

  
**Immunization Update 2015**

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## Faculty Disclosure

- Dr. Giroto has no actual or potential conflicts of interest associated with this presentation.
- Dr. Giroto will be discussing off label use of immunizations. She will provide information as recommended by the Advisory Committee on Immunization Practices (ACIP)/ Centers for Disease Control and Prevention (CDC).

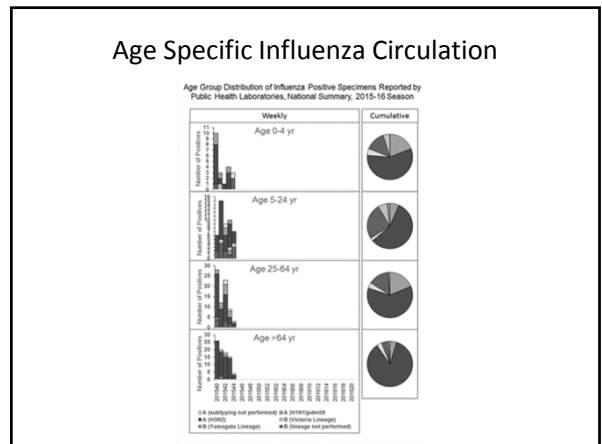
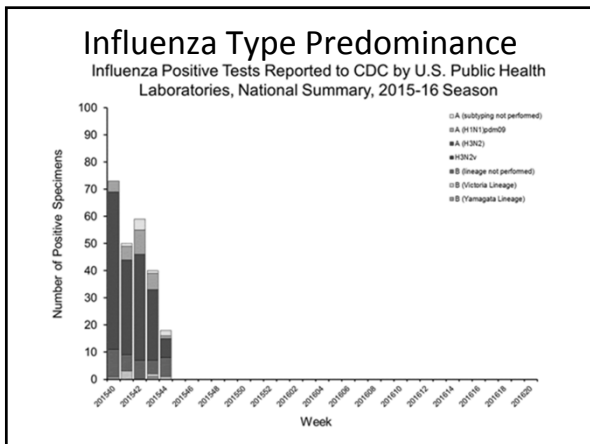


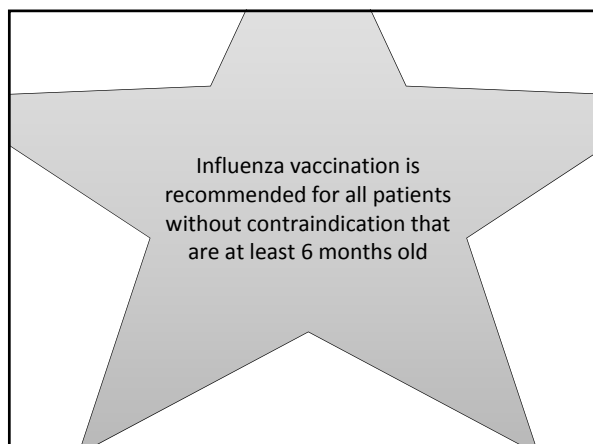
## Objectives

1. Explain influenza vaccine recommendations for the 2015-2016 season
2. Compare the FDA approved meningococcal vaccines
3. Explain the current meningococcal vaccine recommendations
4. Identify differences in the FDA approved human papilloma virus (HPV) vaccines
5. Explain the current HPV ACIP recommendations




## Influenza 2015-2016





## Vaccine Preference...

When more than one vaccine is indicated for a given patient, ACIP/CDC do not express a preference for one vaccine over another...




**2015-2016  
Vaccine Components**

**Trivalent Vaccine Components:**

- A/California/7/2009 (H1N1) pdm09-like
- A/Switzerland/9715293/2013 (H3N2)-like
- B/Phuket/3073/2013 - like virus (Yamagata lineage)

**Quadrivalent Vaccine Components:**

- All of Trivalent strains PLUS:
- B/Brisbane/60/2008 - like virus (Victoria lineage)



**Influenza Vaccines Available for  
2015-2016 Season**

Vaccine Category, Route	Brand Name (Manufacturer)	Recommended Ages	Dose
IV3, intramuscular	Afluria (bioCSL)	≥ 9 years	0.5 mL
	Fluvirin (Novartis vaccines)	≥ 4 years	0.5 mL
	Fluzone (Sanofi Pasteur)	6 – 35 months	0.25 mL
	Fluzone (Sanofi Pasteur)	≥ 36 months	0.5 mL
	Fluzone High-Dose (Sanofi Pasteur)	≥ 65 years	0.5 mL
	Flucelvax (Novartis vaccines)	≥ 18 years	0.5 mL
RIV3, intramuscular	Flublok (Protein Sciences)	≥ 18 years	0.5 mL
IV4, intramuscular	Fluarix Quadrivalent (GlaxoSmithKline)	≥ 3 years	0.5 mL
	FluLaval (ID Biomedical Corp. of Quebec)	≥ 3 years	0.5 mL
	Fluzone Quadrivalent (Sanofi Pasteur)	6 – 35 months	0.25 mL
	Fluzone Quadrivalent (Sanofi Pasteur)	≥ 36 months	0.5 mL
IV4, intra-dermal	Fluzone Intradermal Quadrivalent (Sanofi Pasteur)	18 years – 64 years	0.1 mL
LAIV4, intranasal	FluMist Quadrivalent (MedImmune)	2 years – 49 years	0.1 mL in each nostril

## Influenza Vaccination and Allergic Reactions

- Patients allergic to influenza vaccine should not receive an influenza vaccine
- Patients with egg allergy
  - If  $\geq$  18 years can receive recombinant influenza vaccine
  - If unable to provide recombinant vaccine, severity of egg allergy should be assessed and if only had hives as allergic reaction can receive an inactivated influenza vaccine by provider familiar with allergy manifestations and who can observe patient for 30 minutes and treat if allergic reaction occurs. Otherwise, the patient should be referred to physician that can manage potential reactions

## Influenza Vaccination, Children

- **Children 6 months through 8 years**
  - If have received  $<$  2 doses before July 1, 2015 will require 2 doses of influenza vaccine for 2015-2016 season separated by 28 days
  - If have receive  $\geq$  2 doses before July 1, 2015 require 1 dose of influenza vaccine for the 2015-2016 season

### Influenza Vaccine, Issues in the News...

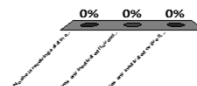
- Influenza vaccine and statins...
  - Statins, especially synthetic statins may reduce the patient’s antibody response to influenza vaccine
  - Statins, may reduce influenza vaccine’s ability to protect against respiratory illness
- As this information is preliminary from 2 studies, and effect not fully known it should not yet affect care.
- In future evaluations on how this effect is caused as well as if alternative vaccines (High-dose or adjuvant based) may help overcome the issue will need to be considered.

[http://www.idsociety.org/Statins\\_On\\_Flu\\_Vaccination/](http://www.idsociety.org/Statins_On_Flu_Vaccination/)

PJ is a 67 year old woman who has been receiving lovastatin, metformin and insulin. She is at your pharmacy today for her flu vaccine.

Per ACIP should she receive a flu vaccine today?

- No she is receiving a statin and the flu vaccine should not be given with it
- Yes, any inactivated flu vaccine is appropriate to give her today
- Yes, any inactivated or live flu vaccine is appropriate to give her today

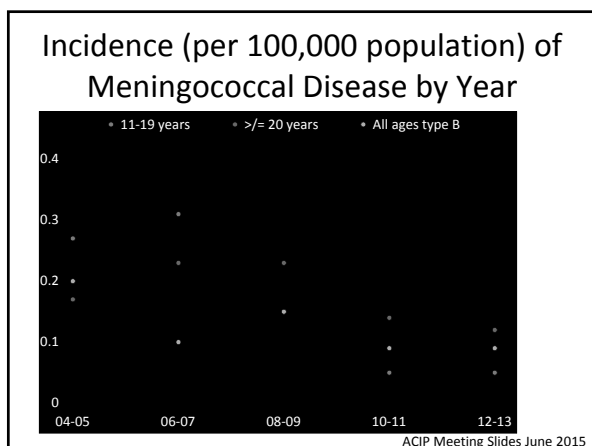


## MENINGOCOCCUS VACCINE UPDATES

University of Connecticut School of Pharmacy

### Meningococcal Vaccines

Trade name	Type of Vaccine	Meningococcal Serogroups Covered	FDA approved ages	ACIP Recommended Ages
Menveo®	Conjugate	A, C, W, Y	2 mos - 55 yrs	2 mos - 55 yrs
Menactra®	Conjugate	A, C, W, Y	9 mos - 55 yrs	9 mos - 55 yrs if not at risk for pneumococcal disease, ≥ 2 yrs and after completing PPSV23 through 55 yrs if at risk for pneumococcal disease
Menomune®	Polysaccharide	A, C, W, Y	≥ 2 yrs	≥ 55 yrs
MenHibrix®	Conjugate	C, Y & Haemophilus influenzae type b (Hib)	6 wks - 18 mos	6 wks - 18 mos
Bexsero®	Recombinant	B	10 yrs - 25 yrs	≥ 10 yrs
Trumenba®	Recombinant	B	10 yrs - 25 yrs	≥ 10 yrs



### MenB Considerations for Routine Administration

- Current estimates 0.18 cases per 100,000 for meningitis in the US
- Type B in its 11-23 yrs is 50-100 cases per year with 5-10 deaths

TABLE 2. Potential cases and deaths prevented and cost-effectiveness of different strategies for MenB vaccination of adolescents and young adults, including college students, by age—United States

Age at MenB series	Cases prevented	Deaths prevented	NNV* to prevent case	NNV to prevent death	Cost per QALY (million \$)
11 yrs	15	2	203,000	1,512,000	8.7
16 yrs	28	5	107,000	788,000	4.1
18 yrs	29	5	102,000	688,000	3.7
College student	9	1	368,000	2,297,000	9.4

Abbreviations: MenB = meningococcal B vaccine; NNV = number needed to vaccinate; QALY = quality-adjusted life years.  
Sources: Unpublished data, ACIP meeting June 2015. Key model assumptions were presented at the June 2015 ACIP meeting. Methods described in Shepard CW, Ortega-Sanchez IR, Scott RD, et al., Rosenstem NE. Cost-effectiveness of conjugate meningococcal vaccination strategies in the United States. Pediatrics. 2005;115:1220-32.

## NEW MENB VACCINES

## Trumenba

- MenB-FHbp, Pfizer approved 2014
- 2 purified recombinant factor H binding protein antigens
- Efficacy
  - After 2<sup>nd</sup> dose ~50% responded to all strains; one month after 3<sup>rd</sup> dose 81-84% responded to all 4 strains
  - Studied in conjunction with other adolescent vaccines and only potential interference was with HPV type 18 where the geometric mean titer criteria was not met 1 month following the 3<sup>rd</sup> dose, but 99% of patients had seroconversion for all 4 strains

Folaranmi T, et al. *MMWR Morb Mortal Wkly Rep.* 2015 Jun 12;64(22):608-12

## Bexsero

- MenB-4C, Novartis approved 2015
  - 3 recombinant proteins and outer membrane vesicles containing outer membrane protein PorA serosubtype P1.4
- Efficacy: 88% against all 3 strains at 1 month and 66% at 11 months

Folaranmi T, et al. *MMWR Morb Mortal Wkly Rep.* 2015 Jun 12;64(22):608-12.

## MenB Vaccines Safety

- Commonly reported adverse effects of the vaccines included local reactions, headache, fatigue
- Severe - rarely been reported, but have included anaphylaxis (both)
- Other potential concerns
  - Both meningococcal type b vaccines contain a factor H binding protein which could possibly cross-react with a human factor H.
  - No specific side effects due to this have been seen to date, although long term post licensure surveillance will be ongoing to look for any potential autoimmune issues resulting from this.

Folaranmi T, et al. *MMWR Morb Mortal Wkly Rep.* 2015 Jun 12;64(22):608-12.

## MenB Duration of Protection

- Vaccine protection expected to be about 2 years, but beyond that is not certain

TABLE 1. Summary of evidence for MenB-FHbp and MenB-4C vaccination of healthy adolescents and young adults, including college students — United States

Outcome	Evidence type*	
	MenB-FHbp	MenB-4C
<b>Benefits</b>		
Short-term immunogenicity	2	2
Persistence in immunogenicity	4	3
MenB immunogenicity with concomitant vaccination	2	†
<b>Harms</b>		
Serious adverse events	2	2
Serious adverse events following concomitant vaccination	2	†

\* Evidence type: 2 = moderate level of evidence; 3 = low level of evidence; 4 = lowest level of evidence.  
† Not assessed because of lack of available data.

## MenB Vaccine Administration

- Trumenba (MenB-FHbp, Pfizer)
  - 3 dose intramuscular administration at 0, 2, & 6 months
- Bexsero (MenB-4C, Novartis)
  - 2 dose intramuscular administration at 0 & 1-6 months
  - Allergy alert: trace amounts of kanamycin & syringe tip cap contains latex

\*\*\*Vaccines are NOT interchangeable once a series is begun\*\*\*

Routine MenB Vaccine Recommendations...

- **MenB**
  - A meningococcal type B series **can be considered** to provide short term protection, for patients 16 - 23 years to protect against most strains of type B disease. Preferred age is 16 - 18 years.

CDC - MMWR October 23, 2015 / 64(41):1171-6

Learning Assessment

What does the permissive recommendation mean that is given for healthy patients 16 - 23 years for the MenB vaccine?

- A. The vaccine series should be given to all patients in this age group
- B. The vaccine series should generally NOT be given to patients in this age group
- C. The vaccine can be considered after discussion with healthcare provider for patients in this age group



MenB High Risk Group Recommendations

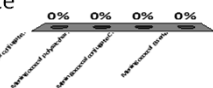
- MenB series **should be** administered to persons 10 years and older at an increased risk for meningococcal disease:
  - Persistent complement deficiency (includes eculizumab)
  - Anatomical or functional asplenia
  - Microbiologists routinely exposed to *N. meningitidis*
  - Persons identified to be at risk due to a Serogroup B outbreak

Meningitis Vaccine Summary

	Ages	Complement deficiency	Functional asplenia	Outbreaks	Travel to endemic areas	Can be used as booster
MenACWY-CRM (Menveo)	2, 4, 6, & 12 mos	Yes	Yes	Yes (A, C, Y, W135)	Yes	Yes
MenACWY-D (Menactra)	9 & 12 mos	Yes	Not in young	Yes (A, C, Y, W135)	Yes	Yes
Hib-MenCY-TT (Menhibrix)	2, 4, 6, 12-15 mos	Yes	Yes	Yes (C & Y)	No	No, need to use other form
MenB (Trumenba)	10-25 yrs (0, 2, & 6 mos)	Yes with MenACWY	Yes with MenACWY	Yes (B)	No	No
MenB (Bexsero)	10-25 yrs (0, 1-6 mos)	Yes with MenACWY	Yes with MenACWY	Yes (B)	No	No

Bobby is a 17 year old boy who comes into the pharmacy to get his meningococcal vaccine. He is otherwise healthy. Per ACIP what vaccine is he indicated to receive?

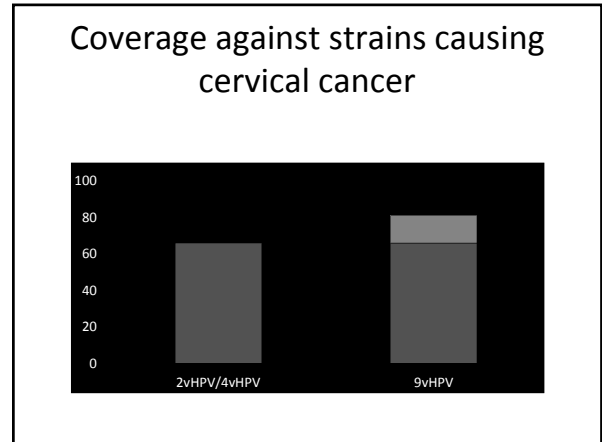
- A. Meningococcal conjugate ACWY
- B. Meningococcal polysaccharide ACWY
- C. Meningococcal conjugate CY & Hib
- D. Meningococcal B series



HPV UPDATES

### HPV Vaccines

	Bivalent (2vHPV)	Quadrivalent (4vHPV)	9 valent (9vHPV)
<b>Brand Name (yr approved)</b>	Cervarix (2009)	Gardasil (2006)	Gardasil 9 (2015)
<b>Strains covered</b>	16, 18	6, 11, 16, 18	6, 11, 16, 18, 31, 33, 45, 52, 58
<b>Manufacturing</b>	<i>Trichoplisia ni</i> insect cell line infected with L1 encoding recombinant baculovirus	<i>Saccharomyces cerevisiae</i> (aka Bakers Yeast), expressing L1	
<b>Adjuvant</b>	Aluminum hydroxide and 3-o-desacyl-4' monophosphoryl lipid A	Amorphous aluminum, hydroxyphosphate sulfate	



- ### 9vHPV
- Protect against additional
    - 14% female cancers
    - 4% male cancers
  - Adverse effects
    - Generally similar to 2vHPV and 4vHPV, except rates of swelling and erythema increased each successive dose of 9vHPV
- <http://www.cdc.gov/hpv/downloads/9vhpv-guidance.pdf>

### HPV Vaccines

	ACIP Recommendations
<b>4vHPV or 9vHPV</b>	Routine administration to males or females (including immunocompromised) 11 - 12 year olds with catch up for females and high risk males through 26 years and low risk males through 21 years
<b>2vHPV</b>	Routine administration to females 11-12 years with catch up through 26 years (not recommended for immunocompromised or males) <ul style="list-style-type: none"> <li>– Any vaccine recommended for that group can be used to finish vaccination</li> <li>– Alternative vaccine schedules for HPV9 currently under study</li> </ul>

Lindsay is a 12 year old girl that has already received a dose of the 2vHPV vaccine. She comes to your pharmacy today asking if she can receive 9vHPV instead. Which of the following is correct?

A. She can continue the current vaccination with 9vHPV

B. She has to continue her vaccine series with the same vaccine that she began (i.e. 2vHPV)

## QUESTIONS