

Immunization: 2019 Immunization Update

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Disclosure

Dr Giroto has no actual or potential conflict of interest associated with this presentation

Objectives

- Identify changes to immunization recommendations in 2019
- Explain what is meant by the new “shared decision making” category
- Recognize which vaccines have a shared decision making recognition for some patient populations

Shared Decision Making...

- Category where risk vs benefit (e.g. often cost-effectiveness) or benefit is limited to a specific group of patients that is outside of usual disease-state or age-based categories.
- Recommends discussion with individual patients comparing the possible benefits with risks they need to take on to work with them to determine if they would feel the vaccine benefit is worth it to them.

Pharmacist Role in Shared Decision Making

- 1) Determine what your pharmacy protocol allows for you to administer. This is a new recommendation category from the CDC.
 - 2) Learn the specific reasons for each vaccine being put into a shared decision category rather than routine recommendation.
 - 3) Explain to patients as best as possible the considerations
- ** Some discussion did exist at ACIP meeting regarding **
- a) If patients already are coming for a specific vaccine to a pharmacy
 - b) Concerns for pharmacist laws in individual states
 - c) Concerns for implementation of shared decision within busy pharmacies

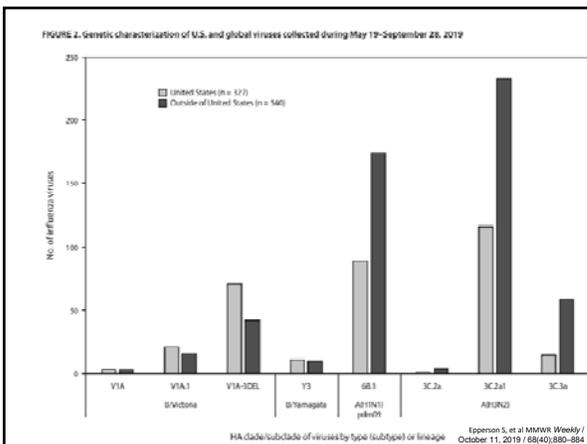
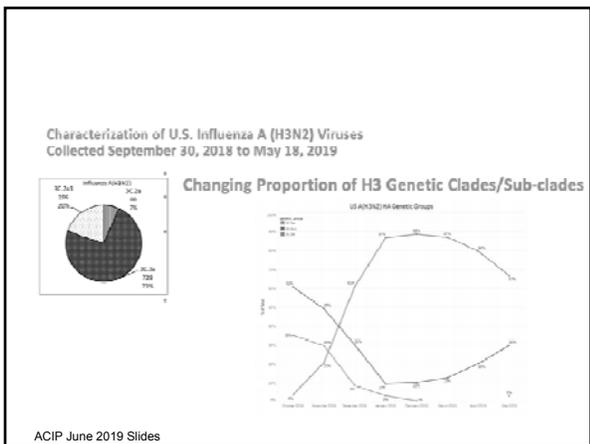
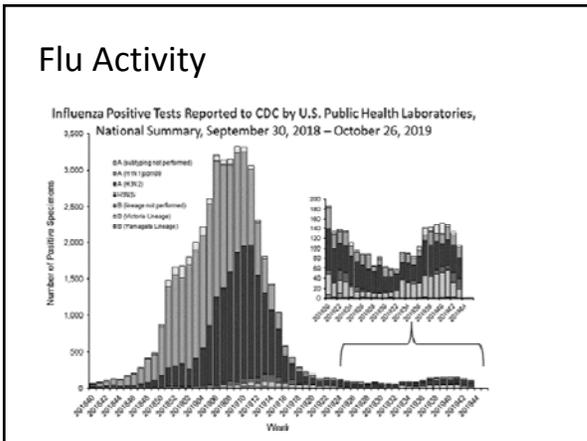
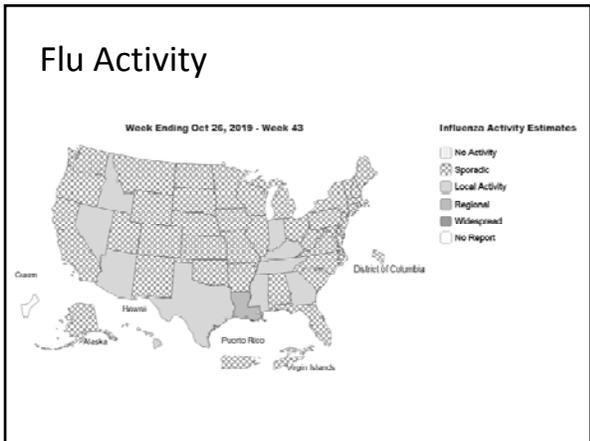
Learning Assessment

If a patient is at the pharmacy and you see they are part of the new shared decision making category which of the following would be the optimal recommendation (if state law allows)

- A. Provide them the vaccine because they are part of shared decision making we can treat it similarly to routine recommendation
- B. Do not provide them the vaccine, they need to discuss with a physician regarding the specifics of the recommendation
- C. Discuss with them the issues surrounding the shared decision making recommendation and together come up with a decision regarding if they are an optimal candidate for the vaccine.

INFLUENZA VACCINE UPDATE

- ### Influenza Vaccine Components
- ALL influenza vaccines
1. A/Brisbane/02/2018 (H1N1)pdm09-like virus (updated)
 2. A/Kansas/14/2017 (H3N2)-like virus (updated is a 3C.3a)
 3. B/Colorado/06/2017-like virus (Victoria lineage)
 4. B/Phuket/3073/2013-like (Yamagata lineage) virus (this strain not included in trivalent vaccines)



ACIP June 2019 Slides

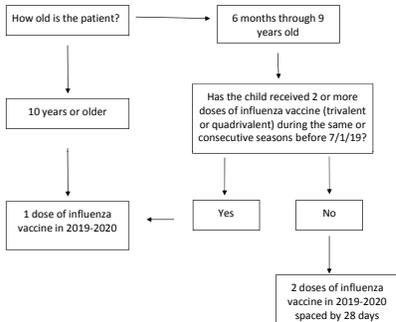
ACIP Vaccine Recommendations 2019 -2020

- All patients 6 months old or greater without contraindication should receive an approved influenza vaccine.

TABLE 1 Influenza vaccines — United States, 2019–20 influenza season*

Vaccine name (Manufacturer)	Presentation	Age indication	HA (HIV) and RVFV or virus count (LAVV) for each vaccine virus (per dose)	Mercury (from thimerosal) (µg/0.5 mL)
BV4—Standard Dose—Egg based†	0.25-mL vial‡	6 through 35 mos	7.5 µg/0.25 mL‡	—
	0.5-mL PFS‡	3–7 yrs	15 µg/0.5 mL‡	—
	5.0-mL MDP§	18 mos (ovoid/lyophilized)	15 µg/0.5 mL‡	24.5
Fluarix Quadrivalent (GSK/Sanofi/Kelco)	0.5-mL PFS	6 through 41 yrs (if injector)	15 µg/0.5 mL	—
	0.5-mL PFS	≥6 mos	15 µg/0.5 mL	—
Fluzone Quadrivalent (Sanofi Pasteur)	3.0-mL MDP	≥6 mos	15 µg/0.5 mL	<23
	0.25-mL PFS**	6 through 35 mos	7.5 µg/0.25 mL**	—
BV4—Standard Dose—Cell culture based (xMNV)	0.5-mL PFS	≥6 mos	15 µg/0.5 mL	—
	5.0-mL MDP**	≥6 mos	15 µg/0.5 mL	25
Fluctrix Quadrivalent (Seqirus)	0.5-mL PFS	≥1 yrs	15 µg/0.5 mL	—
	5.0-mL MDP	≥4 yrs	15 µg/0.5 mL	75
BV3—High Dose—Egg based† (HD BV3)	0.5-mL PFS	≥65 yrs	60 µg/0.5 mL	—
BV2—Standard Dose—Egg based† with MF59 adjuvant (xMNV)	0.5-mL PFS	≥65 yrs	15 µg/0.5 mL	—
BV4—Recombinant HA	0.5-mL PFS	≥18 yrs	45 µg/0.5 mL	—
FluAid Quadrivalent (Sanofi Pasteur)	0.5-mL PFS	≥18 yrs	45 µg/0.5 mL	—
FluMist Quadrivalent (AstraZeneca)	0.2-mL pre-filled single-use intranasal sprayer	2 through 19 yrs	16 HA T4 fluorescent focus units/0.2 mL	NAS

Number of Annual Influenza Doses



ACIP Vaccine Recommendations

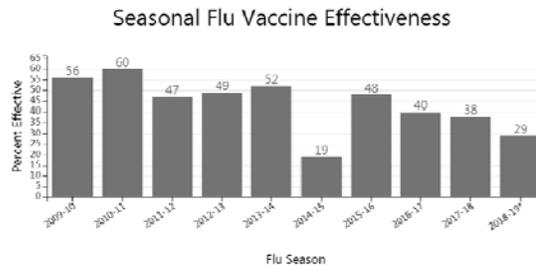
- No preferential recommendation is made for one influenza vaccine product over another, when multiple are recommended by age and underlying conditions.
- General statistics on efficacy provided, when more than one is available it is important for you as the pharmacist to evaluate and recommend based on efficacy
- Pregnant women may receive any licensed, recommended, age-appropriate **inactivated** influenza vaccine

Learning Assessment

A 72 year old patient comes into your pharmacy looking for a flu vaccine. You are very lucky that you have Fluzone HD and Fluzone in stock. Your patient has no contraindications to any of them. You discuss with your patient important considerations including that there has been little of the extra component in the Fluzone regular vaccine circulating (i.e. Yamagata B), but the high dose vaccine has shown to be more effective in older patients. He should know that the high dose has an increased likelihood of mild to moderate redness and pain at the injection site but you would really want him to be protected, so you would recommend for him the high dose vaccine. Although not formally stated this is an example of:

- Provider-based decision
- Shared decision making
- Patient directed decision

Vaccine Efficacy



Vaccine Efficacy Against Death

- Castilla, et al evaluating the flu vaccine over 2 seasons in seniors showed those vaccinated had a 16% reduction in all cause mortality (adjusted rate ratio [RR] = 0.84; 95% confidence interval 0.76-0.93)
 - Number needed to vaccinate to prevent death
 - 65 - 74 years: 649
 - > 75 years: 251
 - All seniors: 328
- Flannery B, et al evaluated pediatric deaths from influenza in US showing that of 291 children where vaccination status was known....
 - 75% of patients unvaccinated
 - 52% of children < 4 years were only partially vaccinated

Castilla J, et al *Medicine* (Baltimore), 2015 Jul;94(30):e1240. Flannery B, et al. *Pediatrics* April 2017, e20164244

New for 2020 -2021

The screenshot shows a Sanofi press release. The main headline is "FDA approves Fluzone® High-Dose Quadrivalent (Influenza Vaccine) for adults 65 years of age and older". Below the headline, it states "It will be available in fall 2020, in time for the 2020-2021 flu season". The page includes a navigation menu with links for "ABOUT US", "SCIENCE & RESEARCH", "PRODUCTS AND SERVICES", "OUR RESPONSE BY", "CAREERS", "INVESTORS", and "MEDIA". A secondary menu includes "PRESS RELEASES", "INVESTOR NEWS", "PRESS EVENTS", "SUBSCRIBE", "MEDIA CONTACTS", "SOCIAL MEDIA", and "PHOTOS & VIDEOS".

HEPATITIS A

Hepatitis A Current Outbreaks

Since the outbreaks were first identified in 2016, 30 states have publicly reported

- Cases: 27,634
- Hospitalizations: 16,679 (60%)
- Deaths: 275



Nov 1, 2019 - Centers for Disease Control and Prevention

Hepatitis A Risk Factors

- People who use drugs (injection or non-injection)
- People experiencing unstable housing or homelessness
- Men who have sex with men
- People who are currently or were recently incarcerated
- People with chronic liver disease, including cirrhosis, hepatitis B, or hepatitis C

Hepatitis A

- June 2019 ACIP Vote
 - All patients 2 through 18 years who have not received hepatitis A vaccination should receive the series.
 - Recommended hepatitis A vaccine for all HIV positive patients 1 year old and greater
 - Recommended to allow for accelerated schedule for Twinrix at 0, 7 days, 21-30 days, and a booster at a year

Will become active recommendation when published in MMWR

MENINGOCOCCAL B

Meningococcal B Update

- Duration of protection data presented at ACIP
- Trumenba approved 10/14; Bexsero approved 1/15
- ACIP vote 6/19 regarding booster doses
 - Recommend booster dose for those 10 years old and greater, who **remain at increased risk of meningococcal disease** (complement deficiency, complement inhibitor therapy, asplenia, microbiologists).
 - First booster, **1 year after the primary series, repeated every 2 – 3 years** as long as the patient remains at increased risk for disease.
 - Patients 10 years old and greater who are at increased risk during an outbreak - should receive a one-time booster dose, if it has been at least 1 year (some DPH may consider 6 months depending on situation) since completion of the MenB primary series.

Meningococcal B Vaccine Update

- **All doses including booster need to be with same brand**
- Booster not recommended for healthy adolescents routinely vaccinated with meningococcal series.
- Also changed category B language for 16 - 23 year olds, changed to newer "shared decision making" category
 - Reminder - low rates of meningococcal disease, but increased risk on college campuses. Paired with short term duration of protection.
- Will become enacted when published in *MMWR*

Learning Assessment

A 19 year old received her Men ACWY vaccine in adolescence and her MenB vaccine which she completed when she was 17 years old. She was informed by the public health department that she has been exposed to MenB as part of an outbreak at her college. Which of the following is/are true?

- She does not need any meningococcal vaccines today
- She should receive a booster with Bexsero
- She should receive a booster with Trumenba
- She should receive a booster with the same MenB vaccine she had received as a 17 year old
- She can receive either MenB vaccine for boosting

Human Papillomavirus (HPV)

HPV Updates

- ACIP Review in June 2019
- Reviewed updated efficacy in patients through age 45 years
 - Prevalence of HPV in original 4vHPV decreased in females
 - 14 through 19 years old - 11.5% (2013) to 1.8% (2016)
 - 20 through 24 years - 18.5% (2013) to 5.3% (2016)

HPV Updates

- ACIP Review in June 2019
 - Evaluated cost-effectiveness for vaccinating patients 26 through 45 years old

Adult Vaccination Strategy	Model				
	HPV-ADVISE	Simplified	Merck	CISNET (Harvard)	CISNET (Policy1-Cervix)
Through age 30 years (vs. current program)	\$630,000	\$507,000	\$01,200	\$527,700	\$341,100
Through age 45 years (vs. current program)	\$1,471,000	\$653,300	\$117,500	\$440,600	\$315,700

ACIP Meeting minutes: June 2019 published Nov 4, 2019

HPV Updates

- ACIP Voted to:
 - Simplify recommendation to HPV vaccination should be caught up for both genders through age 26 years old
 - Reinforced dosing if initiated healthy < 15 yo, only require 2 doses separated by at least 6 months
 - Add additional category of “Shared decision making” for un/undervaccinated adults 27 through 45 years old

Published in MMWR in August 2019

HPV Shared Decision Making

- Overall reinforces optimal timing for HPV vaccination is in early adolescence because it most effective before HPV exposure.
- Adults 27 - 45 years who are not adequately vaccinated are **potential** candidates for HPV vaccination via “shared decision making”, it is recommended to consider discussing HPV vaccination with patients **who are most likely to benefit**.
- The CDC does not recommend HPV vaccination to be discussed with most adults aged >26 years.

Meites E, et al. MMWR, 2019; 68 (32): 698-702

HPV Shared Decision Making

- CDC reinforced 2016 definition of adequate vaccination for HPV
 - “Persons who **initiated** vaccination with 9vHPV, 4vHPV, or 2vHPV before their 15th birthday, and received 2 doses of any HPV vaccine at the recommended dosing schedule (0, 6–12 months), or 3 doses of any HPV vaccine at the recommended dosing schedule (0, 1–2, 6 months), are considered adequately vaccinated.”
 - “Persons who **initiated** vaccination with 9vHPV, 4vHPV, or 2vHPV on or after their 15th birthday, and received 3 doses of any HPV vaccine at the recommended dosing schedule, are considered adequately vaccinated.”

Meites E, et al. MMWR, 2019; 68 (32): 698-702
ACIP Meeting minutes June 2019, posted Nov 4, 2019

Point of Consideration in Evaluation of Potential Patients for HPV Shared Decision Making

- Most sexually active adults have already been exposed to some HPV types. Persons in a long-term, mutually monogamous sexual partnership are unlikely to acquire a new HPV infection.
- Having a new sex partner is a risk factor for acquiring a new HPV infection.
- HPV vaccine efficacy is high in those who have not been exposed to vaccine-type HPV before vaccination. HPV vaccines are prophylactic. They do not prevent progression of HPV infection to disease, decrease time to clearance of HPV infection, or treat HPV-related disease.
- Effectiveness of the HPV vaccine is likely to be lower in patients at high risk such as those with immunocompromising conditions or multiple lifetime sex partners (likely previous infection with vaccine-type HPV)

Meites E, et al. MMWR, 2019; 68 (32): 698-702

Learning Assessment

Which of the following patients might be considered for discussion regarding HPV vaccination?

- A 36 year old patient who is a happily married mother of 3 children
- A 29 year old patient that has been single since you first became her pharmacist
- A 40 year old patient who has recently been divorced after 15 years of marriage

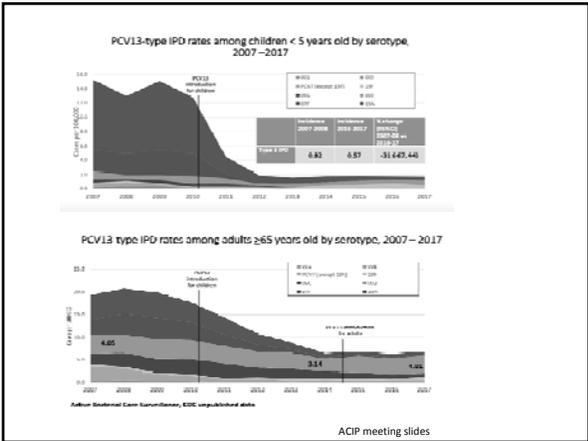
PNEUMOCOCCAL CONJUGATE VACCINE

Pneumococcal Conjugate Vaccine

- Reviewed by ACIP throughout 2018 as part of planned re-evaluation for patients 65 years and older
- Determine if still needed or not with time for herd immunity from infant vaccination to have full effect

ACIP Meeting presented general effectiveness of PCV

- Six to eleven percent effective against overall cases of community acquired pneumonia
- In the elderly, has 45 - 75% effectiveness against invasive pneumococcal disease



Pneumococcal Serotype 3

- Most prevalent invasive pneumococcal serotype is 3, especially in adults over 65 years where ~ 4 cases per 100,000 population
- PCV13
 - In children has shown no population effect against clinical serotype 3 disease in the US
 - Adult data are variable against serotype 3 pneumonia, but no direct or indirect effect against invasive pneumococcal clinical disease (serotype 3).

PCV13 Cost Effectiveness

- In patients > 65 years old based upon effectiveness data including current circulating strains
- Estimated cost-effectiveness ratio is \$250,000 to \$560,000 per quality adjusted life year.
- Number needed to vaccinate to prevent cases:
 - 2600 to prevent a case of outpatient pneumonia
 - 3,000 - 14,000 to prevent a case of inpatient community acquired pneumonia
 - 26,000 to prevent one case of invasive pneumococcal disease

Confusion

- There is already significant confusion regarding pneumococcal vaccinations
 - Which patients should receive which vaccine (PCV, PPSV)
 - When both are needed, what should be the optimal timing
- Two broader covering pneumococcal conjugate vaccines currently in phase 3 trials for adults. PCV15 PCV20
 - Concern if change recommendation now then reinstate again in a year or two will cause more confusion

PCV 13 Vote for Older Adults

- Note this vote was ONLY for healthy patients 65 years and older without any other indication for receiving PCV13
 - This vote does not change anything regarding PPSV23 recommendations
- ACIP voted in June 2019 to move from recommending PCV13 as a single dose to all adults 65 years old and greater to having this be a “shared decision making” decision for these patients
 - Reinforced may have individual protection
 - Not all “healthy” patients over 65 years are the same
 - Include evaluation of lack of reliable protection against serotype 3 which is most prevalent in US currently

Will become formal recommendation when published in MMWR

ACIP June 2019 minutes published Nov 4, 2019

QUESTIONS?