

# Immunizations to Reduce Disease

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# DISCLOSURES

## Financial Relationships with Relevant Commercial Interests

- Receive research funding from
  - Sanofi Pasteur
  - Aztrezeneca/MedImmune
  - NIH
  - CDC
  - Gilead
- Serve on Advisory board
  - Novartis
  - Vaxinnate/Sequirus

# Overview

- Ask Questions
- Will only talk about adults (okay I talk about teenagers once)
- Vaccines should be given and not offered

# Vaccinations in the United States

- Advisory Committee for Immunization Practices (ACIP)
- Input from other professional organizations and other CDC committees.
- ACIP develops written recommendations for the routine administration of vaccines
- [www.cdc.gov/acip](http://www.cdc.gov/acip)

# 2017 Adult Immunization Schedule by age

INFORMATION FOR ADULT PATIENTS

2017 Recommended Immunizations for Adults: By Age

If you are this age, talk to your healthcare professional about these vaccines

If you are this age,	Flu <i>Influenza</i>	Td/Tdap Tetanus, diphtheria, pertussis	Shingles <i>Zoster</i>	Pneumococcal		Meningococcal		MMR Measles, mumps, rubella	HPV <i>Human papillomavirus</i>		Chickenpox <i>Varicella</i>	Hepatitis A	Hepatitis B	Hib <i>Haemophilus influenzae</i> type b
				PCV13	PPSV23	MenACWY or MPSV4	MenB		for women	for men				
19 - 21 years	Green	Green	Light Green	Blue	Blue	Blue	Blue	Green	Green	Blue	Green	Blue	Blue	Blue
22 - 26 years	Green	Green	Light Green	Blue	Blue	Blue	Blue	Green	Blue	Light Green	Green	Blue	Blue	Blue
27 - 59 years	Green	Green	Light Green	Blue	Blue	Blue	Blue	Green	Light Green	Light Green	Green	Blue	Blue	Blue
60 - 64 years	Green	Green	Green	Blue	Blue	Blue	Blue	Light Green	Light Green	Light Green	Green	Blue	Blue	Blue
65+ year	Green	Green	Green	Green	Green	Blue	Blue	Light Green	Light Green	Light Green	Green	Blue	Blue	Blue

# Adult Immunization Schedule by Risk Group

INFORMATION FOR ADULT PATIENTS

2017 Recommended Immunizations for Adults: By Health Condition

If you have this health condition,

talk to your healthcare professional about these vaccines

If you have this health condition,	Flu <i>Influenza</i>	Td/Tdap Tetanus, diphtheria, pertussis	Shingles Zoster	Pneumococcal		Meningococcal		MMR Measles, mumps, rubella	HPV <i>Human papillomavirus</i>		Chickenpox <i>Varicella</i>	Hepatitis A	Hepatitis B	Hib <i>Haemophilus influenzae</i> type b
				PCV13	PPSV23	MenACWY or MPSV4	MenB		for women	for men				
Pregnancy	Green	Green	Light Purple	Green	Blue	Blue	Blue	Light Purple	Green	Green	Light Purple	Blue	Blue	Green
Weakened Immune System	Green	Green	Light Purple	Green	Green	Blue	Blue	Light Purple	Green	Green	Light Purple	Blue	Blue	Green
HIV: CD4 count less than 200	Green	Green	Light Purple	Green	Green	Blue	Blue	Light Purple	Green	Green	Light Purple	Blue	Blue	Green
HIV: CD4 count 200 or greater	Green	Green	White	Green	Green	Blue	Blue	Green	Green	Green	Green	Blue	Blue	Green
Kidney disease or poor kidney function	Green	Green	Green	Green	Green	Blue	Blue	Green	Green	Green	Green	Blue	Blue	Green
Asplenia (if you do not have a spleen or if it does not work well)	Green	Green	Green	Green	Green	Blue	Blue	Green	Green	Green	Green	Blue	Blue	Green
Heart disease Chronic lung disease Chronic alcoholism	Green	Green	Green	Green	Green	Blue	Blue	Green	Green	Green	Green	Blue	Blue	Green
Diabetes (Type 1 or Type 2)	Green	Green	Green	Green	Green	Blue	Blue	Green	Green	Green	Green	Blue	Blue	Green
Chronic Liver Disease	Green	Green	Green	Green	Green	Blue	Blue	Green	Green	Green	Green	Blue	Blue	Green

# Vaccinations for Adults vs. Kids

- Usually disease-based recommendations
- Prevention of morbidity – not disease.
- Poor uptake
- Complicated payment
- Few recommended on RCT data

# Routinely Recommended Vaccines Used in Adults

## Live, attenuated vaccines\*:

- Influenza (intranasal)
- Measles, mumps, rubella
- Varicella
- Zoster
- Oral typhoid
- Yellow fever

## Non-replicating vaccines

- Influenza (IM, intradermal)
- Hepatitis A
- Hepatitis B
- Human papillomavirus (HPV)
- Meningococcal
- Pneumococcal polysaccharide (PPV-23)
- Pneumococcal conjugate (PCV-13)
- Tetanus, diphtheria, pertussis (Td/Tdap)
- Rabies
- Japanese Encephalitis
- Capsular polysaccharide Typhoid vaccine



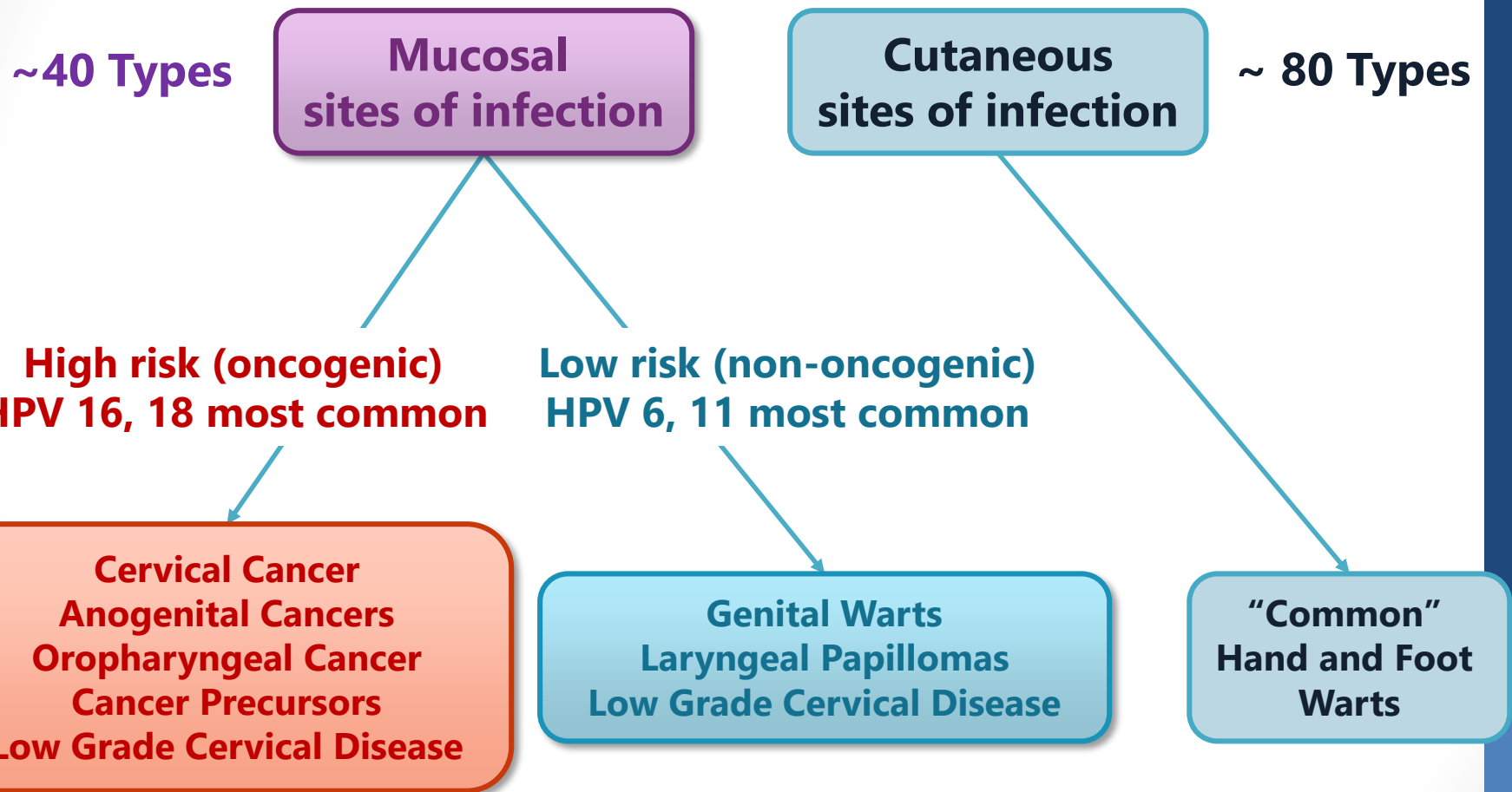
# Level of Immune Suppression

- High level Immunosuppression:
  - Combined primary immunodeficiency
  - Cancer chemotherapy
  - $\leq 2$  months after solid organ transplant
  - HIV with  $<200$  CD4 cells
  - Daily steroids  $\geq 20$ mg prednisone or equivalent for  $\geq 14$  days
  - Biologic immune modulators
- Low level immunosuppression:
  - Asymptomatic HIV infection with CD4 200-499 cells
  - Lower dose of steroids
  - Low levels of Methotrexate, azathioprine, or 6-mercaptopurine

# Case I

- 24 year old woman is seen in your office for follow-up of pap smear results. Her HPV testing was positive for HPV-16. She has not received the HPV vaccine.
  - A. She is too old for the vaccine (it is meant for 11-12 year olds)
  - B. She needs the vaccine to treat her HPV-16.
  - C. No vaccine indicated since she already has HPV-16.
  - D. Immunize her with any of the HPV vaccines available in the United States.

# HPV Types Differ in their Disease Associations

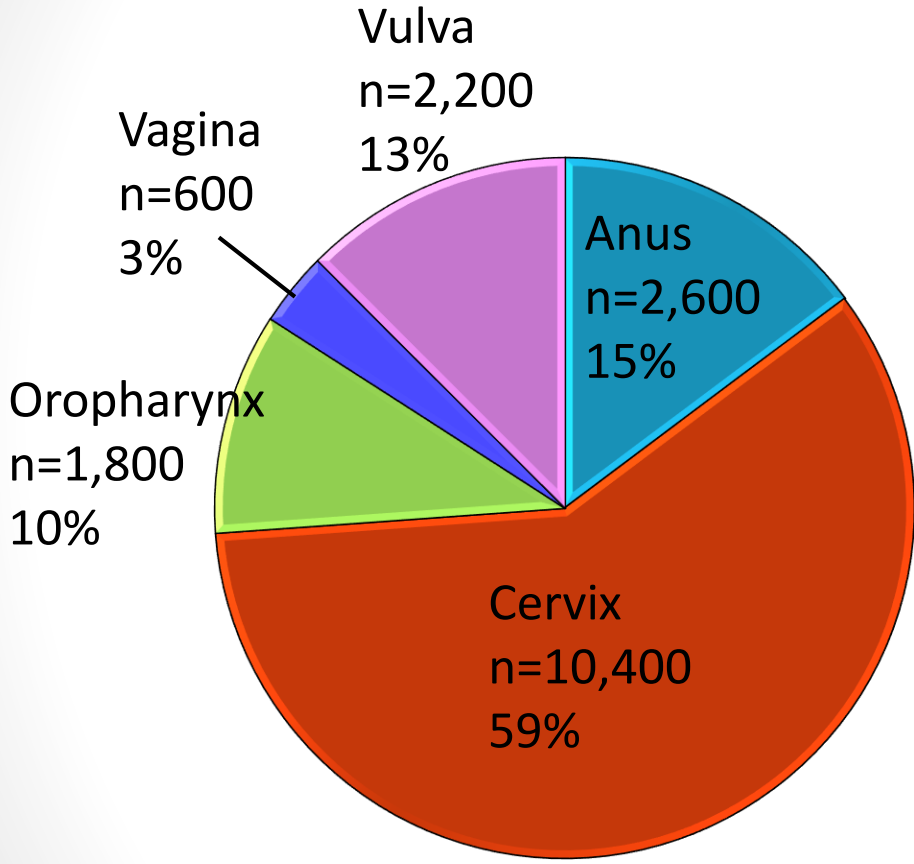


# HPV Infection

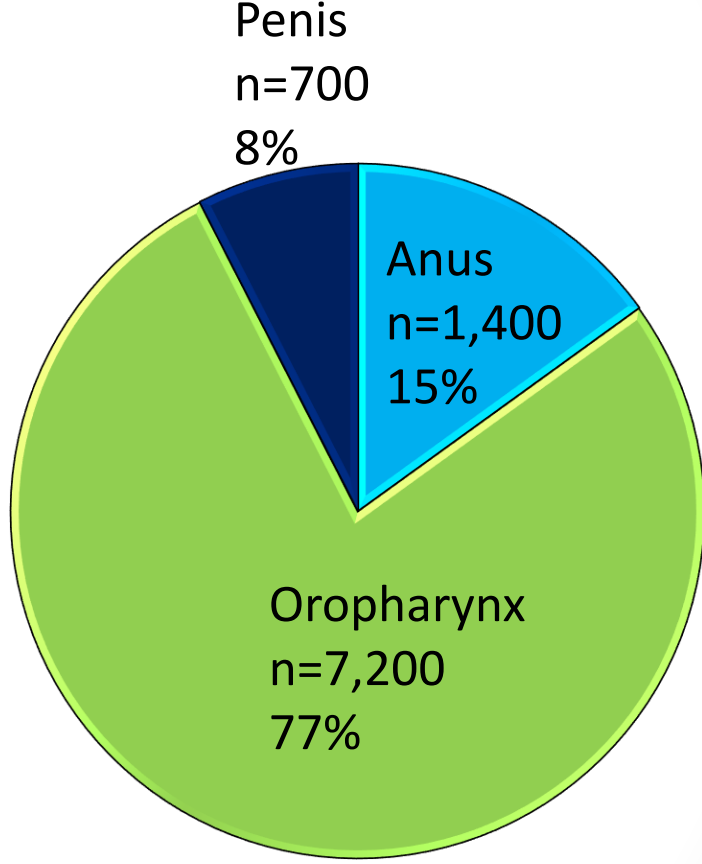
- Most females and males will be infected with at least one type of mucosal HPV at some point in their lives
  - Estimated 79 million Americans currently infected
  - 14 million new infections/year in the US
  - HPV infection is most common in people in their teens and early 20s
- Most people will never know that they have been infected

Slide courtesy of the CDC

# New Cancers Caused by HPV per Year United States 2006-2010



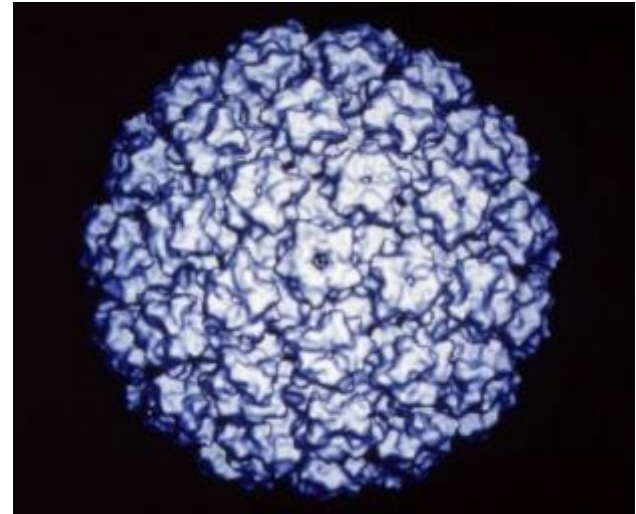
**Women (n = 17,600)**



**Men (n = 9,300)**

# HPV Prophylactic Vaccines

- Recombinant L1 capsid proteins that form “virus-like” particles (VLP)
- Non-infectious and non-oncogenic
- Produce higher levels of neutralizing antibody than natural infection



**HPV Virus-Like Particle**

# HPV Vaccines Currently Licensed in U.S.

	Quadrivalent 4vHPV (Gardasil)	9-Valent 9vHPV (Gardasil 9)
<b>Manufacturer</b>	Merck	Merck
<b>HPV Types Included</b>	6, 11, <b>16, 18</b>	6, 11, <b>16, 18,</b> 31, 33, 45, 52, 58
<b>Contraindications</b>	Hypersensitivity to yeast	Hypersensitivity to yeast
<b>2 Dose Schedule</b>	0 & 6-12 months	0 & 6-12 months
<b>3 Dose Schedule</b>	0, 2, 6 months	0, 2, 6 months

\* May be present in tip of pre-filled syringes

Slide courtesy of the CDC

# ACIP Recommendations

## Age

- Routine vaccination at age 11 or 12 years\*
- Vaccination recommended through **age 26 for females** and through **age 21 for males** not previously vaccinated
- Vaccination recommended for men through age 26 who have sex with men (MSM) or are immunocompromised (including persons HIV-infected)



# Updated ACIP recommendations: 2 dose series

- If the following criteria are met, vaccinees only need **2** not **3** doses of vaccine at 0 and 6-12 months
  - Not immunocompromised
  - Vaccine Series starts before 15<sup>th</sup> birthday
  - Not in the middle of the original series (i.e. if patient has received vaccine at 0 and 1-2 months, they will need the third dose)

# Case 2

70 year old smoker with diabetes is asking if she should receive the new pneumonia vaccine after she saw the commercial for the new “pneumonia” vaccine.

- A. Give her PPV-23 now and PCV-13 in 5 years.
- B. She is too old for any of the pneumococcal vaccines.
- C. Give her conjugate pneumococcal vaccine (PCV-13) now.
- D. Give her either vaccine.

# The Pneumococcus

## Potential Targets for Vaccine Design

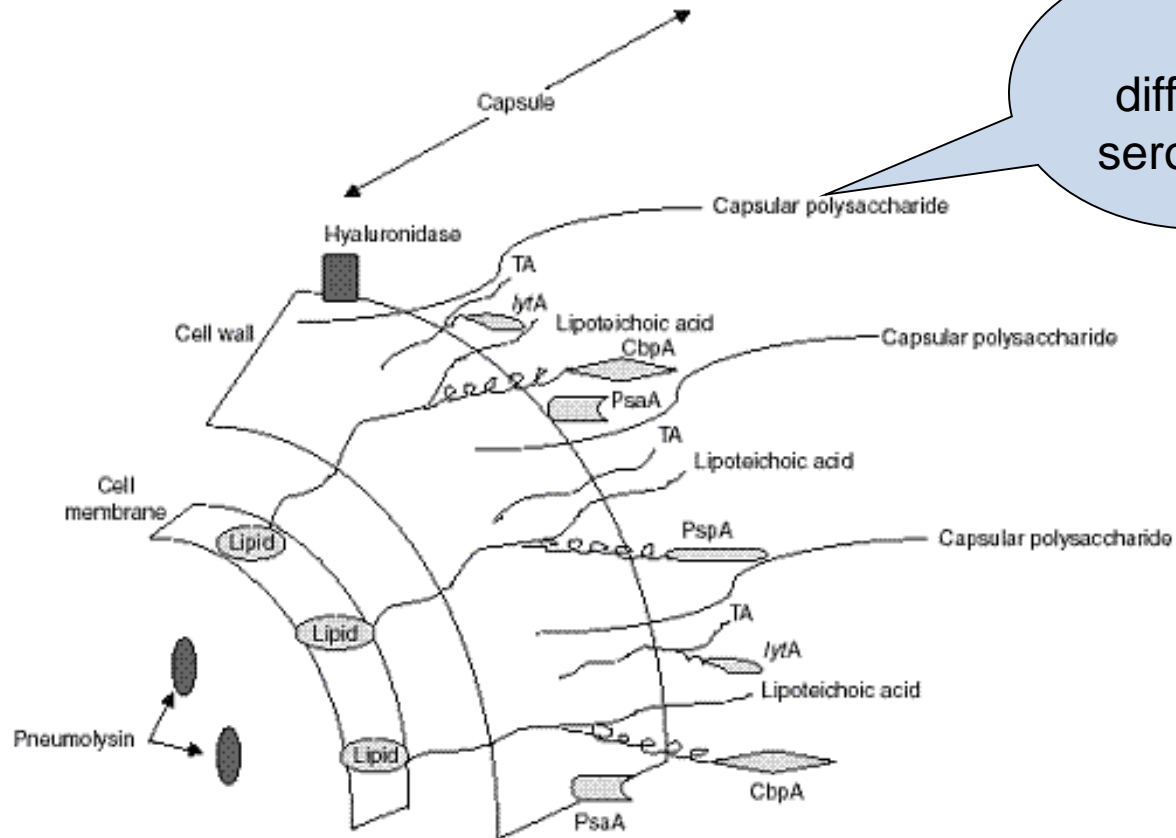


Fig. 1. Diagram of pneumococcal surface. CbpA (PspC) = choline-binding protein A; *lytA* = autolysin; PsaA = pneumococcal surface adhesin A; PspA = pneumococcal surface protein A; TA = teichoic acid.

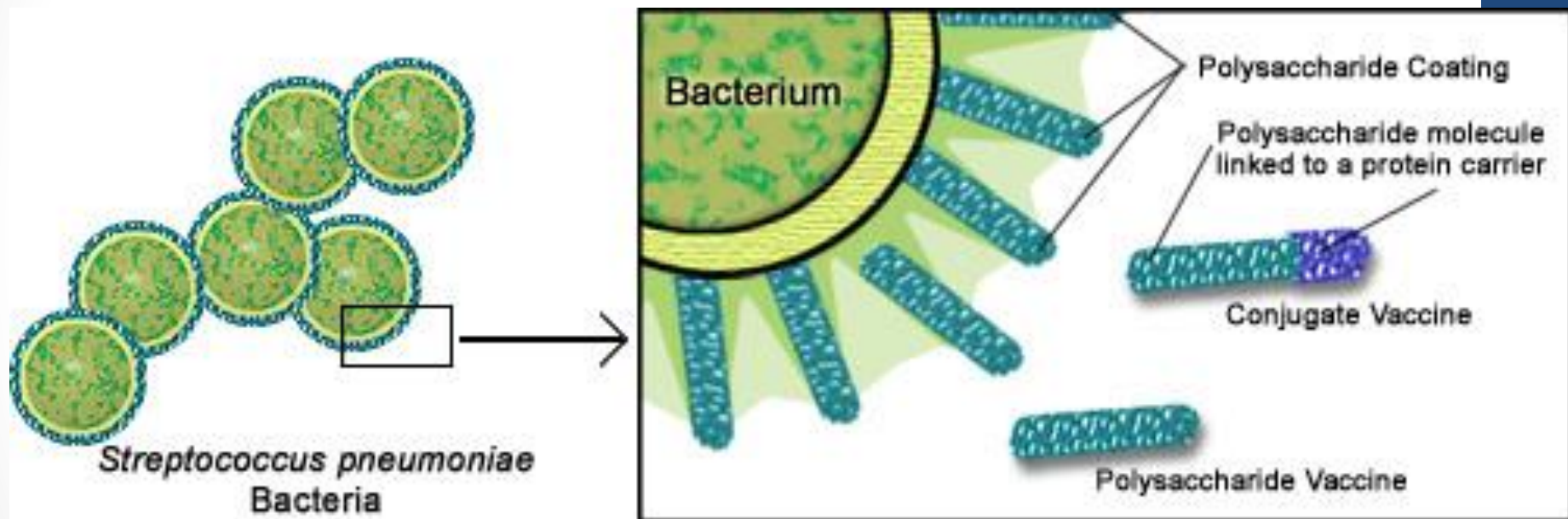
# Most common polysaccharides

- 1, 2, 3, 4, 5, 6A, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F

# Pneumococcal Vaccines

- **PPV-23 or PPV-pneumococcal polysaccharide vaccine**
  - Includes 23 purified capsular polysaccharide antigens of *Streptococcus pneumoniae*
- **PCV-13 Pneumococcal conjugate vaccine**
  - 13 serotypes

# What is conjugation



# Pneumococcal Polysaccharide Vaccine: Important Points

- PPSV prevents bacteremia, not pneumonia.
- Revaccination does not induce booster response.



Risk Group	Underlying Medical Condition	PCV13	PPSV23*	
		Recommended	Recommended	Revaccination
Immuno-competent persons	Chronic heart disease <sup>†</sup>		✓	
	Chronic lung disease <sup>§</sup>		✓	
	Diabetes mellitus		✓	
	CSF leaks	✓	✓	
	Cochlear implants	✓	✓	
	Alcoholism		✓	
	Chronic liver disease		✓	
	Cigarette smoking		✓	
Functional or anatomic asplenia	Sickle cell disease/other hemoglobinopathies	✓	✓	✓
	Congenital or acquired asplenia	✓	✓	✓
Immuno-compromised persons	Congenital/acquired immunodeficiencies	✓	✓	✓
	HIV infection	✓	✓	✓
	Chronic renal failure	✓	✓	✓
	Nephrotic syndrome	✓	✓	✓
	Leukemia	✓	✓	✓
	Lymphoma	✓	✓	✓
	Hodgkin disease	✓	✓	✓
	Generalized malignancy	✓	✓	✓
	Iatrogenic immunosuppression	✓	✓	✓
	Solid organ transplant	✓	✓	✓
Multiple myeloma	✓	✓	✓	

# Indications for PCV13

Adults  $\geq 65$  years of age

Adults 19 years or older with

- Functional or anatomic asplenia
- Immuno-compromising conditions
- Congenital or acquired immunodeficiencies
- HIV infection
- Chronic renal failure or nephrotic syndrome
- Leukemias, lymphomas, Hodgkin disease
- Generalized malignancy
- Treatment with immunosuppressive drugs
- Solid organ transplantation
- Multiple myeloma
- CSF leaks and cochlear implants

# Recommendation for PCV13 and PPSV23 Vaccine Naïve Adults with immunocompromising conditions

- PCV13 dose is given before PPSV23
- Give PPSV23 at least 8 weeks after PCV13
- Recommendations for 2nd dose of PPSV and a dose at age 65 years or older remain unchanged

PCV – PPSV – PPSV + PPSV (@ 65 years or later)  
≥8 weeks      ≥5 years

# Prevention of pneumococcal disease among adults with immunocompromising conditions who have received PPSV

1) PPSV – **PCV** – PPSV + PPSV (@ 65 years or later)

Timeline: PPSV (≥1 year) – **PCV** (≥8 weeks) – PPSV (≥5 years) + PPSV (@ 65 years or later)

2) PPSV – PPSV – **PCV** + PPSV (@ 65 years or later)

Timeline: PPSV (≥5 years) – PPSV (≥1 year) – **PCV** + PPSV (@ 65 years or later)

3) PPSV – PPSV + PPSV (@ 65 +) – **PCV**

Timeline: PPSV (≥5 years) + PPSV (@ 65 +) (≥1 year) – **PCV**

ORIGINAL ARTICLE

# Polysaccharide Conjugate Vaccine against Pneumococcal Pneumonia in Adults

M.J.M. Bonten, S.M. Huijts, M. Bolkenbaas, C. Webber, S. Patterson, S. Gault, C.H. van Werkhoven, A.M.M. van Deursen, E.A.M. Sanders, T.J.M. Verheij, M. Patton, A. McDonough, A. Moradoghli-Haftvani, H. Smith, T. Mellelieu, M.W. Pride, G. Crowther, B. Schmoele-Thoma, D.A. Scott, K.U. Jansen, R. Lobatto, B. Oosterman, N. Visser, E. Caspers, A. Smorenburg, E.A. Emini, W.C. Gruber, and D.E. Grobbee

## ABSTRACT

### BACKGROUND

Pneumococcal polysaccharide conjugate vaccines prevent pneumococcal disease in infants, but their efficacy against pneumococcal community-acquired pneumonia

# Findings

- Randomized, double-blind, placebo-controlled trial
- 84,496 adults 65 + years in the Netherlands
- Community-acquired pneumonia
  - PCV13: 49 persons
  - Placebo Group: 90 persons
  - Vaccine efficacy: 45.6%; (CI: 21.8 - 62.5)
- Nonbacteremic and noninvasive community-acquired pneumonia
  - PCV13: 33 persons
  - Placebo Group: 60 persons
  - Vaccine efficacy: 45.0% (CI:14.2 - 65.3)
- Invasive pneumococcal disease
  - PCV13: 7 persons
  - Placebo Group: 28 persons
  - Vaccine efficacy: 75.0% (CI: 41.4 - 90.8)
- Numbers of serious adverse events and deaths were similar in the two groups, but there were more local reactions in the PCV13 group.

# Adults 65+

- PCV-13 is now recommended for all adults 65+
- Ideally PCV-13 given before PPV-23
- Give PPV-23 one year after PCV-13
- If already received PPV, wait a year before giving PCV-13

# Adult Recommendations PPV-23 Alone

- Persons aged 19 through 64 years with chronic medical conditions, including asthma, diabetes mellitus, COPD.
- Persons aged 19 through 64 years who smoke cigarettes.



Risk Group	Underlying Medical Condition	PCV13	PPSV23*	
		Recommended	Recommended	Revaccination
Immunocompetent persons	Chronic heart disease <sup>†</sup>		✓	
	Chronic lung disease <sup>§</sup>		✓	
	Diabetes mellitus		✓	
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	Alcoholism		✓	
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	Leukemia	✓	✓	✓
	Lymphoma	✓	✓	✓
	Hodgkin disease	✓	✓	✓
	Generalized malignancy	✓	✓	✓
	Iatrogenic immunosuppression	✓	✓	✓
	Solid organ transplant	✓	✓	✓
Multiple myeloma	✓	✓	✓	

# Re-immunization

- Those who receive PPV-23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years or later if at least 5 years have passed since their previous dose.
- Those who receive PPV-23 at or after age 65 years should receive only a single dose.
- A second dose of PPV-23 is recommended 5 years after the first dose for persons aged 19 through 64 years with functional or anatomic asplenia and for persons with immunocompromising conditions.

# Case 3

71 yo male veteran with hypertension, COPD, and rheumatoid arthritis on an TNF-alpha inhibitor had shingles last year.

- A. Do not give vaccine because he had shingles last year.
- B. Don't give the vaccine because he is on a TNF-alpha inhibitor.
- C. Give vaccine because that is always the correct answer
- D. Wait another year to give him 2 years between infection and immunization.
- E. It is covered by Medicare part B

# Routinely Recommended Vaccines Used in Adults

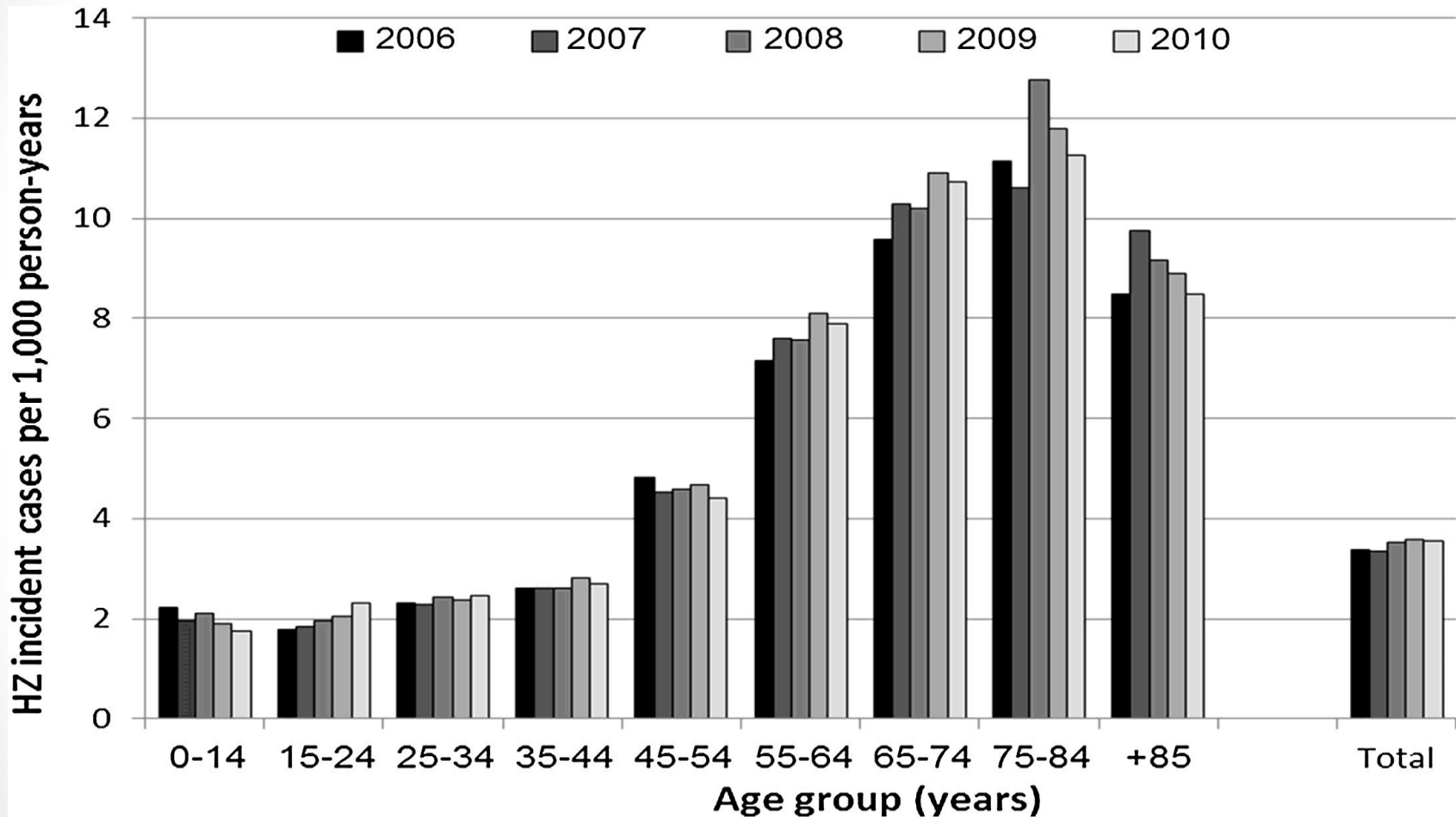
## Live, attenuated vaccines\*:

- Influenza (intranasal)
- Measles, mumps, rubella
- Varicella
- Zoster
- Oral typhoid
- Yellow fever

## Non-replicating vaccines

- Influenza (IM, intradermal)
- Hepatitis A
- Hepatitis B
- Human papillomavirus (HPV)
- Meningococcal
- Pneumococcal polysaccharide (PPV-23)
- Pneumococcal conjugate (PCV-13)
- Tetanus, diphtheria, pertussis (Td/Tdap)
- Rabies
- Japanese Encephalitis
- Capsular polysaccharide Typhoid vaccine

# Zoster Epidemiology in the U.S.



# Shingles Prevention Study

- Randomized, double-blind, placebo-controlled trial of high dose live-attenuated varicella zoster vaccine.
- 38,546 persons aged 60+ enrolled at 22 sites in U.S.
- Active follow-up for 3-5 years for development of shingles.

# Effect of Zoster Vaccine on Incidence of Herpes Zoster

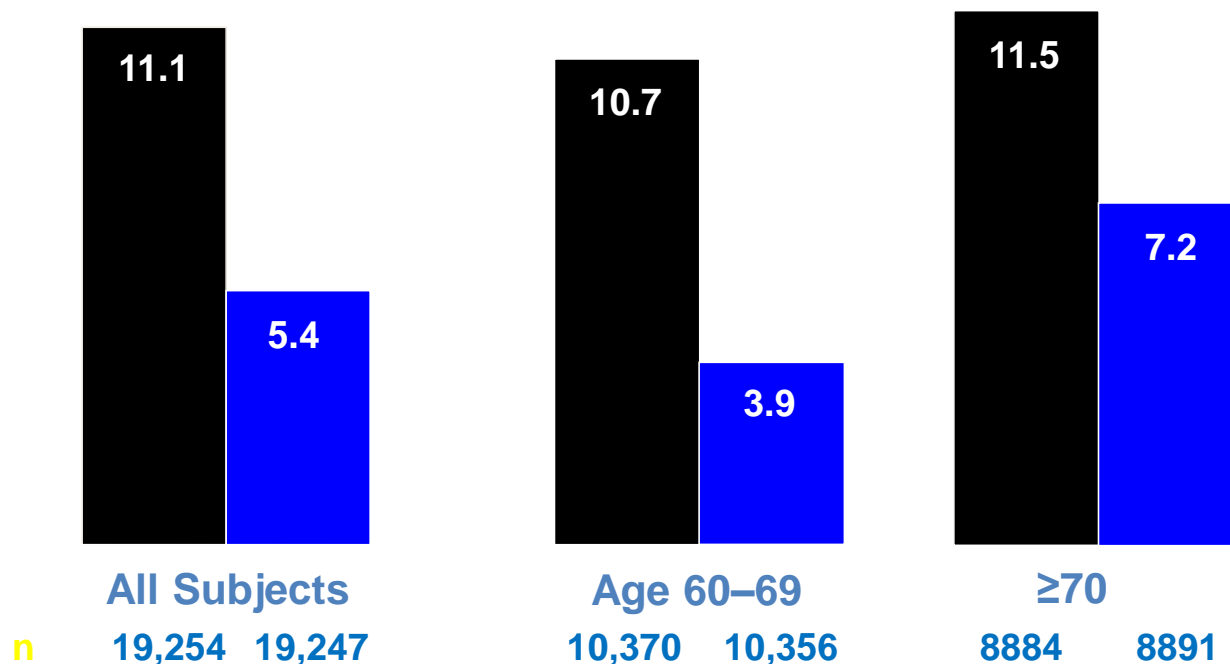
**Efficacy  
(95% CI)**

**51.3%  
(44.2-57.6)**

**63.9%  
(55.5-70.9)**

**37.6%  
(25.0-48.1)**

Incidence of herpes zoster  
(per 1000 person years)



■ Placebo

■ Zoster Vaccine Live

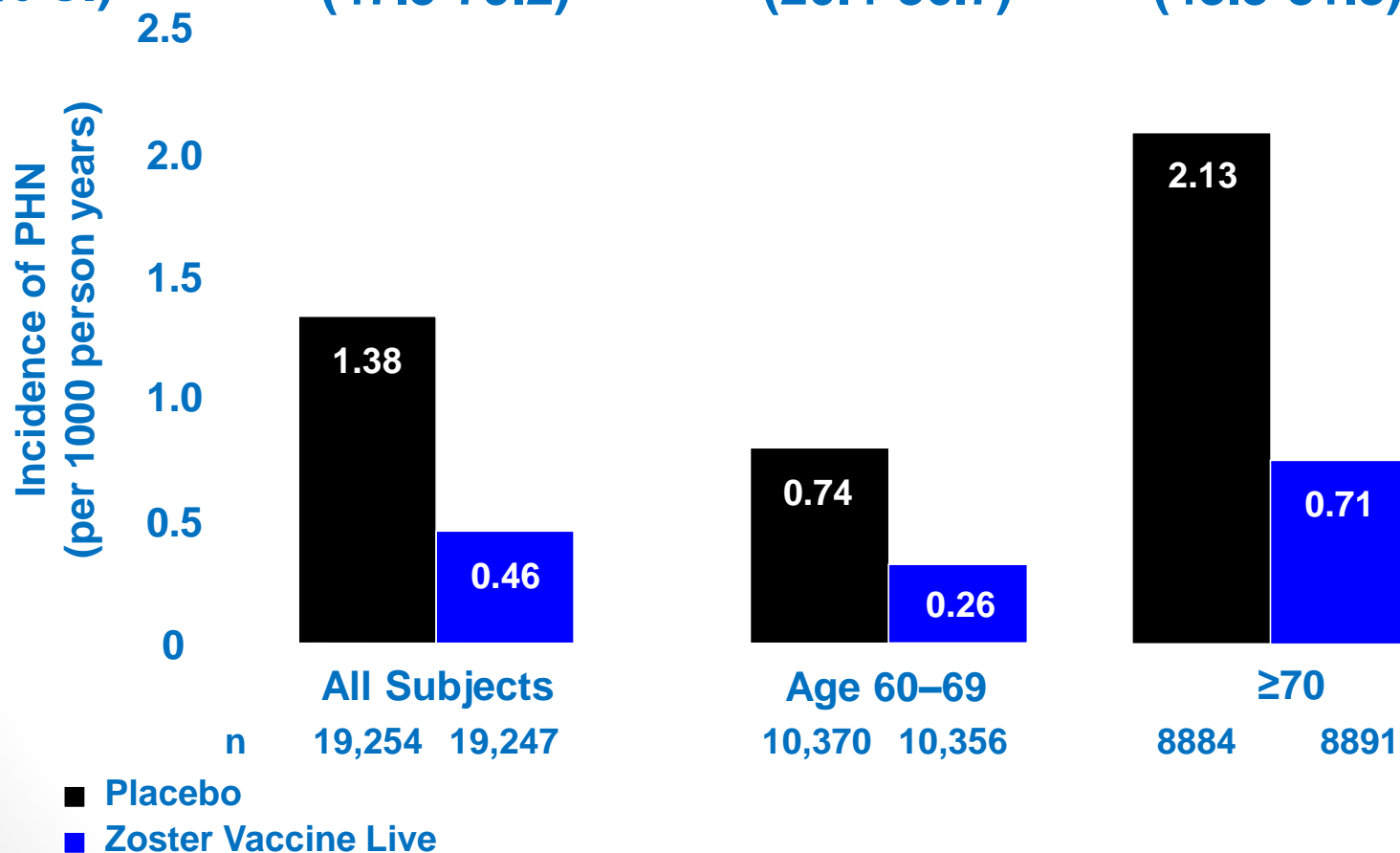
# Effect of Zoster Vaccine on Incidence of Postherpetic Neuralgia

**Efficacy  
(95% CI)**

**66.5%  
(47.5-79.2)**

**65.7%  
(20.4-86.7)**

**66.8%  
(43.3-81.3)**





# ACIP Recommendations

- Recommended for all adults  $\geq 60$  years
- Not intended for treating herpes zoster (HZ)
- Recommended whether or not patient reports history of HZ
- Not recommended for persons who received varicella vaccine
- No recommendations for re-immunization at present

# Contraindications for Varicella Vaccination

- Anaphylactic reaction to vaccine or constituents, (gelatin & neomycin)
- Primary or acquired immunodeficiency.
- HIV with CD4 cells < 200.
- Immunosuppression, i.e., high-dose steroids.
- Active, untreated TB.
- Pregnancy or possibility of pregnancy

# Vaccine Reimbursement

- For those 60-65:
  - Most insurance covers this cost since the vaccine is recommended by the ACIP
- For those 65+:
  - Covered by Medicare Part D -- pharmacy benefit.



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## ORIGINAL ARTICLE

# Efficacy of an Adjuvanted Herpes Zoster Subunit Vaccine in Older Adults

Himal Lal, M.D., Anthony L. Cunningham, M.B., B.S., M.D., Olivier Godeaux, M.D., Roman Chlibek, M.D., Ph.D., Javier Diez-Domingo, M.D., Ph.D., Shinn-Jang Hwang, M.D., Myron J. Levin, M.D., Janet E. McElhaney, M.D., Airi Poder, M.D., Joan Puig-Barberà, M.D., M.P.H., Ph.D., Timo Vesikari, M.D., Ph.D., Daisuke Watanabe, M.D., Ph.D., Lily Weckx, M.D., Ph.D., Toufik Zahaf, Ph.D., and Thomas C. Heineman, M.D., Ph.D., for the ZOE-50 Study Group\*

N Engl J Med 2015; 372:2087-2096 | [May 28, 2015](#) | DOI: 10.1056/NEJMoa1501184

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[Abstract](#)[Article](#)[References](#)[Citing Articles \(173\)](#)[Letters](#)[Metrics](#)

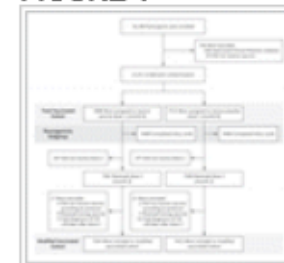
## BACKGROUND

In previous phase 1–2 clinical trials involving older adults, a subunit vaccine containing varicella–zoster virus glycoprotein E and the AS01<sub>B</sub> adjuvant system (called HZ/su) had a clinically acceptable safety profile and elicited a robust immune response.

[Full Text of Background...](#)

## MEDIA IN THIS ARTICLE

### FIGURE 1



Enrollment and

# HZ/su

- A subunit vaccine containing varicella–zoster virus glycoprotein E and the AS01<sub>B</sub> adjuvant
- Randomized, placebo-controlled, phase 3 study
- Adults ≥50 years of age
- 2 intramuscular doses of the vaccine or placebo 2 months apart
- 15,411 participants
- Mean follow-up of 3.2 years,
- Herpes zoster:
  - 6 participants in the vaccine group
  - 210 participants in the placebo group (incidence rate, 0.3 vs. 9.1 per 1000 person-years)
  - Vaccine efficacy = 97.2% (95% CI, 93.7 to 99.0; P<0.001).
- There were solicited or unsolicited reports of grade 3 symptoms in 17.0% of vaccine recipients and 3.2% of placebo recipients.

# Case 4

A 58 year old woman is sooooo excited! Her daughter is expecting the first grandchild – it's a GIRL!!!! It is October and the baby is due in November. What vaccines does grandma-to-be need?

- A. Administer influenza and RSV vaccine.
- B. Administer Tdap
- C. Administer Tdap and quadrivalent influenza vaccine
- D. No vaccines needed.

# Pertussis

- Pertussis is on the rise in all ages.
- Pertussis may be transmitted to contacts
- Pertussis may be transmitted before symptoms appear
- Pertussis is difficult to diagnosis among adults and lethal in the extremes of age.

# Pertussis Vaccine Alphabet Soup

Diphtheria component

- DTaP → Infant and children
- Tdap → Adolescents & Adults
- Td → Adult booster (former?)

Tetanus component

Pertussis component

Size of letter denotes  
size of dose



# Tdap Vaccine Recommendations: General Population

- All adults >18 who have not yet received a dose of Tdap should receive a single dose.
- After receipt of Tdap, persons should continue to receive Td for routine booster immunization.
- One dose should be administered to all pregnant women during 27-36 weeks gestation for EACH pregnancy.

# Case 5

- 75 year old retired professor presents for his annual influenza vaccine. He has heard about the quadrivalent influenza vaccine and the high dose vaccine and wants to know which one to obtain.
- A. Neither vaccine
  - B. High Dose vaccine
  - C. Quadrivalent vaccine
  - D. Either

# Seasonal Influenza Vaccination

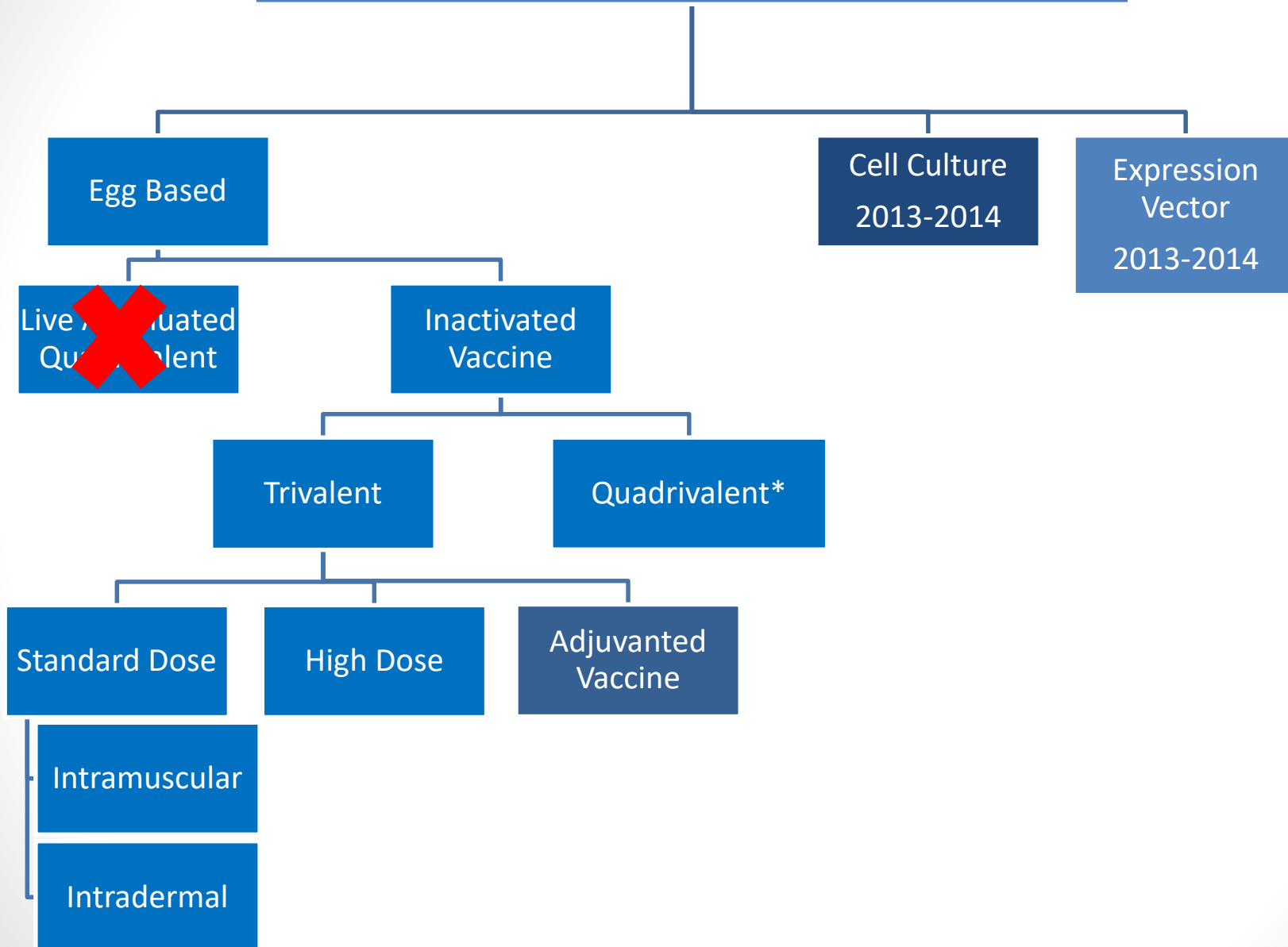
Influenza vaccine should be administered to all persons aged 6 months and older every year.

# Egg Allergy 2016-17

## Recommendations

- Persons with a history of egg allergy who have experienced only hives after exposure to egg should receive influenza vaccine.
- Persons who report having had reactions to egg involving symptoms other than hives, such as angioedema, respiratory distress, lightheadedness, or recurrent emesis; or who required epinephrine or another emergency medical intervention, may similarly receive any licensed and recommended influenza vaccine. Vaccine should be administered in an inpatient or outpatient medical setting AND should be supervised by a health care provider who is able to recognize and manage severe allergic conditions.
- A previous severe allergic reaction to influenza vaccine, regardless of the component suspected of being responsible for the reaction, is a contraindication to future receipt of the vaccine.

# Influenza Vaccines



# IIV3 vs IIV4

	H1N1	H3N2	B-Victoria	B-Yamagata
Trivalent (IIV3)	X	X	X One but not Both B's	
Quadrivalent (IIV4)	X	X	X	X

# Available IIV3 formulations

- Standard Dose (IIV3)
  - 15mcg of HA from each strain (45mcg total)
- High Dose (IIV3-HD)
  - 60mcg of HA from each strain (180mcg total)
- Adjuvanted (aIIV3)
  - 15mcg of HA from each strain + MF59

# IIV-HD

- Persons aged 65 years and over.
- Immunogenicity: High dose > standard dose.  
Relative Efficacy (compared to SD) 24%
- Safety: Injection-site reaction and systemic adverse events were more frequent.
- Quadrivalent High Dose in clinical trials



# aIV

- Licensed in the US over a year ago
- Currently awaiting introduction into US
- Antibody responses non-inferior to standard dose
- Likely has greater cellular immune responses
- Greater local reactions than IIV but mostly mild

# Cell culture

- Grown in insect cells
- No consider egg free since seed stock from eggs

# Expression Vector Vaccines

- Not made in eggs
- No seed stock
- Can be put into rapid production

# Resources

- [cdc.gov](https://www.cdc.gov)
- [Immunize.org](https://www.immunize.org)
- [NFID.org](https://www.nfid.org)



- **VACCINATE**
- **VACCINATE**
- **VACCINATE**
- **VACCINATE**

# Live attenuated influenza vaccine (LAIV, nasal spray)

- Population: Healthy persons aged 2 through 49 years.
  - Upper age range a function of lack of data, not safety concerns.
- Efficacy varies by population, season, strain.
  - Live vaccine superior to TIV in 3 comparative trials in children UNTIL the pandemic.
  - Relative efficacy less clear in adults; TIV superior to LAIV in some studies, but similar in most studies.
- Safety:
  - Common: nasal congestion, sore throat.
  - Rare: wheezing in young children (younger than 2 years).