Immunization Update 2017
Virginia Pharmacists Assoc.

Dennis D. Stanley, BPharm
Certificate in Travel Health®

Objectives

• Identify updated recommendations for specific vaccine use
• Recognize disease risks in certain populations
• Recognize the rationale for providing vaccinations in a pharmacy

Influenza 2016-2017

• Influenza activity was moderate peaking in February
  — Predominantly H3N2 until mid-March
  — Predominantly B through May
• 101 pediatric influenza related deaths
• 2010 to 2014 influenza vaccine reduced the risk of influenza related death in children by 51%
• 2016-2017 influenza vaccine reduced incidence of disease by 42%
• Influenza vaccination reduced deaths, ICU admissions, ICU and hospital length of stay
• Influenza vaccination reduced the risk of getting sick and the risk of seeing a physician by 48%
• ACIP voted that LAIV “nasal vaccine” should not be used

Influenza Recommendations 2017-2018

• Everyone 6 months and older without contraindication should get a flu shot every year
• Emphasis on certain groups at increased risk of effects of influenza
  — Children 6 -59 months
  — Persons ≥50 years old
  — Persons who are immunocompromised
  — Persons with chronic diseases
  — Pregnant women
  — Extensive list of high-risk groups at cdc.gov/flu

Influenza Vaccine Composition 2017-2018

• A/Michigan/45/2015 (H1N1)pdm-09-like
• A/Hong Kong/4801/2014 H3N2-like
• B/Brisbane/60/2008-like
• B/Phuket 3073/2013-like – quad only
Influenza Vaccine

- Sanofi Pasteur
  - 70 million doses anticipated
  - Fluzone Quad, Fluzone High Dose (trivalent), Fluzone Intradermal
- Seqirus
  - >50 million doses anticipated
  - Afluria, Afluria Quadrivalent, Fluarix, Flucelvax Quadrivalent, Fluvirin
- GlaxoSmithKline
  - Fluarix Quadrivalent, Flulaval Quadrivalent

Influenza Vaccine Updates 2017-2018

- Afluria (IIV3, IIV4) is now approved for persons ≥5 years
  - Previously 18 years
- Flublok Quadrivalent approved ≥5 years old
  - Previously 18 years
- Flulaval Quadrivalent approved ≥6 months
  - Previously 5 years
- Pregnant women may take any licensed, recommended and age appropriate vaccine
- LAIV is not recommended for 2017-2018

Pneumococcal Conjugate Vaccine

PCV (Prevnar-13®)

- ACIP recommendations
  - All adults 65 years and older
  - All persons 2 through 64 years old with certain medical conditions
  - All babies and children under 2 years old

Pneumococcal Polysaccharide vaccine

PPSV (Pneumovax-23®)

- ACIP recommendations
  - All adults 65 years and older
  - Persons 2 through 64 with certain medical conditions

PVC-13 “Certain Medical Conditions”

- Anatomic or functional asplenia
- Sickle cell disease
- Cochlear implants
- CSF leaks
- Congenital or acquired immunodeficiencies
- Hodgkin disease
- Solid organ transplant
- HIV infection
PPSV-23 “Certain Conditions”

- Add to the PCV-13 list
  - Diabetes Mellitus
  - Chronic heart disease
  - Chronic lung disease
    - Including COPD, emphysema and asthma
  - Chronic liver disease
  - Alcoholism
  - Smokers – 19 years old and older

PCV/PPSV Intervals

- Immunocompetent persons ≥65 years old
  - Pneumococcal naïve
  - PCV followed by PPSV at ≥ 1 year
  - Do not administer at the same time!

- Immunocompetent persons ≥65 years old
  - Previous dose of PPSV-23
  - 1 dose PCV-13 ≥ 1 after last PPSV-23
  - Continue PPSV-23 on appropriate schedule

PCV/PPSV Interval

- Immunocompromised persons ≥ 19 years old
  - Vaccine naïve
    - PCV-13 followed by PPSV-23 ≥ 8 weeks
    - Additional PPSV should follow recommendations
  - Previous PPSV
    - PCV-13 should be administered ≥ 1 year after last PPSV-23
    - Additional PPSV should follow recommendations

Human Papillomavirus(HPV) Vaccine

- 31,000 women and men are diagnosed annually with cancer caused by HPV
  - Cervical cancer accounts for 1 in 3 cancers
  - Estimated nearly 80 million person in the US are infected
  - About 14 million new infections yearly

- The other 2/3 are oral cancer, cancers of pharynx and cancers of anus and rectum

- HPV vaccination can prevent these unnecessary cancers as well as over 300,000 invasive tests and treatments for potential cancer causing lesions

HPV Vaccine

- Gardasil-9® and Gardasil-4® (Merck)
  - 6,11,16,18
  - 31,33,45,52,58

- Highly immunogenic, near 100%
  - Studies were done in 15 or 16 through 26 year olds
  - Immunogenicity in 9 through 15 year olds was non-inferior
  - 3 dose series at 0, 1-2 months and 6 months
  - Later trials showed a 2 dose series in 9 to 14 year olds was non-inferior

New Gardasil-9 recommendation

- HPV vaccine should be administered to 11 to 12 year olds to protect against cancers caused by Human Papillomavirus
  - The series may be started at 9 years old
  - Females through 26 and males through 21
  - Males 22 through 26 may be vaccinated

- Newest recommendations for 11 to 12 years old is a 2 dose series
  - Dose 2 should be 6 to 12 months after the first dose
Meningococcal Disease

- Most commonly diagnosed in infants, adolescents and young adults
- Can be spread where large groups of people gather together
- Certain medical conditions can put people at increased risk
- International travel may put persons at risk

Risks for meningitis A/C/Y/W

- Complement component deficiency
- Taking Soliris®
- Asplenic
- HIV
- Traveling to a country where meningococcal disease is common
- Risk due to disease outbreak

Meningococcal ACYW Vaccine Recommendations

- ACYW Conjugate Vaccine (Menactra®, Menveo®)
  - All 11 to 12 year old should be vaccinated
  - A booster dose should be administered at 16 years old
  - If the first dose is administered at 13-16 years old, a booster should be administered at 16-18
  - If the first dose is administered at 16, no booster is required
  - One dose to unvaccinated college students 19-21 years old at their first year of college

Risk for meningitis B

- Complement component deficiency
- Taking Soliris®
- Asplenic
- Microbiologist routinely exposed to Neisseria meningitidis
- Persons that are part of a population at increased risk for meningitis B infection

Meningococcal B Vaccine Recommendations

- Meningitis B Vaccine (Trumenba®, Bexsero®)
  - All adolescents and adults aged 16 through 23 MAY be vaccinated
  - Preferred 16 – 18 years old
  - Certain adolescents and adults SHOULD be vaccinated
  - Complement component deficiencies, asplenia, persons taking Soliris®
  - Certain adults should be vaccinated
  - Microbiologists that work with meningococcal bacteria are at risk
  - Those at risk due to meningitis B outbreak

Meningococcal vaccine dosing

- Bexsero
  - 2 doses
    - Healthy or at risk teens
    - 0, ≥ 1 month
- Trumenba
  - 2 doses – 0 and 6 months
    - Healthy teens 16-18
  - 3 doses – 0, 1-2 months, 6 months
    - Adolescents 10 and older at increased risk or due to outbreak
- Bexsero® and Trumenba® are NOT interchangeable
- Men B and Men ACWY may be given at the same time
Measles outbreaks

- 2000 – measles elimination documented in US
- 2014 – record 667 cases in 27 states
- 2015 – 188 cases in 24 states
- 2016 - 70 cases in 16 states
- 2017 – Jan. 1 to Jul 15 – 177 cases in 13 states
- The majority of people who got measles were unvaccinated
  - Majority of these cases are related to infection from international travel or exposure to a person just returned from travel

MMR Recommendations

- All children should get 2 doses
  - Dose 1 at 12-15 months, Dose 2 at 4-6 years old
- Students at post-high school educational facilities that do not have evidence of immunity should get 2 doses
- Adults who do not have evidence of immunity should get 1 dose
- International travelers should be protected prior to travel
- Health care workers should have documentation of immunity or receive 2 doses of vaccine at least 28 days apart

MMR for International Travelers

- Infants 6 – 11 months should get 1 dose of MMR vaccine
- Children 12 months and older should get 2 doses at least 28 days apart
- Teenagers and adults without evidence of immunity should receive 2 doses at least 28 days apart

Evidence of Immunity is...

- Written documentation of vaccination
- Laboratory evidence of immunity
- Laboratory confirmation of disease
- Birth before 1957

Cholera

- Cholera is a acute diarrheal illness caused by *Vibrio cholerae* found in contaminated water or food
  - Profuse watery diarrhea, vomiting, leg cramps
  - Dehydration, shock and death
- 3 to 5 million cases annually worldwide
  - Cases have steadily increased worldwide since 2005
- 100,000 deaths annually worldwide
- Africa, Southeast Asia and Haiti

Cholera vaccine

- VaxChora®(lyophilized CVD 103-HgR) - PaxVax
- Single dose, live vaccine
- ACIP approved for persons 18 to 64 years traveling to an area of active cholera transmission
- It is not recommended for travelers to areas that are not endemic or epidemic
- Vaccine is not required for entry or exit from any country
VaxChora®

- Reported to reduce severe diarrhea by 90% if administered 10 days prior to exposure
- Side Effects include
  - Headache, malaise
  - Abdominal pain, N&V, diarrhea
- Unknown if protection lasts past 3-6 months
- To mix: 100ml purified water + buffer + stir + active component + stir + cloudy + 15 minutes

Yellow Fever

- Primarily found in Africa and South America
  - WHO estimates of 2013 in Africa
    - 80,000-170,000 cases of severe disease
    - 29,000-60,000 deaths
  - Sudden onset of fever, chills, severe headache, back ache, body aches, nausea, vomiting, fatigue and weakness
  - Remission for a day
  - 15% progress to severe disease
  - High fever, jaundice, bleeding, multiple organ system failure, death (20-50%)

Yellow fever vaccine shortage

- Yellow fever vaccination is recommended for travelers traveling to or live in areas of yellow fever risk.
- Yellow fever vaccine is required by some countries for entry and/or exit.
- Countries with yellow fever transmission are in Africa and South America

Stamaril® - yellow fever vaccine

- Produced in France
- Used in more than 70 countries
- Comparable in safety and efficacy as YF-Vax
- To meet the IND requirements, Stamaril® will only be available in a limited number of clinics
- To find a clinic go to www.cdc.gov/travel and access the yellow fever clinic search page

Dengue Fever

- 1/3 of the world's population lives in dengue fever risk areas
  - Global incidence estimated by WHO 50-100 million cases
  - 50,000 cases of DHF
  - 20,000 deaths, mostly of children
- Leading cause of death and illness in tropic and sub-tropic areas of the world
- 4 serotypes – DEN-1, DEN-2, DEN-3 and DEN-4
- There is no known cure only supportive treatment
Dengue Fever

- Sudden fever
- Headache
- Retro-orbital pain
- Flushing of face
- Nausea and vomiting
- Generalized myalgia and arthralgia
- Rash on the trunk, arms, legs, palms and soles of feet
- May have multiple episode with multiple serotypes
- Progression of DF to Dengue Hemorrhagic Fever can be fatal

Dengvaxia® - dengue vaccine

- April 2016 – World Health Organization endorsed Dengvaxia
- It is the first dengue fever vaccine
- In Phase III efficacy studies
  - Reduced all 4 serotypes of dengue in 2/3 of participants
  - Prevented 9 of 10 cases of severe dengue fever
  - Prevented 8 of 10 hospitalizations
  - Showed consistent efficacy and long term safety in persons ≥9 years old

Dengvaxia

- The first licensed dengue fever vaccine
- Live recombinant tetravalent vaccine
- 3 dose series
  - Administered over 6 months
  - Persons aged 9 – 45 years old
  - Living in dengue endemic areas
  - Vaccine efficacy is estimated at 65% against confirmed disease in those ≥9 years old

Td shortage

- Shortage is expected at least until mid-September
- Although Tdap is recommended for one dose in a lifetime, if Td is unavailable;
  - As a booster, use Tdap whether the patient has had a previous dose or not
  - Primary Series, use Tdap at the discretion of the HCP
  - Wound management, use Tdap

Recombivax HB (Merck) shortage

- All pediatric and adult formulations are unavailable until mid-January 2018
- Engerix-B(GSK) in all formulations will remain available
Zika

- Cases in the US and D.C. – 5,435
  - 5,162 travelers returning from affected areas
  - 224 presumed locally acquired mosquito borne
  - 49 through other routes
  - 2,155 pregnant women with any evidence of possible infection
- Cases in US territories – 37,012
  - 147 returning travelers
  - 36,865 presumed locally acquired mosquito borne
  - 0 through other routes
  - 4,481 pregnant women with any evidence of possible infection

Zika Vaccine

- 2016 – multiple entities were working on a vaccine
- 2016 – FDA granted the first approval for human clinical trials
- 2017 – Both subunit and inactivated vaccines are in Phase 2 clinical trials
- Estimates range from 18 months to 10 years to develop an effective vaccine

Chikungunya

- Outbreaks have occurred in Africa, Asia, Europe, Indian and Pacific Oceans and the Caribbean
  - 570,000 cases have been reported in the Americas
- Symptoms can be severe and debilitating
  - Fever and joint pain
  - Headache, muscle pain, joint swelling and rash
  - Infection rarely results in death
- Outbreaks in the Indian Ocean islands of 272,000, in India of 1,500,000

Chikungunya Vaccine

- Three sites in the US are enrolling participants in Phase 1/2 trials
- Sponsored by NIH, National Institute of Allergies and Infectious Diseases
- One study of 25 volunteers resulted in “robust immunological response” in the participants

Outbreaks

- Hepatitis A
  - California Smoothie
  - San Diego
- Measles
  - 177 cases in the US in the first half of this year
- Pertussis in southwestern Michigan

Pharmacists Increase Vaccination Rates

- APHA Foundation, Project IMPACT Immunizations, pilot study in Washington state
- 8 pharmacies over a 6 month period
- Increased the number of vaccines administered by 41.1%
- Pharmacists had bidirectional access to IIS and clinical decision support at the point of care
Not only do we increase rates, but...

- According to a paper published in JAPHA, almost 25% of adults received influenza vaccines in a pharmacy-based setting
- 37.8% of adults ≥65 years old received their influenza vaccine in a pharmacy-based setting
- Based on BRFSS data of 28,954 people in 8 states and Puerto Rico

Shingles Vaccine

- Healthy People 2020 goal is 30%
- With pharmacists involvement we have surpassed the goal

Stuff!!

- “The Vaccine Handbook: A Practical Guide for Clinicians” is available as an app for iPhone and iPad
  - Basic vaccinology
  - Vaccine practice
  - Diseases and vaccines
  - Addressing concerns about vaccines
- CDC Vaccines app
  - Child, Adolescent, Adult and Adult conditions schedules
  - Contraindications
  - Catch-up schedule
- 2018 CDC Health Information for International Travel (the Yellow Book) is available