/index.html). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services. Varicella Zoster Virus - Herpes virus (DNA)

Primary infection results in varicella (chickenpox)

Recurrent infection results in herpes zoster (shingles)

Short survival in environment

# Varicella Complications

- Bacterial infection of lesions
- Hemorrhagic varicella
- CNS manifestations
- Pneumonia (rare in children)
- Congenital varicella
- Perinatal varicella
- Hospitalization ~3 per 1000 cases
  - (11,000/year)
- □ Death ~ 1 per 60,000 cases
  - (100/year)

# Groups at Increased Risk of Complications of Varicella

Infants younger than 1 year

Immunocompromised persons

Newborns of women with rash onset within 5 days before to 48 hours after delivery

## Varicella Fatality Rate in Healthy Persons



Varicella-Containing Vaccines
 Varicella vaccine (Varivax)
 approved for persons 12 months and older

Herpes zoster vaccine (Zostavax)
 FDA approved for persons 50 years and older

## Varicella Vaccine Immunogenicity and Efficacy

#### Detectable antibody

- 97% of children 12 months-12 years after 1 dose
- 99% of persons 13 years and older after 2 doses

 70%-90% effective against any varicella disease (1 dose)
 95%-100% effective against severe varicella disease (1 dose)

98% effective against any varicella disease (2 doses)

Shapiro ED ,et al. J Infect Dis. 2011 Feb 1;203(3):312-5



## Varicella Vaccine Minimum Age and Intervals

Minimum Intervals

Persons 13 years & older

4 weeks

#### Varicella Vaccine Recommendations Older Children and Adults

Two doses are recommended for all persons 4 years of age and older who do not have evidence of varicella immunity

Second dose recommended for persons of any age who have only received one dose

## Acceptable Evidence of Varicella Immunity

Written documentation of age-appropriate vaccination

- Laboratory evidence of immunity or laboratory confirmation of varicella disease
- □ U.S. born before 1980\*
- Healthcare provider diagnosis or verification of varicella disease

History of herpes zoster based on healthcare provider diagnosis

\*Birth year immunity criterion does not apply to healthcare personnel or pregnant women. MMWR 2007;56(RR-4):16-17

# Varicella and HCP Recommended for all susceptible healthcare workers

Pre-vaccination serologic screening probably cost-effective

Post vaccination testing not necessary or recommended

Give 2 doses, 4 weeks apart to susceptible persons

Varicella Vaccine Post exposure Prophylaxis Varicella vaccine is recommended for use in susceptible persons after exposure to varicella

• 70%-100% effective if given within 72 hours of exposure

 Not effective if administered more than 5 days after exposure but will produce immunity if not infected

#### Varicella-Containing Vaccine Contraindications and Precautions

- Severe allergy to prior dose or vaccine component
- Pregnancy
- Immunosuppression
- Moderate or severe acute illness
- Recent blood product (except zoster vaccine)
- MMRV ONLY: a personal or family (i.e., sibling or parent) history of seizure is a precaution

#### Varicella-Containing Vaccines Use in Immunocompromised Persons

Most immunocompromised persons should not receive varicella-containing vaccines

Varicella vaccine may be administered to persons with isolated humoral immunodeficiency

Do not administer zoster vaccine to immunosuppressed persons

## Varicella Vaccine and HIV Infection

Consider varicella vaccination for HIVinfected children with CD4 % of 15% or higher

Consider varicella vaccination for HIVinfected older children and adults with CD4 count of 200 or higher

MMRV not approved for use in persons with HIV infection

## Varicella Vaccine Adverse Reactions

- Local reactions (pain, erythema)
  - 19% (children)
  - 24% (adolescents and adults)
- □ Rash 3%-4%

may be maculopapular rather than vesicular
 average 5 lesions

Systemic reactions not common



# **Zoster Vaccine**

## Now licensed for adults 50-59 years of age

Routine vaccination of adults younger than 60 years NOT recommended by ACIP

Rationale

reduced supply

 burden of complications highest in persons older than 60 years **ACIP Recommendations for Zoster Vaccine** 

Adults 60 years and older should receive a single dose of zoster vaccine

Need for booster dose or doses not known at this time

A history of herpes zoster should not influence the decision to vaccinate

<u>MMWR</u> 2008;57(RR-5)



It is not necessary to inquire about chickenpox or test for varicella immunity before administering zoster vaccine

Persons 60 years of age and older can be assumed to be immune\* regardless of their recollection of chickenpox

*MMWR* 2008;57(RR-5) \*for the purpose of establishing eligibility for zoster vaccine

## Zoster Vaccine Contraindications

# Severe allergic reaction to a vaccine component or following a prior dose

#### Pregnancy or planned pregnancy within 4 weeks

Immunosuppression

MMWR 2008;57(RR-5)

## Zoster Vaccine Contraindications Immunosuppression

Leukemia, lymphoma or other malignant neoplasm affecting the bone marrow or lymphatic system

persons whose leukemia or lymphoma is in remission and who have not received chemotherapy or radiation for at least 3 months can be vaccinated

# AIDS or other clinical manifestation of HIV infection

Includes persons with CD4+ T-lymphocyte values less than 200 per mm<sup>3</sup>, or less than 15% of total lymphocytes any vaccine. For information or a copy of the vaccine reporting form, call the VAERS toll-free number at 1-800-822-7967 or report online to <u>www.vaers.hhs.gov</u>.<sup>2</sup>

#### 7 DRUG INTERACTIONS

#### 7.1 Concomitant Administration with Other Vaccines

In a randomized clinical study, a reduced immune response to ZOSTAVAX as measured by gpELISA was observed in individuals who received concurrent administration of PNEUMOVAX® 23 and ZOSTAVAX compared with individuals who received these vaccines 4 weeks apart. Consider administration of the two vaccines separated by at least 4 weeks [see Clinical Studies (14.3)].

For concomitant administration of ZOSTAVAX with trivalent inactivated influenza vaccine, [see Clinical Studies (14.3)].

#### 1.2 Antiviral Medications

Concurrent administration of ZOSTAVAX and antiviral medications known to be effective against VZV has not been evaluated.

#### 8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

Prograncy Category: Contraindication Icon Contraindications (4.3)]

Zostavax product information, June 2011

# **Zoster and PPSV Vaccines**

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



# **Hepatitis A Epidemiology**

**Reservoir** 

Human (endemic)

□ Transmission Fecal-oral

Temporal pattern None

Communicability\*

2 weeks before to 1 week after onset

\* HAV infection confers lifelong immunity

#### Hepatitis A—United States, 1990-2000 Risk Factors



## Hepatitis A Vaccination Recommendations

- Travelers to areas with moderate or high incidence of hepatitis A
- Men who have sex with men
- Illegal drug users
- Persons with occupational risk
- Persons with clotting-factor disorders
- Persons with chronic liver disease, including hepatitis C
- Household contacts of international adoptees within 60 days of the adoptee's arrival in U.S.

## Hepatitis A Vaccination Recommendations

- Health care workers: not routinely recommended
- Child care centers: not routinely recommended
- Sewer workers or plumbers: not routinely recommended
- Food handlers: may be considered based on local circumstances

## **Hepatitis A Vaccine**



#### Update: Prevention of Hepatitis A After Exposure to Hepatitis A Virus and in International Travelers. Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP)

In 1995, highly effective inactivated hepatitis A vaccines were first licensed in the United States for preexposure prophylaxis against hepatitis A virus (HAV) among persons aged  $\geq 2$  years. In 2005, vaccine manufacturers received Food and Drug Administration approval for use of the vaccines in children aged 12--23 months (*l*).

The Advisory Committee on Immunization Practices (ACIP) issued recommendations for preexposure use of hepatitis A vaccine in 1996, 1999, and 2006 (*l*). Currently, ACIP recommends hepatitis A vaccination of all children at age 12--23 months, catch-up vaccination of older children in selected areas, and vaccination of persons at increased risk for hepatitis A (e.g., travelers to endemic areas, users of illicit drugs, or men who have sex with men) (*l*).

For decades, immune globulin (IG) has been recommended for prophylaxis after exposure to HAV (I). IG also has been recommended in addition to hepatitis A vaccine for preexposure prophylaxis for travelers to countries with high or intermediate hepatitis A endemicity who are scheduled to depart <4 weeks after receiving the initial vaccine dose. This report details updated recommendations, made by ACIP in June 2007, for prevention of hepatitis A after exposure to HAV and in departing international travelers (Box) and incorporates existing ACIP recommendations for prevention of hepatitis A (I).

Rationalo and Mothods for Undated Recommondations

HepA Vaccine Schedule Adult 1 dose Booster 6-18 months after first dose

#### Hepatitis A Post-exposure Prophylaxis

- For healthy persons aged 12 months–40 years, single antigen hepatitis A vaccine at the age-appropriate dose is preferred.
- For persons aged >40 years, IG is preferred; vaccine can be used if IG cannot be obtained.
- For children aged <12 months, immunocompromised persons, persons who have had chronic liver disease diagnosed, and persons for whom vaccine is contraindicated, IG should be used.



#### Hepatitis A: Susceptible International Travelers

 Older adults, immunocompromised persons, and persons with chronic liver disease or other chronic medical conditions planning to depart to an area in <2 weeks should receive the initial dose of vaccine and also simultaneously

 can be administered IG (0.02 mL/kg) at a separate anatomic injection site.

 Travelers who elect not to receive vaccine, are aged <12 months, or are allergic to a vaccine component should receive a single dose of IG (0.02 mL/kg), which provides effective protection for up to 3 months.

#### Hepatitis A Vaccination Recommendations





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DEPARTMENT OF HEALTH AND HUMAN SERVICES

# Twinrix®

- Combination hepatitis B (adult dose) and hepatitis A vaccine (pediatric dose)
- Schedule: 0, 1, 6-12 months
- Approved for persons 18 years of age and older
- New schedule allows doses at 0, 7, 21-30 days, booster at 12 months

# **Hepatitis A and Pregnancy**

- Pregnancy is no longer a precaution for Hepatitis A vaccine
- Inactivated vaccine
- Recommended if another high-risk condition is present

# **Hepatitis B**



## **Hepatitis B Virus Infection**

- More than 350 million carriers worldwide
- Established cause of chronic hepatitis and cirrhosis
- Human carcinogen cause of up to 80% of hepatocellular carcinomas

# Hepatitis B Epidemiology

Reservoir

Human

Transmission

Bloodborne Asymptomatic cases transmit

#### Communicability

1-2 months before and after onset of symptoms Chronic infection

#### **Hepatitis B Vaccine**

•Adolescent and adult recommended schedule •Time 0,1 month,4 month •Time 0,1 month,6 month • Time 0,2 month,4 month •Time 0,1 month,2 month, 12 months

Hepatitis B Vaccine Adolescent and Adult Schedule

Dose
Primary 1
Primary 2
Primary 3

Minimum Interval ----4 weeks

8 weeks\*

\*third dose must be separated from first dose by at least 16 weeks

## Hepatitis B Vaccine Long Term Efficacy

- Immunologic memory established following vaccination
- Exposure to HBV results in anamnestic anti-HBs response (50-75%)
- Chronic infection rarely documented among vaccine responders

## **Hepatitis B Vaccine Indications**

- Medical
- AIDS
- chronic liver disease
- receipt of clotting factors
- Behavior
- multiple sexual partners
- injection drug use
- history of STD
- travel to endemic region
- Demographic
- household contact HBsAg +
- sex partner HBsAg+
- immigrant/refugee from endemic region
- Occupation
- exposure to blood or sharps injury
- staff/resident in developmental disability facility)

# **Hepatitis B**

<u>New Identified Risk Factors</u>
 Diabetics age 23 – 59 years\*
 25 outbreaks in 1996-2011 involving blood glucose monitoring

### Hepatitis B Vaccine Adult Recommendations

#### •Medical

- AIDS
- chronic liver disease
- receipt of clotting factors
- DIABETES for persons 18-59 years

#### Behavior

- multiple sexual partners
- men who have sex with men
- injection drug use
- history of STD
- travel to endemic region

#### •Demographic

- household contact HBsAg +
- sex partner HBsAg+
- immigrant/refugee from endemic region

Occupation

MMWR, December 23, 20119 60(50);1709-1711 staff/resident in developmental disability facility)

#### Updated ACIP Adult Hepatitis B Recommendations



A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States

Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: Immunization of Adults

#### **December 2006**

 Vaccinate all high risk adults & all adults requesting vaccination

 In settings w/ large proportion of high risk adults, consider all unvaccinated adults at high risk

 Implement standing orders in primary care & specialty clinics to identify & vaccinate eligible adults

## **Hepatitis B Vaccination of Adults**

- Many adults are at increased risk of hepatitis B virus infection and should be vaccinated
- ACIP recommends providing vaccine at facilities where adults at increased risk may be accessed
  - **–STD clinics**
  - -Prisons
  - -HIV/AIDS clinics

## Postvaccination Serologic Testing

- Not routinely recommended following vaccination of infants, children, adolescents, or most adults
- Recommended for:
  - Hemodialysis patients and other immunocompromised persons
  - -Persons with HIV infection
  - -Sexual partners of HBsAg+ persons
  - -Certain healthcare personnel

# **Additional Guidance**

TABLE 2. Postexposure management of health-care personnel after occupational percutaneous and mucosal exposure to blood and body fluids, by health-care personnel HepB vaccination and response status

	Postexposure testing		Postexposure	Postvaccination			
Health-care personnel status	Source patient (HBsAg)	HCP testing (anti-HBs)	HBIG*	Vaccination	serologic testing <sup>†</sup>		
Documented responder <sup>§</sup> after complete series (≥3 doses)	No action needed						
Documented nonresponder <sup>¶</sup> after 6 doses	Positive/unknown	**	HBIG x2 separated by 1 month	_	No		
	Negative						
Response unknown after 3 doses	Positive/unknown	<10mIU/mL**	HBIG x1	Initiate	Yes		
	Negative	<10mlU/mL	None	revaccination			
	Any result	≥10mIU/mL	No action needed				
Unvaccinated/incompletely vaccinated or vaccine refusers	Positive/unknown	**	HBIG x1	Complete vaccination	Yes		
	Negative	_	None	Complete vaccination	Yes		

www.cdc.gov/mmwr/pdf/rr/rr6210.pdf

#### **QUESTIONS?**