Maine CDC – Annual Infectious Disease Conference: Session C – Adolescent Vaccines

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Learning objectives

Upon completion of this activity, participants will be able to:

- Describe the importance of adolescent vaccines.
- Describe/identify the schedule for adolescent vaccines.
- Identify common concerns and barriers regarding vaccination of adolescents and strategies to address these.

Disclosures

- I have no relevant financial or non-financial relationships in the vaccines described, reviewed, evaluated or compared in this presentation.

Routine Adolescent Vaccines

- Meningococcal
- HPV
- Tdap
- Influenza

Meningococcal disease

- Pathogen: *Neisseria meningitides* (bacterium)
- Clinical effects: Meningococcus usually causes meningitis (inflammation of the lining of the brain) or sepsis (an infection of the bloodstream). Symptoms of meningitis include stiff neck, headache, fever, and drowsiness. Symptoms of sepsis include fever, shock, and coma. Often rapid progression.
- Epidemiology: 800 to 1,500 people in the United States are infected with meningococcus; about 120 die annually
- Importance of vaccine: Disease can be rapidly fatal (or leave long term deficits in survivors) and vaccine is safe and effective

Meningococcal Vaccines: Menactra

- Men ACWY-D (Menactra)
- Licensed for 2 – 55-year-olds as a single dose
- Recommended for all 11 – 13-year-olds in 2005
- In 2011, licensed as two-dose series at 9 and 12 months
- Two-dose series recommended for infants at highest risk of meningococcal disease

Meningococcal Vaccines: Menveo

- Licensed for 2 – 55 as single dose
- Four-dose infants series (2, 4, 6, and 12 months) licensed by FDA in 2013
- First vaccine licensed for infants that includes serogroups A and W-135

Serogroup B – the problem

- Serogroup B vaccine has been difficult to make.
- Serogroup B polysaccharide mimics a neural cell adhesion molecule (NCAM); as a consequence, poorly immunogenic. Also, theoretical concern for autoimmunity.

MenB vaccines

- Two MenB vaccines are now licensed in the United States for persons 10 – 25 years of age

  Trumenba® (Pfizer) was licensed on October 29, 2014

  Bexsero ® (Novartis/GSK) was licensed on January 23, 2015
- MenB vaccines are distinct from MenACWY conjugate vaccines because they are based on immunity to proteins rather than capsular polysaccharides

ACIP recommendation February 2015

- Give MenB vaccine to patients with complement deficiencies, functional and anatomic asplenia, microbiologists, outbreaks of serogroup B disease
- Outbreaks defined as at least 2 cases in populations of less than 5,000 people and at least 3 cases in populations of more than 5,000 people

ACIP recommendation June 2015

- "A serogroup B meningococcal (MenB) vaccine series may be administered to adolescents and young adults 16 through 23 years of age to provide short-term protection against most strains of serogroup B meningococcal disease. The preferred age for MenB vaccination is 16 through 18 years of age (Category B)."
- MenB will appear on the vaccine schedule, will be covered by the VFC program, and should be covered by health plans.

Current CDC/ACIP routine schedule:

- Single dose of Menactra or Menveo vaccine at age 11 through 12 years, with a booster dose at age 16 years.
- Clinical discretion: 2-dose series of Bexsero or a 3-dose series of Trumenba vaccine for age 16 through 23 years (preferred age range is 16 through 18 years) to provide short-term protection against most strains of serogroup B meningococcal disease. Use same vaccine product for all doses.

Why only a Category B recommendation for MenB?

- Decreased incidence of serogroup B disease even before vaccine
- Modest waning of immunity 2 years after dose
- Not likely to reduce serogroup B carriage (no herd immunity)
- Covers a wide range of circulating strains but not all
- Difficult to get 16 – 18-year-old teens in for shots

HPV disease

- Pathogen: Human papillomavirus (HPV) is a virus that infects the skin, genital area, and lining of the cervix. There are many different types of papillomaviruses (about 100).
- Clinical effects: warts on the skin, including anal and genital areas, and cervical cancer. HPV is the only identified cause of cervical cancer.
- Epidemiology: About 11,500 cases of cervical cancer and 4,000 deaths occur annually. About 12,600 males and 3,100 females are diagnosed with cancers of the head and neck. Babies can also be infected in birth canal and develop recurrent respiratory papillomatosis.
- Importance of vaccine: The best way to protect against HPV-associated cancer.

HPV – Mucosal sites of infection

- High risk (oncogenic) HPV 16, 18 most common
  - Cervical cancer
  - Anogenital cancers
  - Oropharyngeal cancer
  - Cancer precursors
  - Low-grade cervical disease
- Low risk (non-oncogenic) HPV 6, 11 most common
  - Genital warts
  - Laryngeal papillomas (although can be life threatening in young children)
  - Low-grade cervical disease

HPV vaccines

- 2vHPV [Cervarix], girls only
- 4vHPV [Gardasil], both boys and girls
- 9vHPV [Gardasil 9], both boys and girls

9-valent HPV vaccine: includes types 31, 33, 45, 52, and 58

- Will protect against an additional 4,000 cases of cancer and several hundred more deaths caused by HPV in the U.S. every year.
- % of cancers by serotype:

	16,18	31,33,45,52,58
» Cervical	66%	15%
» Vaginal	55%	18%
» Vulvar	49%	14%
» Anal (M)	79%	4%
» Anal (F)	80%	11%
» Penile	48%	9%
» Oropharyngeal (M)	63%	4%
» Oropharyngeal (F)	51%	9%

Current CDC/ACIP routine schedule

- Administer HPV vaccine to all adolescents aged 11 through 12 years.
- The vaccine series may be started at age 9 years
- Recommend on the "same day and in the same way" as other routine vaccinations

HPV update – 2 dose recommendation effective as soon as MMWR is published

- Younger adolescents (aged 9-14 years) who get vaccinated before their 15th birthday will only need two doses of 9-valent HPV vaccine (0, 6-12 months). The second dose may be given anytime 6-12 months after the first dose.
- Teens and young adults who start the series at age 15 through 26 years will continue to need three doses of HPV vaccine (0, 1-2, and 6 months).

Research behind 2 dose recommendation

ACIP reviewed all the available HPV vaccine data and studies of immune response, vaccine effectiveness, and duration of protection:

- Clinical trials showed two doses of HPV vaccine given in younger adolescents (aged 9-14 years) produced an immune response that was similar or higher than the response in young adults (aged 16-26 years) who received three doses.
- 3-dose schedule in older adolescents and young adults provides long-lasting protection.
- 2-dose schedule given to younger adolescents will also provide long-lasting protection.

Conversations with parents

- **Now that your child is 11 (or 12) years old, they are due for three vaccines today to help protect them from meningitis, HPV cancers, and pertussis—or whooping cough."**
- **For parents who have a question or need more information about "why now/why 11-12?" you can tell parents:**
- *"As with all vaccine-preventable diseases, we want to protect your child early. If we start now, it's one less thing for you to worry about. Also, your child will only need two doses of HPV vaccine at this age. If you wait, your child may need three doses in order to get complete protection.*
- *We'll give the first shot today and then you'll need to bring your child back in 6 to 12 months from now for the second dose."*

Conversations with parents

- **If a parent has a question or needs more information about "How long can we wait and still give just two doses?" you can say:**

  "The second dose would have to be given before the 15th birthday, which means the first dose would need to be given before age 14, in order to get both doses in time.

  "However, I don't recommend waiting to give this cancer-preventing vaccine. As children get older and have busier schedules, it becomes more difficult to get them back in. I'd feel best if we started the series today to get them protected as soon as possible."
- **For patients aged 9-14 who have already had two doses given less than 6 months apart, you can tell parents:**

  "In order for the new 2-dose schedule to provide protection, the second dose needs to be given at least 6 months after the first dose. Because your child already started the HPV vaccine series and received the first two doses less than six months apart, we'll need to give a third dose."

Pertussis disease

- Pathogen: *Bordetella pertussis* (bacterium)
- Clinical effects: "Whooping cough". Cough can be so violent that it cracks ribs. Pneumonia or seizures can also develop. Young infants also can experience apnea and respiratory failure.
- Epidemiology: Most children catch the disease from adults, not from other children. Between 600,000 and 900,000 adults and adolescents get pertussis in the US annually.
- Importance of Vaccine: Preventing transmission of pertussis to vulnerable populations. Vaccine is safe and effective.

Tdap waning immunity/pertussis outbreaks

- Acellular vaccine (since 1997) has fewer side effects than previously used whole-cell vaccine but is less immunogenic
- California study of 10 – 17-year-olds showed patients who received only whole-cell vaccines were five times less likely to develop pertussis than those receiving acellular vaccines
- Wisconsin study showed Tdap effectiveness in adolescents decreasing from 75% within the first year of receipt to 12% within 3-4 years
- Outbreaks include California in 2010 (808 hospitalizations and 10 infant deaths), Wisconsin in 2012, and another California outbreak in 2014
- Giving Tdap to every pregnant woman should be an immediate priority

Tdap requirement for secondary school

- Maine is currently one of three states that do not currently require Tdap for secondary school entry

Current CDC/ACIP vaccine schedule

- Administer 1 dose of Tdap vaccine to all adolescents aged 11 through 12 years.
- Tdap may be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.
- Administer 1 dose of Tdap vaccine to pregnant adolescents during each pregnancy (preferred during 27 through 36 weeks gestation) regardless of time since prior Td or Tdap vaccination.

Influenza disease

- Pathogen: influenza virus
- Clinical effects: high fever, chills, severe muscle aches, and headache. Runny nose and cough can last for weeks. Complications include severe, and occasionally fatal, pneumonia. In 1918 a worldwide outbreak killed between 50 and 100 million people in a single influenza season.
- Epidemiology: influenza hospitalizes and kills more people in the US than any other vaccine-preventable disease — about 200,000 hospitalizations and thousands to tens of thousands of deaths occur every year
- Importance of vaccine: The influenza vaccine can cause mild side effects, but given risks of disease, the benefits of the vaccine clearly outweigh its risks.

Influenza – new recommendations

- Two important new recommendations were made for the 2016-17 season:
- Live attenuated influenza vaccine (LAIV, FluMist®, AstraZeneca) is **not** recommended to be used in any setting during the 2016-17 influenza season
- A history of egg allergy is no longer considered to be a contraindication or precaution to influenza vaccination

Why egg allergy doesn't preclude flu shot

- Inactivated influenza vaccines (IIV) contain less than 1ug of ovalbumin
- The lowest quantity of ovalbumin in food that elicits mild objective symptoms in egg allergic patients is 130 ug

Observation period after adolescent vaccines

- ACIP February 2016:
- "Regardless of allergy history, vaccine providers should consider observing all patients, particularly adolescents, with patients seated or lying down for 15 minutes after vaccination to decrease the risk for injury should syncope occur."

Common concerns and barriers

- Skeptics (Are vaccines necessary?)
- Refusers (focused on risks and worried about cover-up)
- Delayers (Can we do it later?)

Contributing factors

- Low disease burden with resulting low disease awareness
- More attention paid to vaccine risks than benefits
- Low tolerance for vaccine risks
- A complicated immunization schedule with many vaccines to be given

Skeptics

- Disease is more "natural" than vaccine
- Vaccine-preventable diseases have disappeared
- Not all vaccines are needed
- Vaccines do not work

Refusers

- Serious adverse reactions
- Potential for long term adverse events
- Inadequate research performed prior to licensure

Strategies for skeptics & refusers (AAP)

- *Use open-ended questions to elicit concerns from parents:*

Why are you concerned about vaccines? What are you most concerned about?

- *Be attentive to concerns and correct misconceptions*

After acknowledging parental concerns, it is important to correct misconceptions in a non-confrontational manner.

Clearly articulate the message that "vaccines are safe and effective, and serious disease can occur if your child and family are not immunized."

Strategies with "Delayers"

- Discuss Pertussis prevalence
- Recommending giving HPV before your teen is sexually active
- Use sports physicals as opportunities for vaccination

Dismissal from medical practice?

- American Academy of Pediatrics recent recommendation (2016) for the first time says dismissal from practice may be acceptable, but significant pros/cons:
- **Pro:**
- Some providers believe that demonstrating just how strongly the provider feels about vaccines may actually help to convince the family to decide to vaccinate their children
- Prevents other patients in practice from being exposed to vaccine preventable diseases
- **Con:**
- No published data regarding the eventual outcome of strict "vaccinate or be dismissed" policies on the eventual acceptance of vaccines and further studies are needed.
- Loss of opportunity to influence family's healthcare choices, may expose child to sub-standard care elsewhere

Why facts and science don't always change people's minds – work of Brendan Nyhan, PhD

How we wish the world worked:

The facts are coming! The facts are coming!

How the world (often) actually works

Recommendations from Dr. Nyhan's research:

- Avoid reinforcing myths
- Use credible sources
- Throwing facts at people isn't the answer

Sources

- Children's Hospital of Philadelphia Vaccine Information Center, including Fall 2015 and Spring 2016 webinars by Paul Offit, MD. http://www.chop.edu/centers-programs/vaccine-education-center
- CDC Child & Adolescent Immunization schedule. http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html
- "Why facts and science don't always change people's minds" Presentation by Brendan Nyhan, PhD, Department of Government, Dartmouth College. https://www.nationalacademies.org/hmd/~/media/Files/Activity%20Files/PublicHealth/PopulationHealthImprovementRT/15-SEP-30/Presentations/Nyhan%20Brendan.pdf
- PediaLink: Challenging Cases - Vaccine Hesitancy. http://cc-vaccine.pedialink.courses.aap.org/?req=20161101540138115

Questions?