Update on Immunizations in High Risk Adults

March 12, 2015
7:45 AM – 9:00 AM
Houston, Texas
Session 1: Update on Immunizations in High Risk Adults

Learning Objectives

1. Identify profiles of specific patients at increased risk for vaccine preventable diseases
2. Implement vaccine recommendations in high risk patients
3. Recognize that health care provider recommendations are key to patient acceptance of vaccinations

Faculty

M. Susan Burke, MD, FACP
Clinical Associate Professor of Medicine
Sidney Kimmel Medical College at Thomas Jefferson University
Philadelphia, Pennsylvania
Senior Advisor, Lankenau Medical Associates
Lankenau Medical Center
Wynnewood, Pennsylvania

Dr M. Susan Burke is a clinical associate professor of medicine at the Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, Pennsylvania; an adjunct associate professor of geriatrics at the Philadelphia College of Osteopathic Medicine in Philadelphia; and senior advisor of Lankenau medical associates at the Lankenau Medical Center, Wynnewood, Pennsylvania, where she has been a clinician and teaching attending for more than 30 years. Having earned her medical degree from the University of Pennsylvania Perelman School of Medicine, Philadelphia, she completed a residency in internal medicine at Lankenau Hospital (now the Lankenau Medical Center). Dr Burke is board certified in internal medicine and geriatrics and is a fellow of the American College of Physicians.

A 2 time recipient of the Blockley-Osler award for excellence in clinical teaching from Thomas Jefferson University, Dr Burke also has received the residents' award for best teacher from the Lankenau Internal Medicine house staff. She has been named best doctor for women and, more recently, top doctor by Main Line Today. Dr Burke lectures nationally and has published chapters and articles on numerous primary care and geriatric topics on continuing medical education web sites as well as in publications such as The Journal of the American Osteopathic Association and Annals of Long-Term Care.

Barbara P. Yawn, MD, MSc, FAAPP
Director of Research
Olmsted Medical Center
Adjunct Professor
Department of Family and Community Health
University of Minnesota
Rochester, Minnesota

Dr Barbara Yawn is a family physician with many years of both practice and research experience. She has published more than 350 articles in peer reviewed journals on a variety of topics including childhood and adult immunizations and, most recently, related to herpes zoster (HZ) burden and impact of the HZ vaccine. She has served on many national guideline panels, including recently cochairing the National Heart, Lung, and Blood Institute’s Sickle Cell Disease Guidelines expert panel as well as serving on the National Asthma Guidelines committee in 2007 and on the World Health Organization’s COPD and Asthma Guidelines committees.
Much of her research is designed to develop tools and methods to translate guidelines into everyday practice to improve patient outcomes. Her research is funded by the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Centers for Disease Control and Prevention. Dr Yawn has been a frequent speaker at Pri-Med. Her role as a primary care educator includes conducting not only podium talks, but webinars, interactive virtual presentations, and group mentoring sessions. Dr Yawn hopes to make adult vaccines as much a part of routine practice as childhood vaccines have become.

Faculty Financial Disclosure Statements
The presenting faculty reported the following:
Dr Burke has received speaker bureau honoraria from Merck & Co, Inc.
Dr Yawn has received consulting fees from Merck & Co, Inc, and GlaxoSmithKline.

Education Partner Financial Disclosure Statement
The content collaborators at Miller Medical Communications, LLC, have no financial relationships to disclose.

Suggested Reading List


SESSION 1
7:45 – 9am
Update on Immunizations in High Risk Adults

SPEAKERS
M. Susan Burke, MD, FACP
Barbara Yawn, MD, MSc, FAAFP

Adult Immunization 2015:
FOCUS ON PREVENTION IN HIGH-RISK PATIENTS

Quite simply, everyone should get the flu shot!!

Adult Immunization 2015:
FOCUS ON PREVENTION IN HIGH-RISK PATIENTS

Quite simply, everyone should get the flu shot!!

Td/Tdap

- Pertussis incidence increasing since 1970s
  - 2012: CDC Surveillance >42,000 cases, likely >10x more
  - Community outbreaks: Most in fall, winter, and in persons of all ages
  - Nosocomial disease: academic, community
    - Med/Surg, OR, L&D, NICU, Oncology, residential care
- Adults/Adolescents do not have ‘classic’ triphasic disease
  - Most have persistent cough: median 4 months (6 studies)
    - 20%-40% ‘whoop’, 40%-55% posttussive emesis
    - 12%-32% lymphocytosis
    - ~10% develop complications (pneumonia most common)


Td/Tdap

- Recommendation
  - All adults should receive a primary tetanus, diphtheria series, followed by a Td ‘booster’ every 10 years
  - Replace 1 dose Td with Tdap
  - Many adults do not receive Td boosters
    - More than 50% of adults do not have protective Td Abs
    - Most boosters given are ‘episodic trauma-related’
- Td/Tdap Contraindications
  - Severe allergy to vaccine components or Arthus reaction following T vaccine
  - Encephalopathy <7 days after pertussis-containing vaccine (Tdap)
  - Unstable neurologic disease, moderate-severe acute illness (Tdap)

Ab, antibody; T, tetanus.
Human Papilloma Virus (HPV)

- > 200 types identified to date
  - HPV-16 and HPV-18 the most common oncogenic HPV types, associated with cervical, anal, penile, and oropharyngeal malignancies
  - HPV-6 and HPV-11 associated with genital warts and respiratory papillomatosis

- Very common infection
  - > 50% of sexually active men and women infected over their lifetime

- Malignancies with persistent infection: HPV responsible for:
  - 99% of cervical cancers/dysplasia
  - 13%-74% of malignancies in oral cavity
  - 50% of penile and vaginal cancers
  - 90%-95% of anal cancers
  - 25,000 HPV-associated cancers in United States annually

HPV Vaccines

<table>
<thead>
<tr>
<th>HPV9</th>
<th>HPV4</th>
<th>HPV2</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 68</td>
<td>HPV types 6, 11, 16 and 18</td>
<td>HPV types 6 and 16</td>
</tr>
<tr>
<td>Prevention of cervical, vaginal and anogenital cancers in females aged 9 to 26 years</td>
<td>Prevention of cervical, vaginal and anogenital cancers in females aged 9 to 24 years</td>
<td>Prevention of cervical cancer and precancerous lesions in females aged 10 to 26 years</td>
</tr>
<tr>
<td>Prevention of genital warts in males and females</td>
<td>Prevention of genital warts in males and females</td>
<td>Prevention of anal cancer in males and females</td>
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<tr>
<td>Prevention of anal and oral intraepithelial neoplasia (AIN) in males and females</td>
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</table>

ACIP Recommendations: HPV9 and HPV2 for females aged 11 to 12 years (approved for ages 9-26 years) and HPV4 for males aged 11 to 12 years (approved for ages 9-26 years) and HPV9 for males aged 13-26 years (approved for ages 9-26 years)

Contraindications/Cautions: Local reaction, bronchospasm reported; not recommended in pregnancy (no data demonstrated); Immunosuppression can reduce efficacy

HPV VACCINE DOES NOT SUBSTITUTE FOR CERVICAL CANCER SCREENING

AbL, adverse events


Meningococcal Vaccine: A,C,Y,W-135

- Neisseria meningitidis
  - Highly contagious gram-negative bacteria
  - Highest mortality in children aged <1 year

- 3 current vaccines for A, C, Y, W-135
  - MCV4: Polyvalent vaccine (SC, 1 dose)
    - Available since 1978, fair efficacy, OK if conjugate not available
    - Recommended for patients 6-15 years and not likely to need booster
  - MCV4 (2 brands): Conjugate vaccines (IM, 1 dose)
    - Approved 2005, 2010
    - Preferred for primary vaccination in persons <5 years and booster doses are likely to be needed
    - Booster may be given selectively after 5 years if high-risk persists

NCHS, meningococcal conjugate vaccine quadrivalent; MCV4, meningococcal polysaccharide vaccine quadrivalent.

ACIP Meningococcal Indications: A, C, Y, W-135

- All children aged 11 to 12 years
- College freshmen who will live in a dormitory
- Terminal complement deficiencies
- Travelers to ‘at-risk areas’: Sub-Saharan Africa, December–June
- Microbiologists [possible occupational contact]
- Revaccinate at 5 years for ongoing risk status
- Prefer conjugate for persons < 56 and revaccination
- Prefer polyacridine for those 56+ and needing only 1 dose
- HIV: NO LONGER AN INDICATION

ACIP Meningococcal Indications: Serogroup B

- ACIP voted on 2/26/15 to recommend serogroup B meningococcal vaccination for persons 2 years old at increased risk for meningococcal disease, including:
- Persons with persistent complement component deficiencies
- Asplenia, anatomic or functional; includes sickle cell
- Microbiologists routinely exposed to isolates of Neisseria meningitidis
- Persons identified to be at increased risk because of a serogroup B meningococcal disease outbreak

Two new serotype B vaccines recently approved: Trumenba (Pfizer) and Bexsero (Novartis)

Pneumococcal Vaccination in Adults: PPV23

Recommended for:
- Adults aged ≥65 years regardless of PPV23 vaccination history
- Adults aged <65 years with chronic lung disease, chronic cardiovascular disease, diabetes mellitus, chronic renal failure, chronic liver disease, cochlear implants, immunocompromising conditions, asplenia
- Residents of nursing homes
- Adults who smoke cigarettes
- Revaccination 5 years after first dose for persons aged 19–64 years with chronic renal failure, immunocompromising conditions, asplenia

Vaccination Rates Are Low Among Adults Aged 19-64 Years Within 3 Years of Newly Diagnosed High-Risk Conditions

Vaccination Rates Among a US Managed Care Population With Selected High-Risk Conditions Diagnosed Between 2007 and 2010

CDC Says Adult Vaccination Rates Are “Unacceptably Low”


Vaccination Rates Among a US Managed Care Population With Selected High-Risk Conditions Diagnosed Between 2007 and 2010

ACIP Recommendation for Herpes Zoster Vaccination

Give to all aged ≥60 years who have no contraindications including:
- Patients who report a previous episode of herpes zoster
- Patients with chronic medical conditions
- CDC recommends offering it at the first encounter with patient aged ≥60 years
- Also FDA approved for those aged 50–59 years; ACIP deferred routine use for this age group, but may be considered in special circumstances
Contraindications to Herpes Zoster Vaccine

- History of immunodeficiency states, including:
  - Leukemia, lymphomas, or other malignant neoplasms affecting the bone marrow or lymphatic system
  - AIDS or other clinical manifestations of infection with HIV
- Immunosuppressive therapy, including high-dose corticosteroids
- Active untreated tuberculosis
- History of anaphylactic/anaphylactoid reaction to neomycin (not including contact dermatitis)
- Serious current illness (or T ≥38.5°C)
- Known or suspected pregnancy


Tdap Recommendations

- Single dose replaces 1 dose Td for all adults
  - Except in pregnancy, only 1 dose Tdap recommended in a lifetime
  - To maximize passive transfer of antibody to fetus, optimal timing is between 27 to 36 weeks’ gestation
  - Immune response peaks 2 weeks after administration
- Current recommendation for subsequent Td q10yr
  - May be given (anytime) <10 years following last Td
  - As little as 2 years demonstrated safe/effective
- Special emphasis:
  - Adults with close infant contact (health care workers, parents, child care workers, etc)
- To follow primary T series [DTaP, DTP, DT, or Td] or as part of primary series


Current Immunization History

- As an adult who previously had no factors for increased risk, Rachel’s adult immunizations to-date have included a Tdap and Hep A [2 doses] and Hep B [3 doses] because she works in a day care setting with many immigrant children
- She also usually gets an influenza immunization, but none is recorded this year in your records or the registry
- As a person now getting ready to begin chemotherapy, Rachel has developed a “transient” highest-risk condition status—induced immune suppression

Hep A, hepatitis A; Hep B, hepatitis B.

What are the “highest-risk conditions” for someone aged <65 years?

- Immune compromise
  - Prednisone 20 mg/d or biologics
- Cancer treatment
- Sickle cell disease
- Transplantation
  - Organ, BMT, Stem Cell
- Immune deficiency—inherited or acquired
- ESRD or nephrotic syndrome
- CSF leaks
- Cochlear implants
- Splenectomy

BMAT, bone marrow transplant; CSF, cerebrospinal fluid; ESRD, end-stage renal disease.

Herpes Zoster vaccine

- A single dose of zoster vaccine is recommended for adults aged 60 years or older regardless of whether they report a prior episode of herpes zoster
- Although the vaccine is licensed by the FDA for use at age 50 years or older, ACIP recommends vaccination begin at age 60 years
- Currently available vaccine is live-attenuated and not appropriate for those with severe immunodeficiency
- Administration of vaccine prior to start of chemotherapy reduces incidence of HZ by 42% if given 60 days or sooner before initiation of induced immune suppression
- The ACIP states that co-administration of HZ vaccine and pneumococcal (PPSV23) vaccine is acceptable.
- Zoster vaccine should be administered at least 14 days before initiation of immunosuppressive therapy if delay is possible


Hepatitis B Vaccination in Adults With Diabetes

- October 2011: ACIP recommends Hepatitis B vaccine in unimmunized patients with diabetes
  - Aged 19-59 years
  - Age 60+ years is at discretion of the treating physician [Category A, type 2 evidence]
- Rates:
  - Why?!
    - Patients with DM2 have 2.1-fold increased risk for acute HBV compared with non-DM
    - NASH more common in individuals with diabetes and this and other chronic liver disease increases HBV-associated morbidity/mortality
    - NHANES: Seroprevalence for HBV [Anti-HBVc IgG] is 60% higher in DM than in non-DM


DM2, diabetes mellitus type 2; HBV, hepatitis B virus; HAV, hepatitis A virus; IgG, immunoglobulin G; NASH, non-alcoholic induced steatohepatitis; NHANES, National Health and Nutrition Examination Survey.

### What other adults should be vaccinated against Hepatitis B?

- **Behavioral and social:**
  - >1 sex partner in 6 months
  - Household contact and sex partners of HBsAg+ people
  - MSM
  - Inmates in long-term correctional facilities

- **Occupational:**
  - Health care worker
  - Public safety workers
  - Staff working with developmentally disabled

- **Medical:**
  - IVDU
  - People seeking STD evaluation or treatment
  - Hemodialysis patients and ESRD patients awaiting dialysis
  - Persons with chronic liver disease

- **Travel:** risk destination or activity

- All adults who want to be protected from hepatitis B (HBV)

HBsAg, hepatitis B surface antigen; IVDU, intravenous drug user; HBV, hepatitis B virus; STD, sexually transmitted disease.

### Hepatitis B Vaccination for Adults

- ACIP indications cover a large portion of adults
  - Recognition and immunization rates are low

- Most who are vaccinated have lifetime protection
  - But antibody may not be detectable...

- Multiple vaccine schedules approved:
  - Standard: Now, 1 month, 6 months
  - Single agent: HBV vaccine alone
  - Combined: HBV/HAV vaccination

- Vaccine series need NOT be restarted if completion is delayed/off schedule

HAV, hepatitis A virus.

### Influenza Vaccination

- **VACCINE:** All And Annually!!
  - Vaccine effectiveness is multifactorial
    - Match with "disease" strains
    - Vaccine availability and timing
    - Patient 'substrate':
      - 'Healthy' young aged <65 @ ~60%-80%
      - 'Sick' older aged >65 @ 30%-40%
  - New data hdIIV vs IIV in seniors
  - No comparative data qIIV vs tIIV

- Ongoing vaccine research


hdIIV, high-dose inactivated influenza vaccine; IIV, inactivated influenza vaccine; qIIV, quadrivalent inactivated influenza vaccine; tIIV, trivalent inactivated influenza vaccine.

### Summary: Vaccination of Adults with Diabetes

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>All Adults, Annually</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egg Allergic</td>
<td>Recombinant vaccine</td>
</tr>
<tr>
<td>Not Egg Allergic, adult aged &lt; 65 years</td>
<td>ANY influenza vaccine! No data to support superiority of one over other products</td>
</tr>
<tr>
<td>Needle aversion</td>
<td>LAIV option if 2-49 years, ID in 18-64 years</td>
</tr>
<tr>
<td>Aged 65+ years</td>
<td>tIIV superior to IIV</td>
</tr>
<tr>
<td>No comparative data qIIV vs tIIV</td>
<td>Anticipate all convert to quad in next few years</td>
</tr>
</tbody>
</table>

### Influenza Vaccine in Seniors

- Live vaccine not indicated in persons aged >50 years
  - No comparative data for qIIV vs tIIV
  - BUT addition of second B strain to vaccine increases likelihood of matched vaccine strain to circulating strains
  - tIIV vs hdIIV
    - Large, active comparison RCT published summer 2014
    - Reduction in clinical influenza in seniors vaccinated with hdIIV vs tIIV

RCT, randomized clinical trial.
Vaccination of Seniors

<table>
<thead>
<tr>
<th>Vaccination</th>
<th>Frequency</th>
<th>In all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza</td>
<td>Annually</td>
<td></td>
</tr>
<tr>
<td>Tdap</td>
<td>Once, interval from last Td unimportant</td>
<td>Resume every 10 years Td afterward</td>
</tr>
<tr>
<td>Pneumococcal highest-risk group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCV13</td>
<td>ONCE</td>
<td>Best given prior to PPV23</td>
</tr>
<tr>
<td>PPV23</td>
<td>ONCE</td>
<td>ACIP 6-12 months after PCV13</td>
</tr>
<tr>
<td>Zoster</td>
<td>ONCE</td>
<td>All age 60+ years</td>
</tr>
</tbody>
</table>

Other vaccine recommendations based on risk factors, not age alone

CMS, Centers for Medicare and Medicaid Services.

Travel Vaccination

- Complex recommendation set based on:
  - Destination
  - Health of traveler
  - Specifics of travel plan
- CDC Travelers’ Health site is a helpful resource
- Travel clinics can be a source of local expertise

Practical Strategies to Increase Immunization of Adults in Your Practice

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CLINICAL ASSOCIATE PROFESSOR OF MEDICINE
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How Can We Improve Adult Vaccination Rates?

Why Do We Want to Improve Vaccination Rates?

- More adults living longer
  - In United States, 10,000 turn 65 years old every day*
- Help keep our patients healthy
  - Focus on prevention: heart disease, cancer screening, immunizations
  - Vaccination is quality-of-care issue that improves health outcomes and will be monitored by health insurers/government in future
- Reduce morbidity and mortality
- Offices that vaccinate adults receive reasonable compensation
- It’s the right thing to do

Successful Vaccines: Polio

So How Do We Improve Vaccination Rates in Our Practices?

- Know the rules
- Establish protocols/standing orders
- Make strong recommendations
- If your office cannot vaccinate, then refer
- You are captain of the immunization ship!

Protocols/Standing Orders

- One of the most effective ways to increase vaccination
- Use EMR to your advantage
  - Use automatic reminders
  - Some can run the daily patient list for immunizations that are due; have staff administer on arrival

Protocols/Standing Orders

- Delegate! Get your staff involved
  - Have them ask about vaccination status when doing vital signs
  - They can provide vaccine information to patient
  - Establish standing orders for automatic administration of other vaccines, not just flu
- Appoint an office champion to spearhead patient identification and vaccination efforts
- Free download of standing order forms at www.immunize.org/standing-orders

Standing Orders Are Among the Most Effective Strategies

- Nonphysicians offer and administer vaccinations
- Established with physician-approved policies and protocols
- Free download of standing orders at:
  - www.immunize.org/standing-orders
  - www.immunizationed.org/standingorders

Make Strong Recommendations

- Your recommendation is key
  - 88% of consumers said they were likely to get vaccinated if recommended by their doctor*
- Make education materials available—wall posters, vaccine information sheets such as Vaccinations for Adults: You’re never too old to get immunized! (available at http://www.immunize.org/catg.d/p4030.pdf)
- Encourage dialogue, answer questions
- Personalize the vaccine experience
  - Would you take the vaccine yourself or give it to your parents? If so, let the patient know. Do not take No for an answer!

Provider Recommendation Can Overcome Negative Attitude Among Patients

Vaccination Rates Among High-Risk Patients With Negative Attitudes

MD, medical doctor.


If Your Office Cannot Vaccinate, Then Refer

- My office does not provide all services to all patients, either
  - I vaccinate, but refer other services when needed
    - Colonoscopy, etc. per guideline recommendations
  - If you are following guidelines for other diseases, you should follow immunization recommendations as well, whether through your office or through referral to others

Barriers

- “But I’m too busy after taking care of all the other diseases I have to address”
  - What makes immunizing your patient less important than other disease issues?
- Turn your office immunizations into a success story!
- You do not have to do it alone—engage the staff; have standing orders; refer to others

Barriers

- “But it’s too costly to give or stock all these vaccines”
  - Reimbursement for adult vaccines better than for pediatric ones
  - Can bill $30-$96 above vaccine cost in addition to vaccine administration cost per vaccine
  - Many companies will provide vaccines up to 90 days before payment is due—can bill for them by then!!
  - Most companies will buy back outdated/damaged product or freezer failures

If You Can’t Vaccinate, Then Refer

- Health centers, travel clinics, ID specialists all stock vaccines
- Growing number of pharmacies offer vaccinations
  - All states have some vaccinating pharmacies
  - Often better access, with expanded evening and weekend hours
  - Patients visit their pharmacy more frequently than they do their doctor!

You can change the course of your patient’s destiny...

Polio: Prevented Through Vaccination
Make Immunizations a Priority: (What’s Not to Like?)

- Better patient care
- More patients into your office
- Primary prevention opportunity
  - Reduce morbidity and mortality
- More revenue for your practice

Give All Your Patients the Best Fighting Chance Against Vaccine-Preventable Diseases!