Vaccines for infants-
What has happened in the last year?

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Lots has happened and it can be a little confusing

Infants used to require 3 repeat Hep B vaccine doses if they didn’t respond the first time. Now they may only need 1 dose

We used to promote the live attenuated nasal influenza vaccine and now we aren’t using it at all?!?

MMR vaccine is a 2-dose vaccine. Why would we give a 3rd dose?

We have two types of meningococcal vaccine, one that is routinely recommended for a small subset of infants but the other is not.

There are two different types of pneumococcal vaccine. Some children need one, some need the other, and some need both
Disclosures
I have no financial disclosures related to this presentation

Disclosure Slide
I have no relevant financial relationships with the manufacturer(s) of any commercial products(s) and/or provider(s) of commercial services discussed within this CME activity.

I do NOT intend to discuss an unapproved or investigative use of a commercial product/device in my presentation.
Objectives

• Explain why the birth dose of hepatitis B vaccine is now supposed to be given within 24 hours of birth to **ALL** babies so that you can work with birth hospitals to get infants immunized

• Describe new options for repeat hepatitis B immunization of infants who don’t respond to the first 3 doses of vaccine so that you can decide which approach to follow

• Explain why LAIV is not being used so that you can explain that to your patients

• Strongly advocate for pregnancy Tdap immunization to protect infants from pertussis

Objectives

• Describe why a third dose of MMR vaccine is sometimes being given so you will be prepared to give it if necessary

• Distinguish between the two types of meningococcal vaccines and remember which one selected infants may need

• Know where to go to quickly figure out which young children may need pneumococcal polysaccharide vaccine (PPSV 23)
Hepatitis B-What can possibly be new?

Why hepatitis B is a problem

Chronic hepatitis B infection occurs in approximately
- 90% of infected infants
- 30% of children infected at <5 years of age
- <5% of children infected at 5 years of age or older

Risk of premature death from cirrhosis or hepatic cancer
- 25% if infected during childhood
- 15% if infected as an adult

How are we doing with Hep B vaccine in high risk infants

Outcomes from Perinatal Hepatitis B Prevention Program, 2014

- Number of infants enrolled: 11,157 (expected: LL 18,807, PE 26,236)
- Percent of infants with PEP within 1 calendar day of birth: 97%
- Percent with HBIG and series complete by 8 months: 74%
- Percent of all enrolled infants with PVST results: 64%
- Percent of all enrolled infants with HBsAg-positive results: 0.4%
- Percent of all enrolled infants with protective levels: 95%
- Percent of all enrolled infants that need revaccination: 2%
- Percent of infants with indeterminate results: 2%

Hepatitis B-What’s New

No more delaying the birth dose

For infants who don’t respond to the first 3 doses of Hep B vaccine you have the option of giving just 1 more dose and rechecking serology
Why push for a birth dose of hepatitis B vaccine?

- Hep B vaccine works better in preventing perinatal transmission when given on day 1 than it does when given later.
- Infants born to mothers with unknown or discrepant Hep B status are less likely to be immunized at birth than infants born to mothers with clear status.
- During the period following the 1999 recommended delay in birth doses of Hep B vaccine for infants born to known HBsAg-negative mothers babies who should have been immunized were not due to errors in record keeping.
- Babies keep falling through the cracks in our systems and get infected.

Smith, Pediatrics 2012;129:609

Recommendations for birth dose of Hep B vaccine

All babies should get a birth dose of Hep B vaccine…and the dose should be given within 24 hours of birth.

Schillie, ACIP October 2016
Single dose revaccination

Response to Single-dose Vaccination Among Infants Enrolled in Perinatal Hepatitis B Prevention Program

- Infants born to HBsAg-positive mothers from 2012-2016* in Georgia, Michigan, and New York City
- Received 3 doses hepatitis B vaccine and PVST with anti-HBs <10mIU/mL, followed by single dose revaccination with anti-HBs measurement
  - 14/15 (93.3%) with anti-HBs ≥10 mIU/mL after single-dose revaccination

* Initial year of range 2011 for one jurisdiction; final year of range 2015 for one jurisdiction.
Influenza—how it happens

FLUVIEW
A Weekly Influenza Surveillance Report Prepared by the Influenza Division
Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, 2016-2017 and Selected Previous Seasons
### Interim adjusted vaccine effectiveness against medically attended influenza, 2016–17

#### Influenza positive

<table>
<thead>
<tr>
<th>Age group (yrs)</th>
<th>Any influenza A or B virus</th>
<th>N vaccinated /Total (%)</th>
<th>Influenza negative</th>
<th>Vaccine Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>335/744 (45)</td>
<td>1317/2400 (55)</td>
<td>33 (21 to 44)</td>
<td>48 (37 to 57)</td>
</tr>
<tr>
<td>6 mos–8</td>
<td>52/97 (55)</td>
<td>330/614 (54)</td>
<td>58 (33 to 73)</td>
<td>51 (22 to 71)</td>
</tr>
<tr>
<td>9–17</td>
<td>36/122 (80)</td>
<td>92/247 (37)</td>
<td>29 (-12 to 56)</td>
<td>32 (-19 to 61)</td>
</tr>
<tr>
<td>18–49</td>
<td>89/208 (43)</td>
<td>363/783 (46)</td>
<td>13 (-18 to 36)</td>
<td>15 (-17 to 43)</td>
</tr>
<tr>
<td>50–64</td>
<td>75/189 (40)</td>
<td>261/425 (61)</td>
<td>58 (40 to 70)</td>
<td>58 (38 to 72)</td>
</tr>
<tr>
<td>≥65</td>
<td>100/128 (78)</td>
<td>271/383 (92)</td>
<td>21% [-31 to 52]</td>
<td>46 [-4 to 70]</td>
</tr>
</tbody>
</table>

* Multivariate logistic regression models adjusted for site, age, sex, race/ethnicity, self-rated general health status, interval from onset to enrollment, and

### Influenza A/H3N2

#### Influenza positive

<table>
<thead>
<tr>
<th>Age group (yrs)</th>
<th>Influenza A/H3N2</th>
<th>N vaccinated /Total (%)</th>
<th>Influenza negative</th>
<th>Vaccine Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>282/595 (47)</td>
<td>1317/2400 (55)</td>
<td>26 (11 to 88)</td>
<td>43 (29 to 54)</td>
</tr>
<tr>
<td>6 mos–8</td>
<td>24/68 (35)</td>
<td>350/614 (54)</td>
<td>53 (21 to 72)</td>
<td>53 (16 to 74)</td>
</tr>
<tr>
<td>9–17</td>
<td>28/94 (30)</td>
<td>92/247 (37)</td>
<td>29 (-19 to 57)</td>
<td>23 (-43 to 59)</td>
</tr>
<tr>
<td>18–49</td>
<td>73/168 (43)</td>
<td>363/783 (46)</td>
<td>11 (-24 to 36)</td>
<td>13 (-30 to 41)</td>
</tr>
<tr>
<td>50–64</td>
<td>70/154 (45)</td>
<td>261/425 (61)</td>
<td>48 (24 to 64)</td>
<td>50 (23 to 67)</td>
</tr>
<tr>
<td>≥65</td>
<td>87/111 (78)</td>
<td>271/383 (82)</td>
<td>20 (-57 to 53)</td>
<td>44 (-3 to 69)</td>
</tr>
</tbody>
</table>

* Multivariate logistic regression models adjusted for site, sex, race/ethnicity, self-rated general health status, interval from onset to enrollment, and calendar time.
It’s tough to make predictions, especially about the future.

2017-2018 Influenza vaccines

• Influenza A (H3N2), and both Influenza B strains unchanged

• New Influenza A (H1N1) strain A/Michigan replaces A/California based on minor changes in circulating strains

• New product licensed for infants!
  • GSK (Flulaval) licensed for children 6 months and older in November 2016
The Flu Vaccines 2016-17

What are the age restrictions?

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>≥6 mon</th>
<th>&gt;3 yrs</th>
<th>&gt;4 yrs</th>
<th>&gt;9 yrs</th>
<th>&gt;18 yrs</th>
<th>2-49 yrs</th>
<th>18-49 yrs</th>
<th>18-64 yrs</th>
<th>&gt;65 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluzone/Sanofi</td>
<td>X</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Flulaval/GSK</td>
<td>X</td>
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</tr>
<tr>
<td>Fluarix/GSK</td>
<td>X</td>
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<tr>
<td>Fluvirin/Novartis</td>
<td>X</td>
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<tr>
<td>Flucelvax/Novartis</td>
<td>X</td>
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<tr>
<td>Afluria IIV3/CSL</td>
<td>X</td>
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<td></td>
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</tr>
<tr>
<td>Afluria IIV4/CSL</td>
<td>X</td>
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<td></td>
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</tr>
<tr>
<td>FluMist/Medimmune</td>
<td>X</td>
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<td></td>
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<tr>
<td>FluBlok/Protein Sciences</td>
<td>X</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluzone-Intradermal</td>
<td>X</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluzone-High dose</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Fluad-adjuvanted</td>
<td>X</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Who is not getting a flu vaccine?

<table>
<thead>
<tr>
<th>Group</th>
<th>2015-2016 Unvaccinated (end of November)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seniors</td>
<td>40%</td>
</tr>
<tr>
<td>Adults &gt;18 years</td>
<td>61%</td>
</tr>
<tr>
<td>Adults, 18-64 years high risk</td>
<td>68%</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>60%</td>
</tr>
<tr>
<td></td>
<td>42% if offered</td>
</tr>
<tr>
<td>Children</td>
<td>61%</td>
</tr>
</tbody>
</table>

http://www.cdc.gov/flu/weekly/

What happened to LAIV?

NOT RECOMMENDED FOR USE THIS INFLUENZA SEASON
• CDC Influenza VE Network study
• Outpatients with cough illness <8 days
• Test-negative design
• PCR confirmed cases

This was not new!
In light of concerns regarding low effectiveness against influenza A(H1N1)pdm09 in the United States during the 2013–14 and 2015–16 seasons, for the 2016–17 season, ACIP makes the interim recommendation that live attenuated influenza vaccine (LAIV4) should not be used.


Influenza-It’s Complicated!

- Investigation into reduced effectiveness of LAIV against H1N1
  - High temperatures can change the conformation of the vaccine proteins which leads to reduced entry into cells
  - Different strains have different susceptibility to pH changes
  - Unknown impact of prior immunization
  - LAIV very unlikely to be recommended for 2017-2018

- New study of trivalent influenza compared to monovalent H1N1 shows that the overall vaccine composition may influence the immune response and effectiveness independent of matching

- Pandemic H1N1 immune response broader than most seasonal vaccines

Bright, CDC Meeting February 2017; Athale, Science Trans. Med 2017; Li, PNAS 2012
Pertussis in California

Figure 2: Number and incidence of reported pertussis cases by year of onset -- California, 1990-2015

Pertussis in the United States

http://www.cdc.gov/pertussis/images/incidence-graph.jpg

Tdap vaccine during pregnancy
Why Immunize at Every Pregnancy?
Tdap during pregnancy works!

Table 2

<table>
<thead>
<tr>
<th>Timing of maternal Tdap vaccination</th>
<th>2-mo Follow-up (Total Pertussis Cases = 17)</th>
<th>12-mo Follow-up (Total Pertussis Cases = 168)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No maternal Tdap</td>
<td>Maternal Tdap</td>
</tr>
<tr>
<td>During pregnancy (6a days before birth)</td>
<td>15 (112.7)</td>
<td>1 (8.7)</td>
</tr>
<tr>
<td>Before pregnancy</td>
<td>15 (95.4)</td>
<td>2 (32.3)</td>
</tr>
<tr>
<td>After delivery</td>
<td>15 (95.3)</td>
<td>4 (129.4)</td>
</tr>
</tbody>
</table>

Baxter et al, Pediatrics 2017;139(5):e20164091

Tdap during pregnancy is safe

Table 2

<table>
<thead>
<tr>
<th>Event</th>
<th>Tdap during pregnancy</th>
<th>Unvaccinated N = 109,233</th>
<th>Adjusted rate ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any 0-3 day event</td>
<td>8.1 (4)</td>
<td>6.8 (74)</td>
<td>3.9 (0.8-1.7)</td>
</tr>
<tr>
<td>Allergic reaction</td>
<td>1.3 (7)</td>
<td>1.2 (11)</td>
<td>1.2 (0.1-11)</td>
</tr>
<tr>
<td>Fever</td>
<td>2.8 (15)</td>
<td>&lt;1 (1)</td>
<td>&lt;1 (1-15)</td>
</tr>
<tr>
<td>Seizures</td>
<td>&lt;1 (1)</td>
<td>&lt;1 (1)</td>
<td>&lt;1 (1)</td>
</tr>
<tr>
<td>Abnormal mentation status</td>
<td>&lt;1 (1)</td>
<td>&lt;1 (1)</td>
<td>&lt;1 (1)</td>
</tr>
<tr>
<td>Local and other reactions</td>
<td>3.2 (18)</td>
<td>3.9 (42)</td>
<td></td>
</tr>
<tr>
<td>Any 0-42 day neurologic event</td>
<td>9.5 (51)</td>
<td>9.6 (104)</td>
<td>0.38 (0.08-1.37)</td>
</tr>
<tr>
<td>Autonomic disorders</td>
<td>&lt;1 (1)</td>
<td>&lt;1 (1)</td>
<td>&lt;1 (1)</td>
</tr>
<tr>
<td>Cranial nerve disorders</td>
<td>3.5 (19)</td>
<td>3.5 (38)</td>
<td>3.5 (1-10)</td>
</tr>
<tr>
<td>Lesions/orchitectural defecting</td>
<td>6.4</td>
<td>&lt;1 (1)</td>
<td>&lt;1 (1)</td>
</tr>
<tr>
<td>Peripheral neuropathy</td>
<td>3.6 (18)</td>
<td>2.5 (27)</td>
<td>2.5 (0.03-20)</td>
</tr>
<tr>
<td>Caffey Dysplasia syndrome</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Seizures</td>
<td>&lt;1 (1)</td>
<td>&lt;1 (1)</td>
<td>&lt;1 (1)</td>
</tr>
<tr>
<td>Movement disorders</td>
<td>2.8 (13)</td>
<td>2.9 (32)</td>
<td>2.9 (0.1-10)</td>
</tr>
<tr>
<td>Paralytic syndromes</td>
<td>&lt;1 (1)</td>
<td>0.0</td>
<td></td>
</tr>
<tr>
<td>Spinoocerebellar disease</td>
<td>0.0</td>
<td>&lt;1 (1)</td>
<td></td>
</tr>
</tbody>
</table>

Kharbanda E et al. Vaccine 2016;34:968-973
Pregnancy Vaccination: How are we doing?

https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/tdap-report.html

Mumps!

Sidney can't play- Mumps!
Mumps is making a comeback!

More on mumps

- Usually only recognized when parotitis occurs
- Not all patients have parotid swelling
- Prodrome of low-grade fever, myalgia, malaise, headache
- Neck/facial swelling usually lasts up to one week
- Need to distinguish from lymph node swelling which is more common
- Complications include orchitis, encephalitis, deafness
Why Mumps?

- Mumps vaccine is less effective than measles vaccine
- Mumps vaccine only available in the U.S. as combined MMR
  - 1 dose-80% effective
  - 2-doses-90% effective
- Vaccine immunity can wane over time
- Mumps is highly contagious
- Recent outbreaks of mumps have included many fully immunized individuals
- A third dose of MMR vaccine is sometimes used to control outbreaks
Meningococcal vaccines-Be careful!

- Two very different vaccine types
  - Men ACWY (Menveo, Menactra)
  - Men B (Trumenba, Bexero)

- Two very different recommendations
  - Men ACWY-routine for adolescents and high-risk individuals including infants
  - Men B-routine only for a subset of high-risk individuals and not infants

- Men ACWY products-difference in recommendations for use under 2 years of age due to vaccine interference

- Men B vaccines-two very different vaccines products
  - Different schedules and different intervals between doses
  - Can’t be interchanged

Meningococcal vaccine background

**MEN ACWY**
- Both an older polysaccharide (Menomune) and newer conjugate (Menactra, Menveo) vaccines available
- Routinely recommended for all adolescents as a 2-dose regimen at 11 and 16 years of age
- Recommended to both younger (down to 2 months) and older (adults) populations at increased risk
- May be used in outbreak settings

**MEN B**
- Licensed in 2014-2015
- Two products available
  - MenB-fHbp (Trumenba)
  - MenB-4C (Bexero)
- MenB-fHbp is now a 2 or 3-dose series depending on the population
- MenB-4C is a 2-dose series but with different intervals than MenB-fHbp
- Recommended for children 10 years of age or older who are at increased risk including outbreak settings
Meningococcal vaccines for high risk individuals

Men ACWY vaccine-high risk groups

- Complement deficiency
- Functional or anatomic asplenia
- During an outbreak of serogroup A, C, W, or Y
- Travel or residence in areas where meningococcal disease is endemic (sub-Saharan Africa, the Hajj in Saudi Arabia)
- 2-dose series required and booster doses needed every 3-5 years depending on age and indication

Meningococcal ACWY vaccine for HIV-infected persons

- HIV-infected persons have 5-24 fold increased risk from meningococcal infection. Most disease is C, W and Y (Not B)
- Antibody responses are lower and wane faster in HIV-infected persons
- Men ACWY vaccine recommended for HIV-infected persons 2 months of age and older
- Should only use MenACWY-CRM (Menveo) for HIV-infected children 2 months-2 years of age. Multiple doses required depending on age.
- 2-dose primary series required for those 2 years of age and older (8 week interval)

MenACWY-D vaccine interactions

- MenACWY-D (Menactra) licensed for use in persons 9 months through 55 years
- MenACWY-D has been shown to decrease pneumococcal conjugate vaccine response. This is of concern particularly for children with anatomic or functional asplenia
  - MenACWY-D not recommended for children with asplenia or HIV infection before 2 years of age
- Interference in meningococcal immune response seen when MenACWY-D given within 30 days of DTaP (Daptacel)
  - For children at increased risk of meningococcal disease MenACWY-D should be given either before or concomitantly with DTaP
Meningococcal B Vaccine
Recommendations for High Risk

A serogroup B meningococcal vaccine (MenB) series should be administered to persons aged >10 years at increased risk for meningococcal disease (Category A). This includes:

- Persons with persistent complement component deficiencies, including those taking eculizomab.
- Persons with anatomic or functional asplenia including those with sickle cell disease
- Microbiologists routinely exposed to isolates of Neisseria meningitides
- Persons identified as being at risk due to a serogroup B meningococcal outbreak

What about everyone else?

A Men B vaccine series MAY be administered to adolescents and young adults aged 16-23 years to provide SHORT-TERM protection against MOST strains of serogroup B meningococcal disease. The preferred age for Men B vaccination is 16-18 years.
2-dose men B-fHbp (Trumenba) vaccine

BE CAREFUL, IT IS COMPLICATED!

Men b-fHbp (Trumenba) 2 dose option

- FDA approved as a 2-dose vaccine in April 2016
- Only for healthy individuals
- For persons with increased risk of meningococcal disease and for use during outbreaks, 3 doses of MenB-fHbp should be used at 0, 1-2, 6 months
- When given to healthy adolescents who are not at increased risk for meningococcal disease, 2 doses of MenB-fHpb should be administered at 0 and 6 months
- If the second dose is given at an interval <6 months a third dose should be given at least 6 months after the first
- Be careful, the two doses of the other vaccine (MebB-4C) are given 1 month apart

ACIP Meeting, October 2016
Pneumococcal conjugate vaccine (PCV13) for older children and adults

Pneumococcal Vaccines

<table>
<thead>
<tr>
<th>POLYSACCHARIDE-PPSV23</th>
<th>PROTEIN CONJUGATE VACCINE-PCV13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneunovax</td>
<td>Prevnar 13</td>
</tr>
<tr>
<td>Available for decades</td>
<td>Induces a better immune response</td>
</tr>
<tr>
<td>Used in high risk populations including all adults ≥65 years of age</td>
<td>Began using PCV7 routinely in young children in the 1990’s</td>
</tr>
<tr>
<td>Immunity wanes so some groups need a repeat dose 5 years after their first PPSV23</td>
<td>PCV13 became available in 2010</td>
</tr>
<tr>
<td>Only limited benefit from repeated doses</td>
<td>Has led to reduced disease even in unimmunized populations</td>
</tr>
<tr>
<td></td>
<td>Licensed for adults &gt;50 years of age in 2011</td>
</tr>
</tbody>
</table>
Two populations should receive BOTH PCV13 and PPSV23

HIGH RISK CHILDREN AND ADULTS

- Immunocompromised (e.g. HIV, malignancy, nephrotic syndrome)
- Anatomic or functional asplenia (e.g. Sickle cell disease)
- Cochlear implants
- CSF leaks

ALL ADULTS 65 YEARS AND OLDER

Who gets both PCV13 and PPSV23

| TABLE 1: Underlying Medical Conditions That Are Indications for Pneumococcal Immunization Among Children, by Risk Group* and Recommended Vaccine |
|-------------------|----------------|----------------|----------------|
| Risk Group        | Condition                  | PCV13          | PPSV23         |
|                   |                             | Recommended    | May Be         | Date | Repeat Dosea |
| Immuno-compromised| Chronic heart disease†       | X              | X              |      |               |
|                   | Chronic lung disease†        | X              | X              |      |               |
|                   | Diabetes mellitus           | X              | X              |      |               |
|                   | CSF leaks                   | X              | X              |      |               |
|                   | Cochlear implant            | X              | X              |      |               |
| Children with functional or anatomic asplenia | Sickled cell disease and other hemoglobinopathies | X | X | | |
| Children with immunocompromising conditions | Congenital or acquired asplenia or splenic dysfunction | X | X | | |
|                   | HIV infection               | X              | X              |      |               |
|                   | Chronic renal failure and nephrotic syndrome | X | X | | |
|                   | Diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease, or solid organ transplantation | X | X | | |
|                   | Congenital immunodeficiency† | X              | X              |      |               |

Pediatrics 2014:134:1230-1233
Summary

- The birth dose of hepatitis B vaccine should be given at birth (<24 hours)
- For infants who don’t respond to hepatitis B vaccine, now a single revaccination dose followed by serology is an option
- Despite the lobbying of your 5yo patients, don’t use LAIV
- Do what you can to get pregnant women immunized with Tdap
- Be on the lookout for mumps
- Men ACWY is recommended for high risk young children beginning at 2 months of age. Men B vaccine is not.
- Don’t forget pneumococcal polysaccharide vaccine (PPSV 23) in high risk infants, starting at age 2