Update on Immunizations

H. Keipp Talbot, M.D., M.P.H.

Vanderbilt University Medical Center

DISCLOSURES

Financial Relationships with Relevant Commercial Interests

- Receive research funding from
  - Sanofi Pasteur
  - CDC
  - Gilead
- Serve on Advisory board
  - Novartis/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**

2017 ADULT IMMUNIZATION SCHEDULE BY AGE

Figure 1. Recommended immunization schedule for adults aged 19 years or older by age group, United States, 2018

This figure should be reviewed with the accompanying footnotes. This figure and the footnotes describe indications for which vaccines, if not previously administered, should be administered unless noted otherwise.

Vaccine	19–21 years	22–26 years	27–49 years	50–64 years	≥65 years
Influenza[1]	1 dose annually				
Tdap[2] or Td[2]	1 dose Tdap, then Td booster every 10 yrs				
MMR[3]	1 or 2 doses depending on indication (if born in 1957 or later)				
VAR[4]	2 doses				
RZV[5] (preferred)				2 doses RZV (preferred)	
or				or	
ZVL[5]					1 dose ZVL
HPV–Female[6]	2 or 3 doses depending on age at series initiation				
HPV–Male[6]	2 or 3 doses depending on age at series initiation				
PCV13[7]	1 dose				
PPSV23[7]	1 or 2 doses depending on indication				1 dose
HepA[8]	2 or 3 doses depending on vaccine				
HepB[9]	3 doses				
MenACWY[10]	1 or 2 doses depending on indication, then booster every 5 yrs if risk remains				
MenB[10]	2 or 3 doses depending on vaccine				
Hib[11]	1 or 3 doses depending on indication				

Adult Immunization Schedule by Risk Group

Figure 2. Recommended immunization schedule for adults aged 19 years or older by medical condition and other indications, United States, 2018

This figure should be reviewed with the accompanying footnotes. This figure and the footnotes describe indications for which vaccines, if not previously administered, should be administered unless noted otherwise.

Vaccine	Pregnancy[1-6]	Immuno-compromised (excluding HIV infection)[3-7,11]	HIV infection CD4+ count (cells/μL)[3-7,9-10]		Asplenia, complement deficiencies[7,10,11]	End-stage renal disease, on hemodialysis[7,9]	Heart or lung disease, alcoholism[7]	Chronic liver disease[7-9]	Diabetes[7,9]	Health care personnel[3,4,9]	Men who have sex with men[6,8,9]
			<200	≥200							
Influenza[1]	1 dose annually										
Tdap[2] or Td[2]	1 dose Tdap each pregnancy	1 dose Tdap, then Td booster every 10 yrs									
MMR[3]	contraindicated				1 or 2 doses depending on indication						
VAR[4]	contraindicated				2 doses						
RZV[5] (preferred)					2 doses RZV at age ≥50 yrs (preferred)						
or					or						
ZVL[5]	contraindicated				1 dose ZVL at age ≥60 yrs						
HPV–Female[6]		3 doses through age 26 yrs			2 or 3 doses through age 26 yrs						
HPV–Male[6]		3 doses through age 26 yrs			2 or 3 doses through age 21 yrs						2 or 3 doses through age 26 yrs
PCV13[7]		1 dose									
PPSV23[7]		1, 2, or 3 doses depending on indication									
HepA[8]	2 or 3 doses depending on vaccine										
HepB[9]	3 doses										
MenACWY[10]	1 or 2 doses depending on indication , then booster every 5 yrs if risk remains										
MenB[10]	2 or 3 doses depending on vaccine										
Hib[11]	3 doses HSCT recipients only				1 dose						

*

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)
- Recominbant Shingles
- 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

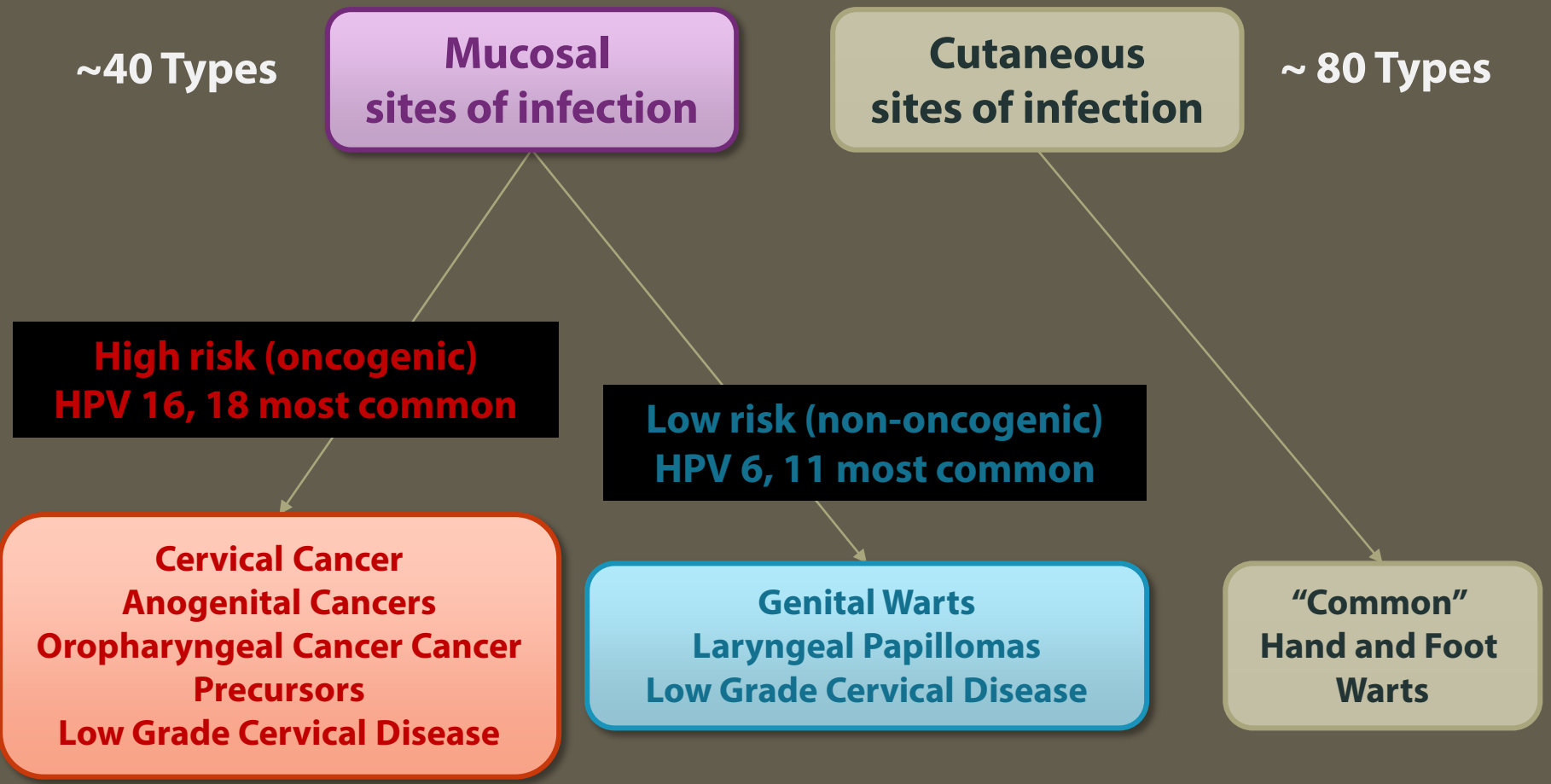
- **High level Immunosuppression:**
  - Combined primary immunodeficiency
  - Cancer chemotherapy
  - ≤ 2 months after solid organ transplant
  - HIV with <200 CD4 cells
  - Daily steroids ≥20mg prednisone or equivalent for ≥14 days
  - Biologic immune modulators
- **Low level immunosuppression:**
 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

CASE 1

- 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 yr 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



Slide courtesy of the CDC

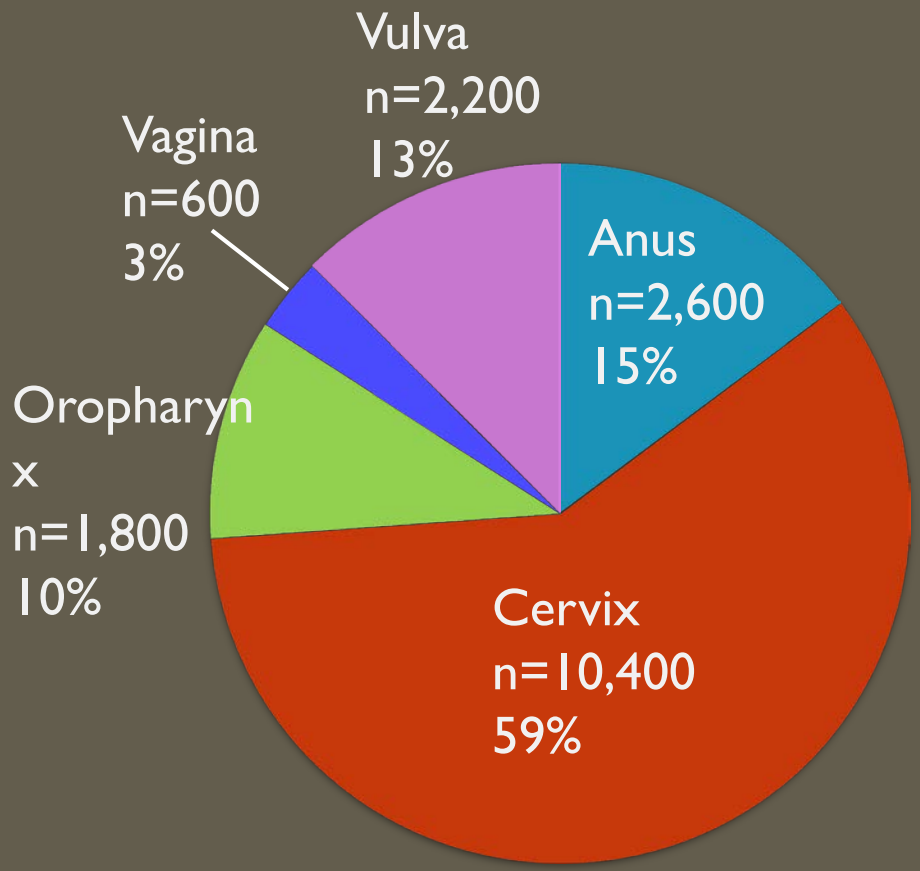
HPV INFECTION

- 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

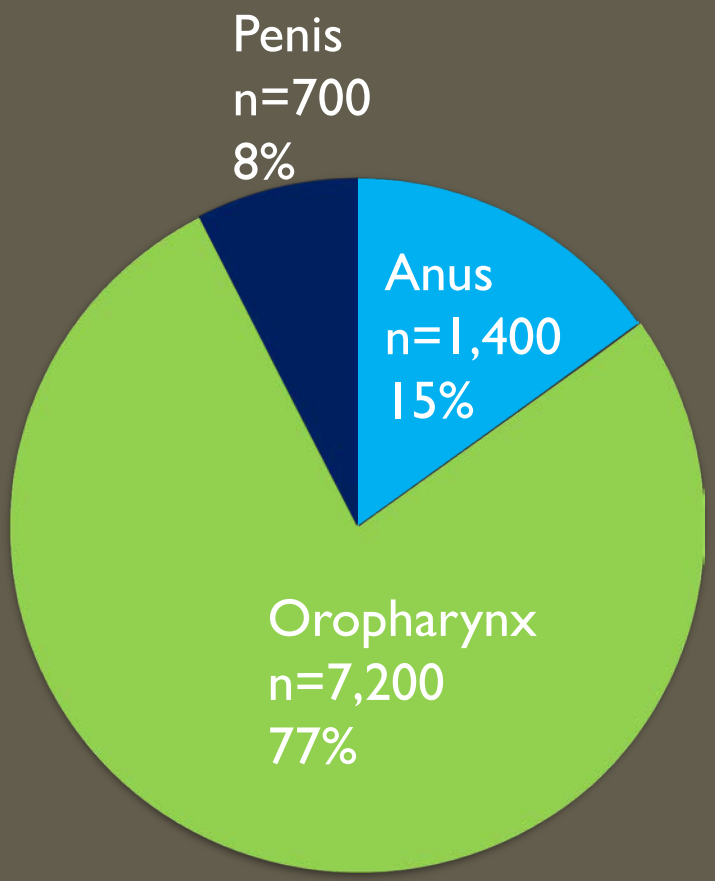
Slide courtesy of the CDC

Jemal A, et al. J Natl Cancer Inst 2013;105:175-201

NEW CANCERS CAUSED BY HPV/YEAR UNITED STATES 2006-2010



Women (n = 17,600)



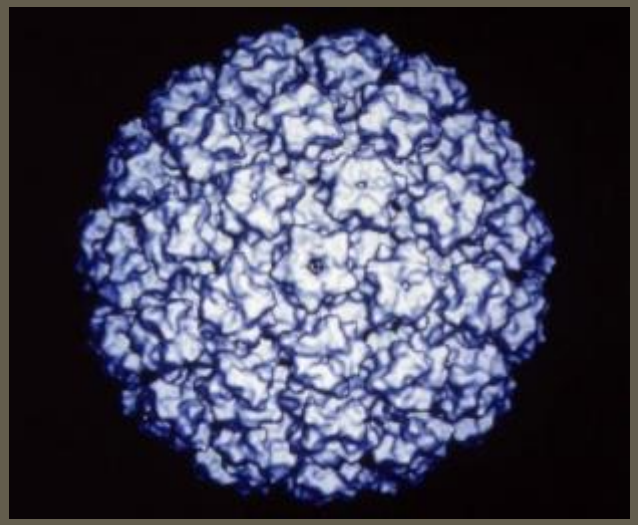
Men (n = 9,300)

CDC, United States Cancer Statistics (USCS), 2006-2010

Slide courtesy of the CDC

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

Slide courtesy of the CDC

HPV VACCINES CURRENTLY LICENSED IN U.S.

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

*vaccination series can be started at 9 years of age
MMWR 2015;64:300-4

Slide courtesy of the CDC

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 15th 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

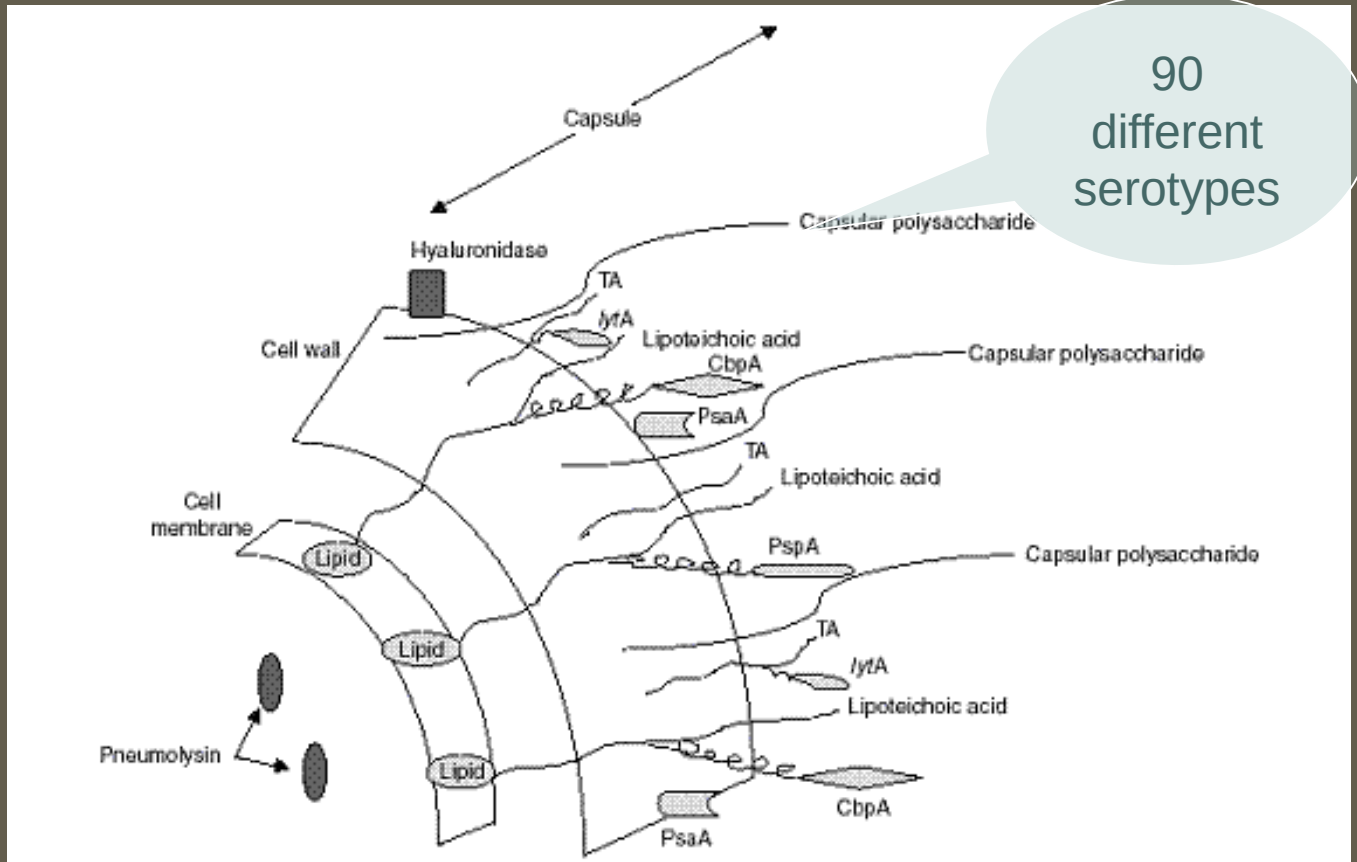


Fig. 1. Diagram of pneumococcal surface. **CbpA** (**PspC**) = choline-binding protein A; ***lyt*A** = autolysin; **PsaA** = pneumococcal surface adhesin A; **PspA** = pneumococcal surface protein A; **TA** = teichoic acid.

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

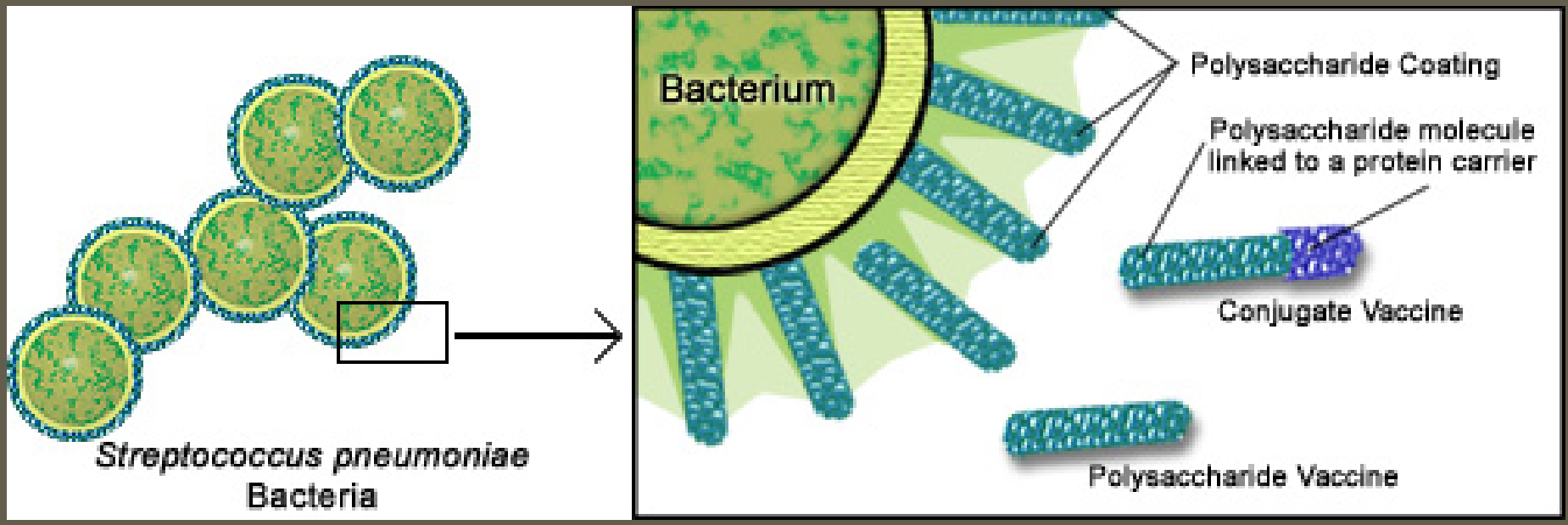
PNEUMOCOCCAL VACCINES

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

PNEUMOCOCCAL POLYSACCHARIDE VACCINE: IMPORTANT POINTS

- PPSV prevents invasive pneumococcal disease -- bacteremia, meningitis, empyema
- PPSV does NOT prevent pneumonia.
- Revaccination does not induce booster response.

WHAT IS CONJUGATION



https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/genrec/10351.asp?seg=H

The NEW ENGLAND JOURNAL of MEDICINE

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)**
- Non-bacteremic and non-invasive 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.

INDICATIONS FOR PCV13

Adults ≥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

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
Immuno-competent persons	Chronic heart disease†		✓	
	Chronic lung disease§		✓	
	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	✓	✓	✓

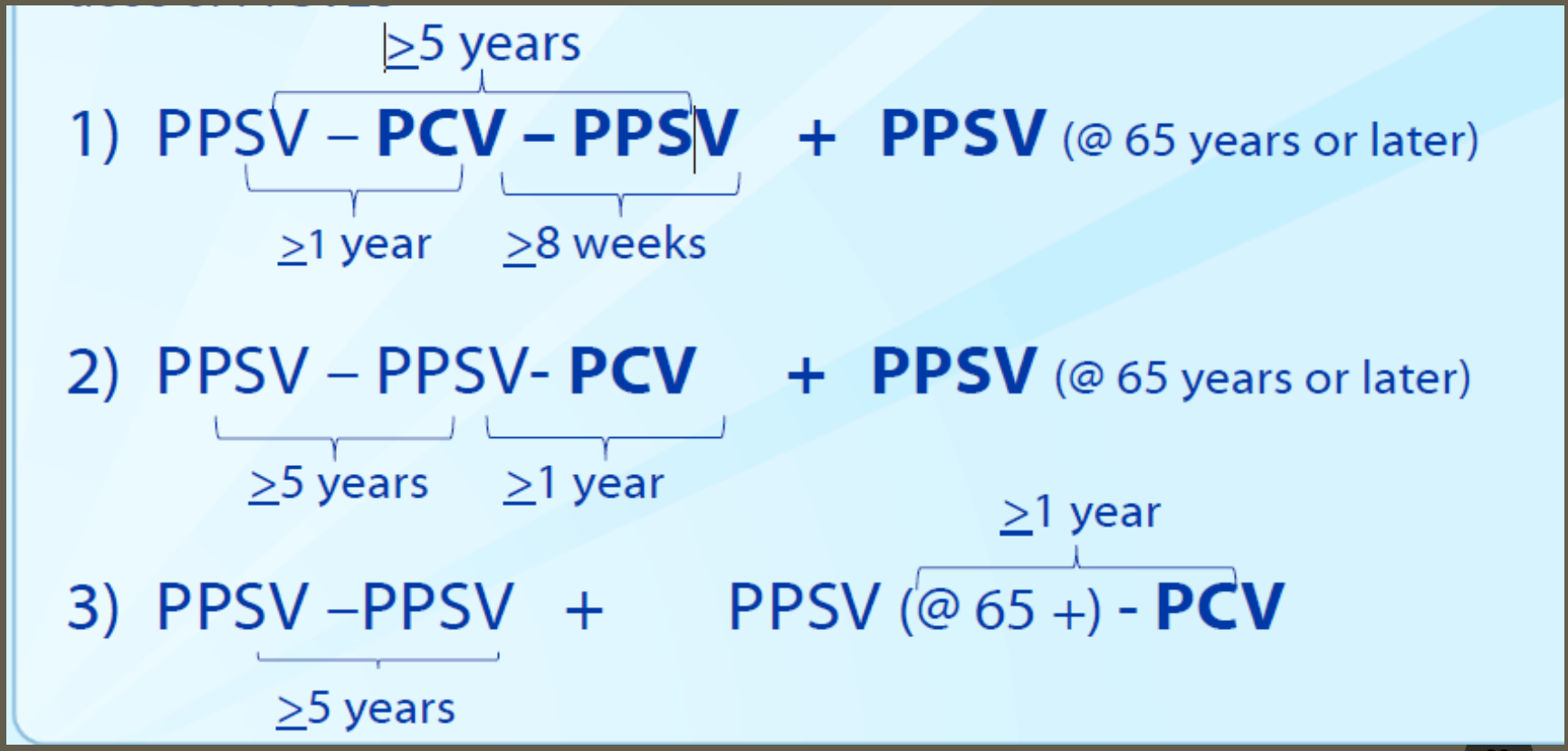
RECOMMENDATION FOR PCV13 & PPSV23 VACCINE **NAÏVE** ADULTS WITH IMMUNOCOMPROMISING CONDITIONS

- 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



Risk Group	Underlying Medical Condition	PCV13	PPSV23*	
		Recommended	Recommended	Revaccination
Immune competent persons	Chronic heart disease†		✓	
	Chronic lung disease§		✓	
	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	✓	✓	✓

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.

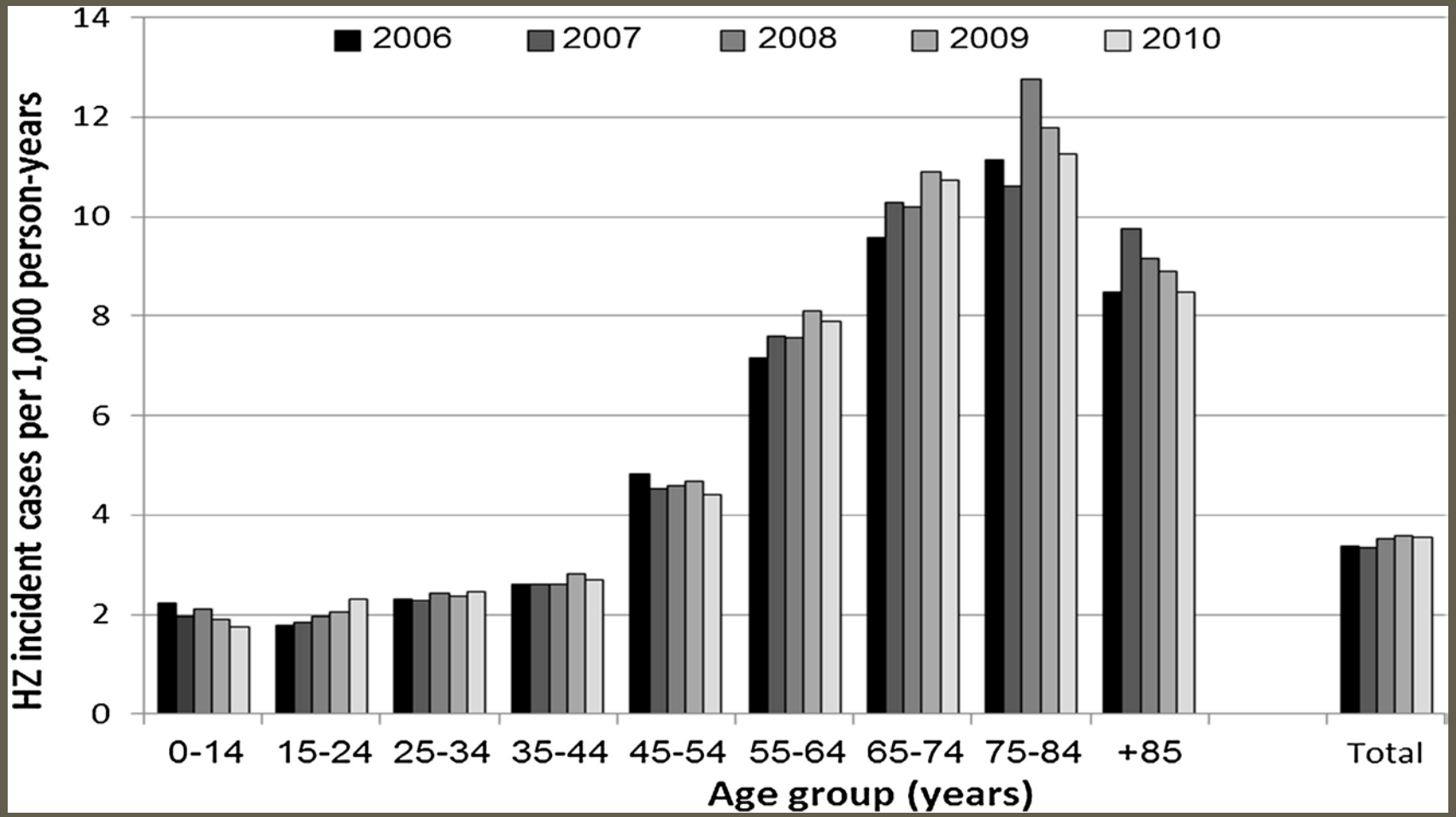
- A second dose of PPV-23 is recommended 5 years after the first dose for persons aged 19 through 64 years with functional or anatomic asplenia and for persons with immunocompromising conditions.

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

ZOSTER EPIDEMIOLOGY IN THE U.S.



Journal of Infection, Volume 67, Issue 5, 2013, 463 - 469

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)
- Recombinant Varicella
- 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

The NEW ENGLAND JOURNAL of MEDICINE

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

BACKGROUND

In previous phase 1–2 clinical trials involving older adults, a subunit vaccine containing varicella–zoster virus glycoprotein E and the $AS01_B$ 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 $AS01_B$ 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.

NEW SHINGLE VACCINE RECOMMENDATIONS

- Administer 2 doses of recombinant zoster vaccine (RZV) (Shingrix) 2–6 months apart to adults aged ≥50 years regardless of past episode of herpes zoster or receipt of zoster vaccine live (ZVL) (Zostavax).
- Administer 2 doses of RZV 2–6 months apart to adults who previously received ZVL at least 2 months after ZVL.
- For adults ≥ 60 years or older, administer either RZV or ZVL (RZV is preferred).

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.

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

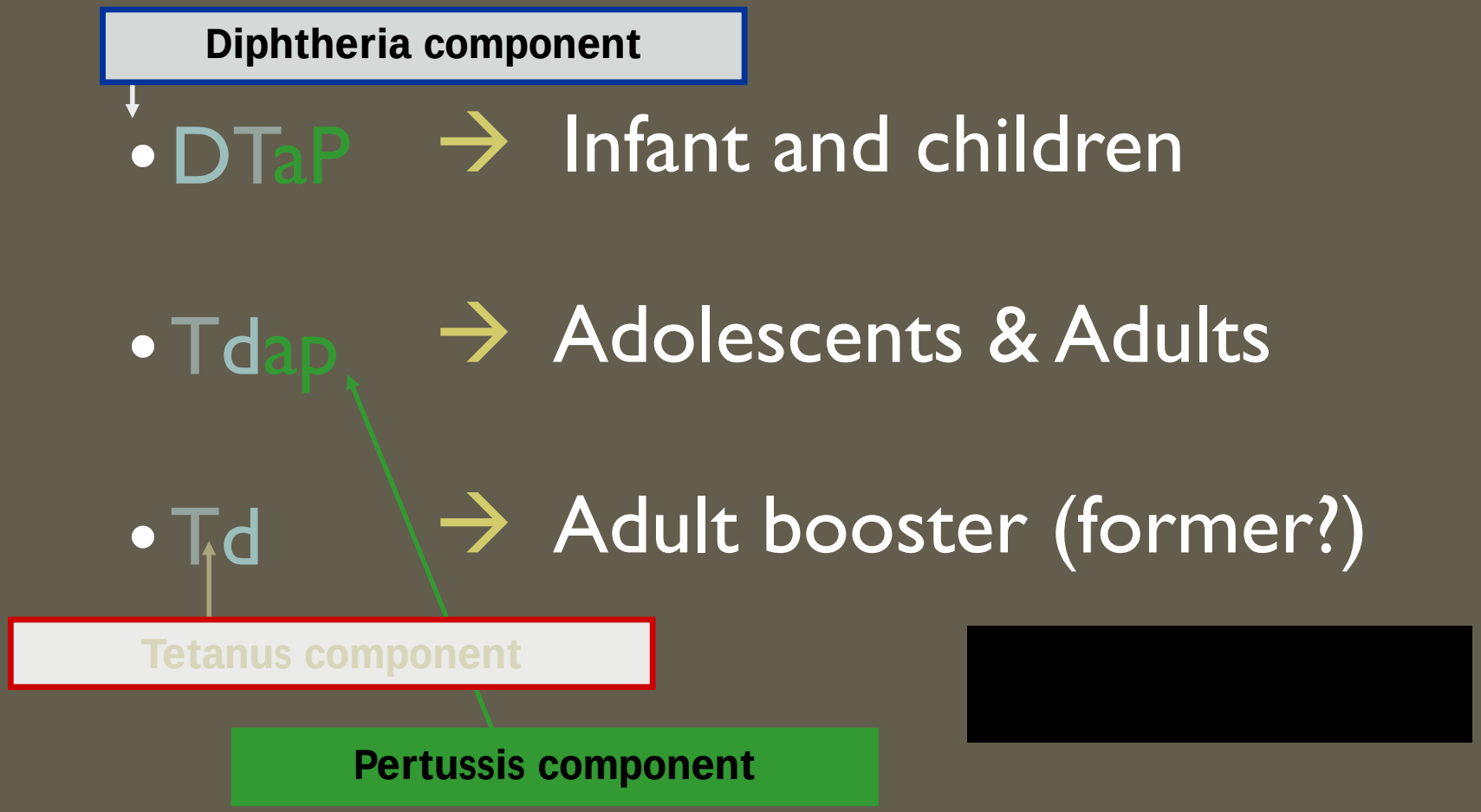
C. Administer Tdap and quadrivalent influenza vaccine

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



TDAP VACCINE RECOMMENDATIONS: GENERAL POPULATION

- Anyone 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. Give him the adjuvanted vaccine
B. High Dose vaccine
C. Quadrivalent vaccine
D. Any of the vaccines listed

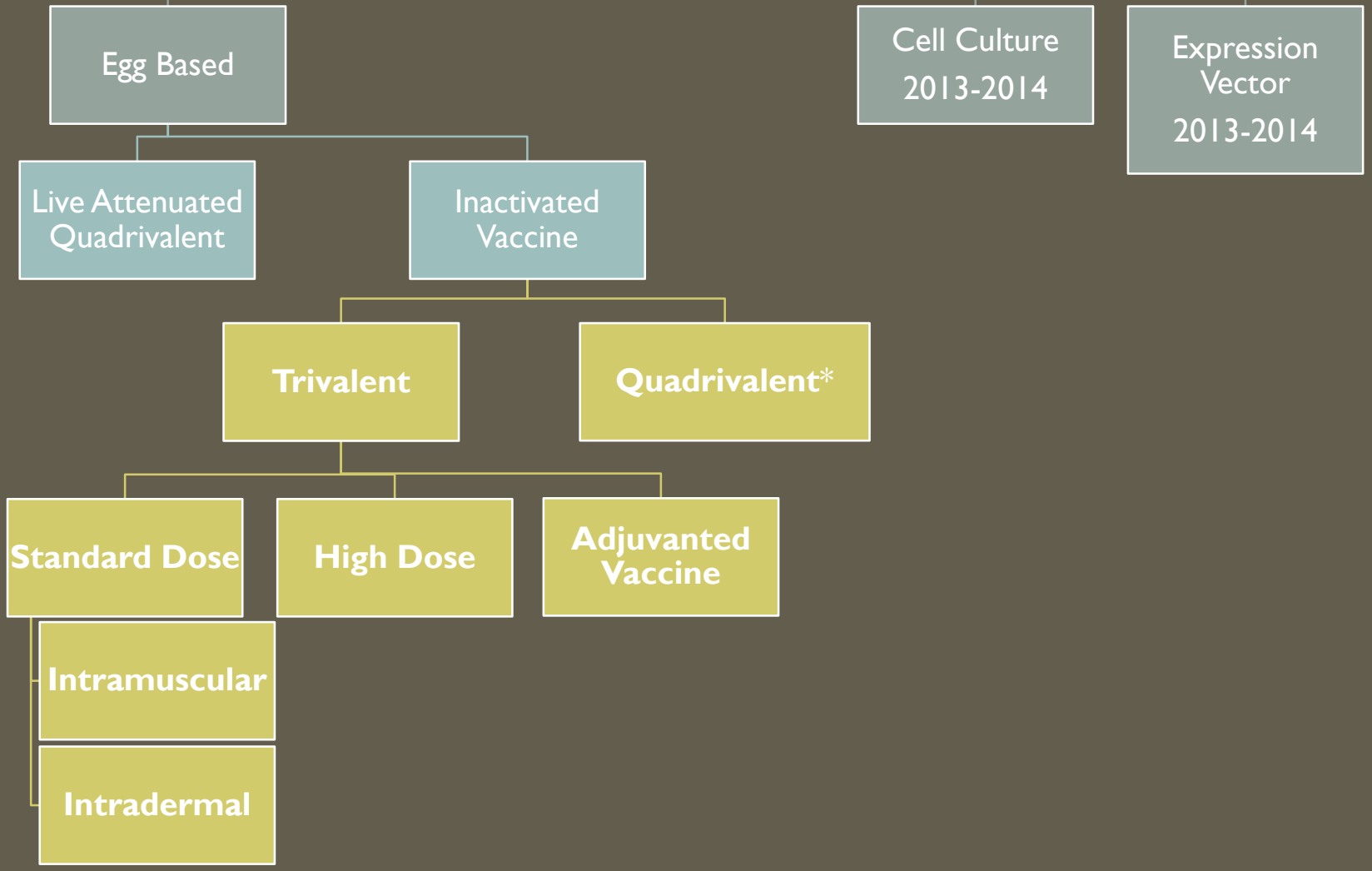
SEASONAL INFLUENZA VACCINATION

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

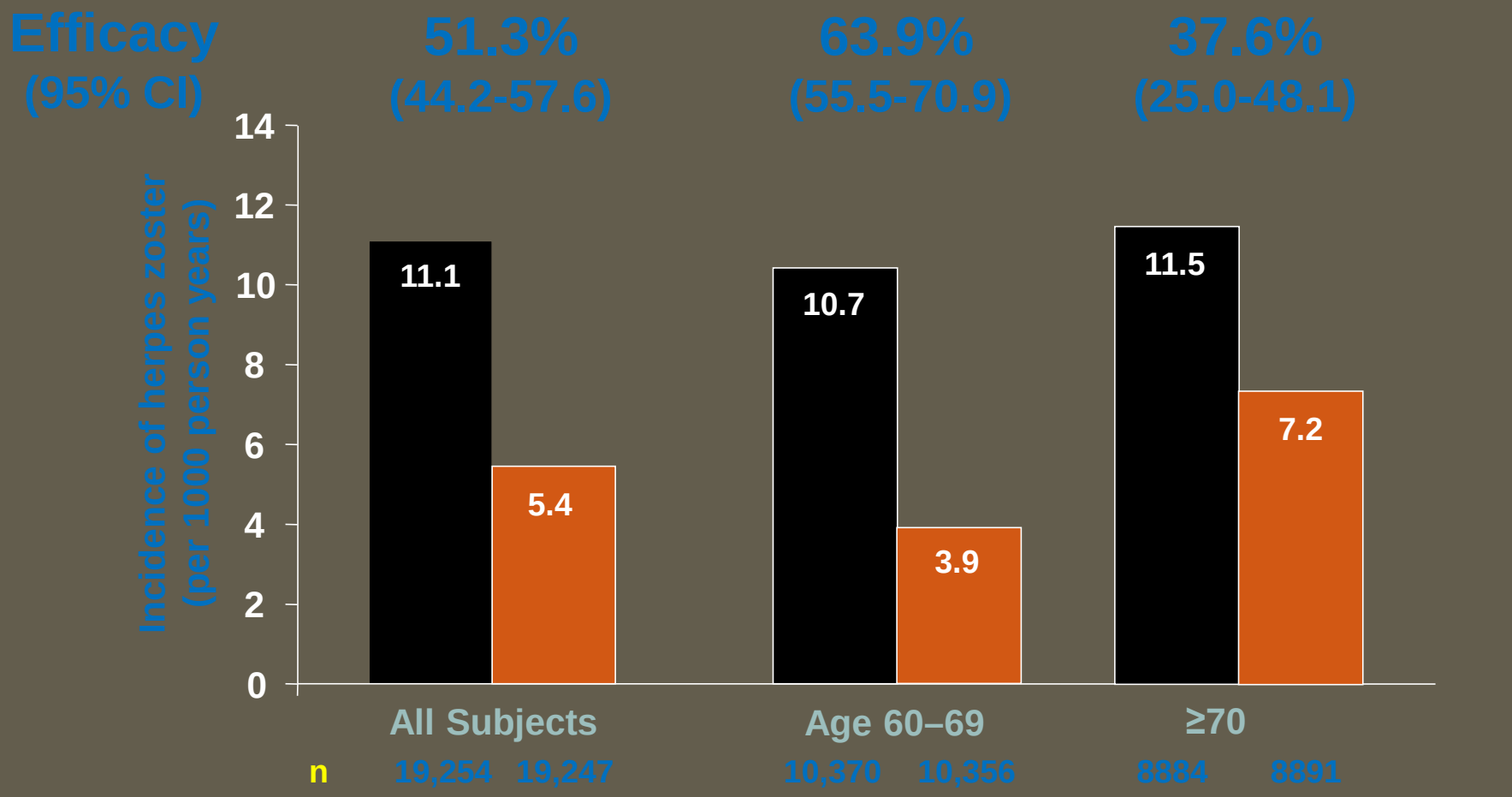
	H1N1	H3N2	B-Victoria	B-Yamagata
Trivalent (IIV3)	X	X	X One but not Both B's	
Quadrivalent (IIV4)	X	X	X	X

EXTRA SLIDES

SHINGLES PREVENTION STUDY

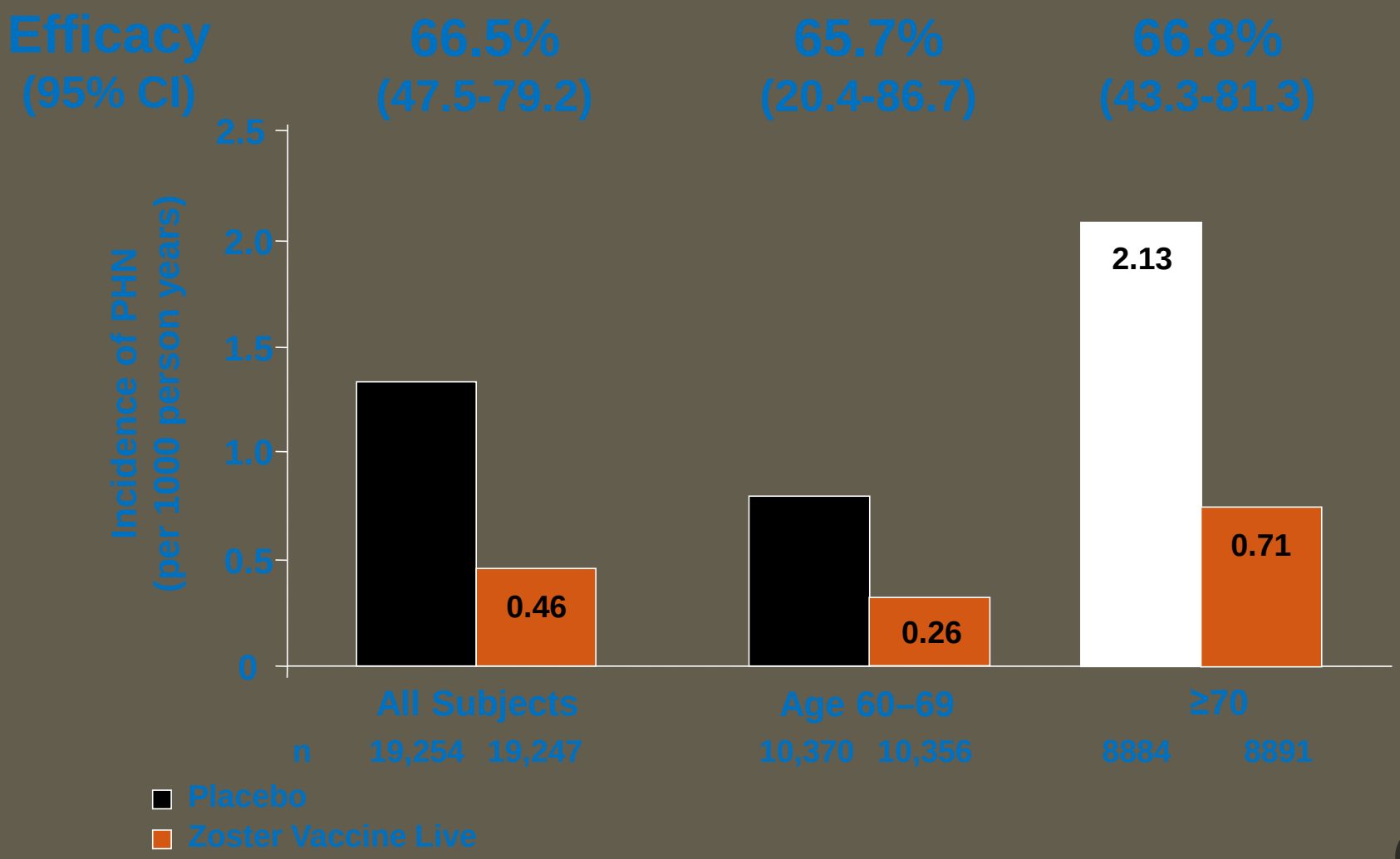
- Randomized, double-blind, placebo-controlled trial of high dose live-attenuated varicella zoster vaccine.
- 38,546 persons aged 60+ enrolled at 22 sites in U.S.
- Active follow-up for 3-5 years for development of shingles.

EFFECT OF ZOSTER VACCINE ON INCIDENCE OF HERPES ZOSTER



Oxman MN et al. N Engl J Med. 2005;352:2271-2284

EFFECT OF ZOSTER VACCINE ON INCIDENCE OF POSTHERPETIC NEURALGIA



Oxman MN et al. N Engl J Med. 2005;352:2271-2284

ACIP RECOMMENDATIONS

- Recommended for all adults ≥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

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

AIIV

- 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
- Immunize.org
- NFID.org

WEBSITE: www.vaers.hhs.gov E-MAIL: info@vaers.org FAX: 1-877-721-0366

VAERS

VACCINE ADVERSE EVENT REPORTING SYSTEM

24 Hour Toll-Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only

VAERS Number _____

Date Received _____

Patient Name:

Last First M.I.

Address

City State Zip

Telephone no. (____) _____

Vaccine administered by (Name):

Responsible Physician _____

Facility Name/Address

City State Zip

Telephone no. (____) _____

Form completed by (Name):

Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other

Address *(if different from patient or provider)*

City State Zip

Telephone no. (____) _____

1. State	2. County where administered	3. Date of birth mm / dd / yy	4. Patient age	5. Sex ☐ M ☐ F	6. Date form completed mm / dd / yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
- ☐ Patient died (date mm / dd / yy)
- ☐ Life threatening illness
- ☐ Required emergency room/doctor visit
- ☐ Required hospitalization (_____days)
- ☐ Resulted in prolongation of hospitalization
- ☐ Resulted in permanent disability
- ☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm / dd / yy Time _____ AM PM

11. Adverse event onset mm / dd / yy Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

No. Previous Doses

- 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).