Immunization: 2019
Immunization Update

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Disclosure

Dr Girotto 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 Components

<table>
<thead>
<tr>
<th>ALL influenza vaccines</th>
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<tbody>
<tr>
<td>1. A/Brisbane/02/2018 (H1N1)pdm09-like virus (updated)</td>
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<tr>
<td>2. A/Kansas/14/2017 (H3N2)-like virus (updated is a 3C.3a)</td>
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<td>3. B/Colorado/06/2017-like virus (Victoria lineage)</td>
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<tr>
<td>4. B/Phuket/3073/2013-like (Yamagata lineage) virus (this strain not included in trivalent vaccines)</td>
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Characterization of U.S. Influenza A (H3N2) Viruses Collected September 30, 2018 to May 18, 2019

Changing Proportion of H3 Genetic Clades/Sub-clades


- United States (n = 1379)
- Outside of United States (n = 248)
• All patients 6 months old or greater without contraindication should receive an approved influenza vaccine.
Number of Annual Influenza Doses

- **How old is the patient?**
  - 6 months through 9 years old
  - 10 years or older

  **Has the child received 2 or more doses of influenza vaccine (trivalent or quadrivalent) during the same or consecutive seasons before 7/1/19?**
  - Yes
  - No

  **1 dose of influenza vaccine in 2019-2020**
  - 2 doses of influenza vaccine in 2019-2020 spaced by 18 days

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:

A. Provider-based decision
B. Shared decision making
C. Patient directed decision

Vaccine Efficacy

Seasonal Flu Vaccine Effectiveness

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</tr>
</thead>
<tbody>
<tr>
<td>Patient Effective</td>
<td>56</td>
<td>60</td>
<td>47</td>
<td>49</td>
<td>52</td>
<td>19</td>
<td>48</td>
<td>40</td>
<td>38</td>
<td>29</td>
</tr>
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</table>
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


New for 2020 -2021

FDA approves Fluzone® High-Dose Quadrivalent (Influenza Vaccine) for adults 65 years of age and older

* Will be available in fall 2020, in time for the 2020-2021 flu season
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?

A. She does not need any meningococcal vaccines today  
B. She should receive a booster with Bexsero  
C. She should receive a booster with Trumenba  
D. She should receive a booster with the same MenB vaccine she had received as a 17 year old  
E. 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

<table>
<thead>
<tr>
<th>Adult Vaccination Strategy</th>
<th>Model</th>
<th>HPV-ADVISE</th>
<th>Simplified</th>
<th>Merck</th>
<th>GISPNET (Harvard)</th>
<th>GISPNET (Policy- Cervix)</th>
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<tbody>
<tr>
<td>Through age 30 years</td>
<td></td>
<td>$830,000</td>
<td>$827,600</td>
<td>$81,200</td>
<td>$627,700</td>
<td>$341,100</td>
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<td>(vs. current program)</td>
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<tr>
<td>Through age 45 years</td>
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<td>$1,471,600</td>
<td>$653,300</td>
<td>$117,500</td>
<td>$440,600</td>
<td>$315,700</td>
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<tr>
<td>(vs. current program)</td>
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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.


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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.”

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)


Learning Assessment

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

A. A 36 year old patient who is a happily married mother of 3 children
B. A 29 year old patient that has been single since you first became her pharmacist
C. 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

QUESTIONS?