Immunization Update
Including New Ways to Give Old Vaccines
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Disclosure
I have no relevant financial relationships with commercial interests to disclose.

Objectives
• Name two new vaccines coming by Spring 2015
• Discuss some talking points that will allow you to give a strong recommendation for HPV vaccine
• List some new ways we are using our existing vaccines, including use of Tdap during each pregnancy
• Describe how we have changed who we give vaccines to, including PCV13 to adolescents
Objectives

• Explain why we are starting to use some of our current vaccines differently, including LAIV in young children
• List the major concerns voiced by the community about vaccines
• List tips in communicating about vaccine safety with patients/parents
• Identify talking points to address each of the major concerns in the community
• Identify useful resources on vaccine safety for providers, parents, and patients

The Good News: HPV9 is coming

• Current HPV vaccines contain two (Cervarix, GSK) or four (Gardasil, Merck) serotypes
• HPV serotypes 16 and 18 are in both vaccines and are the most common causes of cervical cancer
• HPV serotypes 6 and 11 are only in HPV4
• Recommended routinely beginning at 11 years of age
• A new vaccine with 9 HPV serotypes is coming this Spring
• What should we do with people who have already had 3 doses of HPV2 or HPV4?
• What should we do with people who have had only some of their HPV doses?
• Cost
• Can this be used as a 2-dose vaccine?

The Bad News: Coverage rates are low
Top 5 reasons for not vaccinating daughter, among parents with no intention to vaccinate in the next 12 months, NIS-Teen 2012

- Not needed or necessary: 19.1%
- Not recommended by provider: 14.2%
- Safety concern/side effects: 13.3%
- Lack of knowledge: 12.6%
- Not sexually active: 10.1%

Current Strength of Recommendation in Females, Pediatricians and Family Physicians (N=609)*

- 13-15 yo females: 74%
- 16-18 yo females: 74%

HPV Vaccine Communications During the Healthcare Encounter

- HPV vaccine is often presented as 'optional' whereas other adolescent vaccines are recommended
- Some expressed mixed or negative opinions about the 'new vaccine' and concerns over safety/efficacy
- When parents expressed reluctance, providers were hesitant to engage in discussion
- Some providers shared parents' views that teen was not at risk for HPV and could delay vaccination until older

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U.S. HPV Prevalence & Incidence

- Currently infected ~79 million
- New infections/year ~14 million
- HPV infection is most common in people in their teens and early 20s
- HPV is the most common STI
- ...but most people never know that they have been infected -- unless a woman has an abnormal pap test with a positive HPV test

HPV Transmission

- HPV exposure can occur with any type of intimate sexual contact.
- Among a cohort of adolescent women without prior vaginal intercourse (followed longitudinally):
  - HPV was detected in 46% of females prior to 1st vaginal sex
  - 70% of these women reported non-coital behaviors that may in part explain genital transmission
- Vaginal intercourse is not necessary to become infected
- Condoms do not completely stop HPV transmission
Transmission During Intercourse

- Nearly 50% of high school students have already engaged in sexual (vaginal-penile) intercourse
  - 1/3 of 9th graders and 2/3 of 12th graders have engaged in sexual intercourse
  - 24% of high school seniors have had sexual intercourse with 4 or more partners
  - About 50% of people are infected with HPV within 12 months of sexual debut

Receipt of HPV vaccine does not make you go out and have sex!

- Kaiser Permanente Center for Health Research
- 1,398 girls who were 11 or 12 in 2006, 30% of whom were vaccinated, followed through 2010
- No difference in markers of sexual activity, including
  - Pregnancies
  - Counseling on contraceptives
  - Testing for, or diagnoses of, sexually transmitted infections

Rationale for vaccinating early:
Protection prior to exposure to HPV
Three main strains of *Neisseria meningitidis* (Meningococcus) circulate in the United States—Serogroups B, C and Y

- Serogroup B disease is common in young children and becoming more common in adolescents and adults
- *N. meningitidis* causes overwhelming sepsis and meningitis with a high mortality rate (approx 10%)
- The currently licensed meningococcal vaccine contains serogroup A, C, Y, and W
- A new serogroup B vaccine (Bexero, Novartis) has started to be used in Canada, Europe, and Australia

Serogroup B Meningococcal Disease at Princeton University

- 8 cases from March-November, 2013
- Attack rate 134/100,000 in undergraduates
- No deaths, 2 with neurocognitive sequelae
- All undergraduate grade levels affected
- All cases caused by an identical MenB strain
  - 2 of 4 antigens found in Bexsero expressed by Princeton strain
- MenB+OMV vaccination recommended for Princeton undergraduate students and subsequently UC Santa Barbara students
- Two doses required, 2 months apart
Meningococcal serogroup B vaccines

- Submitted to FDA for licensure in Spring 2015
- Recommendations for use not yet made
- Unclear whether a booster dose will be required

Why aren’t we immunizing infants with meningococcal vaccine?

Meningococcal conjugate vaccine licensed for infants

- Hib-MenCY-TT (MenHibrix, GlaxoSmithKline Biologicals) licensed at 2 months of age
- MenACWY-CRM (Menveo, Novartis Vaccines) licensed at 2 months of age
- MenACWY-D (Menactra, Sanofi Pasteur) licensed at 9 months of age

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Burden of Meningococcal Disease in Infants

Table 3. Annual Estimated National Number of Disease, Standardized Incidence (per 100,000 Population), and Annual Estimated Number of Deaths and Case Fatality Rates (CFR) Associated with Meningococcal Disease by Age Group and Serogroup, United States, 1998-2007

<table>
<thead>
<tr>
<th>Age group</th>
<th>Serogroup A</th>
<th>Serogroup C</th>
<th>Serogroup Y</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No of cases</td>
<td>No of deaths</td>
<td>No of cases</td>
<td>No of deaths</td>
</tr>
<tr>
<td>0-1 month</td>
<td>27.6 (95)</td>
<td>2.0 (29)</td>
<td>16.2 (9)</td>
<td>1.2 (19)</td>
</tr>
<tr>
<td>2-3 months</td>
<td>27.6 (95)</td>
<td>2.0 (29)</td>
<td>16.2 (9)</td>
<td>1.2 (19)</td>
</tr>
<tr>
<td>4-6 months</td>
<td>27.6 (95)</td>
<td>2.0 (29)</td>
<td>16.2 (9)</td>
<td>1.2 (19)</td>
</tr>
<tr>
<td>6-7 months</td>
<td>27.6 (95)</td>
<td>2.0 (29)</td>
<td>16.2 (9)</td>
<td>1.2 (19)</td>
</tr>
<tr>
<td>8-11 months</td>
<td>27.6 (95)</td>
<td>2.0 (29)</td>
<td>16.2 (9)</td>
<td>1.2 (19)</td>
</tr>
</tbody>
</table>


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No routine recommendation for meningococcal conjugate vaccines in infants in the near future

What about Tdap boosters?

Pertussis rates by age — United States, 2012

CDC. MMWR. 2012;61(28);517-522.
**Tdap Vaccine Effectiveness**

<table>
<thead>
<tr>
<th>Group</th>
<th>Cases</th>
<th>Controls</th>
<th>Odds Ratio (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCR positive controls</td>
<td>61</td>
<td>1909</td>
<td>0.71 (0.58 - 0.86)</td>
<td>0.008</td>
</tr>
<tr>
<td>PCR negative controls</td>
<td>138</td>
<td>3777</td>
<td>0.76 (0.67 - 0.87)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**What recommendations are not coming?**

- Tdap booster recommendation for the general population
- ?Tdap booster for those around young infants
- ?Tdap booster for healthcare workers

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**Pertussis Update-San Diego**

- 298 cases reported in San Diego so far in 2014. Compared to 53 cases at this time last year.
- Going back to 9/1/13 573 cases
- 12% less than 1 year of age
- 46% were 13-18 years of age
- 18 cases hospitalized
- 80% were up to date with immunization
- Clusters occurring in middle and high schools
- Need to remain suspicious of pertussis in any persistent cough illness
- Post-exposure antibiotic prophylaxis indicated for close contacts, including those that have been immunized

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Should I give Tdap boosters?

- Reasonable to consider for families with newborns
- Reasonable to consider for healthcare workers who are around young babies
- Reasonable interval of 5 years since the last Tdap
- Still need to consider post-exposure antibiotics in immunized contacts

New ways we give old vaccines

- Reduced dose rabies vaccine
- Reduced dose PCV13
- Reduced dose HPV
- Tdap during each pregnancy

Tdap vaccine during pregnancy
Rationale for Tdap during pregnancy

Reported pertussis-related deaths by age-groups, U.S., 1980-2009

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1 month</td>
<td>38</td>
<td>68</td>
<td>152</td>
</tr>
<tr>
<td>2-3 month</td>
<td>11</td>
<td>16</td>
<td>23</td>
</tr>
<tr>
<td>4-5 month</td>
<td>5</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>6-11 month</td>
<td>7</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>1-4 years</td>
<td>13</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>5-10 years</td>
<td>1</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>11-18 years</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>&gt;18 years</td>
<td>1</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>77*</td>
<td>103</td>
<td>194</td>
</tr>
</tbody>
</table>

* Includes one case with unknown age

2 National Notifiable Diseases Surveillance System, CDC, 2009

Pertussis antigens GMC up to 10 years after Tdap (Adacel)

Adults (n=644)

- PT
- FHA
- PRN
- FIM

Tom Clark, CDC, ACIP presentation Feb 2013
Tdap coverage rate pregnancy

Kharbanda, CDC ACIP February 2014

Tdap immunization related to pregnancy

- Do re-immunize pregnant women at every pregnancy to protect their infants
- Do not re-immunize women prenatally or post-partum
- Do not re-immunize the cocoon
- Do immunize the cocoon and everyone else 11 years of age and older one time with Tdap
Changing who we give old vaccines to

- PCV13 vaccine to adolescents and adults
- Hepatitis B vaccine to adults with diabetes
- Influenza vaccine to egg-allergic people

Should I give PCV13 vaccine to adolescents and adults?

- Pneumococcus causes pneumonia and other serious infections in adolescents and adults
- Immunocompromised patients are at greatest risk
- Currently use PPSV23/poly saccharide vaccine for most adolescents and adults

Incidence of IPD in adults aged 18-64 years with selected underlying conditions, United States, 2009

- 20 fold increased risk
- 5-7 fold increased risk

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ACIP Recommendations for PCV13 use in High Risk Adults

- Routinely recommended for PCV13-naïve adults 19 years of age or older
  - Anatomic or functional asplenia, (sickle cell)
  - Cochlear implant, CSF leaks
  - Immunocompromised (e.g., HIV, nephrotic syndrome)
- PPSV23-naïve adults
  - 1 dose of PCV13
  - PPV23 at least 8 weeks after PCV13
- Adults who have received PPV23 previously
  - 1 dose of PCV13 at least one year after PPSV23
  - If additional PPSV23 doses needed, at least 8 weeks after PCV13 dose and at least 5 years after previous PPSV23 dose

Category A

Prevention of pneumococcal disease among children 6 through 18 years old with immunocompromising conditions

- A single dose of PCV13 is recommended for children aged 6–18 years who have not received PCV13 previously and who are at increased risk for invasive pneumococcal disease because of anatomic or functional asplenia, including sickle cell disease, immunocompromising conditions such as HIV infection, cochlear implant, or cerebrospinal fluid leaks, regardless of whether they have previously received PCV7 or PPSV23.
- Recommendations for PPSV23 use for children in this age group remain unchanged

Outbreaks of Hepatitis B Virus Infection associated with Blood Glucose Monitoring United States, 1990 to 2010

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Adjusted Odds* of Acute Hepatitis B among Persons with Diabetes: Multivariate Analyses

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes (no &quot;Other HBV risk factor&quot; present)</td>
<td>1.69 (1.40 - 2.57)</td>
</tr>
<tr>
<td>Diabetes (&quot;Other HBV risk factor&quot; present)</td>
<td>1.10 (0.57 – 2.11)</td>
</tr>
</tbody>
</table>

*Controlling for age, gender, race/ethnicity
No observations deleted based on DF Beta results

Influenza Vaccine and Egg Allergy

![Influenza Vaccine and Egg Allergy Diagram]

Changing why we give some old vaccines differently

- Live attenuated influenza vaccine preferentially to young children
- Mumps 3rd dose to control outbreaks

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Expected ACIP Influenza Vaccine Recommendations 2014-2015

Same vaccine strains in the vaccine
Continue to support annual immunization for everyone 6 months of age and older
All available vaccine products are acceptable for indicated age groups
Possible preference for LAIV in children <9 years of age
Ample supply of vaccine

LAIV vs IIV

Background:
- ACIP currently expresses no preference for LAIV vs. IIV.
- Recent recommendations expressing some degree of preference for LAIV for children

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Age (years)</th>
<th>LAIV</th>
<th>IIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quest</td>
<td>3-17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unity International</td>
<td>3-17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenal</td>
<td>2-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>La Crosse</td>
<td>2-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States-Merck</td>
<td>2-7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Evidence Profile—LAIV vs. IIV—2-5-year-olds Lab-confirmed Influenza—Randomized Studies (2010)
Potential Upcoming Recommendation

• Preferential use of LAIV over IIV for children 8 years and younger
• No change in recommendation for older children and adults
• Emphasis on not missing opportunities if a provider doesn’t have LAIV

Mumps-United States

• 353 cases of mumps in Ohio April/May 2014
• 204 at The Ohio State University (most had 2 doses of MMR)
• 438 cases in the United States in 2013
• 5000 cases in 2009-2010
• 2-dose MMR vaccine effectiveness for prevention of mumps is 88%
• Once an outbreak gets started it is difficult to control
Changing where we give old vaccines

- School-based immunization clinics
- Pharmacies as sites for vaccine administration
Addressing Vaccine Hesitant Parents

Individual vaccine trends

<table>
<thead>
<tr>
<th></th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTaP 3 doses</td>
<td>96.2</td>
<td>95</td>
<td>95</td>
<td>95.5</td>
<td>94.3</td>
</tr>
<tr>
<td>MMR</td>
<td>92.1</td>
<td>90</td>
<td>91.5</td>
<td>91.6</td>
<td>90.8</td>
</tr>
<tr>
<td>Hep B</td>
<td>93.5</td>
<td>92.4</td>
<td>91.8</td>
<td>91.1</td>
<td>89.7</td>
</tr>
</tbody>
</table>

MMWR/September 13, 2013 / 62(36);733-740
Vaccine Safety Concerns

This is what we need instead!

Why are we still talking about this?

Falsehood flies and the truth comes limping after so that when men come to be undeceived it is too late. The jest is over and the tale has had its effect

Jonathan Swift, The Examiner Nov. 9, 1710

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Personal Belief Exemptions (PBE)
Kindergarten Entrance Assessment 2001-2013

Percentage of Children with PBE

Assessment Years


CA SD

2013: San Diego PBE Rate=4.5%, 1,944 kindergarteners with PBE status
Total San Diego kindergarteners=43,253

Personal Belief Exemptions (PBE)
Tdap Entrance Assessment, 2011*-13

Percentage of Children with PBE

Assessment Years

2011* 2012 2013

CA SD

2013: 39,260 7th grade students in San Diego County, 1,368 students with PBE status
2012: 40,244 7th grade students in San Diego County, 1,381 students with PBE status
2011: 40,244 7th grade students in San Diego County, 1,368 students with PBE status

Rank of Kindergarten PBE Rate by District (Fall 2013)

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Remember the Big Dot Schools

- Make parents aware that many schools in your area have high rates of unimmunized children
- Point out that this puts their child at greater risk than average
- For certain diseases the risk is at least 20-fold higher for unimmunized children

Goals of Vaccine Hesitancy Communication

- Have parents use their provider as the source for accurate information about vaccines
- Have parents accurately assess the benefits and risks of vaccines
- Have parents realize that information on the Internet may be incorrect
- Protect more children by increasing immunization coverage rates
It matters how you say it!

- Videotaped 111 vaccine discussions between providers and patients
- 74% of pediatricians took a presumptive approach, “We have to do some shots…”
- 26% took a participatory approach, “What questions do you have about the vaccines we need to give today…”
- Parents involved in a participatory discussion were 17-fold more likely to resist vaccines

Opal, DJ et al. Pediatrics www.pediatrics.org/cgi/doi/10.1542/Peds

Parent Issues

- Are vaccines safe?
- Do vaccines cause autism?
- Aren’t we overwhelming the immune system?
- Isn’t natural immunity better?
- Diseases no longer exist—or aren’t that dangerous
- It is all a giant money-fueled conspiracy
- It’s my right to decide what’s best for my child

What else do you hear….?
Addressing Parent Issues

- Know the source of the information you are receiving
- Vaccines are safe
- Risk from vaccines are less than the risk from the disease
- Vaccines do not cause autism
- Natural immunity is not better
- The diseases are here now and remain dangerous
- A choice not to immunize leaves you/your child at risk and also places others at risk

Know Your Source

- Majority of sites found on an Internet search of “Vaccines” are anti-vaccine sites
- NNII site provides tips on how to evaluate the credibility of Web sites
  http://www.immunizationinfo.org
- How to identify a credible web site
  - Scientific studies cited and are current
  - Lack of financial conflict of interest (selling a book)
  - Experience in field
  - Lack of anecdotes

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Vaccines are Safe

- Hundreds of millions of doses of vaccine given every year in U.S.
- Billions of vaccines are given in the world every year
- Vaccine safety infrastructure is robust
  - Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine Safety Datalink (VSD)
  - Clinical Immunization Safety Assessment Network (CISA)
  - Food and Drug Administration (FDA)
  - Centers for Disease Control (CDC)

Vaccines aren’t studied well enough

- Multiple large population databases scoured for adverse events related to vaccine safety
  - Vaccine Safety Datalink
  - VA Health System and Dept. of Defense
  - PRISM Health Plan/Immunization Registry link
  - IHS
- As an example, more than 10 million vaccine recipients were under evaluated after receiving H1N1 vaccine in 2009-2010.

Vaccine Adverse Event Reporting System (VAERS)

- Sometimes, rare side effects and delayed reactions don’t show up in clinical trials.
- VAERS provides a system to capture adverse events once vaccines are used widely
- Anyone can report to VAERS: providers, parents, vaccine manufacturers
- You can get information about reports to VAERS: www.fda.gov/cber/vaers/vaers
Vaccine Safety Datalink (VSD)

- In 1990, the CDC started its Vaccine Safety Datalink project—VSD for short.
- Eight large health maintenance organizations (HMOs) joined with the CDC to help keep an eye on vaccine safety.
- Since its beginning in 1990, VSD has collected safety statistics on more than 7 million people who have received vaccines. These statistics are a powerful tool for assuring safety.

Clinical Immunization Safety Assessment Centers (CISA)

- In 2001 the Clinical Immunization Safety Assessment Centers (CISA) were started.
- These Centers serve as an expert resource to study vaccine adverse events.

What we know about autism

- Highly heritable (more than breast cancer)
- Behavioral changes of autism often present before 1 year of age
- Autism associated with an increase in the number of neurons (i.e. insult occurs in utero)
- Numerous studies have failed to show a link between vaccines and autism
- Thimerosal out of vaccines and no change in rates of autism
Other Vaccine Components and Autism
It ain’t over yet…

- Aluminum
- Bovine serum albumen
- Adjuvants
- Yeast proteins
- Human cell line derivatives

Do vaccines overwhelm the Immune System?

- Your immune system responds to hundreds of things every day
- No evidence that children get more infections right after they are immunized
- Clinical trials test multiple vaccines
- Increased vaccine purity

Is natural immunity better?

- For some infections natural immunity is “better” because it lasts longer
- Natural immunity is not complete
  - Whooping cough, rotavirus
  - Multiple types of some disease agents (Pneumococcus, influenza)
- Natural immunity is only better if you survive the illness without serious consequences
- Natural immunity comes at a price
  - Deafness, brain damage, hospitalization, pneumonia, paralysis, permanent scars
Diseases no longer exist
Talking Points
- Measles in your community
- Pertussis outbreaks occur regularly
- School-based varicella outbreaks common
- Polio, measles, diphtheria…are just a plane ride away

Vaccines are a Community Endeavor
Talking Points
- Herd immunity is very important
  - Elimination of H. flu disease
  - Decrease in influenza and pneumococcal disease in elderly because of pediatric immunization
  - Drop in Hepatitis A disease in California
  - Outbreaks involve immunized as well as unimmunized

Why Should I Put My Child At Risk For The Greater Good? Talking Points
- Because you are actually putting your child at risk by not having them immunized.
  - Measles exemptors: 35x increased risk
  - Pertussis exemptors: 5.9x increased risk
- When you or your child are not immunized, they put others at risk: measles in San Diego
- None of us want to see a resurgence of the diseases we have largely eliminated
What about the Sears schedule?

The Sears Schedule

- Based on the premise that it is better to spread out vaccines
- Based on Dr. Sears’ opinion about what diseases are dangerous and what diseases a child is likely to encounter
- Based on the assumption that aluminum in vaccines causes a problem
- Based on the premise that as long as enough people don’t follow the schedule, herd immunity will be maintained

What’s Wrong with Alternative Vaccine Schedules?

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What’s Wrong With Alternative Immunization Schedules?

- There is no scientific basis for them
- They leave children at risk for disease
- They leave our community at risk for outbreaks, including among those who are immunized
- They increase healthcare costs

What else do you say...?
Information for Health-Care Professionals

- NNI (www.immunizationinfo.org)
- VEC (www.vaccine.chop.edu)
- IAC (www.immunize.org)
- CDC/NIP (www.cdc.gov/nip)
- AAP (www.aap.org)
- AAFP (www.aafp.org)
- IVS (www.vaccinesafety.edu)
- Vaccine Page (www.vaccines.org)
- Every Child by Two (www.ecbt.org)
- CDPH.gov (shot for shot)
- PKIDS (http://www.pkids.org)

Summary

- Vaccines are one of the most effective and cost-effective preventive strategies we have
- The immunization community continues to innovate and investigate new ways to use vaccines
- Reducing the number of doses needed for certain vaccines is an active area of investigation
- It may not make sense to use some vaccines in some populations
- Vaccination during pregnancy is a viable and important strategy
- The locations at which vaccines are given are expanding